

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,

and

ROBIN HOOD HOLDINGS LIMITED,
a limited liability company.

Docket No. C-4276

DECISION AND ORDER
[Public Record Version]

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 that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order

to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Watson is a corporation organized, existing and doing business under and by virtue of the laws of the State of Nevada, with its headquarters address 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 Respondent Arrow, with its principal place of business 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 the Order, the following definitions 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 this 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 this 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 this 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 IV 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 this 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 this 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 this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final; 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 this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Order.

QQ. “Retained Product(s)” means any Product(s) 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:

A. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Cabergoline Assets, absolutely and in good faith, to Impax pursuant to, and in accordance with, the Cabergoline Divestiture Agreement (which agreement shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Impax or to reduce any obligations of Respondents under such agreement), and such agreement, if it becomes a Remedial Agreement related to the Cabergoline Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Cabergoline Assets to Impax prior to the date the Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Impax is not an acceptable purchaser of the Cabergoline Assets, then Respondents shall immediately rescind the transaction with Impax, in whole or in part, as directed by the Commission, and shall divest the Cabergoline Assets within one hundred eighty (180) days from the date the Order becomes final, 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 Respondents have divested the Cabergoline Assets to Impax prior to the date the Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Cabergoline Assets to Impax (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. Respondents shall:

1. exercise the option to extend the period of time in which to obtain the commercially reasonable assistance of Barr and/or Teva in understanding the Cabergoline Assets pursuant to Section 7.7 of the Barr-Watson Agreement; and
2. at the option of the Acquirer of the Cabergoline Assets, and upon reasonable notice and request, use commercially reasonable efforts to further extend the period of time in

which such Acquirer has a right to obtain the commercially reasonable assistance of Barr and/or Teva in understanding and transferring the Cabergoline Assets to the Acquirer pursuant to the Barr-Watson Agreement by an additional period of no more than nine (9) months; *provided, however*, that Respondents shall not be deemed in violation of this provision if, after Respondents' good faith commercially reasonable efforts, Barr and/or Teva refuses to extend such period of time.

- C. At the option of the Acquirer of the Cabergoline Assets, and upon reasonable notice and request, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist the Acquirer in the transfer of the Product Scientific and Regulatory Materials related to the Cabergoline Product in order to obtain the necessary approvals for the manufacture and sale of the Cabergoline Product in the Geographic Territory.
- D. Respondents shall:
 - 1. submit to the Acquirer of the Cabergoline Assets, at Respondents' expense, all Confidential Business Information related to the Cabergoline Assets;
 - 2. deliver such Confidential Business Information to such Acquirer:
 - 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 Interim Monitor (if one is 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 Cabergoline Assets 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 research, Development, manufacturing, marketing, or sale of the Cabergoline Product other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondents' obligations to the Acquirer of the Cabergoline Assets under the terms of any Remedial Agreement related to the Cabergoline Assets; or

- c. applicable law;
- 5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except the Acquirer of the Cabergoline Assets or other Persons specifically authorized by such Acquirer to receive such information; and
- 6. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the Development, manufacture, marketing or sales of the Cabergoline Assets to the employees associated with business related to those Retained Products that:
 - a. contain the same active pharmaceutical ingredient; or
 - b. are approved, or in Development for use, in the same field as the Cabergoline Product.
- E. Respondents shall not enforce any agreement against a Third Party or an Acquirer of the Cabergoline Assets to the extent that such agreement may limit or otherwise impair the ability of such Acquirer to acquire or use the Product Manufacturing Technology (including all related intellectual property) related to the Cabergoline Product acquired by such Acquirer from the Third Party. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology.
- F. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to an agreement as described in Paragraph II.E that allows the Third Party to provide the relevant Product Manufacturing Technology to the relevant Acquirer of the Cabergoline Assets. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to such Acquirer.
- G. Not later than thirty (30) days after the Closing Date, Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to the Cabergoline Assets by Respondents personnel to all of Respondents' employees who:
 - 1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of the Cabergoline Product;
 - 2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that contain the same active pharmaceutical ingredient or that are approved for use, or in Development for use, in the same field as the Cabergoline Product; and/or
 - 3. may have Confidential Business Information related to the Cabergoline Product.

Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for three (3) year after the Closing Date. Respondents shall provide a copy of such notification to the Acquirer. Respondents shall maintain complete records of all such agreements at Respondents' registered office within the United States of America and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondents shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

H. Until Respondents complete the divestiture required by Paragraph II,

1. Respondents shall take such actions as are necessary to:

- a. maintain the full economic viability and marketability of the businesses associated with the Cabergoline Product;
- b. minimize any risk of loss of competitive potential for such business;
- c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to the Cabergoline Product;
- d. ensure the assets required to be divested are transferred and delivered to each Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the business associated with the Cabergoline Product; and

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

I. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the Acquirer for the research, Development, manufacture, use, import, export, distribution, or sale of the Cabergoline Product under Patents that:

1. are owned or licensed by Respondents as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter, relating to the Cabergoline Products, or that claims a device relating to the use thereof;
2. are owned or licensed at any time after the Acquisition Date by Respondents that claim any aspect of research, Development, manufacture, use, import, export, distribution, or sale of the Cabergoline Products, other than such patents that claim inventions conceived by and reduced to practice after the Acquisition Date;

if such suit would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Cabergoline Product; or (2) the use, import, export, supply, distribution, or sale of the Cabergoline Product within the Geographic Territory.

- J. Respondents shall also covenant to the Acquirer that as a condition of any assignment, transfer, or license to a Third Party of the Patents described in Paragraph II.I, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue the Acquirer under such patents, if the suit would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Cabergoline Product; or (2) the use, import, export, supply, distribution, or sale of the Cabergoline Product within the Geographic Territory.
- K. Upon reasonable written notice and request from the Acquirer of the Cabergoline Assets to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Product Intellectual Property related to the Cabergoline Product, if such litigation would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Cabergoline Product; or (2) the use, import, export, supply, distribution, or sale of the Cabergoline Product within the Geographic Territory.
- L. Respondents shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to the Cabergoline Product a decision the result of which would be inconsistent with the terms of this Order and/or the remedial purposes thereof.
- M. The purpose of the divestiture of the Cabergoline Assets and the related obligations imposed on the Respondents by this Order is:
 - 1. to ensure the continued use of such assets in the research, Development, manufacture, distribution, sale and marketing of the Cabergoline Product within the Geographic Territory;
 - 2. to create a viable and effective competitor in the relevant market alleged in the Complaint who is independent of the Respondents; and
 - 3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

III.

IT IS FURTHER ORDERED that:

- A. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Dronabinol ANDA Assets, absolutely and in good faith, to Impax pursuant to, and in accordance with, the Dronabinol ANDA Agreement (which agreement shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Impax or to reduce any obligations of Respondents under such agreement), and such agreement, if it becomes a Remedial Agreement related to the Dronabinol ANDA Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Dronabinol ANDA Assets to Impax prior to the date the Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Impax is not an acceptable purchaser of the Dronabinol ANDA Assets, then Respondents shall immediately rescind the transaction with Impax, in whole or in part, as directed by the Commission, and shall divest the Dronabinol ANDA Assets within one hundred eighty (180) days from the date the Order becomes final, 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 Respondents have divested the Dronabinol ANDA Assets to Impax prior to the date the Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Dronabinol ANDA Assets to Impax (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. Not later than ten (10) days after the Acquisition Date, Respondents shall divest Arrow's Ownership Interest in Resolution, absolutely and in good faith, to Reso pursuant to, and in accordance with, the Resolution Divestiture Agreement (which agreement shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Reso or to reduce any obligations of Respondents under such agreement), and such agreement, if it becomes a Remedial Agreement related to Resolution is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Ownership Interest in Resolution to Reso prior to the date the Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents

that Reso is not an acceptable purchaser of Ownership Interest in Resolution, then Respondents shall immediately rescind the transaction with Reso, in whole or in part, as directed by the Commission, and shall divest the Ownership Interest in Resolution within one hundred eighty (180) days from the date the Order becomes final, 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 Respondents have divested the Ownership Interest in Resolution to Reso prior to the date the Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Ownership Interest in Resolution to Reso (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- C. At an Acquirer's option, and upon reasonable notice and request, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist that Acquirer in the identification and transfer of, in the case of Reso, the Product Manufacturing Technology related to the Dronabinol Product, and in the case of Impax, the Product Scientific and Regulatory Materials related to the Dronabinol Product.
- D. Respondents shall:
1. submit to the Acquirer of the Dronabinol ANDA Assets, at Respondents' expense, all Confidential Business Information related to the Dronabinol ANDA Assets, other than Confidential Business Information otherwise owned by Resolution;
 2. deliver such Confidential Business Information to such Acquirer:
 - 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 of the Dronabinol ANDA Assets, provide such Acquirer and the Interim Monitor (if one is 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 Dronabinol ANDA Assets 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 research, Development, manufacturing, marketing, or sale of the Dronabinol Product other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondents' obligations to the Acquirer of the Dronabinol ANDA Assets under the terms of any Remedial Agreement related to the Dronabinol ANDA Assets; or
 - c. applicable law;
 5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except the Acquirer of the Dronabinol ANDA Assets or other Persons specifically authorized by such Acquirer to receive such information; and
 6. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the Development, manufacture, marketing or sales of the Dronabinol Product to the employees associated with business related to those Retained Products that:
 - a. contain the same active pharmaceutical ingredient;
 - b. are approved, or in Development for use, in the same field as the Dronabinol Product;
 - c. are approved, or in Development for use, in the same field as the Dronabinol Product.
- E. Not later than thirty (30) days after the Closing Date, Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to the Dronabinol Product by Respondents' personnel to all of Respondents' employees who:
1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of any Dronabinol Product;
 2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that contain the same active pharmaceutical ingredient or that are approved for use, or in Development for use, in the same field as the Dronabinol Product; and/or
 3. may have Confidential Business Information related to the Dronabinol Product.

Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondents shall provide a copy of such notification to the Acquirer.

Respondents shall maintain complete records of all such agreements at Respondents' registered office within the United States of America and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondents shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

F. Until Respondents complete the divestitures required by Paragraph III,

1. Respondents shall take such actions as are necessary to:

- a. maintain the full economic viability and marketability of the businesses associated with the Dronabinol Product including Resolution;
- b. minimize any risk of loss of competitive potential for such business;
- c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to the Dronabinol Product including Resolution;
- d. ensure the assets required to be divested are transferred and delivered to each Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the business associated with the Dronabinol Product; and

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

G. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the Acquirer(s) for the research, Development, manufacture, use, import, export, distribution, or sale of the Dronabinol Product under Patents that:

1. are owned or licensed by Respondents as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter, relating to the Dronabinol Product, or that claims a device relating to the use thereof;
2. are owned or licensed at any time after the Acquisition Date by Respondents that claim any aspect of research, Development, manufacture, use, import, export, distribution, or sale of the Dronabinol Product, other than such patents that claim inventions conceived by and reduced to practice after the Acquisition Date;

if such suit would have the potential to interfere with either Acquirers' freedom to practice the following: (1) the research, Development, or manufacture of the Dronabinol Product; or (2) the use, import, export, supply, distribution, or sale of the Dronabinol Product within the Geographic Territory.

- H. Respondents shall also covenant to the Acquirer(s) that as a condition of any assignment, transfer, or license to a Third Party of the Patents described at Paragraph III.G, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue the Acquirer(s) under such patents, if the suit would have the potential to interfere with the Acquirer(s) freedom to practice the following: (1) the research, Development, or manufacture of the Dronabinol Product; or (2) the use, import, export, supply, distribution, or sale of the Dronabinol Product within the Geographic Territory.
- I. Upon reasonable written notice and request from the Acquirer(s) of the Dronabinol ANDA Assets or Resolution to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist the Acquirer(s) to defend against, respond to, or otherwise participate in any litigation related to the Product Intellectual Property related to the Dronabinol Product, if such litigation would have the potential to interfere with the Acquirer(s) freedom to practice the following: (1) the research, Development, or manufacture of the Dronabinol Product; or (2) the use, import, export, supply, distribution, or sale of the Dronabinol Product within the Geographic Territory.
- J. Respondents shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to the Dronabinol Product a decision the result of which would be inconsistent with the terms of this Order and/or the remedial purposes thereof.
- K. The purpose of the divestiture of the Dronabinol ANDA Assets, Resolution, and the related obligations imposed on the Respondents by this Order is:
 - 1. to ensure the continued use of such assets in the research, Development, manufacture, distribution, sale and marketing of the Dronabinol Product within the Geographic Territory;
 - 2. to create a viable and effective competitor in the relevant market alleged in the Complaint who is independent of the Respondents; and
 - 3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

IV.

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, the Order to Maintain Assets (collectively, “Order”), 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 appointed pursuant to this Order may be the same person appointed as a Divestiture Trustee pursuant to Paragraph V of this Order.

V.

IT IS FURTHER ORDERED that:

- A. If Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Divestiture Products as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*l*), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a

Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey such assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondents have 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 Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
 - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.
 - 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, that the Commission may extend the divestiture period only two (2) times.
 - 3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the

Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, that 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 Respondents from among those approved by the Commission; *provided further, however*, that Respondents 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 Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to Paragraph IV of this Order and the relevant provisions of the Order to Maintain Assets in this matter.

8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
 9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
 - F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

VI.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, Respondents shall assure that Respondents' counsel (including 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 Respondents' compliance with this Order, the Order to Maintain Assets, any Remedial Agreement, 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 Divestiture Products or assets and businesses associated with those Divestiture Products;

provided, however, that Respondents may disclose such information as necessary for the purposes set forth in this Paragraph VI pursuant to an appropriate confidentiality order, agreement or arrangement;

provided further, however, that pursuant to this Paragraph VI, Respondents shall: (1) require those who view such unredacted documents or other materials to enter into

confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if such Acquirer withholds such agreement unreasonably); and (2) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VII.

IT IS FURTHER ORDERED that:

- A. Any failure by a Respondent to comply with any term of any Remedial Agreement shall constitute a failure to comply with this Order.
- B. Respondents shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligations to the Acquirer pursuant to this Order.
- C. Respondents shall also include in each applicable Remedial Agreement a representation from the Acquirer that such Acquirer shall use commercially reasonable efforts to secure the approvals necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product and to have any such manufacture be independent of Respondents, all as soon as reasonably practicable.
- D. Respondents shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission.

VIII.

IT IS FURTHER ORDERED that:

- A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondents have fully complied with its obligations under Paragraphs II and III of this Order, 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. Respondents shall submit at the same time a copy of their report concerning compliance with this Order to the Interim Monitor(s). Respondents shall include in their 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 a full description of all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all Persons contacted, including copies

of all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning completing the obligations.

- C. One (1) year after the date this Order becomes final, annually for the next nine years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which they have complied and are complying with the Order.

IX.

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 this Order.

X.

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

- A. access, during business office hours of such 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 such Respondent related to compliance with this Order, which copying services shall be provided by such Respondent at the request of the authorized representative(s) of the Commission and at the expense of such Respondent; and
- B. to interview officers, directors, or employees of such Respondent, who may have counsel present, regarding such matters.

XI.

IT IS FURTHER ORDERED that this Order shall terminate on January 7, 2020.

By the Commission, Commissioner Harbour not participating.

Donald S. Clark
Secretary

SEAL
ISSUED: January 7, 2010

NON-PUBLIC APPENDIX I.

CABERGOLINE DIVESTITURE AGREEMENT

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

NON-PUBLIC APPENDIX II.

DRONABINOL ANDA DIVESTITURE AGREEMENT

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

NON-PUBLIC APPENDIX III.

RESOLUTION DIVESTITURE AGREEMENT

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