121 0132

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: Jon Leibowitz, Chairman
J. Thomas Rosch
Edith Ramirez
Julie Brill
Maureen K. Ohlhausen

In the Matter of	)	
WATSON PHARMACEUTICALS INC., a corporation;	)	
ACTAVIS INC., a corporation;	)	
ACTAVIS PHARMA HOLDING 4 EHF., a private limited liability company;	)	Docket No. C-4373
and	)	
ACTAVIS S.Á.R.L., a limited liability corporate entity.	)	
	)	

DECISION AND ORDER
[Redacted Public Version]

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Watson Pharmaceuticals Inc., ("Watson") of Respondents Actavis Inc., Actavis Pharma Holding 4 ehf., and Actavis S.á.r.l. (collectively, "Actavis"), 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"), dd TD (rs00 0.14.5200 0.0000 TD (m0

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

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent Watson is a corporation organized, existing a

K. “Application(s)” mea

a. to require Respondents to discontinue the use of NDC Numbers related to each Divestiture Product in the sale or marketing of the specified Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the date agreed upon by the relevant Acquirer and *except* as may be required by applicable Law;

b. to prohibit Respondents

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

15. 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;

16. 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;

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

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

provided, however, that "Categorized Assets" *excludes*: (i) documents relating to a Respondent's general business strategies or practices relating to research, Development, manufacture, marketing or sales 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 Interim Monitor or the Acquirer of the specified Divestiture Product; (iv) formulas used to determine the final pricing of any Divestiture Product and/or Retained Products to customers and competitively sensitive pricing 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 a 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 a Respondent has a legal obligation to retain the original copies, the Respondent shall be

N. "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.

O. "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.

P. "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.

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

the definition of the specified Divestiture Product in this Order exclusively for the purposes of:

1. researching and Developing the specified Divestiture Product for marketing, distribution or sale within the Geographic Territory;

2. using, making, having made, distributing, offering for sale, promoting, advertising, or selling the specified Divestiture Product within the Geographic Territory;

3. importing or exporting the specified Divestiture Product to or from the Geographic Territory to the extent related to the marketing, distribution or sale of the specified Divestiture Product in the Geographic Territory; and

4. having the specified Divestiture Product made anywhere in the World for distribution or sale within, or import into the Geographic Territory;

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

CC. "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 licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.

GG. "Fentanyl Transdermal System Products" means all Products in Development, manufactured, marketed or sold by Respondent Actavis pursuant to ANDA No. 077062 and any supplements, amendments, revisions thereto.

HH. "Generic Products (Group One)" means the following Divestiture Products:

1. Adapalene/Benzoyl Peroxide Products;

2. Amphetamine Salts Extended Release Products;

3. Diltiazem Hydrochloride Extended Release (Group One) Products;

4. Fentanyl Transdermal System Products;

5. Glipizide Extended Release Products;

6. Methylphenidate Hydrochloride Extended Release Products;

7. Metoclopramide Hydrochloride Products;

8. Morphine Sulphate Extended Release Products;

9. Nifedipine Extended Release Products;

10. Oxycodone Extended Release Products;

11. Oxymorphone Extended Release Products;

12. Rivastigmine Patch Film Products;

13. Ursodiol Products; and

14. Varenicline Tartrate Products.

II. "Generic Products (Group One) Assets" means all of Respondents' rights, title and interest in and to all assets related to Respondents' business within the Geographic Territory related to each of the respective Generic Products (Group One) to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of each such Generic Products (Group One), including, without limitation, the Categorized Assets related to the Generic Products (Group One).

JJ. "Generic Products (Group One) Divestiture Agreements" means all of the following agreements:

4. Dextromethorphan Hydrobromide/Quinidine Sulfate Products.

LL. "Generic Products (Group Two) Assets" means all of Respondents' rights, title and interest in and to all assets related to Respondents' business within the Geographic Territory related to each of the respective Generic Products (Group Two) to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of each such Generic Products (Group Two), including, without limitation, the Categorized Assets related to the Generic Products (Group Two)

MM. "Generic Products (Group Two) Divestiture Agreements" means all of the following agreements:

1. *Asset Purchase Agreement* between Actavis Elizabeth LLC and Sandoz Inc., dated as of September 19, 2012, and all amendments, exhibits, attachments, agreements, and schedules thereto;

2. *Asset Purchase Agreement* between Actavis South Atlantic LLC and Sandoz Inc., dated as of September 19, 2012, and all amendments, exhibits, attachments, agreements, and schedules thereto;

3. *Asset Purchase Agreement* between Watson Laboratories, Inc. (a Nevada Corporation) and Sandoz Inc., dated as of September 19, 2012, and all amendments, exhibits, attachments, agreements, and schedules thereto; and,

4. *Supply Agreement* between Actavis Elizabeth LLC and Sandoz Inc., dated as of September 19, 2012, and all amendments, exhibits, attachments, agreements, and schedules thereto;

related to the Generic Products (Group Two) Assets that have been approved by the Commission to accomplish the requirements of this Order. The Generic Products (Group Two) Divestiture Agreements are attached to this Order and contained in Non-Public Appendix B.

NN. "Geographic Territory" means the United States of America, including all of its territories and possessions, unless otherwise specified.

OO. "Glipizide Extended Release Products" means all Products in Development, manufactured, marketed or sold by Respondent Actavis pursuant to ANDA No. 076159 and any supplements, amendments, or revisions thereto.

PP. "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.

QQ. "High Volume Account(s)" means any retailer, wholesaler or distributor whose annual aggregate purchase volumes, in units or in dollars, of a Divestiture Product from a Respondent were among the largest customers of the Respondent for that Divestiture Product in the United States of America and which customers, when aggregated together, represent at least 80% of that Respondent's sales to for that Divestiture Product during (i) 2011 and (ii) the first (6) months of 2012.

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

SS. "Isradipine Products" means all Products in Development, manufactured, marketed or sold pursuant to ANDA No. 77-169 and any supplements, amendments, revisions thereto.

TT. "Isradipine Product Assets" means all rights, title and interest in and to all assets and rights solely and exclusively related to the Isradipine Products. "Isradipine Product Assets" includes, without limitation,

1. any rights to research, Develop, manufacture, distribute, promote, market, or sell the Isradipine Products in the Geographic Territory;

2. any rights to any future interest or profits in the Isradipine Products;

3. any rights to any Confidential Business Information related to the Isradipine Products;

4. any rights to consent to the offer to sell, or sale of, the Isradipine Products;

5. any rights to consent to the offer to sell, or sale of, any asset solely and exclusively related to the Isradipine Products; and

6. any other rights that are solely and exclusively related to the Isradipine Products that were either granted to, or reserved by, the Respondent Actavis pursuant to the *Asset Purchase Agreement* between Actavis Totowa LLC and Mikah Pharma LLC dated June 16, 2010. This agreement is attached to this Order and contained in Non-Public Appendix C.

UU. "Isradipine Product Divestiture Agreement" means the *Amendment and Waiver to the Asset Purchase Agreement* (referencing the Asset Purchase Agreement dated June 16, 2010 between the parties) executed by Actavis Inc. and agreed and accepted by Mikah Pharma LLC, dated August 27, 2012. The Isradipine Divestiture Agreement is attached to this Order and contained in Non-Public Appendix C.

VV. "Law" means a gru1tion,, or dinance Tj 91.2000 0.0000 TD (, amd cther rr)Tj 18.5200 0.0000 TD

WW. "Lorazepam Products" means all Products in Development, manufactured, marketed or sold by Respondent Actavis pursuant to the following ANDAs:

1. ANDA No. 071403 and any supplements, amendments, or revisions thereto;

2. ANDA No. 071404 and any supplements, amendments, or revisions thereto; and

3. ANDA No. 071141 and any supplements, amendments, or revisions thereto.

XX. "Loxapine Products" means all Products in Development, manufactured, marketed or sold pursuant to ANDA No. 76-868 and any supplements, amendments, or revisions thereto.

YY. "Loxapine Product Assets" means all rights, title and interest in and to all assets and rights solely and exclusively related to the Loxapine Products. "Loxapine Product Assets" includes, without limitation,

1. any rights to research, Develop, manufacture, distribute, promote, market, or sell the Loxapine Products in the Geographic Territory;

2. any rights to any future interest or profits in the Loxapine Products;

3. any rights to any Confidential Business Information related to the Loxapine Products;

4. any rights to consent to the offer to sell, or sale of, the Loxapine Products;

5. any rights to consent to the offer to sell, or sale of, any asset solely and exclusively related to the Loxapine Products; and

6. any other rights that are solely and exclusively related to the Loxapine Products that were either granted to, or reserved by, the Respondent Actavis pursuant to the *Asset Purchase Agreement* between Actavis Totowa LLC and Mikah Pharma LLC dated August 26, 2011. This agreement is attached to this Order and contained in Non-Public Appendix C.

ZZ. "Loxapine Product Divestiture Agreement" means the *Amendment and Waiver to the Asset Purchase Agreement* (referencing the Asset Purchase Agreement dated August 26, 2011, between the parties) executed by Actavis Inc. and agreed and accepted by Mikah Pharma LLC, dated August 27, 2012. The Loxapine Divestiture Agreement is attached to this Order and contained in Non-Public Appendix C.

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

BBB. "Methylphenidate Hydrochloride Extended Release Products" means all Products in Development, manufactured, marketed or sold by Respondent Actavis that contain the

active pharmaceutical ingredient Methylphenidate and that are in Development using an extended-release delivery system and to be indicated for the treatment of attention deficit hyperactivity disorder.

CCC. "Metoclopramide Hydrochloride Products" means all Products in Development, manufactured, marketed or sold by Respondent Actavis pursuant to ANDA No. 070581 and any supplements, amendments, or revisions thereto.

DDD. "Mikah Pharma" means Mikah Pharma LLC is a limited liability company organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarter address located at 20 Kilmer Drive, Hillsborough, New Jersey 08844.

EEE. "Morphine Sulphate Extended Release Products" means all Products in Development, manufactured, marketed or sold by Respondent Watson pursuant to ANDA No. 200812 and any supplements, amendments, or revisions thereto.

FFF. "Morphine Sulphate Naltrexone Extended Release Products" means all Products in Development, manufactured, marketed or sold pursuant to NDA No. 22321 and any supplements, amendments, or revisions thereto.

GGG. "Morphine Sulphate Naltrexone Extended Release Product Agreement" means the *Development and Manufacturing Services Agreement* by and between Actavis Elizabeth LLC and Alpharma.

3. rights to move or transfer the above-described equipment, at Respondents' expense, to a facility chosen by Pfizer;

4. rights to move or transfer manufacturing, at Respondents' expense, of the Morphine Sulphate Naltrexone Extended Release Products by Pfizer at any time chosen by Pfizer, during the term of the Morphine Sulphate Naltrexone Extended Release Product Agreement as amended by the Morphine Sulphate Naltrexone Extended Release Product Divestiture Agreement;

5. rights to (i) require Respondents to prepare technical transfer protocols consistent with Technology Transfer Standards, (ii) require Respondents to assist Pfizer in such technical transfer of the manufacturing of the Morphine Sulphate Naltrexone Extended Release Products at any time chosen by Pfizer and at a facility chosen by Pfizer, and (iii) receive such preparation and assistance from the Respondents at no greater than Respondents' Direct Cost, during the term of the Morphine Sulphate Naltrexone Extended Release Product Agreement as amended by the Morphine Sulphate Naltrexone Extended Release Product Divestiture Agreement;

6. rights to extend the requirement for Respondents to supply the Morphine Sulphate Naltrexone Extended Release Product to Pfizer for term not to exceed four (4) years from the date of first commercial sale of the Morphine Sulphate Naltrexone Extended Release Product as reformulated and relaunched after the Acquisition Date; *provided, however*, that, if the relaunch of the Morphine Sulphate Naltrexone Extended Release Product does not occur within three (3) years of the date of the Morphine Sulphate Naltrexone Extended Release Product Divestiture Agreement, then this requirement for Respondents' to supply such Product to Pfizer shall expire three (3) years from the date of the Morphine Sulphate Naltrexone Extended Release Product Divestiture Agreement;

7. rights to prohibit Respondents from terminating the Morphine Sulphate Naltrexone Extended Release Product Agreement as a result of the Acquisition;

8. rights to terminate the Morphine Sulphate Naltrexone Extended Release Product Agreement at will; and

9. rights to all Confidential Business Information related to the Morphine Sulphate Naltrexone Extended Release Products, and rights to control the use and dissemination thereof.

JJJ.

LLL. "Order Date" means the date on which this Decision and Order is issued by the Commission to become final and effective.

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

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

OOO. "Oxycodone Extended Release Products" means all Products in Development, manufactured, marketed or sold by Respondent Actavis pursuant to ANDA No. 202434 and any supplements, amendments, or revisions thereto.

PPP. "Oxymorphone Extended Release Products" means all Products in Development, manufactured, marketed or sold by Respondent Watson pursuant to ANDA No. 200792 and any supplements, amendments, or revisions thereto.

QQQ. "Par" means Par Pharmaceutical, Inc., a corporation organized, existing and doing business under and by virtue of the laws of Delaware, with its headquarters address at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

RRR. "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 existing as of 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, related to any Product of or owned by a Respondent as of the Closing Date (*except* where this Order specifies a different time).

SSS. "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.

TTT. "Pfizer" means Pfizer Pharmaceuticals Inc., a corporation organized, existing and doing business under and by virtue of the laws of Delaware, with its headquarters address at 235 E. 42nd Street, New York, New York 10017.

UUU. "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.

VVV. [illegible]

States of America, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application.

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

1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from a Respondent unless such contract applies generally to the Respondent's sales of Products to that Third Party;

2. pursuant to which a Respondent purchases 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 packages the specified Divestiture Product on behalf of a Respondent;

7. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to a Respondent;

8. pursuant to which a Third Party is licensed by a Respondent to use the Product Manufacturing Technology;

9. constituting confidentiality agreements involving the specified Divestiture Product;

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

11. 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 limi112.4400 184.4400 TD dengement involving

12. 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 assign 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).

XXX. "Product Copyrights" means rights to all original works of authorship of any kind directly related to the specified 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 such Divestiture Product or of any materials used in the research, Development, manufacture, marketing or sale of such Divestiture Product, including all copyrights in raw data relating to Clinical Trials of such Divestiture Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, and the specifie

4. all correspondence to a Respondent from the FDA and from a Respondent to the FDA relating to the Application(s) submitted by, on behalf of, or acquired by, the Respondent 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/serious adverse event summaries 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 purpose 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.

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

1. a complete and accurate list containing the name of each Divestiture Product Core Employee (including former employees who were employed by the specified Respondent 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, the specified Respondent 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 the relevant Respondent's 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.

AAAA. "Product Intellectual Property" means all of the following related to a Divestiture Product (other than a 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, 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 violations of any of the foregoing;

provided, however, "Product Intellectual Property" *excludes* the coporate names or corporate trade dress of "Watson" or "Actavis", or the related cor

compliance, and labeling and all other information related to the manufacturing process, and supplier lists;

2. all active pharmaceutical ingredients related to the specified Divestiture Product; 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 the specified Divestiture Product.

EEEE. "Product Marketing Materials" means all marketing materials used specifically

particular assets or rights required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by a Respondent pursuant to this Order.

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

1. any agreement between a Respondent 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, 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 and a Third Party to effect the assignment of assets or rights of the Respondent 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 and effective;

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

LLLL. "Retained Product" means any Product(s) Developed, manufactured, marketed or sold by a Respondent that is not a Divestiture Product.

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

NNNN. "Rivastigmine Patch Film Products" means all Products in Development, manufactured, marketed or sold by Respondent Actavis pursuant to ANDA No. 202399 and any supplements, amendments, or revisions thereto.

OOOO. "Sandoz" means Sandoz Inc., a subsidiary of Novartis AG, that is organized, existing and doing business under and by virtue of the laws of the State of Colorado, with its headquarters address located at 506 Carnegie Center, Princeton, New Jersey 08540.

PPPP. "Supply Cost" means a cost no

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.

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

SSSS. "Ursodiol Products" means all Products in Development, manufactured, marketed or sold by Respondent Actavis pursuant to ANDA No. 202540 and any supplements, amendments, or revisions thereto.

TTTT. "Varenicline Tartrate Products" means all Products in Development, manufactured, marketed or sold by Respondent Actavis pursuant to ANDA No. 201785 and any supplements, amendments, or revisions thereto.

oved 14.0400 0.0000 TD (,)Tj s,800 6Q i 17.6400 0.0000 TDa6400 0.0000 TD

Urlkeo ans anyesu n thle o1.2800 0.0000 TD-(nt t)T) l1.2800 0.0000 TD (n th)To 14.4000 0.0000 TD

nt.SSSS.

provided, however, that if Respondents have divested the Generic

provided further, however, that if Respondents have divested the Generic Products (Group Two) Assets and granted the above-described Divestiture Product License to Sandoz 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 Generic Products (Group Two) Assets or grant of the above-described Divestiture Product License, as applicable, to Sandoz (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.

C. 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 assets required to be divested pursuant to this Order to an Acquirer, and to permit the relevant Acquirer to continue the research, Development, manufacture, sale, marketing or distribution 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.

D. Respondents shall provide, or cause to be provided to each Acquirer in a manner consistent with the Technology Transfer Standards the following:

1. all Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Product(s) being acquired by that Acquirer; and

2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed by a 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.

E. Respondents shall:

1. upon reasonable written notice and request from an Acquirer to Respondents, Contract Manufacture and deliver to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products related to the Divestiture Products acquired by that Acquirer at Respondents' Supply Cost, for a period of time sufficient to allow that 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 source sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary

components listed in the relevant Respondent's Application(s) for the Divestiture Product(s) acquired by that Acquirer from Persons other than the Respondents;

2. make representations and warranties to the Acquirer(s) 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 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 a Respondent to meet cGMP. This obligation may be made contingent upon the Acquirer giving the Respondent prompt written notice of such claim and cooperating fully in the defense of such claim. The Remedial Agreement shall be consistent with the obligations assumed by Respondents under this Order;

   provided, however, that Respondents 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 Respondents' 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;

   provided further, however, that in each instance where: (i) an agreement to divest relevant assets or to 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 by a Respondent 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 de2.2000 0.0000 TD (rve the)Tj 32.

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 between a Respondent and an Acquirer, upon written request of that Acquirer or the Interim Monitor (if any has been appointed), make available to the Acquirer and the Interim Monitor (if any has been appointed) all records that relate to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;

assets or other Persons specifically authorized by that Acquirer to receive such information; 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 Divestiture Products to Respondents' employees responsible for making pricing decisions related to those Retained Products that are prescription pharmaceuticals for the treatment of the same disease(s) as the Divestiture Products;

provided, however, that the restrictions contained in this Order regarding the Respondents' use, conveyance, provision, or disclosure of Confidential Business Information shall not apply to the following: (i) information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by the Respondents; (ii) information that is required by Law or rules of an applicable stock exchange to be publicly disclosed; (iii) information specifically excluded from the Divestiture Product Assets; and (iv) all intellectual property licensed on a non-exclusive basis to the particular Acquirer.

G. Respondents shall require that each of Respondents' employees that has had access to Confidential Business Information within the one (1) year period prior to the Acquisition Date sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the non-disclosure of that information to all other employees, executives or other personnel of Respondents (other than as necessary to comply with the requirements of the Orders).

H. Not later than thirty (30) days after the Acquisition Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondents' personnel to all of Respondents' employees who are covered by Paragraph II.F.6. 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 date the Order to Maintain Assets is issued by the Commission to become final and effective. Respondents shall provide a copy of the notification to the relevant Acquirer. Respondents shall maintain complete records of all such notifications at Respondents' registered office within the United States and shall provide an officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Respondents shall provide the relevant Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

I. Respondents shall not enforce any agreement against [illegible]

Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology.

J. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to an agreement as described in Paragraph II.I. 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.

K. Respondents shall:

1. for each Divestiture Product, for a period of six (6) months from the Closing Date or until the hiring of twenty (20) Divestiture Product Core Employees by an Acquirer or its Manufacturing Designee, whichever occurs earlier, provide that Acquirer with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, and manufacture the Divestiture Product consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Product and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product has occurred, inc

composition of matter, relating to the Divestiture Product(s) acquired by that Acquirer, or that claims a device relating to the use thereof;

2. any Patent owned or license

b. the distribution, sale and marketing of the respective Divestiture Products in the Geographic Territory; and,

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

III.

IT IS FURTHER ORDERED that:

A. Not later than the earlier of: (i) ten (10) days after the Acquisition Date or (ii) ten (10) days after the Order Date, Respondents shall divest the Isradipine Product Assets (to the extent that such assets are not already owned, controlled or in the possession of Mikah Pharma), absolutely and in good faith, to Mikah Pharma pursuant to, and in accordance with, the Isradipine Product Divestiture Agreement (which agreement shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Mikah Pharma or to reduce any obligations of Respondents under such agreement) and the agreement, if it becomes a Remedial Agreement related to the Isradipine Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Isradipine Product Assets to Mikah Pharma 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 Isradipine Product Assets to Mikah Pharma (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;

provided further, however, neither this Order nor any Remedial Agreement related to the divestiture of the Isradipine Product Assets shall be construed to confer any rights to Mikah Pharma to restrict the Respondents from researching, Developing, manufacturing, distributing, marketing, or selling a Product that is the generic equivalent of the Isradipine Products.

B. Not later than the earlier of: (i) ten (10) days after the Acquisition Date or (ii) ten (10) days after the Order Date, Respondents shall divest the Loxapine Product Assets (to the extent that such assets are not already owned, controlled or in the possession of Mikah Pharma), absolutely and in good faith, to Mikah Pharma pursuant to, and in accordance with, the Loxapine Product Divestiture Agreement (which agreement shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Mikah Pharma or to reduce any obligations of Respondents under such agreement) and the agreement, if it becomes a

Remedial Agreement related to the Loxapine Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Loxapine Product Assets to Mikah Pharma 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 Loxapine Product Assets to Mikah Pharma (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.

provided further, however, neither this Order nor any Remedial Agreement related to the divestiture of the Loxapine Product Assets shall be construed to confer any rights to Mikah Pharma to restrict the Respondents from researching, Developing, manufacturing, distributing, marketing, or selling a Product that is the generic equivalent of the Loxapine Products.

C. The purpose of the divestiture of the Isradipine Product Assets and the Loxapine Product Assets is:

1. to ensure the continued use of such assets in the research, Development, and manufacture of the Isradipine Products and the Loxapine Products and for the purposes of the business associated with each of these Products within the Geographic Territory;

2. to provide for the future use of such assets for the distribution, sale and marketing of the Isradipine Products and the Loxapine Products in the Geographic Territory;

3. to create a viable and effective competitor, that is independent of the Respondents:

   a. in the research, Development, and manufacture of the Isradipine Products and the Loxapine Products for the purposes of the business associated with these Products within the Geographic Territory; and

   b. the distribution, sale and marketing of the Isradipine Products and the Loxapine Products in the Geographic Territory; and,

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

IV.

IT IS FURTHER ORDERED that:

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

provided, however, that if Respondents have divested the Morphine Sulphate Naltrexone Extended Release Product Assets and granted the above-described Divestiture Product License to Pfizer 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 Morphine Sulphate Naltrexone Extended Release Product Assets or grant of the above-described Divestiture Product License, as applicable, to Pfizer (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

provided further, however, neither this Order nor any Remedial Agreement related to the divestiture of the Morphine Sulphate Naltrexone Extended Release Product Assets shall be construed to confer any rights to Pfizer to restrict the Respondents from researching, Developing, manufacturing, distributing, marketing, or selling a Product that is the generic equivalent of the Morphine Sulphate Naltrexone Extended Release Products.

B. Respondents shall:

1. upon request by Pfizer, submit to Pfizer, at Respondents' expense, any Confidential Business Information related to the Morphine Sulphate Naltrexone Extended Release Products;

2. deliver such Confidential Business Information to Pfizer:

   a. in good faith;

b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delay

information that is required by Law or rules of an applicable stock exchange to be publicly disclosed; and (iii) [illegible]

b. the distribution, sale and marketing of the Morphine Sulphate Naltrexone Extended Release Products in the Geographic Territory; and,

4. 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 Respondent Watson signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondents expeditiously complies with all of their obligations and performs all of their responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements.

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

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

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

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

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

3. The Interim Monitor shall serve until the date of completion by the Respondents of the divestiture of all Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and until the earliest of:

a. with respect to each D

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

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 Respondent Watson which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent Watson has 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 Respondent Watson of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.

D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.

2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be

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

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee 1.00000 0.00000 0.00000 scn 0.0000 0.0000 cm 0.00 0.00 0.00 rg BT

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

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however,* that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of 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

requirement if that Acquirer withholds such agreement unreasonably); and (2) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

IX.

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 the Respondents' obligations to the Acquirer pursuant to this Order.

D. Respondents shall also include in each Remedial Agreement a representation from the Acquirer that that 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 Respondents, all as soon as reasonably practicable.

E. Respondents shall not 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. Respondents shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission.

X.

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 the following Paragraphs II.A , II.B., II.C., II.D., II.E., II.F.1. - II.F.3, II.G., II.J., II.K.1. - II.K.4, II.L., III.A. III.B., and IV.A., Respondents shall submit to the Commission a verified written report setting forth in detail the manner

and form in which they intend to comply, are complying, and have complied with the Orders. Respondents shall submit at the same time a copy of their report concerning

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

XII.

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

A. access, during business office hours of that Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of that Respondent related to compliance with this Order, which copying services shall be provided by that 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 that Respondent, who may have counsel present, regarding such matters.

XIII.

IT IS FURTHER ORDERED that this Order shall terminate on December 13, 2022.

By the Commission.

Donald S. Clark
Secretary

SEAL
ISSUED: December 13, 2012

NON-PUBLIC

APPENDIX A

GENERIC PRODUCTS (GROUP ONE) DIVESTITURE AGREEMENTS

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

NON-PUBLIC

APPENDIX B

GENERIC PRODUCTS (GROUP TWO) DIVESTITURE AGREEMENTS

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

NON-PUBLIC

APPENDIX C

THE ISRADIPINE DIVESTITURE AGREEMENT

AND

THE LOXAPINE DIVESTITURE AGREEMENT

AND

RELATED AGREEMENTS

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

NON-PUBLIC

APPENDIX D

THE MORPHINE SULPHATE NALTREXONE EXTENDED RELEASE PRODUCT DIVESTITURE AGREEMENT

AND

RELATED AGREEMENTS

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