1210132

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.,	)	**Docket No. C-**
a private limited liability company;	)	
	)	

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"), cdd TD(rs00 0.14.5200 0.0000 TD(m0.000i"

employees, agents, representatives, successors, and assigns of each. After the A

K. "Application(s)" means all of the following: "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug Application" ("SNDA"), or "Marketing Authorization Application" ("MAA"), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between a Respondent and the FDA related thereto. The term "Application" also includes an "Investigational New Drug Application" ("IND") filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between a Respondent and the FDA related thereto.

L. "Bupropion Hydrochloride Extended Release Products" means all Products in Development, manufactured, marketed or sold by Respondent Actavis pursuant to ANDA No. 077475 and any supplements, amendments, or revisions thereto.

M. "Categorized Assets" means, for each specified Divestiture Product, all of the specified Respondent's rights, title and interest in and to all assets related to the Respondent's busin0 0.0000 TD(s)TjET0.0000 cmrsbusin0 0.0000 TD(s)TjEr0008e Respondent'

a. to require Respondents to discontinue the use of the 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

b. anticipated reorder dates for each customer as of the Closinf t

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, exportation, cost, supply, sales, sales support, or use of a Divestiture Product(s). The term "Confidential Business Information" *excludes* (i) information relating to the Respondents' general business strategies or practices relating to research, Development, manufacture, marketing, or sales of Products that does not discuss with particularity the Divestiture Products, (ii) information that is protected by the attorney work product, attorney-client, joint defense or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws, and (iii) information that is contained in documents, records, or books of the Respondents provided to the Acquirer by the Respondents that is unrelated to the Divestiture Products or that is exclusively related to Retained Product(s).

R. "Contract Ma

W. “Diltiazem Hydrochloride Extended Release (Group Two) Products” means all Products in Development, manufactured, marketed or sold by Respondent Actavis pursuant to ANDA

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.

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

EE. "Domain Name" means the domain name(s), URL(s) (universal resource locator(s)), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration. "Domain Name" *excludes* any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.

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

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, or 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:

1. *Asset Purchase Agreement* between Actavis South Atlantic LLC, and Par Pharmaceutical, Inc., dated as of September 24, 2012, and all amendments, exhibits, attachments, agreements, and schedules thereto;

2. *Asset Purchase Agreement* between Actavis Elizabeth LLC, and Par Pharmaceutical, Inc., dated as of September 24, 2012, and all amendments, exhibits, attachments,

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 Corpora 0t0,re

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

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 Teva (nd) nHgavi8ts.

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. 22-321 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 Pharmaceuticals LLC, dated February 1, 2008. The Morphine Sulphate Naltrexone Extended Release Product Agreement is attached to this Order and contained in Non-Public Appendix D.

HHH. "Morphine Sulphate Naltrexone Extended Release Product Divestiture Agreement" means the *Second Amendment to Development and Manufacturing Services Agreement* by and between Pfizer Pharmaceuticals Inc. and Actavis Elizabeth LLC, dated September 24, 2012, (referencing the Morphine Sulphate Naltrexone Extended Release Product Agreement). The Morphine Sulphate Naltrexone Extended Release Product Divestiture Agreement is attached to this Order and contained in Non-Public Appendix D.

III. "Morphine Sulphate Naltrexone Extended Release Product Assets" means the following:

1. all Product Intellectual Property exclusively related to the Morphine Sulphate Naltrexone Extended Release Products that has been Developed for the purposes of the Morphine Sulphate Naltrexone Extended Release Products;

2. exclusive rights to use all equipment that has been improved or modified to manufacture the Morphine Sulphate Naltrexone Extended Release Products where such improvements or modifications to such equipment has been paid for by Pfizer; *provided, however*, that, with the prior approval of Pfizer, Respondents may use such equipment for any other purposes granted to Respondents by Pfizer;

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), TjET1.00000 0.00000 0.00000 1.00000 0.0000 0.0000g

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 limited to, consultation arrangements; and/or

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

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 purposes of resolving any product or process issues, including without limitation, identification and sources of impurities;

15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of the specified Divestiture Product;

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

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

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

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

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

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 (as appli e 's most r),nt st iab

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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 corporate names or corporate trade dress of "Watson" or "Actavis", or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by Respondents or the related corporate logos thereof, or general registered images or symbols by which Watson or Actavis can be identified or defined.

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

1. Patents that are common to a Divestiture Product and a Retained Product;

2. Product Manufacturing Technology that is common to a Divestiture Product and a Retained Product; and

3. for any specified Divestiture Product that is the subject of a risk evaluation mitigation strategy (REMS) that is being prepared for, has been prepared for, submitted to, or approved by the FDA, rights to use such REMS and rights to access all submissions to the FDA related to that REMS.

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

DDDD. "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 specified Divestiture Product, 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 cGM

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 in the marketing or sale of the specified Divestiture Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used fsint da

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, an investigation for the purpose

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

QQQQ. "Technology Transfer Standards" means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*,

1. designating employees knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;

2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product that are acceptable to the Acquirer;

3. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee; and

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

    a. manufacture the specified Divestiture Product in the quality and quantities achieved by the Respondent, or the manufacturer and/or developer of such Divestiture Product;

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

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

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.

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provided, however, that if Respondents have divested the Generic Products (Group One) Assets and granted the above-described Divestiture Product License to Par 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 Par is not an acceptable purchaser of the Generic Products (Group One) Assets, then Respondents shall immediately rescind the transaction with Par, in whole or in part, as directed by the Commission, and shall divest the Generic Products (Group One) Assets and grant the above-described Divestiture Product License within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer(s) that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

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

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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

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 use or sale;

4. make representations and warranties to each Acquirer that Respondents shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by Respondents to deliver the Contract Manufacture Products in a timely manner as required by the Remedial Agreement(s) unless Respondents can demonstrate that their failure was beyond the control of Respondents and not the result of negligence or willful misconduct by Respondents;

   provided, 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,

independently

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 m

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

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 licensed by Respondents at any time after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the Divestiture Product(s) acquired by that Acquirer;

if such suit would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture of the Divestiture Product(s) anywhere in the World for the purposes of marketing or sale in the United States of America; or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of a particular Divestiture Product. Respondents shall also covenant to that 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 that Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture of the Divestiture Product(s) anywhere in the World for the purposes of marketing or sale in the United States of America; or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of a particular Divestiture Product;

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

N. For any patent infringement suit in which a Respondent is alleged to have infringed a Patent of a Third Party prior to the Closing Date or for such suit as a Respondent has prepared or is preparing as of the Closing Date to defend against such infringement claim(s), and where such a suit would have the potential to interfere with the relevant Acquirer's freedom to practice the following: (i) the research, Development, or manufacture of the Divestiture Product(s) acquired by that Acquirer; or (ii) the use, import, export, supply, distribution, or sale of that Divestiture Product(s), Respondents shall:

1. cooperate with that 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 that Divestiture Product;

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

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

O. Respondents shall not, in the Geographic Territory:

1. use the Product Trademarks contained in the Product Intellectual Property 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 relevant Acquirer's use and registration of such Product Trademarks; or

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

provided, however, that this paragraph shall not preclude Respondents from continuing to use all trademarks, tradenames, or service marks that have been in use in commerce on a Retained Product at any time prior to the Acquisition Date.

P. The purpose of the divestiture of the Generic Products (Group One) Assets and the Generic Products (Group Two) Assets and the transfer and delivery of the related Product Manufacturing Technology 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, and manufacture of the respective Divestiture Products and for the purposes of the business associated with such Divestiture Products within the Geographic Territory;

2. to provide for the future use of such assets for the distribution, sale and marketing of the respective Divestiture 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 each Divestiture Product for the purposes of the business associated with the respective Divestiture Products within the Geographic Territory; and

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 1.0000 TD())Tj3.9600 0.(n)Tj0.00n a40.0000 TD(t)Tj1.00

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.

b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and

c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;

3. pending complete delivery of all such requested Confidential Business Information to Pfizer, provide Pfizer with access at reasonable business hours to all such Confidential Business Information and Respondents' employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Morphine Sulphate Naltrexone Extended Release Products that contain such requested Confidential Business Information and facilitating the delivery in a manner consistent with this Order;

4. upon request by Pfizer, destroy any and all reproductions or summaries of any Confidential Business Information related to the Morphine Sulphate Naltrexone Extended Release Products that may have been prepared, in which event such destruction shall be promptly carried out;

5. not use, directly or indirectly, any such Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the Morphine Sulphate Naltrexone Extended Release Products other than as necessary to comply with the following:

   a. the requirements of this Order;

   b. Respondents' obligations to Pfizer under the terms of any related Remedial Agreement or Respondents' ongoing obligations to Pfizer under the terms of the Morphine Sulphate Naltrexone Extended Release Product Agreement; or

   c. applicable Law;

6. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except Pfizer or other Persons specifically authorized by Pfizer to receive such information; and

7. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information any of Respondents' employees other than those employees specifically authorized by Pfizer to receive such information;

provided, however, that the restrictions contained in this Order regarding the Respondents' use, conveyance, provis

information that is required by Law or rules of an applicable stock exchange to be publicly disclosed; and (iii) all intellectual property licensed on a non-exclusive basis to Pfizer.

C. Respondents shall require that each of Respondents' employees that has had access to, and/or is authorized by Pfizer to receive, Confidential Business Information related to the Morphine Sulphate Naltrexone Extended Release Products sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Morphine Sulphate Naltrexone Extended Release

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 t

a. with respect to each Divestiture Product, the date the Acquirer of such Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture such Divestiture Product and able to manufacture such Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of the Respondents;

b. with respect to each Divestiture Product, the date the Acquirer of that Divestiture Product notifies the Commission and the Respondents of its intention to abandon its efforts to manufacture such Divestiture Product; or

c. with respect to each Divestiture Product, the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the rele

7. Respondents shall report to the I

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 responsib4.00rs440(I)3.072g0BT.0TD(consistent seeking,)Tj

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

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

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to 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 to a div

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 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 necessary or appropriate to accomplish the divestiture required by this Order.

VII.

IT IS FURTHER ORDERED that:

A. Until Respondents complete the divestitures required by this Order and fully provides, or causes to be provided, the Product Manufacturing Technology related to a particular Divestiture Product to the relevant Acquirer,

1. Respondents shall take actions as are necessary to:

   a. maintain the full economic viability and marketability of the businesses associated with that Divestiture Product;

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

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

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

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

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

VIII.

IT IS FURTHER ORDERED

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 compliance with the Orders to the Interim Monitor, if any Interim Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a detailed description of their efforts to comply with the relevant paragraphs of the Orders, including:

1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondents to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and

2. a detailed description the timing for the completion of such obligations.

C. One (1) year after the Order Date, annually for the next five (5) years on the anniversary of the Order Date, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

XI.

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

A. any proposed dissolution of a Respondent;

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

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]