

UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION

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

\_\_\_\_\_)  
In the Matter of )  
AKORN, INC., ) Docket C-4479  
a corporation. )  
\_\_\_\_\_)

**DECISION AND ORDER**  
**[Public Record Version]**

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Akorn, Inc. (“Akorn” or “Respondent”) of the voting securities of VersaPharm Incorporated (“VersaPharm”), and Respondent 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 Respondent Akorn 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

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has 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 Akorn is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Louisiana, with its headquarters address located at 1925 W. Field Court, Suite 300, Lake Forest, Illinois 60045.
2. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

## **ORDER**

### **I.**

**IT IS ORDERED** that, as used in the Order, the following definitions shall apply:

- A. “Akorn” means Akorn, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Akorn, Inc. (including, without limitation, Akorn Enterprises, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Akorn shall include VersaPharm.
- B. “VersaPharm” means VersaPharm Incorporated, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by VersaPharm Incorporated, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Actavis” means Actavis plc, a corporation organized, existing and doing business under and by virtue of the laws of Ireland, with its world headquarters located in Dublin, Ireland, and its United States headquarters address located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.
- D. “Watson” means Watson Laboratories, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its headquarters address located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Watson Laboratories, Inc. is a wholly owned subsidiary of Actavis plc.
- E. “Respondent” means Akorn.
- F. “Commission” means the Federal Trade Commission.
- G. “Acquirer(s)” means the following:
  1. a Person specified by name in this Order to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the

Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective; or

2. a Person approved by the Commission to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.

- H. "Acquisition" means Respondent's acquisition of the voting securities of VersaPharm. Respondent entered an *Agreement and Plan of Merger* between Akorn, Inc., Akorn Enterprises II, Inc., VPI Holdings Corp., and Tailwind Management LP, dated as of May 9, 2014, that was submitted to the Commission.
- I. "Acquisition Date" means the date on which the Acquisition is consummated.
- J. "Agency(ies)" means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term "Agency" includes, without limitation, the United States Food and Drug Administration ("FDA").
- K. "Akorn Rifampin Product" means the Product in Development, manufactured, owned or controlled by Respondent pursuant to ANDA No. 206736 filed with the FDA on December 27, 2013, and any supplements, amendments, or revisions thereto.
- L. "Akorn Rifampin Product Assets" means all rights, title and interest in and to all assets related to the Business within the Geographic Territory of Respondent related to the Akorn Rifampin Product, to the extent legally transferable, including, without limitation, the following assets and rights of Respondent, as such assets and rights are in existence as of the date Respondent signs the Consent Agreement in this matter and as are maintained by Respondent in accordance with the Order to Maintain Assets until the Closing Date:
1. all rights to all of the Applications related to the Akorn Rifampin Product;
  2. all Product Intellectual Property related to the Akorn Rifampin Product that is not Product Licensed Intellectual Property;
  3. all Product Approvals related to the Akorn Rifampin Product;
  4. all Product Manufacturing Technology related to the Akorn Rifampin Product that is not Product Licensed Intellectual Property;
  5. all Product Marketing Materials related to the Akorn Rifampin Product;
  6. all Product Scientific and Regulatory Material related to the Akorn Rifampin Product;
  7. all Website(s) related exclusively to the Akorn Rifampin Product;
  8. the content related exclusively to the Akorn Rifampin Product that is displayed on any Website that is not dedicated exclusively to the Akorn Rifampin Product;

9. a list of all of the NDC Numbers related to the Akorn Rifampin Product, and rights, to the extent permitted by Law, and to the extent they are assigned to the Respondent:
  - a. to require Respondent to discontinue the use of those NDC Numbers in the sale or marketing of the Akorn Rifampin Product *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement;
  - b. to prohibit Respondent from seeking from any customer any type of cross-referencing of those NDC Numbers with any Retained Product(s) *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law;
  - c. to seek to change any cross-referencing by a customer of those NDC Numbers with a Retained Product (including the right to receive notification from the Respondent of any such cross-referencing that is discovered by Respondent);
  - d. to seek cross-referencing from a customer of the Respondent's NDC Numbers related to the Akorn Rifampin Product with the Acquirer's NDC Numbers related to the Akorn Rifampin Product;
  - e. to approve the timing of Respondent's discontinued use of those NDC Numbers in the sale or marketing of the Akorn Rifampin Product *except* for returns, rebates, allowances, and adjustments for the Akorn Rifampin Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement; and
  - f. to approve any notification(s) from Respondent to any customer(s) regarding the use or discontinued use of such NDC numbers by Respondent prior to such notification(s) being disseminated to the customer(s);
10. all Product Development Reports related to the Akorn Rifampin Product;
11. at the option of the Acquirer of the Akorn Rifampin Product, all Product Assumed Contracts related to the Akorn Rifampin Product (copies to be provided to that Acquirer on or before the Closing Date);
12. all patient registries related to the Akorn Rifampin Product, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data, and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the Akorn Rifampin Product (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA); and

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

*PROVIDED, HOWEVER*, that "Akorn Rifampin Product Assets" shall not include: (i) documents relating to Respondent's general business strategies or practices relating to the conduct of its Business of generic pharmaceutical Products, where such documents do not discuss with particularity the Akorn Rifampin Product; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of the Akorn Rifampin Product by the Monitor or the Acquirer of the Akorn Rifampin Product; (iv) 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 Akorn Rifampin Product and to Retained Products or Businesses of Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Akorn Rifampin Product; or (ii) for which Respondent has a legal obligation to retain the original copies, the Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the Akorn Rifampin Product, Respondent shall provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that Respondent provides the Acquirer with the above-described information without requiring Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

M. "Akorn Rifampin Product Divestiture Agreements" means the following:

1. The Asset Purchase Agreement between Akorn, Inc. and Watson Laboratories, Inc., dated as of July 21, 2014; and
2. The Manufacturing Supply Agreement attached as an exhibit to the above-described Asset Purchase Agreement to be executed as of the Closing Date;

all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Akorn Rifampin Product Assets that have been approved by the Commission to accomplish the requirements of this Order. The Akorn Rifampin Product Divestiture Agreements are contained in Non-Public Appendix A.

N. "Application(s)" means "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug Application" ("SNDA"), or "Marketing Authorization Application" ("MAA"), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 *et seq.*, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the 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, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the Respondent and the FDA related thereto.

- O. “Business” means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement, and sale of a Product.
- P. “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.
- Q. “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.
- R. “Closing Date” means the date on which Respondent (or a Divestiture Trustee) consummates the transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to the Akorn Rifampin Product to an Acquirer pursuant to this Order.
- S. “Confidential Business Information” means all information owned by, or in the possession or control of, Respondent that is not in the public domain and that is directly related to the conduct of the Business related to the Akorn Rifampin Product. The term “Confidential Business Information” *excludes* the following:
  - 1. information relating to Respondent’s general business strategies or practices that does not discuss with particularity the Akorn Rifampin Products;
  - 2. information specifically excluded from the Akorn Rifampin Product Assets conveyed to the Acquirer; and
  - 3. 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.
- T. “Contract Manufacture” means:
  - 1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer;
  - 2. to manufacture, or to cause to be manufactured, a Product that is the therapeutic equivalent (as that term is defined by the FDA) and in the identical dosage strength, formulation and presentation as a Contract Manufacture Product on behalf of an Acquirer; and
  - 3. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Contract Manufacture Product on behalf of an Acquirer.

- U. “Contract Manufacture Product(s)” means :
1. the Akorn Rifampin Product; and
  2. any ingredient, material, or component used in the manufacture of the Akorn Rifampin Product, including the active pharmaceutical ingredient, excipients, or packaging materials;
- PROVIDED HOWEVER*, that with the consent of the Acquirer of the Akorn Rifampin Product, Respondent may substitute a therapeutic equivalent (as that term is defined by the FDA) form of such Product in performance of Respondent’s agreement to Contract Manufacture.
- V. “Development” means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.
- W. “Direct Cost” means a cost not to exceed the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of Respondent’s employees’ labor shall not exceed the average hourly wage rate for such employee;
- PROVIDED, HOWEVER*, in each instance where (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, “Direct Cost” means such cost as is provided in such Remedial Agreement for the Akorn Rifampin Product.
- X. “Divestiture Product License” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) under a Remedial Agreement with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, or controlled by Respondent:
1. to research and Develop the Akorn Rifampin Products for marketing, distribution, or sale within the Geographic Territory;
  2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the Akorn Rifampin Products within the Geographic Territory;
  3. to import or export the Akorn Rifampin Products to or from the Geographic Territory to the extent related to the marketing, distribution, or sale of the Akorn Rifampin Products in the Geographic Territory; and

4. to have the Akorn Rifampin Products made anywhere in the world for distribution or sale within, or imported 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 prior to the Acquisition, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to Respondent.

- Y. “Divestiture Product Releasee(s)” means the following Persons:
1. the Acquirer for the assets related to the Akorn Rifampin Product;
  2. any Person controlled by or under common control with the Acquirer; and
  3. any Manufacturing Designees, licensees, sublicensees, manufacturers, suppliers, distributors, and customers of the Acquirer, or Acquirer-affiliated entities.
- Z. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.
- AA. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration; *PROVIDED, HOWEVER*, “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- BB. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- CC. “Geographic Territory” shall mean the United States of America, including all of its territories and possessions, unless otherwise specified.
- DD. “Government Entity” means any federal, state, local, or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.
- EE. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- FF. “Manufacturing Designee” means any Person other than the Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- GG. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- HH. “NDC Number(s)” means the National Drug Code number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code for a specific Product.
- II. “Orders” means this Decision and Order and the related Order to Maintain Assets.
- JJ. “Order Date” means the date on which the Decision and Order in this matter is issued by the Commission.



- KK. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Consent Agreement.
- LL. “Patent(s)” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention, and applications for certificates of invention and statutory invention registrations, in each case filed, or in existence, on or before the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions, and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.
- MM. “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.
- NN. “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.
- OO. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage or transport of a Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application related to that Product.
- PP. “Product Assumed Contracts” means all 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 Akorn Rifampin Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the Akorn Rifampin Product from the Respondent unless such contract applies generally to the Respondent’s sales of Products to that Third Party;
  2. pursuant to which Respondent had or has as of the Closing Date the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party for use in connection with the manufacture of the Akorn Rifampin Product;
  3. relating to any Clinical Trials involving the Akorn Rifampin Product;
  4. with universities or other research institutions for the use of the Akorn Rifampin Product in scientific research;

5. relating to the particularized marketing of the Akorn Rifampin Product or educational matters relating solely to the Akorn Rifampin Product(s);
6. pursuant to which a Third Party manufactures the Akorn Rifampin Product on behalf of Respondent;
7. pursuant to which a Third Party provides any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of the Akorn Rifampin Product on behalf of Respondent;
8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the Akorn Rifampin Product to Respondent;
9. pursuant to which a Third Party is licensed by Respondent to use the Product Manufacturing Technology;
10. constituting confidentiality agreements involving the Akorn Rifampin Product;
11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the Akorn Rifampin Product;
12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture, or distribution of the Akorn Rifampin Product to the Respondent including, but not limited to, consultation arrangements; and/or
13. pursuant to which any Third Party collaborates with the Respondent in the performance of research, Development, marketing, distribution or selling of the Akorn Rifampin Product or the Business related to the Akorn Rifampin Product;

*PROVIDED, HOWEVER*, that where any such contract or agreement also relates to a Retained Product(s), Respondent shall assign the Acquirer all such rights under the contract or agreement as are related to the Akorn Rifampin Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

QQ. “Product Copyrights” means rights to all original works of authorship of any kind directly related to the Akorn Rifampin Product and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and educational materials for the sales force; copyrights in all preclinical, clinical, and process development data and reports relating to the research and Development of that Product or of any materials used in the research, Development, manufacture, marketing, or sale of that Product, including all copyrights in raw data relating to Clinical Trials of that Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports, and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, that Product’s sales forecasting models, medical education

materials, sales training materials, and advertising and display materials; all records relating to employees of Respondent who accept employment with the Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to that Product or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA or any other Agency.

RR. “Product Development Reports” means:

1. pharmacokinetic study reports related to the Akorn Rifampin Product;
2. bioavailability study reports (including reference listed drug information) related to the Akorn Rifampin Product;
3. bioequivalence study reports (including reference listed drug information) related to the Akorn Rifampin Product;
4. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from, or otherwise conducted with, the FDA relating to the Application(s) related to the Akorn Rifampin 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 Akorn Rifampin Product;
7. currently used or planned Product package inserts (including historical change of controls summaries) related to the Akorn Rifampin Product;
8. FDA-approved patient circulars and information related to the Akorn Rifampin Product;
9. adverse event reports, adverse experience information, descriptions of material events and matters concerning safety or lack of efficacy related to the Akorn Rifampin Product;
10. summary of Product complaints from physicians related to the Akorn Rifampin Product;
11. summary of Product complaints from customers related to the Akorn Rifampin Product;
12. Product recall reports filed with the FDA related to the Akorn Rifampin 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 Akorn Rifampin Product;
14. reports related to the Akorn Rifampin 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 Akorn Rifampin Product that relate to the specifications, degradation, chemical interactions, testing, and historical trends of the production of the Akorn Rifampin Product;
16. analytical methods development records related to the Akorn Rifampin Product;
17. manufacturing batch records related to the Akorn Rifampin Product;
18. stability testing records related to the Akorn Rifampin Product;
19. change in control history related to the Akorn Rifampin Product; and
20. executed validation and qualification protocols and reports related to the Akorn Rifampin Product.

SS. “Product Intellectual Property” means all of the following related to a Divestiture Product (other than Product Licensed Intellectual Property):

1. Patents;
2. Product Copyrights;
3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information; and
4. rights to obtain and file for patents, 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” does not include the corporate names or corporate trade dress of “Akorn” or “VersaPharm” or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by Respondent or the related corporate logos thereof, or general registered images or symbols by which Respondent, or VersaPharm can be identified or defined.

- TT. “Product Licensed Intellectual Property” means the following:
1. Patents that are related to the Akorn Rifampin Product that the Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date; and
  2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to the Akorn Rifampin Product and that the Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date.
- UU. “Product Manufacturing Technology” means all of the following related to the Akorn Rifampin Divestiture Product:
1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable, or otherwise) related to the manufacture of that Product, including, but not limited to, all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;
  2. all ingredients, materials, or components used in the manufacture of that Product including the active pharmaceutical ingredient, excipients, or packaging materials; and
  3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer’s option, all such equipment used to manufacture that Product.
- VV. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of the Akorn Rifampin Product in the Geographic Territory, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter, or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the

production of packaging components, television masters, and other similar materials related to the Akorn Rifampin Product.

- WW. “Product Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and Clinical Trial materials and information.
- XX. “Product Trade Dress” means the current trade dress of a Product including, but not limited to, Product packaging and the lettering of the Product trade name or brand name.
- YY. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for a Product.
- ZZ. “Remedial Agreement(s)” means the following:
1. any agreement between 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 Respondent and a Third Party to effect the assignment of assets or rights of Respondent related to the Akorn Rifkamin 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 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 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 the 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 has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

AAA. “Retained Product” means any Product(s) other than the Akorn Rifampin Product.

BBB. “Supply Cost” means a cost not to exceed the Respondent’s average direct per unit cost in United States dollars of manufacturing the Akorn Rifampin 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 the Akorn Rifampin Product.

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

1. designating employees of the Respondent knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer, or its Manufacturing Designee, and the Monitor (if one has been appointed), for the purpose of effecting such delivery;
2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the Akorn Rifampin 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 Akorn Rifampin Product in the quality and quantities achieved by Respondent, or the manufacturer and/or developer of the Akorn Rifampin Product;
  - b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee to manufacture, distribute, market, and sell the

Akorn Rifampin Product in commercial quantities and to meet all Agency-approved specifications for the Akorn Rifampin Product; and

- c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the Akorn Rifampin Product.

DDD. “Third Party(ies)” means any non-governmental Person other than the Respondent, or the Acquirer.

EEE. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by Respondent; *PROVIDED, HOWEVER*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by the Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that Respondent can convey its rights, if any, therein; or (2) content unrelated to the Akorn Rifampin Product.

## II.

### 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, Respondent shall divest the Akorn Rifampin Product Assets and grant the related Divestiture Product License, absolutely and in good faith, to Watson pursuant to, and in accordance with, the Akorn Rifampin Product Divestiture Agreement(s) (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Watson or to reduce any obligations of Respondent under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Akorn Rifampin Product Assets is incorporated by reference into this Order and made a part hereof;

*PROVIDED, HOWEVER*, that if Respondent has divested the Akorn Rifampin Product Assets to Watson prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that Watson is not an acceptable purchaser of the Akorn Rifampin Product Assets, then Respondent shall immediately rescind the transaction with Watson, in whole or in part, as directed by the Commission, and shall divest the Akorn Rifampin Product Assets within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

*PROVIDED FURTHER, HOWEVER*, that if Respondent has divested the Akorn Rifampin Product Assets to Watson prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such



modifications to the manner of divestiture of the Akorn Rifampin Product Assets to Watson (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Prior to the Closing Date, Respondent shall secure all consents and waivers from all Third Parties that are necessary to permit Respondent to divest the assets required to be divested pursuant to this Order to an Acquirer, and to permit the relevant Acquirer to continue the Business of the Akorn Rifampin Product;

*PROVIDED, HOWEVER*, Respondent may satisfy this requirement by certifying that the relevant Acquirer for the Divestiture Product has executed all such agreements directly with each of the relevant Third Parties.

- C. Respondent shall:

1. submit to the Acquirer, at Respondent's expense, all Confidential Business Information related to the Akorn Rifampin Product being acquired;
2. deliver all Confidential Business Information related to the Akorn Rifampin Product being acquired:
  - a. in good faith;
  - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
  - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all such Confidential Business Information to the Acquirer, provide the Acquirer and the Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Akorn Rifampin Product that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
4. not use, directly or indirectly, any such Confidential Business Information related to the Business of the Akorn Rifampin Product other than as necessary to comply with the following:
  - a. the requirements of this Order;
  - b. Respondent's obligations to the Acquirer under the terms of the Remedial Agreement; or
  - c. applicable Law;

5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the Akorn Rifampin Product, (ii) other Persons specifically authorized by the Acquirer to receive such information, (iii) the Commission, or (iv) the Monitor (if any has been appointed); and
  6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Akorn Rifampin Product to the marketing or sales employees associated with the Business related to those Retained Products that are the therapeutic equivalent (as that term is defined by the FDA) of the Akorn Rifampin Product.
- D. Until the Acquirer (or the Manufacturing Designee of the Acquirer) (i) obtains 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 Respondent, and (ii) identifies sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in the Application(s) of Respondent for the Akorn Rifampin Product, Respondent shall:
1. provide, or cause to be provided to the Acquirer all correspondence, submissions, notifications, communications, registrations, or other filings made to, received from, or otherwise conducted with the FDA relating to the Application(s) related to the Akorn Rifampin Product in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner; and
  2. cooperate with, and assist, Acquirer in responding to all correspondence, submissions, notifications, communications, registrations, or other filings received from, or otherwise conducted with the FDA relating to the Application(s) related to the Akorn Rifampin Product in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner, with copies and notice to the Monitor and the Acquirer of such contacts with the FDA in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner.
- E. Respondent shall provide, or cause to be provided to the 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 Akorn Rifampin Product; and
  2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to Respondent related to the Akorn Rifampin Product.

Respondent shall obtain any consents from Third Parties required to comply with this provision. Respondent shall not enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Akorn Rifampin Product acquired by the Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology. Not later than ten (10) days after the Closing Date, Respondent shall grant a release to each Third Party that is subject to such agreements that allows the Third Party to provide the relevant Product Manufacturing Technology to that Acquirer. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to that Acquirer.

F. Respondent shall:

1. No later than the date on which the Acquirer obtains all of the relevant Product Approvals necessary to manufacture in commercial quantities (and in a manner consistent with cGMP) the Akorn Rifampin Product, Contract Manufacture and deliver, or cause to be manufactured and delivered, to the Acquirer, in a timely manner and under reasonable terms and conditions, a supply of the Akorn Rifampin Product(s) at Supply Cost;
2. continue to Contract Manufacture and deliver such supply of Akorn Rifampin Product(s) to the Acquirer, until the earlier of (i) thirty (30) months from the date of Respondent's first delivery of the Akorn Rifampin Product to the Acquirer, or (ii) the date the Acquirer (or the Manufacturing Designee of the Acquirer) obtains 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 Respondent, and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in the Application(s) of Respondent for the Akorn Rifampin Product ("Acquirer Rifampin Manufacture Date");
3. make representations and warranties to such Acquirer that the Contract Manufacture Product supplied by Respondent pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract Manufacture Product 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 supplied to the Acquirer pursuant to a Remedial Agreement by the 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;

*PROVIDED, HOWEVER*, that Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with the Respondent's responsibilities to supply the Contract Manufacture Products in the manner required by this Order;

*PROVIDED FURTHER, HOWEVER*, that this obligation shall not require Respondent 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 Respondent to the Acquirer in an agreement to Contract Manufacture;

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

4. give priority to supplying a Contract Manufacture Product to the Acquirer over manufacturing and supplying of Products for Respondent's own use or sale;
5. make representations and warranties to each Acquirer that Respondent shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure of the Contract Manufacture Products to be delivered in a timely manner as required by the Remedial Agreement(s) unless Respondent can demonstrate that the failure was beyond the control of Respondent and in no part the result of negligence or willful misconduct by Respondent;

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

6. during the term of any agreement to Contract Manufacture, upon written request of the Acquirer or the Monitor (if any has been appointed), make available to the Acquirer and the Monitor (if any has been appointed) all records that relate directly to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;
7. during the term of any agreement to Contract Manufacture, Respondent shall take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);

8. in the event (i) Respondent becomes unable to supply or produce a Contract Manufacture Product from the facility or facilities originally contemplated under a Remedial Agreement with an Acquirer, and (ii) that Product is the subject of an ANDA, then Respondent shall provide a therapeutically equivalent (as that term is defined by the FDA) Product from another of Respondent's facility or facilities in those instances where such facilities are being used or have previously been used, and are able to be used, by Respondent to manufacture such Product;
9. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Monitor to monitor compliance with the obligations to Contract Manufacture; and
10. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of Respondent and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all Product Approvals to manufacture the Contract Manufacture Products acquired by that Acquirer in the same quality achieved by, or on behalf of, Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent and sufficient to satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the Contract Manufacture Products;

The foregoing provisions, II.F.3-10., shall remain in effect for the time period described in Paragraph II.F.2.

- G. Respondent shall not terminate any agreement with the Acquirer before the end of the term without:
1. prior approval of the Commission;
  2. written agreement of the Acquirer, and thirty-days (30) notice to the Commission; or
  3. in cases of a proposed unilateral termination by Respondent due to an alleged breach of an agreement by the Acquirer, sixty-days (60) notice of such termination. *PROVIDED, HOWEVER*, that such sixty-days (60) notice shall be given only after Respondent and Acquirer have:
    - a. attempted to settle the dispute between themselves, and
    - b. either engaged in arbitration, and received an arbitrator's decision, or received a final court decision after all appeals. *PROVIDED, HOWEVER*, that in the event the Acquirer fails to make any payment more than sixty (60) days after it is due, and such payment is not disputed in good faith by the Acquirer, upon ninety-days' (90) notice to the Acquirer, Respondent may discontinue or withhold manufacturing, supplying, or delivery of the

disputed product or service until such payment of all overdue and outstanding undisputed amounts are made.

- H. Respondent shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each employee that has had responsibilities related to the marketing or sales of the Akorn Rifampin Product within the one (1) year period prior to the Closing Date and each employee that has responsibilities related to the marketing or sales of those Retained Products that are the therapeutic equivalent (as that term is defined by the FDA) of the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order).
- I. Not later than thirty (30) days after the Closing Date, Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondent's personnel to all of their employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondent shall provide a copy of the notification to the Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's 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. Respondent shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.
- J. For the Acquirer of the Akorn Rifampin Product, Respondent shall, for a period of one (1) year from the Acquirer Rifampin Manufacture Date, not, directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product ("Divestiture Product Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or hire any Divestiture Product Employee;
- PROVIDED, HOWEVER*, Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

*PROVIDED FURTHER, HOWEVER*, that Respondent may do the following: (i) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product Employee who contacts Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from Respondent.

K. Until Respondent completes the divestiture required by this Order and fully provides, or causes to be provided, the Product Manufacturing Technology related to the Akorn Rifampin Product to the Acquirer,

1. Respondent shall take actions as are necessary to:
  - a. maintain the full economic viability and marketability of the Businesses associated with the Akorn Rifampin 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 the Akorn Rifampin Product;
  - d. ensure the assets related to each Divestiture Product are provided to the relevant Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Business associated with each Divestiture Product; and
  - e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and
2. Respondent 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 the Akorn Rifampin Product.

L. Respondent shall not join, file, prosecute, or maintain any suit, in law or equity, against the Acquirer or the Divestiture Product Releasee(s) of the Acquirer under the following:

1. any Patent owned by or licensed to Respondent as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof; or
2. any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to Respondent at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

if such suit would have the potential directly to limit or interfere with the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Akorn Rifampin Product for the purposes of marketing, sale or offer for sale within the United States of America of the Akorn Rifampin Product; or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Akorn Rifampin Product. Respondent shall also

covenant to the Acquirer that as a condition of any assignment or license from Respondent to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue the Acquirer or the related Divestiture Product Releasee under such Patents, if the suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Akorn Rifampin Product for the purposes of marketing, sale, or offer for sale within the United States of America of the Akorn Rifampin Product; or (ii) the use within, import into, export from, or the supply, distribution, or sale, or offer for sale within, the United States of America of the Akorn Rifampin Product. The provisions of this Paragraph do not apply to any Patent owned by, acquired by or licensed to or from Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date.

- M. Upon reasonable written notice and request from an Acquirer to Respondent, Respondent shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent to assist the Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to the Akorn Rifampin Product, if such litigation would have the potential to interfere with the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Akorn Rifampin Product for the purposes of marketing, sale, or offer for sale within the United States of America of the Akorn Rifampin Product; or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Akorn Rifampin Product.
- N. For any patent infringement suit filed prior to the Closing Date in which Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Akorn Rifampin Product for the purposes of marketing, sale, or offer for sale within the United States of America of the Akorn Rifampin Product; or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of the Akorn Rifampin Product, that Respondent shall:
1. cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from Respondent in connection with obtaining resolution of any pending patent litigation related to the Akorn Rifampin Product;
  2. waive conflicts of interest, if any, to allow Respondent's outside legal counsel to represent the Acquirer in any ongoing patent litigation related to the Akorn Rifampin Product; and



3. permit the transfer to the Acquirer of all of the litigation files and any related attorney work-product in the possession of Respondent's outside counsel related to the Akorn Rifampin Product.
- O. The purpose of the divestiture of the Akorn Rifampin Product Assets and the provision of the related Product Manufacturing Technology and the related obligations imposed on the Respondent by this Order is:
1. to ensure the continued use of such assets for the purposes of the Business associated with the Akorn Rifampin Product within the Geographic Territory; and
  2. to create a viable and effective competitor that is independent of Respondent and VersaPharm the Business of each Divestiture Product within the Geographic Territory; and,
  3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

### **III.**

#### **IT IS FURTHER ORDERED** that:

- A. Quantic Regulatory Services, LLC (F. William Rahe) shall serve as the Monitor pursuant to the agreement executed by the Monitor and Respondent and attached as Appendix B ("Monitor Agreement") and Non-Public Appendix C ("Monitor Compensation"). The Monitor is appointed to assure that Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements.
- B. Not later than ten (10) days after the appointment of the Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondent's compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.
- C. If a Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
1. The Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.
  2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
  3. The Monitor shall serve until the date of completion by Respondent of the divestiture of the Akorn Rifampin Product Assets, the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the

requirements of this Order and, with respect to each Divestiture Product that is a Contract Manufacture Product, until the earliest of: (i) the date the Acquirer of the Akorn Rifampin Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell the Akorn Rifampin Product and able to manufacture the Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent; (ii) the date the Acquirer of the Akorn Rifampin Product notifies the Commission and Respondent of its intention to abandon its efforts to manufacture the Akorn Rifampin Product; or (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the Akorn Rifampin Product;

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

- D. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent's compliance with the Orders.
- E. The Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
- F. Respondent shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor.
- G. Respondent shall report to the Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Respondent with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement. Within thirty (30) days from the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order. *PROVIDED, HOWEVER*, beginning ninety (90) days after

Respondent has filed its final report pursuant to Paragraph VII.B, and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by the Acquirer toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent.

- H. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *PROVIDED, HOWEVER*, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- I. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- J. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor:
  - 1. The Commission shall select the substitute Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after the notice by the staff of the Commission to Respondent of the identity of any proposed Monitor, Respondent shall be deemed to have consented to the selection of the proposed Monitor.
  - 2. Not later than ten (10) days after the appointment of the substitute Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all rights and powers necessary to permit the Monitor to monitor Respondent's compliance with the relevant terms of the Order in a manner consistent with the purposes of the Order.
- K. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- L. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

#### IV.

##### **IT IS FURTHER ORDERED** that:

- A. If Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Akorn Rifampin 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, Respondent 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 Respondent to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent 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 of the identity of any proposed Divestiture Trustee, Respondent 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, Respondent 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, Respondent 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 may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall

cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *PROVIDED, HOWEVER*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondent from among those approved by the Commission; *PROVIDED FURTHER, HOWEVER*, that Respondent shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *PROVIDED, HOWEVER*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.
  8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
  9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *PROVIDED, HOWEVER*, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

## V.

**IT IS FURTHER ORDERED** that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

- A. To assure Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or

- B. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of the Akorn Rifampin Products or the assets and Businesses associated with the Akorn Rifampin Products;

*PROVIDED, HOWEVER*, that Respondent may disclose such information as necessary for the purposes set forth in this Paragraph V pursuant to an appropriate confidentiality order, agreement or arrangement;

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

## **VI.**

**IT IS FURTHER ORDERED** that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondent shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligation to the Acquirer pursuant to this Order.
- D. Respondent 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.
- E. Respondent shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

## **VII.**

**IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition, Respondent 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 Respondent has fully complied with Paragraph II.F.2., Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent shall submit at the same time a copy of its report concerning compliance with this Order to the Monitor, if any Monitor has been appointed. Respondent shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including:
  - 1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by Respondent to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
  - 2. a detailed description of the timing for the completion of such obligations.
- C. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondent 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.

## **VIII.**

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

- A. any proposed dissolution of Respondent;
- B. any proposed acquisition, merger or consolidation of Respondent; or
- C. any other change in Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.



**IX.**

**IT IS FURTHER ORDERED** that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to 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 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 Respondent related to compliance with this Order, which copying services shall be provided by Respondent at the request of the authorized representative(s) of the Commission and at the expense of Respondent; and
- B. to interview officers, directors, or employees of Respondent, who may have counsel present, regarding such matters.

**X.**

**IT IS FURTHER ORDERED** that this Order shall terminate on September 16, 2024.

By the Commission.

Donald S. Clark  
Secretary

SEAL  
ISSUED: September 16, 2014

**NON-PUBLIC APPENDIX A  
AGREEMENTS RELATED TO THE DIVESTITURE**

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

**PUBLIC APPENDIX B  
MONITOR AGREEMENT**

**NON-PUBLIC APPENDIX C  
MONITOR COMPENSATION**

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