1510202

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Maureen K. Ohlhausen
Terrell McSweeny

In the Matter of	)	
LUPIN LTD, **a limited corporation;**	)	
GAVIS PHARMACEUTICALS LLC, **a limited liability corporation;**	)	**Docket C-4566** **PUBLIC VERSION**
and	)	
NOVEL LABORATORIES, INC., **a corporation.**	)	

DECISION AND ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Lupin Ltd. ("Lupin") of the voting securities of Respondent Gavis Pharmaceuticals LLC ("Gavis") and Respondent Novel Laboratories, Inc. ("Novel"), collectively "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, and having duly considered the comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure described in 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 Lupin is a corporation organized, existing and doing business under and by virtue of the laws of India with its principal executive offices located at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai, 200 051, India, and its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: Corporate Secretary, Lupin Pharmaceuticals, Inc., 111 South Calvert Street, Baltimore, MD 21202.

2. Respondent Gavis is a limited liability corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 400 Campus Drive, Somerset, NJ 08873.

3. Respondent Novel is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 400 Campus Drive, Somerset, NJ 08873.

4. The Commission has jurisdiction over 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. "Lupin" means: Lupin Ltd., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates, in each case controlled by Lupin Ltd., including, but not limited to, Lupin Pharmaceuticals, Inc., Lupin Inc., and the respective directors, officers, employees,

agents, representatives, successors, and assigns of each. After the Acquisition, Lupin shall include Gavis and Novel.

B. "Gavis" means: Gavis Pharmaceuticals LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates in each case controlled by Gavis Pharmaceuticals LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "Novel" means: Novel 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 Novel Laboratories, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

D. "Respondents" means Lupin, Gavis, and Novel, individually and collectively.

E. "Commission" means the Federal Trade Commission.

F. "Acquirer(s)" means the following:

1. G&W Laboratories, Inc. ("G&W"); 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 Lupin's proposed acquisition of one hundred percent (100%) of the voting securities of Respondent Gavis and Respondent Novel, respectively, pursuant to a *Purchase and Sale Agreement* dated July 23, 2015, to effect the Acquisition by and among VGS Pharma, LLC, Mendham Holdings, LLC, Veerappan Subramanian and Govindammal Subramanian, Anu Radha Subramanian, and Lupin Inc., that was submitted to the Commission.

H. "Acquisition Date" means the date on which the Acquisition is consummated.

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 the holder and the FDA related thereto. "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 holder 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 and rights of the specified Respondent(s) (as that Respondent(s) is identified in the definition of the specified Divestiture Product), 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 maintained by the Respondents in accordance with the Order to Maintain Assets until the Closing Date for each Divestiture Product:

1. all rights to all of the Applications related to the specified Divestiture Product;
2. all Product Intellectual Property related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
3. all Product Approvals related to the specified Divestiture Product;
4. all Product Manufacturing Technology related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
5. all Product Marketing Materials related to the specified Divestiture Product;
6. all Product Scientific and Regulatory Material related to the specified Divestiture Product;
7. all Website(s) related exclusively to the specified Divestiture Product;
8. the content related exclusively to the specified Divestiture Product that is displayed on any Website that is not dedicated exclusively to the specified Divestiture Product;
9. for each specified Divestiture Product that has been marketed or sold by a Respondent prior to the Closing Date, a list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by Law:
    a. to require Respondents to discontinue the use of those NDC Numbers in the sale or marketing of the specified Divestiture Product *except* for returns, rebates, allowances, and adjustments for such 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 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 Respondent's NDC Numbers related to such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;

e. to approve the timing of Respondent's 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 specified Divestiture Product;

11. at the option of the Acquirer of the specified Divestiture Product, all Product Contracts related to the specified Divestiture Product;

12. all patient registries related to the specified Divestiture Product, 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 specified Divestiture Product (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);

13. for each specified Divestiture Product that has been marketed or sold by the Respondents prior to the Closing Date,

a. a list of all customers and targeted customers for the specified Divestiture Product and a listing of the net sales (in either units or dollars) of the specified Divestiture Product to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of the specified Divestiture Product on behalf of the High Volume Account and his or her business contact information;

b. for each month for each High Volume Account for the one (1) year period immediately prior to the Closing Date, a list containing the following historical information for the specified Divestiture Product: the average net price per unit, *i.e.*, the final price per unit charged by the Respondent (as that Respondent is identified in the definition of the Divestiture Product) net of all discounts, rebates, or promotions; the highest net price per unit; and the lowest net price per unit; and

c. for each month for the one (1) year period immediately prior to the Closing Date, a list containing the following historical information for the specified Divestiture Product: average wholesale price; wholesale acquisition cost; and price to Medicare;

14. for each specified Divestiture Product, a list of all active pharmaceutical ingredient suppliers listed on any Application of a Retained Product that is the Therapeutic Equivalent of that Divestiture Product;

15. for each specified Divestiture Product that is a Contract Manufacture Product:

    a. a list of the inventory levels (weeks of supply) for each customer (*i.e.*, retailer, group purchasing organization, wholesaler, or distributor) as of the Closing Date; and

    b. anticipated reorder dates for each customer as of the Closing Date;

16. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process, and finished goods related to the specified Divestiture Product;

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

18. at the option of the Acquirer of the specified Divestiture Product, all unfilled customer purchase orders for the specified Divestiture Product; and

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

Provided, however, that "Categorized Assets" shall not include: (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 specified Divestiture Product; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of the specified Divestiture Product by the Monitor or the Acquirer of the specified Divestiture Product; (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 specified Divestiture Product and to Retained Products or Businesses of any Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Divestiture Product; or (ii) for which any Respondent has a legal obligation to retain the original copies, the specified Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the specified Divestiture Product, the specified Respondent shall provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the specified Respondent provides the Acquirer with the above-described information without requiring the Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

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, as to each Divestiture Product, the date on which a Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.

P. "Confidential Business Information" means all information owned by, or in the possession or control of, any Respondent that is not in the public domain and that is directly related to the conduct of the Business related to a Divestiture Product(s). The term "Confidential Business Information" *excludes* the following:

1. information relating to any Respondent's general business strategies or practices that does not discuss with particularity the Divestiture Products;

2. information specifically excluded from the Divestiture Product Assets conveyed to the Acquirer of the related Divestiture Product(s);

3. information that is contained in documents, records, or books of any Respondent that is provided to an Acquirer by a Respondent that is unrelated to the Divestiture Products acquired by that Acquirer or that is exclusively related to Retained Product(s); and

4. information that is protected by the attorney work product, attorney-client, joint defense, or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.

Q. "Contract Manufacture" means the following:

1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer;

2. to manufacture, or to cause to be manufactured, a Product that is the Therapeutic Equivalent and in the identical dosage strength, formulation, and presentation as a Contract Manufacture Product on behalf of an Acquirer;

3. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Contract Manufacture Product on behalf of an Acquirer.

R. "Contract Manufacture Product" means:

1. Doxycycline; and

2. any ingredient, material, or component used in the manufacture of the foregoing Products including the active pharmaceutical ingredient, excipients, or packaging materials (including, without limitation, drug vials);

Provided, however, that with the consent of the Acquirer of the specified Product, a Respondent may substitute a Therapeutic Equivalent form of such Product in performance of that Respondent's agreement to Contract Manufacture.

S. "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.

T. "Direct Cost" means a cost not to exceed the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. "Direct Cost" to the Acquirer for its use of any of a Respondent's employees' labor shall not exceed the average hourly wage rate for such employee;

Provided, however, 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.

U. "Divestiture Product(s)" means the following, individually and collectively:

1. Doxycycline; and
2. Mesalamine.

V. "Divestiture Product Assets" means the following, individually and collectively:

1. Doxycycline Assets; and
2. Mesalamine Assets.

W. "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 Respondents:

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

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

X. "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.

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

Z. "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; *provided, however*, "Domain Name" shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.

AA. "Doxycycline" means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Respondents Gavis and/or Novel pursuant to ANDA No. 204446, and any supplements, amendments, or revisions to this ANDA.

BB. "Doxycycline Assets" means all rights, title, and interest in and to all assets related to the Business of Respondents Gavis and Novel within the Geographic Territory related to Doxycycline, to the extent legally transferable, including, without limitation, the Categorized Assets related to Doxycycline.

CC. "Doxycycline Core Employees" means the Product Research and Development Employees and the Product Manufacturing Employees related to the Contract Manufacture Product.

DD. "Doxycycline Divestiture Agreements" means the following:

1. *Asset Purchase Agreement* by and between Novel Laboratories, Inc., and G&W Laboratories, Inc., dated as of February 3, 2016;
2. *Supply Agreement* by and between Novel Laboratories, Inc., and G&W Laboratories, Inc., to be executed on or before the Closing Date; and
3. all amendments, exhibits, attachments, agreements, and schedules attached thereto and submitted with the foregoing listed agreements.

The Doxycycline Divestiture Agreements are contained in Non-Public Appendix I. The Doxycycline Divestiture Agreements that have 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 are Remedial Agreements.

EE. "Doxycycline Employee Information" means the following, for each Doxycycline Core Employee, as and to the extent permitted by Law:

1. a complete and accurate list containing the name of each Doxycycline Core Employee (including former employees who were employed by the specified Respondent within ninety (90) days of the execution date of any Remedial Agreement); and
2. with respect to each such employee, the following information:
    a. direct contact information including, but not limited to, a telephone number;
    b. the date of hire and effective service date;

c. job title or position held;

d. a specific description of the employee's responsibilities related to Doxycycline; *provided, however*, in lieu of this description, the specified Respondent may provide the employee's most recent performance appraisal;

e. the base salary or current wages;

f. the most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year and current target or guaranteed bonus, if any;

g. employment status (*i.e.*, active or on leave or disability; full-time or part-time);

h. all other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and

i. at the Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.

FF. "Drug Master File(s)" means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.

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

HH. "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.

II. "G&W" means G&W Laboratories, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of New Jersey with its principal executive offices located at 111 Coolidge Street, South Plainfield, NJ 07080.

JJ. "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 United States of America from the 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 for the relevant assets; or (iv) the end of the last quarter following the Acquisition or the Closing Date.

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

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

MM. "Mesalamine" means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Respondents Gavis and/or Novel pursuant to ANDA No. 205841, and any supplements, amendments, or revisions to this ANDA.

NN. "Mesalamine Assets" means all rights, title, and interest in and to all assets related to the Business of Respondents Gavis and Novel within the Geographic Territory related to Mesalamine, to the extent legally transferable, including, without limitation, the Categorized Assets related to Mesalamine.

OO. "Mesalamine Divestiture Agreement" means the *ANDA Purchase Agreement* by and between Novel Laboratories, Inc., and G&W Laboratories, Inc., dated as of February 2, 2016, and all amendments, exhibits, attachments, agreements, and schedules attached to and submitted with the foregoing listed agreements.

The Mesalamine Divestiture Agreement is contained in Non-Public Appendix II. The Mesalamine Divestiture Agreement 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 is a Remedial Agreement.

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

QQ. "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.

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

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

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

UU. "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.

VV. "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.

WW. "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.

XX. "Product Approval(s)" means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage, or transport of a Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses, or authorizations granted in connection with any Application related to that Product.

YY. "Product Contracts" means all contracts or agreements:

1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from a Respondent unless such contract applies generally to the Respondent's sales of Products to that Third Party;
2. pursuant to which a Respondent had or has as of the Closing Date the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s), or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party, for use in connection with the manufacture of the specified Divestiture Product;
3. relating to any Clinical Trials involving the specified Divestiture Product;
4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;
5. relating to the particularized marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
6. pursuant to which a Third Party manufactures or plans to manufacture the specified Divestiture Product as a finished Product on behalf of a Respondent;
7. pursuant to which a Third Party provides or plans to provide any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of the specified Divestiture Product on behalf of Respondent;
8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to a Respondent;
9. pursuant to which a Third Party is licensed by a Respondent to use the Product Manufacturing Technology;
10. constituting confidentiality agreements involving the specified Divestiture Product;

11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;

12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture, or distribution of the specified Divestiture Product to a Respondent including, but not limited to, consultation arrangements; and/or

13. pursuant to which any Third Party collaborates with a Respondent in the performance of research, Development, marketing, distribution, or selling of the specified Divestiture Product or the Business related to such Divestiture Product;

Provided, however, that where any such contract or agreement also relates to a Retained Product(s), the Respondents shall, at the Acquirer's option, assign or otherwise make available to the Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

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

AAA. "Product Development Reports" means:

1. pharmacokinetic study reports related to the specified Divestiture Product;
2. bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product;
3. bioequivalence study reports (including reference listed drug information) related to the specified 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 the specified 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 the specified Divestiture Product;
7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Divestiture Product;
8. FDA approved patient circulars and information related to the specified Divestiture Product;
9. adverse event reports, adverse experience information, and descriptions of material events and matters concerning safety or lack of efficacy related to the specified Divestiture Product;
10. summary of Product complaints from physicians related to the specified Divestiture Product;
11. summary of Product complaints from customers related to the specified Divestiture Product;
12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies, and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;
14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including, without limitation, identification and sources of impurities;
15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing, and historical trends of the production of the specified Divestiture Product;

16. analytical methods development records related to the specified Divestiture Product;

17. manufacturing batch records related to the specified Divestiture Product;

18. stability testing records related to the specified Divestiture Product;

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

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

BBB. "Product Intellectual Property" means all of the following intellectual property related to a Divestiture Product (other than Product Licensed Intellectual Property) that is owned, licensed, or controlled by Respondents Gavis and Novel as of the Closing Date:

1. Patents;

2. Product Copyrights;

3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information; and

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

Provided, however, that "Product Intellectual Property" does not include the corporate names or corporate trade dress of "Lupin", "Gavis" or "Novel", or the related corporate logos thereof; or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondent or the related corporate logos thereof; or general registered images or symbols by which Lupin, Gavis, or Novel can be identified or defined.

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

1. all of the following intellectual property related to a Divestiture Product that is owned, licensed, or controlled by Respondents Gavis and Novel as of the Closing Date, as follows:

   a. Patents that are related to a Divestiture Product that the Respondents 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

   b. 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 Respondents 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

2. in those instances in which the Respondent (i) is the holder of an NDA for a Product that is the Therapeutic Equivalent of any Divestiture Product that is the subject of an ANDA, (ii) the NDA is not subject to an exclusive license to a Third Party, and (iii) the Product subject to such NDA is a Retained Product, a full, complete, and unlimited Right of Reference or Use to the Drug Master File related to the NDA for this Retained Product to reference or use in any Application related to that Divestiture Product.

DDD. "Product Manufacturing Employees" means all salaried employees of a Respondent who have directly participated in the planning, design, implementation, or operational management of the Product Manufacturing Technology of the specified Divestiture Product (irrespective of the portion of working time involved unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

EEE. "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, at the Acquirer's option, all such equipment used to manufacture that Product.

FFF. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of the specified 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 the specified Divestiture Product.

GGG. "Product Research and Development Employees" means all salaried employees of a Respondent who have directly participated in the research, Development, regulatory approval process, or clinical studies of the specified Divestiture Product (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

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

III. "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.

JJJ. "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.

KKK. "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.

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

1. any agreement between a Respondent(s) and G&W that is specifically referenced and attached to 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 to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;

2. any agreement between a Respondent(s) and a Third Party to effect the assignment of assets or rights of that Respondent(s) related to a Divestiture Product to the

benefit of G&W that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;

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

4. any agreement between a Respondent(s) and a Third Party to effect the assignment of assets or rights of that Respondent(s) related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

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

NNN. "Right of Reference or Use" means the authority to rely upon, and otherwise use, (i) an investigation of the quality, safety or efficacy of a Product (including any or all such investigations conducted *in vitro, in vivo,* or *in silico* and any and all Clinical Trials), (ii) Product Development Reports, or (iii) Product Scientific and Regulatory Material 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, Product Development Reports, or Product Scientific and Regulatory Material for FDA audit, if necessary.

OOO. "Supply Cost" means a cost not to exceed the Respondent's (as that Respondent is identified in the definition of the respective Divestiture Product) average direct per unit cost in United States dollars of manufacturing the specified Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date. "Supply Cost" shall expressly exclude any intracompany business transfer profit; *provided, however,* that in each instance where: (i) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, "Supply Cost" means the cost as specified in such Remedial Agreement for that Divestiture Product.

PPP. "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 or its Manufacturing Designee, and the 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 the specified Divestiture Product that are acceptable to the 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 the Acquirer or its Manufacturing Designee; and

4. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:

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

    b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell the specified 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 the specified Divestiture Product.

QQQ. "Therapeutic Equivalent" means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product.

RRR. "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.

SSS. "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; *provided, however,* "Website" shall not include the following: (1) 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 (2) 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 Doxycycline Assets and grant the related Divestiture Product License, absolutely and in good faith, to G&W pursuant to, and in accordance with, the Doxycycline Divestiture Agreements (which agreements 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 G&W or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Doxycycline Assets is incorporated by reference into this Order and made a part hereof;

Provided, however, that if Respondents have divested the Doxycycline Assets to G&W 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 G&W is not an acceptable purchaser of the Doxycycline Assets, then Respondents shall immediately rescind the transaction with G&W, in whole or in part, as directed by the Commission, and shall divest the Doxycycline Assets within one hundred eighty (180) days after 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 Doxycyline Assets to G&W 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 Doxycycline Assets to G&W (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. For the Acquirer of a Contract Manufacture Product, Respondents shall provide, or cause to be provided, to that Acquirer in a manner consistent with the Technology Transfer Standards the following:

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

Respondents shall obtain any consents from Third Parties required to comply with this provision. No Respondent shall enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of

that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Products acquired by that Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to such agreements that allows the Third Party to provide the relevant Product Manufacturing Technology to that Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to that Acquirer.

C. For the Acquirer of a Contract Manufacture Product, Respondents shall:

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

2. make representations and warranties to the Acquirer that the Contract Manufacture Product(s) supplied by a Respondent pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract Manufacture Product(s) to be marketed or sold in the Geographic Territory, the supplying Respondent shall agree to indemnify, defend, and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to result from the failure of the Contract Manufacture Product(s) supplied to the Acquirer pursuant to a Remedial Agreement by that Respondent to meet cGMP. This obligation may be made contingent upon the Acquirer giving that Respondent prompt written notice of such claim and cooperating fully in the defense of such claim;

   Provided, however, that a Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with that Respondent's responsibilities to supply the Contract Manufacture Products in the manner required by this Order; *provided further, however,* that this obligation shall not require Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the

representations and warranties made by a Respondent to the Acquirer in an agreement to Contract Manufacture;

Provided further, however, that in each instance where: (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on a Respondent's aggregate liability resulting from the failure of the Contract Manufacture Products supplied to the Acquirer pursuant to such Remedial Agreement to meet cGMP;

3. give priority to supplying a Contract Manufacture Product to the relevant Acquirer over manufacturing and supplying of Products for Respondents' own use or sale;

4. make representations and warranties to each Acquirer that Respondents shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure of the Contract Manufacture Products to be delivered in a timely manner as required by the Remedial Agreement(s), unless Respondents can demonstrate that the failure was beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents;

   provided, *however*, that in each instance where: (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on a Respondent's aggregate liability for such a failure;

5. during the term of any agreement to Contract Manufacture, upon written request of that Acquirer or the Monitor (if any has been appointed), make available to the Acquirer and the Monitor (if any has been appointed) all records that relate directly to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;

6. during the term of any agreement to Contract Manufacture, take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);

7. in the event Respondents become (i) unable to supply or produce a Contract Manufacture Product from the facility or facilities originally contemplated under a Remedial Agreement with an Acquirer, and (ii) that Product is the subject of an ANDA: provide Product that is the Therapeutic Equivalent of such Contract Manufacture Product from the facility(ies) that Respondents use or have used to source their own supply of the Product that is the Therapeutic Equivalent of the Contract Manufacture Product, where such facility(ies) is still suitable for use for such manufacturing;

8. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Monitor to monitor compliance with the obligations to Contract Manufacture; and

9. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of the Respondents and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all Product Approvals to manufacture the Contract Manufacture Products acquired by that Acquirer in the same quality achieved by, or on behalf of, the relevant Respondent (as that Respondent is identified in the definition of the respective Divestiture Product) and in commercial quantities, and in a manner consistent with cGMP, independently of Respondents and sufficient to satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the Contract Manufacture Products.

The foregoing provisions, II.C.1. - 9., shall remain in effect with respect to each Contract Manufacture Product until the earliest of: (i) the date the Acquirer (or the Manufacturing Designee(s) of that Acquirer) is approved by the FDA to manufacture and sell such Contract Manufacture Product in the United States and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents; (ii) the date the Acquirer notifies the Commission and Respondents of its intention to abandon its efforts to manufacture the relevant Contract Manufacture Product; (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the relevant Contract Manufacture Product; or (iv) three (3) years after the Closing Date.

D. Respondents shall require, as a condition of continued employment post-divestiture of the Doxycycline Assets, that each employee that has had responsibilities related to the marketing or sales of Doxycycline within the one (1) year period prior to the Closing Date and each employee that has responsibilities related to the marketing or sales of those Retained Products that are the Therapeutic Equivalent of the Doxycycline Product, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Doxycycline Product as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of Respondents (other than as necessary to comply with the requirements of this Order).

E. Not later than thirty (30) days after the Closing Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to Doxycycline by Respondents' personnel to all of their employees who (i) may be in possession of such Confidential Business Information or (ii) may have

access to such Confidential Business Information. Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondents shall provide a copy of the notification to the relevant Acquirer. Respondents shall maintain complete records of all such notifications at Respondents' registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondents shall provide the relevant Acquirer with copies of all certifications, notifications, and reminders sent to Respondents' personnel.

F. For the Acquirer of a Contract Manufacture Product, Respondents shall:

1. for a period of twelve (12) months after the Closing Date or until the hiring of twenty (20) Doxycycline Core Employees by that Acquirer or its Manufacturing Designee, whichever occurs earlier, provide that Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Doxycycline Core Employees. This period is hereinafter referred to as the "Doxycycline Core Employee Access Period;"

2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to Respondents to provide the Doxycycline Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Doxycycline Employee Information related to the Doxycycline Core Employees. Failure by Respondents to provide the Doxycycline Employee Information for any Doxycycline Core Employee within the time provided herein shall extend the Doxycycline Core Employee Access Period with respect to that employee in an amount equal to the delay; *provided, however*, that the provision of such information may be conditioned upon the Acquirer's or Proposed Acquirer's written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide, or providing to Doxycycline Core Employees the opportunity to enter into employment contracts during a Doxycycline Core Employee Access Period, and (iii) restrict access to the information to such of the Acquirer's or Proposed Acquirer's employees who need such access in connection with the specified and permitted use;

3. during the Doxycycline Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Doxycycline Core Employees, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any non-compete or nondisclosure provision of employment with respect to a Divestiture Product, or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by that Acquirer or its

Manufacturing Designee. In addition, Respondents shall not make any counteroffer to any Doxycycline Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

Provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit Respondents from continuing to employ any Doxycycline Core Employee under the terms of that employee's employment with Respondents prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

4. until the Closing Date, provide all Doxycycline Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture and/or market Doxycycline consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Doxycycline Assets and to ensure successful execution of the pre-Acquisition plans for Doxycycline. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Closing Date for the divestiture of the Doxycycline Assets has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

   provided, however, that this Paragraph does not require nor shall be construed to require Respondents to terminate the employment of any employee or to prevent Respondents from continuing to employ the Doxycycline Core Employees in connection with the Acquisition; and

5. for a period of one (1) year after the Closing Date, not directly or indirectly solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to Doxycycline ("Divestiture Product Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or hire any Divestiture Product Employee;

   Provided, however, 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 non-solicitation 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.

G. 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 that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to Doxycycline, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture of Doxycycline anywhere in the world for the purposes of marketing, sale, or offer for sale within the United States of America; or (ii) the import, export, use, supply, distribution, sale, or offer for sale of Doxycycline, into, from, or within, the United States of America.

H. 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, and where such a suit would have the potential directly to limit or interfere with the relevant Acquirer's freedom to practice the following: (i) the research, Development, or manufacture of Doxycycline anywhere in the world of Doxycycline for the purposes of marketing, sale, or offer for sale within the United States of America; or (ii) the import, export, use, supply, distribution, or sale, or offer for sale of Doxycycline, into, from, or within, the United States of America of Doxycycline:

1. cooperate with the relevant 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 Doxycycline;
2. waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent the relevant Acquirer in any ongoing patent litigation related to Doxycycline; and
3. permit the transfer to the relevant Acquirer of all of the litigation files and any related attorney work product in the possession of Respondent's outside counsel related to Doxycycline.

III.

IT IS FURTHER ORDERED that:

A. Not later than immediately prior to the Acquisition Date, Respondents Gavis and Novel shall divest the Mesalamine Assets and grant the related Divestiture Product License, absolutely and in good faith, to G&W pursuant to, and in accordance with, the Mesalamine 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 G&W or to reduce any obligations of Respondents under such agreement), and such agreement, if it becomes a

Remedial Agreement related to the Mesalamine Assets, is incorporated by reference into this Order and made a part hereof.

B. Respondent Lupin may not complete the Acquisition until after Respondents Gavis and Novel have divested the Mesalamine Assets to a Commission-approved Acquirer pursuant to a Remedial Agreement.

IV.

IT IS FURTHER ORDERED that:

A. Prior to the Closing Date for each respective Divestiture Product, Respondents shall provide the Acquirer with the opportunity to review all contracts or agreements that are Product Contracts related to the Divestiture Products being acquired by the Acquirer for the purposes of the Acquirer's determination whether to assume such contracts or agreements.

B. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the Divestiture Product Assets required to be divested pursuant to this Order to an Acquirer, and to permit the Acquirer to continue the Business of the Divestiture Product(s) being acquired by that Acquirer;

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

C. Respondents shall:

1. submit to the Acquirer, at Respondents' expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;
2. deliver all Confidential Business Information related to the Divestiture Products being acquired by the Acquirer to that Acquirer:
    a. in good faith;
    b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
    c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all such Confidential Business Information to the Acquirer, provide that Acquirer and the Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products acquired by that

Acquirer that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;

4. not use, directly or indirectly, any such Confidential Business Information related to the Business of the Divestiture Products other than as necessary to comply with the following:
    a. the requirements of this Order;
    b. Respondents' obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
    c. applicable Law;
5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Products, (ii) other Persons specifically authorized by that Acquirer to receive such information (*e.g.*, employees of the Respondent responsible for the Contract Manufacture of a Divestiture Product on behalf of an Acquirer), (iii) the Commission, or (iv) the Monitor (if any has been appointed); and
6. not provide, disclose, or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Divestiture Products to the marketing or sales employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products.

D. Until Respondents complete the divestitures required by this Order and fully provide, or cause to be provided, the Product Manufacturing Technology related to a particular Divestiture Product to the Acquirer:

1. Respondents shall take actions as are necessary to:
    a. maintain the full economic viability and marketability of the Businesses associated with 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 the relevant Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Business associated with each Divestiture Product; and
    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 Divestiture Product Assets (other than in the manner prescribed in this Order) nor take any

action that lessens the full economic viability, marketability, or competitiveness of the Businesses associated with that Divestiture Product.

E. 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:

1. under 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;

2. under 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 Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer within the United States of America. Respondents shall also covenant to the Acquirer(s) that as a condition of any assignment or license from Respondent(s) 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 the Acquirer(s) or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale of such Divestiture Product(s) within the United States of America; or (ii) import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer into, from, or within the United States of America. 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.

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

1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the Geographic Territory; and

2. to create a viable and effective competitor, that is independent of Respondents in the Business of each Divestiture Product within the Geographic Territory; and

3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

V.

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 ("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. The Commission hereby appoints Francis J. Civille as the Monitor and approves the Monitor Agreements between Mr. Civille and Respondents.

B. Not later than one (1) day after the appointment of the Monitor, Respondents shall execute one or more agreement(s) that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondents' compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.

C. Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:

1. The Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.

2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.

3. The Monitor shall serve until the date of completion by the Respondents of the divestiture of all Divestiture Product Assets and, with respect to the Doxycycline Assets, the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order until the earliest of: (i) the date the Acquirer of the Doxycycline Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell the Doxycycline Product and is able to manufacture the Doxycycline Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents; (ii) the date the Acquirer of the Doxycycline Product notifies the Commission and Respondents of its intention to abandon its efforts to manufacture the Doxycycline Product; or (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the Doxycycline Product;

Provided, however, that the Monitor's service shall not extend more than five (5) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

D. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to 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 Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with the Orders.

E. The Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.

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

G. Respondents shall report to the Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Respondents, and any reports submitted by each Acquirer with respect to the performance of Respondents' obligations under the Order or the Remedial Agreement(s). Within thirty (30) days after the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Order; *provided, however*, beginning ninety (90) days after Respondents have filed their final report pursuant to Paragraph IX.B, and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by the Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture the Doxycycline Product and obtaining the ability to manufacture the Doxycycline Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents.

H. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality

agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.

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

J. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor.

K. In the event a substitute Monitor is required, the Commission shall select the Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of the proposed substitute Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed substitute Monitor, Respondent shall be deemed to have consented to the selection of the proposed substitute Monitor. Not later than ten (10) days after appointment of a substitute Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the substitute Monitor all the rights and powers necessary to permit the substitute Monitor to monitor Respondent's compliance with the terms of this Order, the Order to Maintain Assets, and the Remedial Agreements in a manner consistent with the purposes of this Order.

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

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

VI.

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 an 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 agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time

for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however,* if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission; *provided further, however,* that Respondents shall select such Person within five (5) days after receiving notification of the Commission's approval.

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

VII.

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 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 VII pursuant to an appropriate confidentiality order, agreement, or arrangement;

Provided further, *however*, that pursuant to this Paragraph VII, the Respondent needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VIII.

IT IS FURTHER ORDERED that:

A. Any Remedial Agreement shall be deemed incorporated into this Order.

B. Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.

C. Respondents shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligation to the Acquirer pursuant to this Order.

D. For each Divestiture Product that is a Contract Manufacture Product, Respondents shall include in the Remedial Agreement(s) related to that Divestiture Product a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product, as applicable, and to have any such manufacture to be independent of the Respondents, all as soon as reasonably practicable.

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.

IX.

IT IS FURTHER ORDERED that:

A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.

B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondents have fully complied with Paragraphs II, III, and IV, 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 Monitor, if any 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, (ii) transitional services being provided by the Respondents to the Acquirer, and (iii) the agreement(s) to Contract Manufacture; 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.

X.

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.

XI.

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 the 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 the 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 the Respondent; and

B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

XII.

IT IS FURTHER ORDERED that this Order shall terminate on April 20, 2026.

By the Commission.

April J. Tabor
Acting Secretary

SEAL

ISSUED: April 20, 2016

NON-PUBLIC APPENDIX I
DOXCYCLINE DIVESTITURE AGREEMENTS

NON-PUBLIC APPENDIX II
MESALAMINE DIVESTITURE AGREEMENT