UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS:	Jon Leibowitz, Chairman Pamela Jones Harbour William E. Kovacic J. Thomas Rosch		
In the Matter of)	
WATSON PHARMACEUTICALS, INC., a corporation,)	Docket No. C-4276
and)	
ROBIN HOOD HOLDINGS LIMITED, a limited liability company.)	
)	

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Watson Pharmaceuticals, Inc. ("Watson"), of Respondent Robin Hood Holdings Limited d/b/a Arrow Group ("Arrow"), and Respondents having been furnished thereafter with a copy of a draft Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

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

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place 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 issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

- 1. Respondent Watson is a corporation organized, existing and doing business under and by virtue of the laws of the State of Nevada, with its corporate head office and principal place of business located at 311 Bonnie Circle, Corona, California 92880.
- 2. Respondent Arrow is a private limited liability company organized, existing and doing business under and by virtue of the laws of Malta, with its headquarters address at 57 St. Christopher Street, Valletta, Malta. Cobalt Laboratories Inc. is a wholly-owned subsidiary of Proposed Respondent Arrow, with headquarters address at 24870 S. Tamiami Trl., Suite 1, Bonita Springs, FL 34134.
- 3. The Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. "Watson" means Watson Pharmaceuticals, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Watson (including, but not limited to, Watson Laboratories, Inc.), and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each. After the Acquisition, Watson shall include Arrow.
- B. "Arrow" means Robin Hood Holdings Limited d/b/a Arrow Group, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Arrow (including, but not limited to, Resolution Chemicals Limited, Cobalt Laboratories Inc., and Cobalt Pharmaceuticals Inc.), and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.
- C. "Respondent(s)" means Watson and Arrow, individually and collectively.
- D. "Commission" means the Federal Trade Commission.
- E. "Acquirer(s)" means the following:

- 1. Impax;
- 2. Reso; or
- 3. a Person approved by the Commission to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- F. "Acquisition" means the acquisition of shares of Arrow by Watson as contemplated by the Share Purchase Agreement ("Share Purchase Agreement"), dated as of June 16, 2009, by and among Watson Laboratories, Inc., a wholly-owned subsidiary of Watson, Robin Hood Holdings Limited, the shareholders of Robin Hood Holdings Limited, and Anthony Selwyn Tabatznik, an individual solely with respect to Section 6.15 and related provisions of the Share Purchase Agreement, and all attachments, amendments, exhibits, and schedules related thereto.
- G. "Acquisition Date" means the date on which the Acquisition occurs pursuant to the Share Purchase Agreement.
- H. "Agency(ies)" means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term "Agency" includes, without limitation, the United States Food and Drug Administration ("FDA"), and the United States Drug Enforcement Agency ("DEA").
- I. "ANDA" means abbreviated new drug application 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.
- J. "API" means active pharmaceutical ingredient.
- K. "Barr-Watson Agreement" means the Asset Purchase Agreement between Barr Laboratories, Inc., and Watson Laboratories, Inc., dated November 24, 2008.
- L. "Cabergoline API Agreement" means the agreement, dated August 7, 2003, by and among Teva Pharmaceutical Industries Ltd., Chemicals Works of Gedeon Richter Ltd., and Gedeon Richter USA, Inc., as subsequently assigned to Barr Laboratories, Inc., and thereafter to Watson Laboratories, Inc., pursuant to the Barr-Watson Agreement.
- M. "Cabergoline Assets" means all of Respondent Watson's rights, title and interest in and to, the following assets:
 - 1. ANDA No. 77-843, and any supplements, amendments, or revisions thereto;

- 2. Product Scientific and Regulatory Material related to the Cabergoline Product;
- 3. Cabergoline API Agreement; and
- 4. any other assets relating to the Cabergoline Product divested by Barr Laboratories, Inc. to Watson in the Barr-Watson Agreement.

N. "Cabergoline Divestiture Agreement" means:

- 1. the Asset Purchase Agreement between Watson Laboratories, Inc., and Impax Laboratories, Inc., dated November 4, 2009, and any attachments, amendments, exhibits, and schedules related thereto. This Asset Purchase Agreement is attached to this Order and contained in non-public Appendix I; or
- 2. any agreement that receives the prior approval of the Commission between Respondents and an Acquirer for the divestiture of the Cabergoline Assets entered into pursuant to Paragraph II.A (or Paragraph V) of this Order, and any attachments, amendments, exhibits, and schedules related thereto.
- O. "Cabergoline Product" means all Products that contain the active pharmaceutical ingredient generically known as cabergoline in Development, manufactured, marketed or sold by Respondent Watson pursuant to ANDA No. 77-843, and any supplements, amendments, or revisions thereto.
- 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. "Closing Date" means the date on which the Respondents (or a Divestiture Trustee) consummate a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets or rights related to a Divestiture Product to an Acquirer pursuant to this Order.
- R. "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 the Divestiture Product(s);
 - provided however, that the restrictions contained in this Order regarding the Respondents' use, conveyance, provision, or disclosure of "Confidential Business Information" shall not apply to the following:
 - 1. information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by Respondent(s);

- 2. information related to the Cabergoline Product that were researched, Developed, manufactured, marketed, or sold by Respondent Watson that Respondent Arrow can demonstrate it obtained without the assistance of Respondent Watson prior to the Acquisition;
- 3. information related to the Dronabinol Product that were researched, Developed, manufactured, marketed, or sold by Respondent Arrow that Respondent Watson can demonstrate it obtained without the assistance of Respondent Arrow prior to the Acquisition;
- 4. information that is required by law to be publicly disclosed;
- 5. information that does not directly relate to the Divestiture Product(s);
- 6. information relating to either Respondent's general business strategies or practices relating to research, Development, manufacture, marketing or sales of Products that does not discuss with particularity the Divestiture Product(s); or
- 7. information specifically excluded from the assets to be divested.
- S. "Development" means all preclinical and clinical drug development activities, including formulation, test method development and stability testing, toxicology, 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.
- T. "Direct Cost" means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service.
- U. "Divestiture Product(s)" means the Cabergoline Product and/or the Dronabinol Product.
- V. "Divestiture Trustee" means any trustee appointed by the Commission pursuant to Paragraph V of the Decision and Order.
- W. "Dronabinol ANDA Assets" means all of Respondent Arrow's rights, title and interest in and to, the following assets:
 - 1. ANDA No. 77-740, and any supplements, amendments, or revisions thereto; and
 - 2. Product Scientific and Regulatory Material related to the Dronabinol Product.

- X. "Dronabinol ANDA Divestiture Agreement" means:
 - 1. the Asset Purchase Agreement between Cobalt Pharmaceuticals Inc., and Impax Laboratories, Inc., dated November 4, 2009, and any attachments, amendments, exhibits, and schedules related thereto. The Dronabinol ANDA Agreement is attached to the Decision and Order and contained in non-public Appendix II; or
 - 2. any agreement that receives the prior approval of the Commission between Respondents and an Acquirer for the divestiture of the Dronabinol ANDA Assets entered into pursuant to Paragraph III.A (or Paragraph V) of the Decision and Order, and any attachments, amendments, exhibits, and schedules related thereto.
- Y. "Dronabinol Development and API Business" means all of Respondent Arrow's rights, title and interest in and to, the following:
 - 1. Product Intellectual Property related to the Dronabinol Product;
 - 2. Product Manufacturing Technology related to the Dronabinol Product; and
 - 3. the business related to the research, Development, manufacture and supply of the Dronabinol Product API.
- Z. "Dronabinol Product" means all Products that contain the active pharmaceutical ingredient generically known as tetrahydrocannabinol or "THC" in Development, manufactured, marketed or sold by Respondent Arrow pursuant to ANDA No. 77-740, and any supplements, amendments, or revisions thereto.
- AA. "Geographic Territory" shall mean the United States of America, including all its territories and possessions, unless otherwise specified.
- BB. "Impax" means Impax 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 at 30831 Huntwood Avenue, Hayward, CA 94544.
- CC. "Interim Monitor" means any monitor appointed pursuant to Paragraph III of this Order.
- DD. "Order to Maintain Assets" means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders in this matter.
- EE. "Ownership Interest" means any and all rights, present or contingent, to hold any voting or nonvoting stock, share capital, equity or other interests, or beneficial ownership in a Person.
- FF. "Patents" 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, and

- includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any Product of or owned by Respondent as of the Closing Date.
- GG. "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.
- HH. "Product" means any pharmaceutical, biological, or generic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient.
 - II. "Product Intellectual Property" means all of the following related to a Divestiture Product:
 - 1. Patents;
 - 2. Product Trademarks, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and
 - 3. rights to obtain and file for patents and copyrights and registrations thereof;
 - provided, however, "Product Intellectual Property" does not include the corporate names or corporate trade dress of "Watson" or "Arrow", or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by Respondents or the related logos thereof.
 - JJ. "Product Manufacturing Technology" means all manufacturing technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of the Divestiture Product(s) including, but not limited to, the following: all product specifications, processes, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA applications conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, supplier lists, and other master documents necessary for the manufacture, control and release of the Product that are owned or controlled by Respondent(s) or which Respondent(s) have the right to receive.
- KK. "Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and clinical trial materials and information related to the Divestiture Product(s) that are owned and controlled by Respondent(s) or which Respondent(s) have a right to receive including, but not limited to:

- 1. pharmacokinetic study reports related to the specified Divestiture Product(s);
- 2. bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product(s);
- 3. bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product(s);
- 4. all correspondence to the Respondent(s) from the FDA and from the Respondent(s) to the FDA relating to the ANDA submitted by, on behalf of, or acquired by, the Respondent(s) related to the specified Divestiture Product;
- 5. annual and periodic reports related to the above-described ANDA, including any safety update reports;
- 6. FDA approved Product labeling related to the specified Divestiture Product(s);
- 7. currently used product package inserts (including historical change of controls summaries) related to the specified Divestiture Product(s);
- 8. FDA approved patient circulars and information related to the specified Divestiture Product(s);
- 9. adverse events/serious adverse event summaries related to the specified Divestiture Product(s);
- 10. summary of Product complaints from physicians related to the specified Divestiture Product(s);
- 11. summary of Product complaints from customers related to the specified Divestiture Product(s); and
- 12. Product recall reports filed with the FDA related to the specified Divestiture Product(s).
- LL. "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 the Divestiture Product(s).
- MM. "Reso" means Reso Holdings Limited, a limited company organized, existing, and doing business under and by virtue of the laws the United Kingdom, with its headquarters address at Wedgwood Way, Stevenage, Hertfordshire SG1 4QT, United Kingdom.

NN. "Resolution" means Resolution Chemicals Limited, a limited company, organized, existing, and doing business under and by virtue of the laws of the United Kingdom, with its headquarters address at Wedgwood Way, Stevenage, Hertfordshire SG1 4QT, United Kingdom. "Resolution" includes, among other things, the Dronabinol Development and API Business.

OO. "Resolution Divestiture Agreement" means:

- 1. the Purchase Agreement between Arrow Group ApS and Reso Holdings Limited, dated November 3, 2009, and any attachments, amendments, exhibits, and schedules related thereto. The Dronabinol Business Agreement is attached to the Decision and Order and contained in non-public Appendix III; or
- 2. any agreement that receives the prior approval of the Commission between Respondents and an Acquirer for the divestiture of Resolution entered into pursuant to Paragraph III.B (or Paragraph V) of Decision and Order, and any attachments, amendments, exhibits, and schedules related thereto.

PP. "Remedial Agreements" means:

- 1. any agreement between Respondent(s) and an Acquirer that is specifically referenced and attached to the Decision and Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Decision and Order in connection with the Commission's determination to make Decision and Order final; and/or
- 2. any agreement between Respondent(s) and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of the Decision and Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Decision and Order.
- QQ. "Retained Product(s)" means any Product owned by Respondent(s) that are not the Divestiture Products.
- RR. "Teva" means Teva Pharmaceutical Industries Limited, a corporation organized, existing, and doing business under and by virtue of the laws of the Israel, with its headquarters address at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131 Israel. "Teva" includes wholly-owned subsidiary Barr Pharmaceuticals, Inc. ("Barr"), a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.

SS. "Third Party(ies)" means any non-governmental Person other than the following: Respondent Watson, Respondent Arrow, or the Acquirer of the affected assets, rights and Divestiture Product(s).

II.

IT IS FURTHER ORDERED that from the date this Order to Maintain Assets becomes final:

- A. Respondents shall maintain the full economic viability, marketability and competitiveness of the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution, and shall prevent the destruction, removal, wasting, deterioration, or impairment of the Cabergoline Assets, Dronabinol ANDA Assets, and Resolution except for ordinary wear and tear. Respondents shall not sell, transfer, encumber or otherwise impair the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution (other than in the manner prescribed in the Decision and Order) nor take any action that lessens the full economic viability, marketability or competitiveness of the businesses related to the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution.
- B. Respondents shall maintain the operations of the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and shall use their best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; customers; Agencies; employees; and others having business relations with the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution. Respondents' responsibilities shall include, but are not limited to, the following:
 - 1. providing the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution;
 - 2. continuing, at least at their scheduled pace, any additional expenditures for the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution, authorized prior to the date the Consent Agreement was signed by Respondents including, but not limited to, all research, Development, manufacturing, distribution, marketing and sales expenditures;
 - 3. providing such resources as may be necessary to respond to competition against the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution and/or to prevent any diminution in sales of the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution, prior to divestiture;

- 4. making available for use by the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution;
- 5. providing the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution with such funds as are necessary to maintain the full economic viability, marketability and competitiveness of the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution;
- 6. providing such support services to the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution as were being provided to such business by Respondent(s) as of the date the Consent Agreement was signed by Respondents; and
- 7. maintaining a work force at least as equivalent in size, training, and expertise to what has been associated with the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution for each assets' last fiscal year.
- C. Pending divestiture of the Cabergoline Assets and the Dronabinol ANDA Assets, Respondents shall:
 - 1. not use, directly or indirectly, any Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the relevant Divestiture Product(s) other than as necessary to comply with the following: (1) the requirements of the Orders; (2) Respondents' obligations to an Acquirer under the terms of any Remedial Agreement related to relevant Divestiture Product(s); or (3) applicable Law;
 - 2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except the relevant Acquirer or Persons specifically authorized by the relevant Acquirer or the Commission to receive such information;
 - 3. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the relevant Divestiture Product(s) to the employees associated with business related to those Retained Products that contain the same API or that are approved for the same use as the Divestiture Product(s); and
 - 4. promptly after the date the Agreement Containing Consent Orders is signed, institute procedures and requirements to ensure that Respondents' employees, associated with the Retained Products that contain the same API or that are approved for the same use as the Divestiture Product(s), do not:
 - a. provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Order to Maintain Assets; and

- b. solicit, access or use any Confidential Business Information that they are prohibited under this Order to Maintain Assets from receiving for any reason or purpose.
- D. Not later than thirty (30) days following the Closing Date, Respondents shall provide to all of Respondents' employees and other personnel who may have access to Confidential Business Information related to the Divestiture Product(s) written or electronic notification of the restrictions on the use of such information by Respondents' personnel. At the same time, if not provided earlier, Respondents shall provide a copy of such notification by e-mail with return receipt requested or similar transmission, and keep an electronic file of such receipts for three (3) year after the Closing Date for the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution. Respondents shall provide a copy of the form of such notification to the relevant Acquirer, the Interim Monitor (if one is appointed), and the Commission. Respondents shall also obtain from each employee covered by this Paragraph II.D an agreement to abide by the applicable restrictions. Respondents shall maintain complete records of all such agreements at Respondents' registered office within the United States and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondents shall monitor the implementation by its employees and other personnel of all applicable restrictions, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets. Respondents shall provide the relevant Acquirer with copies of all certifications, notifications and reminders sent to Respondents' employees and other personnel.
- E. Respondents shall adhere to and abide by the Remedial Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of the Orders, it being understood that nothing in the Orders shall be construed to reduce any obligations of Respondents under such agreement(s)), which are incorporated by reference into this Order to Maintain Assets and made a part hereof.
- F. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution within the Geographic Territory through their full transfer and delivery to an Acquirer, to minimize any risk of loss of competitive potential for the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution within the Geographic Territory, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution except for ordinary wear and tear.

III.

IT IS FURTHER ORDERED that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order to Maintain Assets, the proposed Decision and Order (collectively, "Orders"), and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. If an Interim Monitor is appointed, Respondents shall consent to the following terms and conditions regarding the powers, duties, authority, and responsibilities of the Interim Monitor:
 - 1. The Interim Monitor shall have the power and authority to monitor Respondents' compliance with: the divestiture and asset maintenance obligations of the Orders; the restrictions on the use, conveyance, provision, or disclosure of the identified confidential business information under the Orders; and, the related requirements of the Orders. The Interim Monitor shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.
 - 2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
 - 3. The Interim Monitor shall serve until the date Respondents complete the divestiture of the Divestiture Products in a manner that fully satisfies the requirements of this Order and until the earliest of:
 - a. With respect to each Divestiture Product, the date the Acquirer(s) are 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 Respondents;

- b. With respect to each Divestiture Product, the date the Acquirer(s) notifies the Commission and 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 Acquirer(s) have abandoned their efforts to manufacture such Divestiture Product;

provided, however, that, with respect to each Divestiture Product, the Interim Monitor's service shall not exceed three (3) years from the date the Order becomes final;

provided further, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- 4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondents shall cooperate with all reasonable requests of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Orders.
- 5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
- 6. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim 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 Interim Monitor.

- 7. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by an Acquirer with respect to the performance of Respondents' obligations under the Orders or any Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of its obligations under the Orders; *provided, however*, beginning one hundred twenty (120) days after Respondents have filed its final report pursuant to Paragraph VIII.B, and every one hundred twenty (120) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by the Acquirer(s) 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 Respondents.
- 8. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
- G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- H. The Interim Monitor shall serve until termination of this Order to Maintain Assets pursuant to Paragraph VII.
- I. The Interim Monitor appointed pursuant to this Order may be the same person appointed as a Divestiture Trustee pursuant to Paragraph V of the proposed Decision and Order.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets becomes final, and every thirty (30) days thereafter until Respondents have fully complied with their obligations to assign, grant, license, divest, transfer, deliver or otherwise convey relevant assets as required by Paragraphs II and III of the related Decision and Order in this matter, 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 this Order to Maintain Assets and the related Decision and Order; *provided*, *however*, that, after the Decision and Order in this matter becomes final, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondents pursuant to Paragraph VIII of the Decision and Order.

V.

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

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

VI.

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

A. access, during business office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents related to compliance with this Order, which copying services shall be provided by Respondents at the request authorized representative(s) of the Commission and at the expense of the Respondents; and

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

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on the earlier of:

- A. Three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. The later of:
 - 1. The day after the divestiture of all of the Cabergoline Assets, the Dronabinol ANDA Assets, and Resolution, as required by and described in the proposed Decision and Order, has been completed and each Interim Monitor, in consultation with Commission staff and the Acquirer(s), notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers and other transitions related to such divestitures are complete, or the Commission otherwise directs that this Order to Maintain Assets is terminated; or
 - 2. The day the related Decision and Order becomes final.

By the Commission, Commissioner Harbour recused.

Donald S. Clark Secretary

SEAL

ISSUED: December 1, 2009