0710002

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Deborah Platt Majoras, Chairman**
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

In the Matter of	)	
HOSPIRA, INC.,	)	
a corporation, and	)	**Docket No. C-**
MAYNE PHARMA LIMITED, a corporation.	)	

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Hospira, Inc. ("Hospira") of Respondent Mayne Pharma Limited ("Mayne"), hereinafter referred to as "Respondents," and Respondents having been furnished thereafter with a copy of a draft Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and that, 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 (attached to this Order as Appendix I), and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent Hospira, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 275 North Field Drive, Lake Forest, Illinois 60045.

2. Respondent Mayne Pharma Limited is a corporation organized, existing and doing business under and by virtue of the laws of the Commonwealth of Australia, with its headquarters address at L

D. “Commission” means the Federal Trade Commission.

E. “Acquirer” means the following:

1. an entity specified by name in this Order to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final; or

2. an entity approved by the Commission to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.

F. “Acquisition” means the Respondent Hospira’s acquisition of fifty percent (50%) or more of the voting securities of Respondent Mayne pursuant to the executed Scheme Implementation Agreement, dated September 20, 2006, by and among Hospira, Hospira Holdings (S.A.) Pty Ltd. And Mayne Pharma Limited.

G. “Aguadilla Manufacturing Facility” means Respondent Mayne’s manufacturing facility located at 170 Parallel Road, Aguadilla, Puerto Rico 00604.

H. “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, but is not limited to, the United States Food and Drug Administration (“FDA”) and the Uit4cj14aen0[illegible]

J. “Barr” means Barr Pharmaceuticals, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.

K. “Categorized Assets” means the following assets related to the specified Divestiture Product(s):

1. all Product Intellectual Property related to such Divestiture Product(s);

2. perpetual, fully paid-up and royalty-free license(s) with rights to sublicense to all Product Licensed Intellectual Property to use, make, distribute, offer for sale, promote, advertise, sell, import, export, or have used, made, distributed, offered for sale, promoted, advertised, sold, imported, or exported the Divestiture Product(s) within the specified Geographic T

or as specified in any agreement that is specifically referenced and attached to this Order where such agreement becomes a Remedial Agreement for such Divestiture Product;

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

7. all rights to all of Respondents' Applications related to such Divestiture Product(s);

8. Right of Reference or Use to the Drug Master Files related to the above-described Applications including, but not limited to, the pharmacology and toxicology data contained in all Application(s);

9. all Product Development Reports related to such Divestiture Product(s);

10. at the relevant Acquirer's option, all Product Assumed Contracts related to such Divestiture Product(s) (copies to be provided to the relevant Acquirer on or before the Closing Date);

11. a perpetual, fully paid-up and royalty-free license(s) with rights to sublicense to all Product Risk Management Program(s) related to: (1) such Divestiture Products; and/or (2) any Retained Product that is approved for the same indications and has the same active pharmaceutical ingredient as the relevant Divestiture Product, that:

    a. have been approved by the FDA;

    b. Respondents are in the process of formulating or planning (including, but not limited to, any potential changes in any Product Risk Management Program already approved by, or submitted to, the FDA); and/or

    c. Respondents have submitted to the FDA for FDA approval.

12. all patient registries related to such Divestiture Product(s), and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to such Divestiture Product(s);

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

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only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the relevant Acquirer, the relevant party shall provide such Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that Respondents provide the relevant Acquirer with the above-described information without requiring Respondents completely to divest itself of information that, in content, also relates to Retained Product(s).

L. "cGMP" means current Good Manufacturing Practice as set forth in the United States Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated thereunder.

M. "Closing Date" means, as to each Divestiture Product, the date on which Respondents (or a Divestiture Trustee) consummate 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.

N. "Confidential Business Information" means all information owned by, or in the possession or control of, Respondents that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation,

O. “Contract Manufacture” means the manufacture of a Divestiture Product to be supplied by Respondents or a Designee to an Acquirer.

P. “Deferoxamine Products” means all of the following: all Products in Development, manufactured, marketed or sold at any time by Respondent Mayne pursuant to the following of Respondent Mayne’s ANDAs (pending FDA approval):

1. ANDA 77-970; and

2. any supplements, amendments, or revisions thereto;

research, Development, manufacture, distribution, marketing, and sale of the Divestiture Products, including, without limitation, the Categorized Assets related to the Divestiture Products.

V. "Divestiture Product Core Employees" means the Product Research and Development Employees and the Product Manufacturing Employees related to each Divestiture Product.

W. "Divestiture Product Divestiture Agreements" means the following agreements:

1. "Asset Purchase Agreement" by and between Hospira, Inc. and Barr Laboratories, Inc. dated as of December 18, 2006; and

2. "First Amendment to Manufacture and Supply Agreement for Hydromorphone" by and between Hospira, Inc. and Barr Laboratories, Inc. dated as of December 18, 2006 (related to the Contract Manufacture of the Hydromorphone Hydrochloride Products);

3. "Development and Supply Agreement" by and between Barr Laboratories, Inc., and Hospira Worldwide, Inc. dated as of December 18, 2006;

4. "Supply Agreement" by and between Barr Laboratories, Inc., and Hospira Worldwide, Inc. dated as of December 18, 2006 (related to the Contract Manufacture of the Deferoxamine Products, Morphine Products, and the Nalbuphine Products); and

5. all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Divestiture Products that have been approved by the Commission to accomplish the requirements of this Order.

The Divestiture Product Divestiture Agreements are attached to this Order and contained in non-public Appendix II.A.

X. "Divestiture Product Releasee(s)" means the Acquirer for the assets related to a particular Divestiture Product or any entity controlled by or under common control with such Acquirer, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of such Acquirer, or of such Acquirer-affiliated entities.

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

Z. "Domain Name" means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any entity or authority that issues and maintains the domain name registration. "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. "Drug Master Files" means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.

BB. "Effective Date" means the date on which the Acquisition occurs.

CC. "Geographic Territory" shall mean the United States of America (including all of the territories within its jurisdiction or control) unless otherwise specified.

DD. "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.

EE. "High Volume Account(s)" means any retailer, wholesaler or distributor whose annual and/or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States from the Respondent Hospira or Respondent Mayne (whichever party is relevant to such Divestiture Product) was, is, or is projected to be among the top twenty highest of such purchase amounts by Respondent Hospira or Respondent Mayne (whichever party is relevant to such Divestiture Product) U.S. customers on any of the following dates: (1) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (2) the end of the last quarter that immediately preceded the Effective Date; (3) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or 4) the end of the last quarter following the Acquisition and/or the Closing Date.

FF. "Hydromorphone Hydrochloride Products" means all of the following:

1. all Products in Development, manufactured, marketed or sold at any time by Respondent Mayne pursuant to the following of Respondent Mayne's ANDAs:

    a. ANDA 074-598 (includes the following Products: Hydromorphone Hydrochloride Inje

any Retained Product that, as of the Effective Date, are being manufactured, marketed or sold by Respondent Hospira for sale within the United States that contain the active pharmaceutical ingredient nalbuphine hydrochloride.

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

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

3. relating to any clinical trials involving the Divestiture Product(s);

4. with universities or other research institutions for the use of the Divestiture Product(s) in scientific research;

5. relating to the particularized marketing of the Divestiture Product(s) or educational matters relating solely to the Divestiture Product(s);

6. pursuant to which a Third Party manufactures the Divestiture Product(s) on behalf of Respondent Hospira or Respondent Mayne (whichever party is relevant to such Divestiture Product);

7. pursuant to which a Third Party provides the Product Manufacturing Technology or related equipment related to the Divestiture Product(s) to Respondent Hospira or Respondent Mayne (whichever party is relevant to such Divestiture Product);

8. constituting confidentiality agreements involving the Divestiture Product(s);

9. involving any royalty, licensing, or similar arrangement involving the Divestiture Product(s);

10. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the Divestiture Products to Respondent Hospira or Respondent Mayne (whichever party is relevant to such Divestiture Product) including, but not limited to, consultation arrangements; and/or

11. pursuant to which any Third Party collaborates with Respondent Hospira or Respondent Mayne (whichever party is relevant to such Divestiture Product) in the performance of research, Development, marketing, distribution or selling of the Divestiture Product(s) or the Divestiture Product(s) business;

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

RR. "Product Copyrights" means rights to all original works of authorship of any kind directly related to the Divestiture Product(s) 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; educational materials for the sales force; copyrights in all preclinical, clinical and process development data and reports relating to the research and Development of the Divestiture Product(s) or of any materials used in the research,

Development, manufacture, marketing or sale of the Divestiture Product(s), including all raw data relating to clinical trials of the Divestiture Product(s), 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; customer information, promotional and marketing materials, the Divestiture Product(s) sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees who accept employment with the Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all 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 data contained in laboratory notebooks relating to the Divestiture Product(s) or relating to its biology; all adverse experience reports and files related thereto (including source documentation) and all periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all analytical and quality control data; and all correspondence with the FDA.

SS. "Product Development Reports" means:

1. Pharmacokinetic study reports related to the specified Divestiture Product(s);

2. Bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product(s);

3. Bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product(s);

4. all correspondence to the Respondent Hospira or Respondent Mayne (whichever party is relevant to such Divestiture Product) from the FDA and from Respondent Hospira or Respondent Mayne (whichever party is relevant to such Divestiture Product) to the FDA relating to the Application(s) submitted by, on behalf of, or acquired by, Respondent Hospira or Respondent Mayne (whichever party is relevant to such Divestiture Product) 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(s);

7. currently used product package inserts (including historical change of controls summaries) related to the specified Divestiture Product(s);

8. FDA approved patient circulars and information related to the specified Divestiture Product(s);

9. adverse event/serious adverse event summaries related to the specified Divestiture Product(s);

10. summary of Product complaints from physicians related to the specified Divestiture Product(s);

11. summary of Product complaints from customers related to the specified Divestiture Product(s); and

12. Product recall reports filed with the FDA related to the specified Divestiture Product(s).

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

1. a complete and accurate list containing the name of each relevant employee (including former employees who were employed by Respondents within ninety (90) days of the execution date of any Remedial Agreement);

2. with respect to each such employee, the following information:

    a. the date of hire and effective service date;

    b. job title or position held;

    c. a specific description of the employee's responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, Respondents may provide the employee's most recent performance appraisal;

    d. the base salary or current wages;

    e. the most recent bonus paid, aggregate annual compensation for Respondents' last fiscal year and current target or guaranteed bonus, if any;

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

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

3. 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.

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

1. Patents;

2. Product Copyrights;

3. Product Trademarks, 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 and copyrights and registrations thereof;

provided, however, "Product Intellectual Property" does not include the names or trade dress of "Hospira", "Mayne", or the names or trade dress of any other corporations, companies, or brands owned or sold at any time by Respondents or the related logos to the extent used on Respondents' Retained Products.

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

1. Patents that are related to a Divestiture Product that Respondents can demonstrate have been routinely used, prior to the Effective Date, by either Respondent Hospira or Respondent Mayne (whichever party is relevant to such Divestiture Product) for a Retained Product(s) that:

   a. has been marketed or sold on an extensive basis by Respondent Hospira or Respondent Mayne (whichever party is relevant to such Divestiture Product) within the two-year period immediately preceding the Acquisition; or

   b. for which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell such a Retained Product on an extensive basis by Respondent Hospira or Respondent Mayne; and

2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, busine37.t0T, Trade Dress, tra

a. has been marketed or sold on an extensive basis by either Respondent Hospira or Respondent Mayne (whichever party is relevant to such Divestiture Product) within the two-year period immediately preceding the Acquisition; or

b. for which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell such a Retained Product on an extensive basis by Respondent Hospira or Respondent Mayne;

provided however, that, in cases where the aggregate retail sales in dollars within the two-year period immediately preceding the Acquisition of the Retained Product(s) collectively are less than the aggregate retail sales in dollars within the same period of the Divestiture Product(s) collectively, the above-described intellectual property shall be considered, at the Acquirer's option, to be Product Intellectual Property and, thereby, subject to assignment to the Acquirer; *provided further, however*, that in such cases, Respondents may take a license back from the Acquirer for such intellectual property for use in connection with the Retained Products.

WW. "Product Manufacturing Employees" means all salaried employees of Respondents who have directly participated in the planning, design, implementation or use of the Product Manufacturing Technology of the specified Divestiture Product(s) (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.

XX. "Product Manufacturing Technology" means:

1. all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of the Divestiture Product(s) including, but not limited to, the following: all product specifications, processes, 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; and,

2. 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 the Divestiture Product(s).

YY. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of a Divestiture Product(s) 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 purchases 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 Divestiture Product(s).

ZZ. "Product Registrations" means all 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, or sale of the Product within the Geographic Territory, including all Applications in existence for the Product as of the Closing Date.

AAA. "Product Research and Development Employees" means all salaried employees of Respondents who directly have participated in the research, Development, or regulatory approval process, or clinical studies of the specified Divestiture Product(s) (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.

BBB. "Product Risk Management Program" means a strategic safety program designed to decrease product risk by using one or more interventions or tools beyond the package insert, which program may be modified or amended from time to time and may be a condition of FDA approval.

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

DDD.

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

1. any agreement between Respondents and an Acquirer 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, 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;

2. any agreement between Respondents and a Third Party to effect the assignment of assets or rights of Respondents related to a Divestiture Product to the benefit of an Acquirer 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;

3. any agreement between Respondents 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, and that has been approved by the Commission to accomplish the requirements of this Order; and/or

4. any agreement between Respondents and a Third Party to effect the assignment of assets or rights of Respondents 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.

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

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

III. "Supply Cost" means a cost not to exceed the manufacturer's average direct per unit cost of manufacturing the Divestiture Product for the twelve (12) month period immediately preceding the Effective Date. "Supply Cost" shall expressly exclude any intracompany business transfer profit.

JJJ. "Third Party(ies)" means any private entity other than the following: (1) Respondents; or (2) the relevant Acquirer for the affected assets, rights and Divestiture Product(s).

KKK. "Website" means the content of the Website(s) located at the Domain Names, the Domain

3. include in the Remedial Agreement a representation from the relevant Acquirer that such 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 and to have any such manufacture to be independent of Respondents, all as soon as reasonably practicable;

4. upon reasonable notice and request from the Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist the Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Product Intellectual Property related to the relevant Divestiture Product(s);

5. for any patent infringement suit in which either Respondent is a party prior to the Closing Date or for such Respondent has prepared or is preparing as of the Closing Date to be a party, and where such a suit would have the potential to interfere with the Acquirer's freedom to practice in the research, Development, manufacture, use, import, export, distribution or sale of the relevant Divestiture Product(s), Respondents shall:

    a. cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from Respondents in connection with obtaining resolution of any pending patent litigation involving a Divestiture Product;

    b. waive conflicts of interest, if any, to allow either Respondents' outside legal counsel to represent the Acquirer in any ongoing patent litigation involving a Divestiture Product; and

    c. permit the transfer to the Acquirer of all of the litigation files and any related attorney work-product in the possession of Respondents' outside counsel relating to such Divestiture;

6. Respondents shall not seek pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement a decision the result of which would be inconsistent with the terms of this Order and/or the remedial purposes thereof;

7. upon reasonable notice and request from the Acquirer to Respondents, Respondents shall Contract Manufacture and deliver to the Acquirer, in a timely manner and under reasonable terms and conditions a supply of each of the relevant Divestiture Products or, in substitute for this, a supply of the relevant Retained Product that is the generic equivalent to the Divestiture Product, at Respondents' Supply Cost, for a period of time sufficient to allow the Acquirer (or the Designee of the Acquirer) to obtain all of the relevant Agency approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the relevant finished drug product independently of

(1) advise, assist, or prepare all necessary documentation to apply, obtain, and/or amend a DEA quota on behalf of the Acquirer; and

(2) advise and assist in making an equitable determination of the allocation of the DEA quota among the Respond

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 research, Development, manufacturing, marketing, or sale of the relevant Divestiture Product(s) other than as necessary to comply with the following:

   a. the requirements of this Order;

   b. Respondents' obligations to the Acquirer under the terms of any Remedial Agreement related to relevant Divestiture Product(s); or

   c. applicable Law;

5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any person except the Acquirer; and

6. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the relevant Divestiture Products to the employees associated with business related to those Retained Products that are approved by the FDA for the same or similar indications or purposes as the relevant Divestiture Products.

E. Respondents shall not enforce any agreement against a Third Party or the Acquirer to the extent that such agreement may limit or otherwise impair the ability of the Acquirer to acquire the Product Manufacturing Technology related to the relevant Divestiture Product(s) or related equipment from the Third Party. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology.

compensation and benefits offered by Respondents until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product(s) has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by

other employee retained by Respondents and designated by the Interim Monitor (if applicable) sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondents (other than as necessary to comply with the requirements of this Order).

L. Not later than thirty (30) days after the Effective Date, Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to the Divestiture Products by Respondents' personnel to all of Respondents' employees who:

1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of each of the relevant Divestiture Products;

2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that are approved by the FDA for the same or similar indications as each of the relevant Divestiture Products prior to the Acquisition; and/or

3. may have Confidential Business Information related to the Divestiture Products.

Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the relevant Closing Date. Respondents shall provide a copy of such notification to the Acquirer. Respondents shall maintain complete records of all such agreements at Respondents' corporate headquarters and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondents shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

M. Upon reasonable notice and request by the Acquirer(s), Respondents shall make available to the Acquirer(s), at no greater than Direct Cost (or, in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, then at such cost as may be provided therein) such personnel, assistance and training as the Acquirer(s) might reasonably need to transfer the assets related to the Divestiture Product(s) and shall continue providing such personnel, assistance and training, at the request of the Acquirer(s), until either: (1) the relevant Acquirer (or the Designee(s) of such Acquirer) is approved by the FDA to manufacture each of the relevant Divestiture Products and able to manufacture such Divestiture Products in commercial quantities, in a manner consistent with cGMP, independently of Respondents, or (2) the relevant Acquirer notifies the Commission and the Respondents of its intention to abandon its efforts to obtain approval by the FDA to manufacture a particular Divestiture Product, in which instance, the Respondents' obligations related to such Divestiture Product under the foregoing provision shall end.

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if such suit would have the potential to interfere with the relevant Acquirer's freedom to practice the research, Development, manufacture, use, import, export, distribution, or sale of the relevant Divestiture Products. Respondents shall also covenant to the relevant Acquirer that as a condition of any assignment, transfer, or license 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 relevant Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential to interfere with the relevant Acquirer's freedom to practice in the research, Development, manufacture, use, import, export, distribution, or sale of the relevant Divestiture Products.

Respondents shall include the above-described covenants in the Remedial Agreement(s) with the relevant Acquirer.

Q. Respondents shall not, in the Geographic Territory:

1. use the Product Trademarks related to the Divestiture Products or any mark confusingly similar to such Product Trademarks, as a trademark, trade name, or service mark;

2. attempt to register such Product Trademarks;

3. attempt to register any mark confusingly similar to such Product Trademarks;

4. challenge or interfere with the Acquirer(s)'s use and registration of such Product Trademarks; or

5. challenge or interfere with the Acquirer(s)'s efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties;

provided however, that nothing in this Order shall preclude Respondents from continuing to use those trademarks, tradenames, or service marks related to the Retained Products as of the Effective Date.

R. The purpose of the divestiture of the Divestiture Product Assets and the related obligations imposed on the Respondents by this Order is:

1. to ensure the continued use of such assets in the research, Development, manufacture, distribution, sale and marketing of the each of the Divestiture Products, respectively;

2. to create a viable and effective competitor in the relevant markets alleged in the Commission's Complaint who is independent of the Respondents; 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.

commercial quantities, in a manner consistent with cGMP, independently of

7. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by the Acquirer with respect to the performance of Respondents' obligations under the Order or the Remedial Agreement. Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Order.

8. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.

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

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

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

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

IV.

IT IS FURTHER ORDERED that:

A. If Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey relevant assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver or otherwise convey the assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed pursuant to each of the relevant Paragraphs in a manner that satisfies the requirements of each such Paragraph. 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 the relevant 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

or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an acquirer as required by this Order; *provided, however,* if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondents from among those approved by the Commission; and, *provided further, however,* that Respondents shall select such entity 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 misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of 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*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

E. 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.

F. 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 nece

forth in this Paragraph pursuant to an appropriate confidentiality order, agreement or arrangement;

provided, however, that pursuant to this Paragraph V, Respondents shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if the relevant Acquirer withholds such agreement unreasonably); and (2) use their best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VI.

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 Acquisitions occurred.

B. Within five (5) days of the completion of the divestiture described in Paragraph II.A., Respondents shall submit to the Commission a letter certifying the date on which Respondents completed such divestiture and describing the manner in which Respondents completed such divestiture.

C. Within thirty (30) days after the date this Order becomes final, and every sixty (60) days thereafter until 00 0.00 0.0c000 TD(in)Tj9.3600 0.0000 TD(th)Tj12.3600 0.0000 TD(ir)Tj7.3200 0.0000 TD(

internal memoranda, and all reports and recommendations concerning completing the obligations.

D. One (1) year after the date this Order becomes final, annually for the next nine years on the anniversary of the date this Order becomes final, 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 they have complied and are complying with the Order.

VII.

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

A. any proposed dissolution of Respondents;

B. any proposed acquisition, merger or consolidation of Respondents; or

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

VIII.

IT IS FURTHER ORDERED that Respondents shall not modify or amend any of the terms of any Remedial Agreement that are related to the Divestiture Products without the prior approval of the Commission.

IX.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to Respondents made to their principal United States offices or their headquarters address, Respondents shall, without restraint or interference, permit any duly authorized representative of the Commission:

A. access, during business office hours of Respondents 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 Respondents related to compliance with this Order, which copying services shall be provided by Respondents at the request of the authorized representative(s) of the

Commission; and

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

X.

IT IS FURTHER ORDERED that this Order shall terminate ten (10) years from the date on which the Order becomes final.

By the Commission.

Donald S. Clark
Secretary

SEAL
ISSUED:

PUBLIC
APPENDIX I
ORDER TO MAINTAIN ASSETS

NON-PUBLIC APPENDIX II.A.
DIVESTITURE PRODUCT DIVESTITURE AGREEMENTS

[Redacted From the Public Record Version But Incorporated by Reference]