

**UNITED STATES OF AMERICA  
BEFORE FEDERAL TRADE COMMISSION**

**COMMISSIONERS:**      **Deborah Platt Majoras, Chairman**  
                                 **Pamela Jones Harbour**  
                                 **Jon Leibowitz**  
                                 **William E. Kovacic**  
                                 **J. Thomas Rosch**

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| <b>In the Matter of</b>                     |  | ) |
|   |  | ) |
| <b>TEVA PHARMACEUTICAL INDUSTRIES LTD.,</b> |  | ) |
| <b>a corporation;</b>                       |  | ) |
|   |  | ) |
| <b>and</b>                                  |  | ) |
|   |  | ) |
| <b>IVAX CORPORATION</b>                     |  | ) |
| <b>a corporation.</b>                       |  | ) |
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**Docket No. C-**

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

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Teva Pharmaceutical Industries Limited (“Teva”) of Respondent IVAX Corporation (“IVAX”), hereinafter referred to as “Respondents,” 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 that, 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 of 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 (attached to this Order as Appendix I), 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 Teva is a corporation organized, existing and doing business under and by virtue of the laws of the State of Israel, with its offices and principal place of business located at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131 Israel.
2. Respondent IVAX is a corporation organized, existing and doing business under and by virtue of the laws of the State of Florida, with its offices and principal place of business located at 4400 Biscayne Boulevard, Miami, Florida 33137.
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. "Teva" means Teva Pharmaceutical Industries Limited, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Teva (including, but not limited to, Ivory Acquisition Sub, Inc., Ivory Acquisition Sub II, Inc., Teva Pharmaceuticals USA Inc. and Novopharm Limited), and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each. After the Acquisition, Teva shall include IVAX.
- B. "IVAX" means IVAX Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by IVAX (including, but not limited to, IVAX Pharmaceuticals, Inc.), and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.
- C. "Respondents" means Teva and IVAX, individually and collectively.

- D. “Acquisition” means the acquisition contemplated by the “Agreement and Plan of Merger” dated as of July 25, 2005, by and among IVAX Corporation, Teva Pharmaceutical Industries Limited, Ivory Acquisition Sub, Inc. and Ivory Acquisition Sub II, Inc.
- E. “Commission” means the Federal Trade Commission.
- F. “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, but is not limited to, the United States Food and Drug Administration (“FDA”).
- G. “Application,” “Investigational New Drug Application (“IND”), “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDA”), or “Marketing Authorization Application” (“MAA”) means the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Respondent(s) and the FDA.
- H. “Assignment Product(s)” means a Product that is the subject of an assignment of rights under this Order, *i.e.*, the GSK Authorized Generic Products, the Genzyme Leuprolide Products, and the Genix Calcitriol Products, individually and collectively.
- I. “Barr” means Barr Laboratories, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, having its principal place of business located at Two Quaker Road, P.O. Box 2900, Pomona, New York 10970.
- J. “Cabergoline” means all Products Developed, manufactured, marketed or sold by Respondent Teva pursuant to Respondent Teva’s ANDA No. 77-843 and any supplements, amendments, or revisions thereto.
- K. “Categorized Assets” means the following assets related to the specified Divestiture Product(s):
1. all Product Intellectual Property related to such Divestiture Product(s);
  2. perpetual, fully paid-up and royalty-free license(s) with rights to sublicense to all Product Licensed Intellectual Property to use, make, distribute, offer for sale, promote, advertise, sell, import, export, or have used, made, distributed, offered for sale, promoted, advertised, sold, imported, or exported the Divestiture Product(s) within the specified Geographic Territory;

3. all Product Registrations related to such Divestiture Product(s);
4. all Product Manufacturing Technology related to such Divestiture Product(s);
5. all Product Marketing Materials related to such Divestiture Product(s);
6. a list of all of the NDC Numbers related to such Divestiture Product(s), and rights, to the extent permitted by Law:
  - a. to require Respondents to discontinue the use of those NDC Numbers in the sale or marketing of Products other than with respect to returns, rebates, allowances, and adjustments for Divestiture Products sold prior to the Effective Date;
  - b. to prohibit Respondents from seeking from any customer any type of cross-referencing of those NDC Numbers with any Retained Product(s);
  - c. to seek to change any cross-referencing by a customer of those NDC Numbers with the Retained Product(s) (including the right to receive notification from Respondents of any such cross-referencing that is discovered by Respondents);
  - d. to seek cross-referencing from a customer of those NDC Numbers with the relevant Commission-approved Acquirer's NDC Numbers related to the Divestiture Product(s);
  - e. to approve the timing of Respondents' discontinued use of those NDC Numbers in the sale or marketing of Products other than with respect to returns, rebates, allowances, and adjustments for Divestiture Products sold prior to the Effective Date;
  - f. to approve any notification(s) from the Respondents to any customer(s) regarding the use or discontinued use of such numbers by the Respondents prior to such notification(s) being disseminated to the customer(s);
7. all rights to all of the relevant Respondent's Applications related to such Divestiture Product(s);
8. Right of Reference or Use to the Drug Master Files related to the above-described Applications including, but not limited to, the pharmacology and toxicology data contained in all Application(s);
9. all Product Development Reports related to such Divestiture Product(s);
10. at the relevant Commission-approved Acquirer's option, all Product Assumed Contracts

related to such Divestiture Product(s) (copies to be provided to the relevant Commission-approved Acquirer on or before the Closing Date);

11. all strategic safety program(s) submitted to the FDA related to such Divestiture Product(s) that is designed to decrease product risk by using one or more interventions or tools beyond the package insert;
12. all patient registries related to such Divestiture Product(s), and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the such Divestiture Product(s);
13. list of all customers and/or targeted customers for such Divestiture Product(s) and the net sales (in either units or dollars) of such Divestiture Products to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of such Divestiture Products on behalf of the High Volume Account and his or her business contact information;
14. at the relevant Commission-approved Acquirer's option and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to such Divestiture Product(s);
15. copies of all unfilled customer purchase orders for the Divestiture Product(s) as of the Closing Date, to be provided to the relevant Commission-approved Acquirer not later than two (2) days after the Closing Date;
16. at the relevant Commission-approved Acquirer's option, subject to any rights of the customer, all unfilled customer purchase orders for the Divestiture Products; and
17. all of the specified Respondent's books, records, and files directly related to the foregoing or to such Divestiture Product(s);

*provided, however,* that "Categorized Assets" shall not include documents relating to Respondents' general business strategies or practices relating to research, development, manufacture, marketing or sales of generic pharmaceutical Products, where such documents do not discuss with particularity the Divestiture Products;

*provided further,* the "Categorized Assets" shall not include administrative, financial, and accounting records;

*provided further*, the Respondents may exclude from the “Categorized Assets” quality control records that are determined by the Interim Monitor or the Commission-approved Acquirer not to be material to the manufacture of the Divestiture Product(s);

*provided further*, that in cases in which documents or other materials included in the relevant assets to be divested contain information: (1) that relates both to such Divestiture Product(s) and to other Products or businesses of the specified Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to such Divestiture Product(s); or (2) for which the specified Respondent has a legal obligation to retain the original copies, the specified Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the relevant Commission-approved Acquirer, the specified Respondent shall provide such Commission-approved Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that the Respondent(s) provides the relevant Commission-approved Acquirer with the above-described information without requiring the Respondent(s) completely to divest itself of information that, in content, also relates to Products and businesses other than such Divestiture Product(s).

- L. “Cefaclor ER” means all Products Developed, manufactured, marketed or sold by Respondent IVAX pursuant to Respondent IVAX’s ANDA No. 65-057 and any supplements, amendments, or revisions thereto.
- M. “Closing Date” means, as to each Divestiture Product and as to each Assignment Product, the date on which the Respondent(s) (or a Divestiture Trustee) consummate a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to a Commission-approved Acquirer pursuant to this Order.
- N. “Clozapine” means all Products Developed, manufactured, marketed or sold by Novopharm Limited pursuant to Novopharm Limited’s ANDA No. 75-162 and any supplements, amendments, or revisions thereto.
- O. “Commission-approved Acquirer” means the following: (1) an entity specified by name in this Order to acquire particular assets or rights that the Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final; or (2) an entity approved by the Commission to acquire particular assets or rights that the Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.

- P. “Confidential Business Information” means all information owned by, or in the possession or control of, Respondents 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 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 Respondents;
  2. information related to the IVAX Generic Divestiture Products (Group 1) or the IVAX Generic Divestiture Products (Group 2) that Respondent Teva can demonstrate it obtained without the assistance of Respondent IVAX prior to the Acquisition;
  3. information related to the Teva Generic Divestiture Products (Group 1), the Teva Generic Divestiture Products (Group 2) or the Novopharm Generic Divestiture Product that Respondent IVAX can demonstrate it obtained without the assistance of Respondent Teva 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 Respondents’ general business strategies or practices relating to research, development, manufacture, marketing or sales of generic pharmaceutical Products that does not discuss with particularity the Divestiture Product(s); or
  7. information specifically excluded from the Categorized Assets.
- Q. “Contract Manufacture” means the manufacture of a Divestiture Product to be supplied by Respondent or a Designee to a Commission-approved Acquirer.
- R. “Designee” means any entity other than Respondents that will manufacture a Divestiture Product for a Commission-approved Acquirer.
- S. “Development” means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use,

storage, import, export, transport, promotion, marketing, and sale of a Product (including any Government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.

- T. “Direct Cost” means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent they are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Commission-approved Acquirer for its use of any of the Respondents’ employees’ labor shall not exceed the average hourly wage rate for such employee.
- U. “Divestiture Product(s)” means a Product(s) the assets and business of which is the subject of a divestiture under this Order, *i.e.*, the IVAX Generic Divestiture Products (Group 1), the IVAX Generic Divestiture Products (Group 2), the Teva Generic Divestiture Products (Group1), the Teva Generic Divestiture Products (Group2) and the Novopharm Generic Divestiture Product, individually and collectively.
- V. “Divestiture Product Core Employees” means the Product Research and Development Employees and the Product Manufacturing Employees related to each Divestiture Product(s).
- W. “Divestiture Product Releasee(s)” means the Commission-approved Acquirer for the assets related to a particular Divestiture Product(s) or any entity controlled by or under common control with such Commission-approved Acquirer, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of such Commission-approved Acquirer, or of such Commission-approved Acquirer-affiliated entities.
- X. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- Y. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- Z. “Effective Date” means the earlier of the following dates:
  - 1. the date the Respondents close on the Acquisition pursuant to the Acquisition Agreement; or
  - 2. the date the merger contemplated by the Acquisition Agreement becomes effective by filing the certificate of merger with the Secretary of State of the State of Florida.
- AA. “Estazolam” means all Products Developed, manufactured, marketed or sold by Respondent IVAX pursuant to Respondent IVAX’s ANDA No. 74-826 and any supplements, amendments, or revisions thereto.

- BB. “Flutamide” means all Products Developed, manufactured, marketed or sold by Respondent Teva pursuant to Respondent Teva’s ANDA No. 75-298 and any supplements, amendments, or revisions thereto.
- CC. “Genix” means Genix Therapeutics, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Illinois, having its principal place of business located at 505 North Wolf Road, Wheeling, Illinois 60090.
- DD. “Genix Calcitriol Products” means the Products that are the subject of the Genix Calcitriol Products Agreement.
- EE. “Genix Calcitriol Products Agreement” means the “Distribution and Supply Agreement (Calcitriol Injectable 1mcg/ml)” by and between IVAX Pharmaceuticals, Inc. and Genix Therapeutics, Inc. dated as of October 1, 2004, and all amendments, exhibits, attachments, agreements, and schedules thereto. The Genix Calcitriol Products Agreement is attached to this Order and contained in non-public Appendix V.
- FF. “Genix Calcitriol Products Assignment Agreement” means the “Assignment and Assumption Agreement” between Par Pharmaceutical, Inc. and IVAX Pharmaceuticals, Inc., dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto. The Genix Calcitriol Assignment Agreement is attached to this Order and contained in non-public Appendix V.
- GG. “Genzyme” means Genzyme Corporation, a corporation organized, existing, and doing business under and by virtue of the laws of the State of Massachusetts, having its principal place of business located at 500 Kendall Street, Cambridge, Massachusetts 02142.
- HH. “Genzyme Leuprolide Products” means the Products that are the subject of the Genzyme Leuprolide Products Agreement.
- II. “Genzyme Leuprolide Products Agreement” means the “Supply Agreement (Leuprolide Acetate)” between Zenith Goldline Pharmaceuticals, Inc. and Genzyme Corporation, dated as of July 13, 2000, and all amendments, exhibits, attachments, agreements, and schedules thereto. The Genzyme Leuprolide Products Agreement is attached to this Order and contained in non-public Appendix IV.
- JJ. “Genzyme Leuprolide Products Assignment Agreement” means the “Assignment and Assumption Agreement (Leuprolide Supply Agreement)” between Par Pharmaceutical, Inc. and IVAX Pharmaceuticals, Inc., dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto. The Genzyme Leuprolide Products Assignment Agreement is attached to this Order and contained in non-public Appendix IV.

- KK. “Geographic Territory” shall mean the United States of America (including all of the territories within its jurisdiction or control) unless otherwise specified.
- LL. “Glipizide & Metformin” means all Products Developed, manufactured, marketed or sold by Respondent IVAX pursuant to Respondent IVAX’s ANDA No. 76-345 and any supplements, amendments, or revisions thereto.
- MM. “Government Entity” means any Federal, state, local or non-U.S. government, or any court, legislature, Government agency, or Government commission, or any judicial or regulatory authority of any government.
- NN. “GSK” means SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, a corporation organized, existing, and doing business under and by virtue of the laws of the State of Pennsylvania, having its principal place of business located at One Franklin Plaza, Philadelphia, Pennsylvania 19102.
- OO. “GSK Authorized Generic Products” means the Products that are the subject of the GSK Authorized Generic Products Agreements.
- PP. “GSK Authorized Generic Products Agreements” means the following agreements: (1) “Supply Agreement” among SmithKline Beecham Corporation, SmithKline Beecham P.L.C. and IVAX Pharmaceuticals, Inc. dated as of June 22, 2004, a/k/a., *GSK IVAX Generic Augmentin ES-600 Supply Agreement*, and all amendments, exhibits, attachments, agreements, and schedules thereto; and (2) “Supply Agreement” between SmithKline Beecham Corporation and IVAX Pharmaceuticals, Inc. dated as of December 2, 2003, a/k/a., *GSK IVAX Amoxicillin Supply Agreement*, and all amendments, exhibits, attachments, agreements, and schedules thereto. The GSK Authorized Generic Agreements are attached to this Order and contained in non-public Appendix III.
- QQ. “GSK Authorized Generic Products Assignment Agreements” means the following agreements: (1) “Consent and Agreement” by and among Teva Pharmaceuticals USA, Inc., IVAX Pharmaceuticals, Inc., SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, and SmithKline Beecham P.L.C. dated as of December 14, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto; and (2) “Assignment, Assumption and Consent Agreement between Par Pharmaceuticals, Inc., IVAX Pharmaceuticals, Inc., SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, and SmithKline Beecham P.L.C. dated as of December 14, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto. The GSK Consent and Agreement is attached to this Order and contained in non-public Appendix III.
- RR. “High Volume Account(s)” means any retailer, wholesaler or distributor whose annual and/or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States from the divesting Respondent was,

is, or is projected to be among the top twenty highest of such purchase amounts by Respondent's U.S. customers on any of the following dates: (1) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (2) the end of the last quarter that immediately preceded the Effective Date; (3) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or 4) the end of the last quarter following the Acquisition and/or the Closing Date.

- SS. "Interim Monitor" means any monitor appointed pursuant to Paragraph VI of this Order or Paragraph III of the related Order to Maintain Assets.
- TT. "IVAX Generic Divestiture Products (Group 1)" means the following Products, individually and collectively: Cefaclor ER, Estazolam, Nabumetone, and Propoxyphene.
- UU. "IVAX Generic Divestiture Products (Group 1) Agreement(s)" means the "Asset Purchase Agreement" between IVAX Pharmaceuticals, Inc. and Par Pharmaceutical, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, the "Supply Agreement" between IVAX Pharmaceuticals, Inc. and Par Pharmaceutical, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, and the "Supply Agreement" between Teva Pharmaceutical Industries Ltd. and Par Pharmaceutical, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto related to the IVAX Generic Divestiture Products (Group 1) that have been approved by the Commission to accomplish the requirements of this Order. The IVAX Generic Divestiture Products (Group 1) Agreements are attached to this Order and contained in non-public Appendix II.A.
- VV. "IVAX Generic Divestiture Products (Group 1) Assets" means all of Respondent IVAX's rights, title and interest in and to all assets related to Respondent IVAX's business within the Geographic Territory related to the IVAX Generic Divestiture Products (Group 1) to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the IVAX Generic Divestiture Products (Group 1), including, without limitation, the Categorized Assets related to the IVAX Generic Divestiture Products (Group 1).
- WW. "IVAX Generic Divestiture Products (Group 2)" means the following Products, individually and collectively: Glipizide & Metformin, and Nicardipine.
- XX. "IVAX Generic Divestiture Products (Group 2) Agreement(s)" means the "Asset Purchase Agreement" between IVAX Pharmaceuticals, Inc. and Barr Laboratories, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto and the "Supply Agreement" between IVAX Pharmaceuticals Inc. and Barr Laboratories, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, and the "Supply Agreement" between Teva Pharmaceutical Industries Ltd. and Barr Laboratories, Inc. dated as of December 22, 2005,

and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the IVAX Generic Divestiture Products (Group 2) that have been approved by the Commission to accomplish the requirements of this Order. The IVAX Generic Divestiture Products (Group 2) Agreements are attached to this Order and contained in non-public Appendix II.B.

YY. “IVAX Generic Divestiture Products (Group 2) Assets” means all of Respondent IVAX’s rights, title and interest in and to all assets related to Respondent IVAX’s business within the Geographic Territory related to the IVAX Generic Divestiture Products (Group 2) to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the IVAX Generic Divestiture Products (Group 2), including, without limitation, the Categorized Assets related to the IVAX Generic Divestiture Products (Group 2).

ZZ. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.

AAA. “Nabumetone” means all Products Developed, manufactured, marketed or sold by Respondent IVAX pursuant to Respondent IVAX’s ANDA No. 76-009 and any supplements, amendments, or revisions thereto.

BBB. “NDC Numbers” means the National Drug Code numbers(s), including both the labeler code assigned by the FDA and the additional numbers assigned by the Application holder as a product code for a specific Product.

CCC. “Nifedipine” means all Products Developed, manufactured, marketed or sold by Respondent IVAX pursuant to Respondent IVAX’s ANDA No. 74-439 and any supplements, amendments, or revisions thereto.

DDD. “Novopharm Generic Divestiture Product” means Clozapine.

EEE. “Novopharm Generic Divestiture Product Agreement(s)” the “Asset Purchase Agreement” between Novopharm Limited and Par Pharmaceutical, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto and the “Supply Agreement” between Novopharm Limited and Par Pharmaceutical, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Novopharm Generic Divestiture Product that have been approved by the Commission to accomplish the requirements of this Order. The Novopharm Generic Divestiture Product Agreements are attached to this Order and contained in non-public Appendix II.A.

FFF. “Novopharm Generic Divestiture Product Assets” means all of Respondent Teva’s rights, title and interest in and to all assets related to Respondent Teva’s business within the Geographic Territory related to the Novopharm Generic Divestiture Product to the extent

legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Novopharm Generic Divestiture Product, including, without limitation, the Categorized Assets related to the Novopharm Generic Divestiture Product.

- GGG. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders. The Order to Maintain Assets is attached to this Order and contained in Appendix I.
- HHH. “Par” means Par Pharmaceutical, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, having its principal place of business located at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.
- III. “Patents” means all patents, patent applications, including provisional patent applications, and statutory invention registrations, in each case existing as of the Closing Date (*except* where this Order specifies a different time), and includes all reissues, 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(s) as of the Closing Date (*except* where this Order specifies a different time).
- JJJ. “Pergolide Mesylate” means all Products Developed, manufactured, marketed or sold by Respondent Teva pursuant to Respondent Teva’s ANDA No. 76-061 and any supplements, amendments, or revisions thereto.
- KKK. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, joint venture, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- LLL. “Product” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient.
- MMM. “Product Assumed Contracts” means all of the following contracts or agreements (copies of each such contract to be provided to the Commission-approved Acquirer on or before the relevant Closing Date and segregated in manner that clearly identifies the purpose(s) of each such contract):
1. that makes specific reference to the Divestiture Product(s) and pursuant to which any Third Party is obligated to purchase the Divestiture Product(s) from the specified Respondent unless such contract applies generally to the divesting Respondent’s sales of generic Products to that Third Party;
  2. pursuant to which the specified Respondent purchases the active pharmaceutical

ingredient(s) or had planned to purchase the active pharmaceutical ingredient(s) from any Third Party for use in connection with the manufacture of the Divestiture Product(s);

3. relating to any clinical trials involving the Divestiture Product(s);
4. with universities or other research institutions for the use of the Divestiture Product(s) in scientific research;
5. relating to the particularized marketing of the Divestiture Product(s) or educational matters relating solely to the Divestiture Product(s);
6. pursuant to which a Third Party manufactures the Divestiture Product(s) on behalf of the specified Respondent;
7. pursuant to which a Third Party provides the Product Manufacturing Technology or related equipment to the specified Respondent;
8. constituting confidentiality agreements involving the Divestiture Product(s);
9. involving any royalty, licensing, or similar arrangement involving the Divestiture Product(s);
10. pursuant to which a Third Party provides any specialized services necessary to the research, Development, or manufacture of the Divestiture Products to the Respondents, including consultation arrangements; and/or
11. pursuant to which any Third Party collaborates with the specified Respondent in the performance of research, Development, marketing or selling of the Divestiture Product(s) or the Divestiture Product(s) business;

*provided, however,* that where any such contract or agreement also relates to a Retained Product(s), Respondent(s) shall assign the Commission-approved Acquirer all such rights under the contract or agreement as are related to the Divestiture Product(s), but concurrently may retain similar rights for the purposes of the Retained Product(s).

NNN. “Product Copyrights” means rights to all original works of authorship of any kind directly related to the Divestiture Product(s) and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers; all promotional materials for patients; educational materials for the sales force; copyrights in all pre-clinical, clinical and process development data and reports relating to the research and Development of the Divestiture Product(s) or of any materials used in the research, Development, manufacture, marketing or sale of the Divestiture Product(s), including all

raw data relating to clinical trials of the Divestiture Product(s), all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; customer information, promotional and marketing materials, the Divestiture Product(s) sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees who accept employment with the Commission-approved Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all data contained in laboratory notebooks relating to the Divestiture Product(s) or relating to its biology; all adverse experience reports and files related thereto (including source documentation) and all periodic adverse experience reports and all data contained in electronic data bases relating to adverse experience reports and periodic adverse experience reports; all analytical and quality control data; and all correspondence with the FDA.

OOO. “Product Development Reports” means:

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 (including reference listed drug information) related to the specified Divestiture Product(s);
4. all correspondence to the specified Respondent from the FDA and from the specified Respondent to the FDA relating to the Application(s) submitted by, on behalf of, or acquired by, the specified Respondent related to the specified Divestiture Product;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to the specified Divestiture Product(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 event/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).

PPP. “Product Employee Information” means the following, for each Divestiture Product Core Employee, as and to the extent permitted by the Law:

1. a complete and accurate list containing the name of each relevant employee (including former employees who were employed by Respondent(s) within ninety (90) days of the execution date of any Remedial Agreement);
2. with respect to each such employee, the following information:
  - a. the date of hire and effective service date;
  - b. job title or position held;
  - c. a specific description of the employee’s responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, Respondent(s) may provide the employee’s most recent performance appraisal;
  - d. the base salary or current wages;
  - e. the most recent bonus paid, aggregate annual compensation for the Respondent’s last fiscal year and current target or guaranteed bonus, if any;
  - f. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and
  - g. any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
3. at the Commission-approved Acquirer’s option or the Proposed Acquirer’s option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.

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

1. Patents;
2. Product Copyrights;
3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and
4. rights to obtain and file for patents and copyrights and registrations thereof;

*provided, however*, “Product Intellectual Property” does not include the names or trade dress of “Teva”, “IVAX,” “Novopharm”, or the names or trade dress of any other corporations, companies, or brands owned or sold by Respondents or related logos to the extent used on Respondent Teva’s or Respondent IVAX’s Retained Products.

RRR. “Product Licensed Intellectual Property” means the following:

1. Patents that are related to a Divestiture Product that Respondent(s) can demonstrate have been routinely used, prior to the Effective Date, by either Respondent Teva or Respondent IVAX (as applicable) for a Retained Product(s) that: 1) have been marketed or sold on an extensive basis by the relevant Respondent within the two-year period immediately preceding the Acquisition; or 2) for which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell such a Retained Product on an extensive basis by the Respondents; and
2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in any jurisdiction to limit the use or disclosure thereof, that are related to a Divestiture Product and that Respondent(s) can demonstrate have been routinely used, prior to the Effective Date, by either Respondent Teva or Respondent IVAX (as applicable) for Retained Product(s) that: 1) have been marketed or sold on an extensive basis by the relevant Respondent within the two-year period immediately preceding the Acquisition; or 2) for which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell such a Retained Product on an extensive basis by the Respondents;

*provided however*, that, in cases where the aggregate retail sales in dollars within the two-year period immediately preceding the Acquisition of the Retained Product(s) collectively are less than the aggregate retail sales in dollars within the same period of the Divestiture Product(s) collectively, the above-described intellectual property shall be considered, at the Commission-approved Acquirer’s option, to be Product Intellectual Property and, thereby, subject to assignment to the Commission-approved Acquirer; *provided further*,

*however*, that in such cases, Respondents may take a license back from the Commission-approved Acquirer for such intellectual property for use in connection with the Retained Products.

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

*provided, however*, the Respondents may exclude from the “Product Manufacturing Employees” those employees that are determined by the Interim Monitor or the Commission-approved Acquirer not to be material to the planning, design, implementation or use of the Product Manufacturing Technology of the specified Divestiture Product(s).

TTT. “Product Manufacturing Technology” means all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of the Divestiture Product(s) (including, for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Commission-approved Acquirer’s option, all such equipment used to manufacture 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 Application(s) conformance and current good manufacturing practices compliance, and labeling and all other information related to the manufacturing process, and supplier lists.

UUU. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of a Divestiture Product(s) in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (e.g., detailing reports, vendor lists, sales data), marketing information, (e.g., competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research, customer information (including customer net purchases information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists), promotional and marketing materials, artwork for the production of packaging components, television masters and other similar materials related to the Divestiture Product(s); provided however, “Product Marketing Materials” excludes the pricing of the Divestiture Product to customers.

- VVV. “Product Registrations” means all registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, or sale of the Product within the Geographic Territory, including all Applications in existence for the Product as of the Closing Date.
- WWW. “Product Research and Development Employees” means all salaried employees of Respondent(s) who directly have participated in the research, Development, or regulatory approval process, or clinical studies of the specified Divestiture Product(s) (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date;
- provided, however,* the Respondents may exclude from the “Product Research and Development Employees” those employees that are determined by the Interim Monitor or the Commission-approved Acquirer not to be material to the research, Development, or regulatory approval process, or clinical studies of the specified Divestiture Product(s).
- XXX. “Product Trade Dress” means the current trade dress of the Divestiture Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.
- YYY. “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 Product(s).
- ZZZ. “Proposed Acquirer” means an entity proposed by the Respondent(s) (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by Respondent(s) pursuant to this Order.
- AAAA. “Propoxyphene” means all Products Developed, manufactured, marketed or sold by Respondent IVAX pursuant to Respondent IVAX’s ANDA No. 80-269 and any supplements, amendments, or revisions thereto.
- BBBB. “Remedial Agreement(s)” means the following: (1) any agreement between Respondent(s) and a Commission-approved 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; (2) any agreement between Respondent(s) and a Third Party to effect the assignment of assets or rights of the Respondent(s) related to a Divestiture Product or an Assignment Product to the benefit of a Commission-approved Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final; (3) any agreement between the Respondent(s) and a Commission-approved Acquirer (or between a Divestiture Trustee and a Commission-approved 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 this Order; and/or (4) any agreement between Respondent(s) and a Third Party to effect the assignment of assets or rights of the Respondent(s) related to a Divestiture Product or an Assignment Product to the benefit of a Commission-approved Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

- CCCC. "Retained Product" means any Product(s) other than a Divestiture Product.
- DDDD. "Right of Reference or Use" means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an Application, including the ability to make available the underlying raw data from the investigation for FDA audit.
- EEEE. "Supply Cost" means a cost not to exceed the manufacturer's average direct per unit cost of manufacturing the Divestiture Product for the twelve (12) month period immediately preceding the Effective Date. "Supply Cost" shall expressly exclude any intracompany business transfer profit.
- FFFF. "Teva Generic Divestiture Products (Group 1)" means the following Products, individually and collectively: Clozapine, Flutamide, and Pergolide Mesylate.
- GGGG. "Teva Generic Divestiture Products (Group 1) Agreement(s)" means the "Asset Purchase Agreement" between Teva Pharmaceutical Industries Ltd. and Par Pharmaceutical, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto and the "Supply Agreement" between Teva Pharmaceutical Industries Ltd. and Par Pharmaceutical, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Teva Generic Divestiture Products (Group 1) that have been approved by the Commission to accomplish the requirements of this Order. The Teva Generic Divestiture Products (Group 1) Agreements are attached to this Order and contained in non-public Appendix II.A.

- HHHH. “Teva Generic Divestiture Products (Group 1) Assets” means all of Respondent Teva’s rights, title and interest in and to all assets related to Respondent Teva’s business within the Geographic Territory related to the Teva Generic Divestiture Products (Group 1) to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Teva Generic Divestiture Products (Group 1), including, without limitation, the Categorized Assets related to the Teva Generic Divestiture Products (Group 1).
- III. “Teva Generic Divestiture Products (Group 2)” means the following Products, individually and collectively: Cabergoline and Tramadol/Acetaminophen.
- JJJJ. “Teva Generic Divestiture Products (Group 2) Agreement(s)” means the “Asset Purchase Agreement” between Teva Pharmaceutical Industries Ltd. and Barr Laboratories, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, the “Supply Agreement” between Teva Pharmaceutical Industries Ltd. and Barr Laboratories, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto and the “Supply Agreement” between IVAX Pharmaceuticals Inc. and Barr Laboratories, Inc. dated as of December 22, 2005, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Teva Generic Divestiture Products (Group 2) that have been approved by the Commission to accomplish the requirements of this Order. The Teva Generic Divestiture Products (Group 2) Agreements are attached to this Order and contained in non-public Appendix II.B.
- KKKK. “Teva Generic Divestiture Products (Group 2) Assets” means all of Respondent Teva’s rights, title and interest in and to all assets related to Respondent Teva’s business within the Geographic Territory related to the Teva Generic Divestiture Products (Group 2) to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Teva Generic Divestiture Products (Group 2), including, without limitation, the Categorized Assets related to the Teva Generic Divestiture Products (Group 2).
- LLLL. “Third Party(ies)” means any private entity other than the following: (1) the Respondents; or (2) the relevant Commission-approved Acquirer for the affected assets, rights and Divestiture Product(s).
- MMMM. “Tramadol/Acetaminophen” means all Products Developed, manufactured, marketed or sold by Respondent Teva pursuant to Respondent Teva’s ANDA No. 76-914 and any supplements, amendments, or revisions thereto.

## II.

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

- A. Not later than ten (10) days after the Effective Date, Respondents shall divest the IVAX Generic Divestiture Products (Group 1) Assets, the Teva Generic Divestiture Products (Group 1) Assets, and the Novopharm Generic Divestiture Product Assets, absolutely and in good faith, to Par pursuant to and in accordance with, respectively, the IVAX Generic Divestiture Products (Group 1) Agreements, the Teva Generic Divestiture Products (Group 1) Agreements, and the Novopharm Generic Product Asset Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Par or to reduce any obligations of the Respondents under such agreements), and each such agreement, if it becomes the Remedial Agreement related to the IVAX Generic Divestiture Products (Group 1) Assets, the Teva Generic Divestiture Products (Group 1) Assets, or the Novopharm Generic Divestiture Product Assets respectively, is incorporated by reference into this Order and made a part hereof;

*provided, however,* that if Respondents have divested the IVAX Generic Divestiture Products (Group 1) Assets, the Teva Generic Divestiture Products (Group 1) Assets, or Novopharm Generic Divestiture Product Assets to Par prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Par is not an acceptable purchaser of the IVAX Generic Divestiture Products (Group 1) Assets, the Teva Generic Divestiture Products (Group 1) Assets, or the Novopharm Generic Divestiture Product Assets then Respondents shall immediately rescind the transaction with Par and shall divest the IVAX Generic Divestiture Products (Group 1) Assets, the Teva Generic Divestiture Products (Group 1) Assets, or the Novopharm Generic Divestiture Product Assets as is required, within one hundred eighty (180) days from the date the Order becomes final, absolutely and in good faith, at no minimum price, to a Commission-approved Acquirer(s) and only in a manner that receives the prior approval of the Commission;

*provided further* that if the Respondents have divested the IVAX Generic Divestiture Products (Group 1) Assets, the Teva Generic Divestiture Products (Group 1) Assets or the Novopharm Generic Divestiture Product Assets to Par prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies the Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct the Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the IVAX Generic Divestiture Products (Group 1) Assets, the Teva Generic Divestiture Products (Group 1) Assets or the Novopharm Generic Divestiture Product Assets to Par (including, but not limited to, entering into additional agreements or arrangements) as the

Commission may determine are necessary to satisfy the requirements of this Order.

- B. Not later than ten (10) days after the Effective Date, Respondents shall divest the IVAX Generic Divestiture Products (Group 2) Assets and the Teva Generic Divestiture Products (Group 2) Assets, absolutely and in good faith, to Barr pursuant to and in accordance with, respectively, the IVAX Generic Divestiture Products (Group 2) Agreements and the Teva Generic Divestiture Products (Group 2) Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Barr or to reduce any obligations of the Respondents under such agreements), and each such agreement, if it becomes the Remedial Agreement related to the IVAX Generic Divestiture Products (Group 2) Assets or the Teva Generic Divestiture Products (Group 2) Assets, respectively, is incorporated by reference into this Order and made a part hereof;

*provided, however,* that if Respondents have divested the IVAX Generic Divestiture Products (Group 2) Assets or the Teva Generic Divestiture Products (Group 2) Assets to Barr prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Barr is not an acceptable purchaser of the IVAX Generic Divestiture Products (Group 2) Assets or the Teva Generic Divestiture Products (Group 2) Assets, then Respondents shall immediately rescind the transaction with Barr and shall divest the IVAX Generic Divestiture Products (Group 2) Assets or the Teva Generic Divestiture Products (Group 2) Assets, as is required, within one hundred eighty (180) days from the date the Order becomes final, absolutely and in good faith, at no minimum price, to a Commission-approved Acquirer(s) and only in a manner that receives the prior approval of the Commission;

*provided further* that if the Respondents have divested the IVAX Generic Divestiture Products (Group 2) Assets or the Teva Generic Divestiture Products (Group 2) Assets to Barr prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies the Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct the Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the IVAX Generic Divestiture Products (Group 2) Assets or the Teva Generic Divestiture Products (Group 2) Assets to Barr (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. Any Remedial Agreement shall be deemed incorporated into this Order, and any failure by Respondents to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- D. After the Closing Date for the assets related to a specified Divestiture Product(s),

Respondents shall not receive any payment or other compensation from the relevant Commission-approved Acquirer that is: (1) based on the actual amount of sales or profits of such Divestiture Product(s) realized at any time after the Closing Date or (2) due upon the realization of any aggregate amount of sales or profits of such Divestiture Product(s), *provided however*, Respondents may receive payments from the Commission-approved Acquirer based on units of Divestiture Product(s) supplied to the relevant Commission-approved Acquirer pursuant to a Remedial Agreement to Contract Manufacture such Divestiture Product(s).

- E. Respondents shall include in each Remedial Agreement for each Divestiture Product a specific reference to this Order and the remedial purpose thereof and shall include among the provisions in those Remedial Agreement(s) the following provisions:
1. upon reasonable notice and request from the Commission-approved Acquirer to the Respondents, Respondents shall Contract Manufacture and deliver to the Commission-approved Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the relevant Divestiture Products at the divesting Respondent's Supply Cost, for a period of time sufficient to allow the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to obtain all of the relevant Agency approvals necessary to manufacture in commercial quantities the relevant finished drug product independently of Respondents and to secure sources of supply of the relevant active pharmaceutical ingredients, excipients, and other ingredients specified in the relevant Respondent's Application(s) for the Product from entities other than the Respondents; *provided, however*, that in each instance where: (1) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, Supply Cost shall be determined as specified in such Remedial Agreement;
  2. Respondents shall make representations and warranties to the Commission-approved Acquirer that the Product(s) supplied through Contract Manufacture pursuant to the Remedial Agreement meet the relevant Agency-approved specifications. For the Product(s) to be marketed or sold in the Geographic Territory, Respondents shall agree to indemnify, defend and hold the Commission-approved Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Product(s) supplied to the Commission-approved Acquirer pursuant to the Remedial Agreement by the Respondents to meet current good manufacturing practices of the FDA, as set forth in 21 C.F.R. Parts 210 and 211. This obligation may be made contingent upon the Commission-approved Acquirer giving Respondents prompt, adequate notice of such claim and cooperating fully in the defense of such claim. The Remedial Agreement shall be consistent with the obligations assumed by Respondents under this Order; *provided, however*, that Respondents may reserve the right to control the defense of any such litigation, including the right to settle the litigation, so long as such settlement is consistent with the Respondents'

responsibilities to supply the ingredients in the manner required by this Order; *provided further* that this obligation shall not require Respondents to be liable for any negligent act or omission of the Commission-approved Acquirer or for any representations and warranties, express or implied, made by the Commission-approved Acquirer that exceed the representations and warranties made by the Respondents to the Commission-approved Acquirer; *provided further* that in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on Respondents' aggregate liability resulting from the failure of the Products supplied to the Commission-approved Acquirer pursuant to such Remedial Agreement by the Respondents to meet current good manufacturing practices of the FDA (as set forth in 21 C.F.R. Parts 210 and 211);

3. Respondents shall make representations and warranties to the Commission-approved Acquirer that Respondents shall hold harmless and indemnify the Commission-approved Acquirer for any liabilities or loss of profits resulting from the failure by Respondents to deliver the Products in a timely manner as required by the Remedial Agreement unless the Respondents can demonstrate that their failure was entirely beyond the control of the Respondents and in no part the result of negligence or willful misconduct by Respondents; *provided, however*, that in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on Respondents' aggregate liability for such a breach;
4. during the term of the Contract Manufacture between Respondent(s) and the Commission-approved Acquirer, upon request of the Commission-approved Acquirer or Interim Monitor (if applicable), Respondents shall make available to the Commission-approved Acquirer and the Interim Monitor (if applicable) all records that relate to the manufacture of the relevant Divestiture Products that are generated or created after the Closing Date;
5. upon reasonable notice and request from the Commission-approved Acquirer to the Respondents, Respondents shall provide in a timely manner at no greater than Direct Cost the following:
  - a. assistance and advice to enable the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to obtain all necessary permits and approvals from any Agency or Government Entity to manufacture and sell the relevant Divestiture Products;
  - b. assistance to the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to manufacture the relevant Divestiture Product(s) in substantially the same manner, quality, and quantity(ies) employed or achieved by

either Respondent IVAX or Respondent Teva for the relevant Divestiture Product; and

- c. consultation with knowledgeable employees of Respondents and training, at the request of the Commission-approved Acquirer and at a facility chosen by the Commission-approved Acquirer, until the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) obtains all FDA approvals necessary to manufacture in commercial quantities the relevant Divestiture Product(s) independently of the Respondents and sufficient to satisfy management of the Commission-approved Acquirer that its personnel (or the Designee's personnel) are adequately trained in the manufacture of the relevant Divestiture Product(s);
  - d. personnel, assistance and training as the Commission-approved Acquirer(s) might reasonably need to transfer the assets related to the Divestiture Products;
6. The foregoing provisions II.E.1-5 shall remain in effect until the relevant Commission-approved Acquirer(s) (or the Designee(s) of such Commission-approved Acquirer(s)) is fully validated, qualified, and approved by the FDA, and able to manufacture in commercial quantities each of the relevant Divestiture Products independently of Respondents;
  7. the relevant Commission-approved Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture in commercial quantities each such Divestiture Product and to manufacture such quantities of each such Divestiture Product independently of Respondents, all as soon as reasonably practicable;
  8. upon reasonable notice and request from the Commission-approved Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of the Respondents to assist the Commission-approved Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Product Intellectual Property related to the relevant Divestiture Product(s);
  9. for any patent infringement suit in which a Respondent is a party prior to the Closing Date or for which a Respondent has prepared or is preparing as of the Closing Date to be a party, and where such a suit would have the potential to interfere with the Commission-approved Acquirer's freedom to practice in the research, Development, manufacture, use, import, export, distribution or sale of the relevant Divestiture Product(s), the respective Respondent shall:
    - a. cooperate with the Commission-approved Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from

Respondent in connection with obtaining resolution of any pending patent litigation involving a Divestiture Product;

- b. waive conflicts of interest, if any, to allow Respondent's outside legal counsel to represent the Commission-approved Acquirer in any ongoing patent litigation involving a Divestiture Product; and
  - c. permit the transfer to the Commission-approved Acquirer of all of the litigation files and any related attorney work-product in the possession of respective Respondent's outside counsel relating to such Divestiture;
10. Respondents shall covenant to the relevant Commission-approved Acquirer that Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the Commission-approved Acquirer under Patents that: (1) are owned or licensed by Respondents as of the Effective Date; or (2) may be assigned, granted, licensed, or otherwise conveyed to Respondents after the Effective Date, if such suit would have the potential to interfere with the Commission-approved Acquirer's freedom to practice in the research, Development, manufacture, use, import, export, distribution or sale of the relevant Divestiture Product(s);
11. Respondents shall covenant to the Commission-approved Acquirer that: (1) as a condition of any assignment, transfer or license to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue the Divestiture Product Releasees under such Patents, if the suit would have the potential to interfere with the Commission-approved Acquirer's freedom to practice in the research, Development, manufacture, use, import, export, distribution or sale of the relevant Divestiture Product(s); and (2) with respect to any Third Party rights licensed to Respondents as of or after the Effective Date, and as to which Respondents do not control the right of prosecution of any legal action, Respondents shall not actively induce, assist or participate in any legal action or proceeding relating to the relevant Product(s) against the Divestiture Product Releasees, unless required by Law or contract (such contract not to be solicited or entered into for the purpose of circumventing any of the requirements of this Order); and
12. Respondents shall not seek pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement a decision the result of which would be inconsistent with the terms of this Order and/or the remedial purposes thereof.

F. Respondents shall:

- 1. submit to the Commission-approved Acquirer, at Respondents' expense, all Confidential Business Information related to the relevant Divestiture Product(s);

2. deliver such Confidential Business Information as follows: (1) in good faith; (2) as soon as practicable, avoiding any delays in transmission of the respective information; and (3) 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 Commission-approved Acquirer, provide the Commission-approved Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the relevant Divestiture Product(s) 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 relevant Divestiture Product(s) other than as necessary to comply with the following: (1) the requirements of this Order; (2) the Respondents' obligations to the Commission-approved Acquirer under the terms of any Remedial Agreement related to relevant Divestiture Product(s); or (3) applicable Law;
  5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any person except the Commission-approved Acquirer; and
  6. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the relevant Divestiture Products to the employees associated with business related to those Retained Products that are approved by the FDA for the same or similar indications as the relevant Divestiture Products.
- G. Respondents shall not enforce any agreement against a Third Party or the Commission-approved Acquirer to the extent that such agreement may limit or otherwise impair the ability of the Commission-approved Acquirer to acquire the Product Manufacturing Technology related to the relevant Divestiture Product(s) or related equipment 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.
- H. 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.G. that allows the Third Party to provide the relevant Product Manufacturing Technology or related equipment to the Commission-approved Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to the Commission-approved Acquirer for the relevant assets.

I. Respondents shall:

1. for a period of at least six (6) months from the relevant Closing Date, provide the relevant Commission-approved Acquirer with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by such Commission-approved Acquirer. Each of these periods is hereinafter referred to as the “Divestiture Product Employee Access Period(s)”; and
2. not later than the earlier of the following dates: (1) ten (10) days after notice by staff of the Commission to the Respondents to provide the Product Employee Information; or (2) ten (10) days after the relevant Closing Date, provide the relevant Commission-approved Acquirer or the relevant Proposed Acquirer with the Product Employee Information related to the relevant Divestiture Product Core Employees. Failure by Respondents to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Employee Access Period(s) with respect to that employee in an amount equal to the delay.

J. Respondents shall:

1. during the Divestiture Product Employee Access Period(s), not interfere with the hiring or employing by the relevant Commission-approved Acquirer of the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by such Commission-approved Acquirer, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with the relevant Commission-approved Acquirer, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by the relevant Commission-approved Acquirer. In addition, Respondents shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from the relevant Commission-approved Acquirer;

*provided, however,* that this Paragraph II.J.1 shall not prohibit the Respondents from making offers of employment to or employing any Divestiture Product Core Employee during the Divestiture Product Employee Access Period;

2. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, and manufacture the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for such Divestiture Product(s). Such incentives shall include a continuation of all employee

compensation and benefits offered by Respondents until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product(s) has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

*provided, however,* that nothing in this Order requires or shall be construed to require the Respondents to terminate the employment of any employee or prevents the Respondents from continuing the employment of the Divestiture Product Core Employees (other than those conditions of continued employment prescribed in this Order) in connection with the Acquisition; and

3. for a period of one (1) year from the relevant Closing Date, not:

- a. directly or indirectly, solicit or otherwise attempt to induce any employee of the Commission-approved Acquirer with any amount of responsibility related to a Divestiture Product (“Divestiture Product Employee”) to terminate his or her employment relationship with the relevant Commission-approved Acquirer; or
- b. hire any Divestiture Product Employee; *provided, however,* Respondents may hire any former Divestiture Product Employee whose employment has been terminated by the relevant Commission-approved Acquirer or who independently applies for employment with the Respondents, as long as such employee was not solicited in violation of the nonsolicitation requirements contained herein;

*provided, however,* Respondents may do the following: (1) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (2) hire a Divestiture Product Employee who contacts Respondents on his or her own initiative without any direct or indirect solicitation or encouragement from the Respondents.

K. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit the Respondents to divest the assets required to be divested pursuant this Order to the relevant Commission-approved Acquirer(s), and/or to permit such Commission-approved Acquirer to continue the research, Development, manufacture, sale, marketing or distribution of the Divestiture Products;

*provided, however,* Respondents may satisfy this requirement by certifying that the relevant Commission-approved Acquirer has executed all such agreements directly with each of the relevant Third Parties.

L. Respondents shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each Divestiture Product Core Employee retained by Respondents, the direct supervisor(s) of any such employee, and any

other employee retained by Respondents and designated by the Interim Monitor (if applicable) sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondents (other than as necessary to comply with the requirements of this Order).

- M. Not later than thirty (30) days after the Effective Date, Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to the Divestiture Products 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 Divestiture Products;
  2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that are approved by the FDA for the same or similar indications as the relevant Divestiture Products prior to the Acquisition; and/or
  3. may have Confidential Business Information related to the Divestiture Products.

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 relevant Closing Date. Respondents shall provide a copy of such notification to the Commission-approved Acquirer. Respondents shall maintain complete records of all such agreements at Respondents' corporate headquarters 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 Commission-approved Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

- N. Upon reasonable notice and request by the Commission-approved Acquirer(s), Respondents shall make available to the Commission-approved Acquirer(s), at no greater than Direct Cost (or, in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, then at such cost as may be provided therein) such personnel, assistance and training as the Commission-approved Acquirer(s) might reasonably need to transfer the assets related to the Divestiture Product(s) and shall continue providing such personnel, assistance and training, at the request of the Commission-approved Acquirer(s), until the relevant Commission-approved Acquirer(s) (or the Designee(s) of such Commission-approved Acquirer(s)) is fully validated, qualified, and approved by the FDA, and able to manufacture in commercial quantities each of the relevant Divestiture Products independently of the Respondents.

O. Pending divestiture of the assets required to be divested pursuant to this Order, Respondents shall take such actions as are necessary to maintain the full economic viability and marketability of the business associated with such assets, to minimize any risk of loss of competitive potential for such business, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of these assets except for ordinary wear and tear.

P. Respondents shall maintain manufacturing facilities necessary to manufacture each Divestiture Product in finished form until the relevant Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) is fully validated, qualified and approved by the FDA and able to manufacture in commercial quantities the relevant Divestiture Product in finished form in a facility that is independent of Respondents;

*provided, however,* the Commission may eliminate, or limit the duration of, the Respondents' obligation under this provision if the Commission determines that the relevant Commission-approved Acquirer is not using commercially reasonable efforts to secure the FDA approvals necessary to manufacture in commercial quantities each such Divestiture Product in finished form in a facility that is independent of Respondents and to enable itself to manufacture such quantities of each such Divestiture Product independently of Respondents.

Q. Counsel for Respondents (including in-house counsel under appropriate confidentiality arrangements) may retain unredacted copies of all documents or other materials provided to the Commission-approved Acquirer(s) and may have access to original documents (under circumstances where copies of documents are insufficient or otherwise unavailable) provided to the Commission-approved Acquirer(s) only in order to do the following:

1. comply with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
2. 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 Products; *provided, however,* that Respondents may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement or arrangement;

*provided, however,* that pursuant to this Paragraph II.Q., Respondents shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Commission-approved Acquirer (but shall not be deemed to have violated this requirement if the relevant Commission-approved Acquirer withholds such agreement unreasonably); and (2) use their best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

- R. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the relevant Commission-approved Acquirer(s) or the Divestiture Product Releasee(s) for the research, Development, manufacture, use, import, export, distribution, or sale of the relevant Divestiture Product(s) under the following:
1. any Patents owned or licensed by Respondents as of the Effective Date that claim the use of the respective Divestiture Product;
  2. any Patents owned or licensed at any time after the Effective Date by Respondents that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the respective Divestiture Products, other than such Patents that claim inventions conceived by and reduced to practice after the Effective Date.
- S. Respondents shall not, in the Geographic Territory: (1) use the Product Trademarks related to the Divestiture Products or any mark confusingly similar to such Product Trademarks, as a trademark, trade name, or service mark; (2) attempt to register such Product Trademarks; (3) attempt to register any mark confusingly similar to such Product Trademarks; (4) challenge or interfere with the Commission-approved Acquirer(s)'s use and registration of such Product Trademarks; or (5) challenge or interfere with the Commission-approved Acquirer(s)'s efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties; *provided however*, that nothing in this Order shall preclude Respondents from continuing to use those trademarks, tradenames, or service marks related to the Retained Products as of the Effective Date.
- T. The purpose of the divestiture of the IVAX Generic Divestiture Products (Group 1) Assets, the Teva Generic Divestiture Products (Group 1) Assets, the Novopharm Divestiture Product Assets, the IVAX Generic Divestiture Products (Group 2) Assets, and the Teva Generic Divestiture Products (Group 2) Assets is to ensure the continued use of such assets in the same business, independent of Respondents, in which such assets were engaged at the time of the announcement of the Acquisition, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

### III.

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

- A. Not later than ten (10) days after the Effective Date, Respondents shall assign their rights under the GSK Authorized Generic Products Agreements, absolutely and in good faith, to Par pursuant to and in accordance with the GSK Authorized Generic Products Assignment Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Par or to reduce any obligations of the

Respondents under such agreements), and such agreement, if it becomes the Remedial Agreement related to the GSK Authorized Generic Products is incorporated by reference into this Order and made a part hereof;

*provided however*, that if the Respondents have assigned their rights under the GSK Authorized Generic Products Agreements to Par prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies the Respondents that the manner in which the assignment was accomplished is not acceptable, the Commission may direct the Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of assignment of such rights to Par (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. The GSK Authorized Generic Products Assignment Agreements shall be deemed incorporated by reference into this Order and made a part hereof, and any failure by Respondents to comply with any term of the GSK Authorized Generic Products Assignment Agreements, if such agreements are approved by the Commission in connection with the Commission's determination to make this Order final shall constitute a failure to comply with this Order. Any other Remedial Agreement related to the GSK Authorized Generic Products shall also be deemed incorporated into this Order, and any failure by Respondents to comply with any term of such Remedial Agreement related to the GSK Authorized Generic Products shall constitute a failure to comply with this Order.
- C. After the Closing Date for the assignment of rights related to the GSK Authorized Generic Products, Respondents shall not receive any payment or other compensation from the Commission-approved Acquirer that is: (1) based on the actual amount of sales or profits of such Product(s) realized at any time after the Closing Date or (2) due upon the realization of any aggregate amount of sales or profits of such Product(s), *provided however*, Respondents may receive payments from the Commission-approved Acquirer based on units of such Product(s) supplied to the relevant Commission-approved Acquirer pursuant to a Remedial Agreement to Contract Manufacture such Product(s).
- D. The purpose of Paragraph III of this Order is to ensure the continued manufacture, marketing and sale of the GSK Authorized Generic Products independently of Respondents and for the same purposes for which the Products were researched, Developed, manufactured, marketed and sold by IVAX and GSK at the time of the announcement of the Acquisition, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

#### IV.

**IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) days after the Effective Date, Respondents shall assign their rights under the Genzyme Leuprolide Products Agreement, absolutely and in good faith, to Par pursuant to and in accordance with the Genzyme Leuprolide Products Assignment Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Par or to reduce any obligations of the Respondents under such agreement), and such agreement, if it becomes the Remedial Agreement related to the Genzyme Leuprolide Products is incorporated by reference into this Order and made a part hereof;

*provided however*, that if the Respondents have assigned their rights under the Genzyme Leuprolide Products Agreement to Par prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies the Respondents that the manner in which the assignment was accomplished is not acceptable, the Commission may direct the Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of assignment of such rights to Par (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. The Genzyme Leuprolide Products Assignment Agreement shall be deemed incorporated by reference into this Order and made a part hereof, and any failure by Respondents to comply with any term of the Genzyme Leuprolide Products Assignment Agreement, if such agreement is approved by the Commission in connection with the Commission's determination to make this Order final shall constitute a failure to comply with this Order. Any other Remedial Agreement related to the Genzyme Leuprolide Products shall also be deemed incorporated into this Order, and any failure by Respondents to comply with any term of such Remedial Agreement related to the Genzyme Leuprolide Products shall constitute a failure to comply with this Order.
- C. After the Closing Date for the assignment of rights related to the Genzyme Leuprolide Products, Respondents shall not receive any payment or other compensation from the Commission-approved Acquirer that is: (1) based on the actual amount of sales or profits of such Product(s) realized at any time after the Closing Date or (2) due upon the realization of any aggregate amount of sales or profits of such Product(s), *provided however*, Respondents may receive payments from the Commission-approved Acquirer based on units of such Product(s) supplied to the relevant Commission-approved Acquirer pursuant to a Remedial Agreement to Contract Manufacture such Product(s).
- D. The purpose of Paragraph IV of this Order is to ensure the continued manufacture,

marketing and sale of the Genzyme Leuprolide Products independently of Respondents and for the same purposes for which the Products were researched, Developed, manufactured, marketed and sold by IVAX and Genzyme at the time of the announcement of the Acquisition, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

V.

**IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) days after the Effective Date, Respondents shall assign their rights under the Genix Calcitriol Products Agreement, absolutely and in good faith, to Par pursuant to and in accordance with the Genix Calcitriol Products Assignment Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Par or to reduce any obligations of the Respondents under such agreements), and such agreement, if it becomes the Remedial Agreement related to the Genix Calcitriol Products is incorporated by reference into this Order and made a part hereof;

*provided however*, that if the Respondents have assigned their rights under the Genix Calcitriol Products Agreement to Par prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies the Respondents that the manner in which the assignment was accomplished is not acceptable, the Commission may direct the Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of assignment of such rights to Par (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. The Genix Calcitriol Products Assignment Agreement shall be deemed incorporated by reference into this Order and made a part hereof, and any failure by Respondents to comply with any term of the Genix Calcitriol Products Assignment Agreement, if such agreement is approved by the Commission in connection with the Commission's determination to make this Order final shall constitute a failure to comply with this Order. Any other Remedial Agreement related to the Genix Calcitriol Products shall also be deemed incorporated into this Order, and any failure by Respondents to comply with any term of such Remedial Agreement related to the Genix Calcitriol Products shall constitute a failure to comply with this Order.
- C. After the Closing Date for the assignment of rights related to the Genix Calcitriol Products, Respondents shall not receive any payment or other compensation from the Commission-approved Acquirer that is: (1) based on the actual amount of sales or profits of such Product(s) realized at any time after the Closing Date or (2) due upon the realization of any

aggregate amount of sales or profits of such Product(s), *provided however*, Respondents may receive payments from the Commission-approved Acquirer based on units of such Product(s) supplied to the relevant Commission-approved Acquirer pursuant to a Remedial Agreement to Contract Manufacture such Product(s).

- D. The purpose of Paragraph V of this Order is to ensure the continued manufacture, marketing and sale of the Genix Calcitriol Products independently of Respondents and for the same purposes for which the Products were researched, Developed, manufactured, marketed and sold by IVAX and Genix at the time of the announcement of the Acquisition, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

## VI.

### **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 and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent Teva, which consent shall not be unreasonably withheld. If Respondent Teva has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent Teva of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.
- D. If an Interim Monitor is appointed, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
  - 1. The Interim Monitor shall have the power and authority to monitor Respondents' compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the

purposes of the Order and in consultation with the Commission.

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

3. The Interim Monitor shall serve until the later of:

a. the completion by Respondents of:

(1) the divestiture of all Divestiture Assets in a manner that fully satisfies the requirements of this Order; and

(2) notification by each of the relevant Commission-approved Acquirers to the Interim Monitor that it is fully capable of manufacturing, independently of Respondents, the relevant Divestiture Product(s) in commercial quantities and in a manner consistent with current good manufacturing practices of the FDA; and

b. the completion by Respondents of the last obligation under the Orders pertaining to the Interim Monitor's service;

*provided, 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 their obligations under the Order, including, but not limited to, their obligations related to the relevant assets. Respondents shall cooperate with any reasonable request 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 Order.

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 the 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 misfeasance, 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 the Commission-approved Acquirer with respect to the performance of Respondents' obligations under the Order or the Remedial Agreement. Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Order.
  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 Order.
  - H. The Interim Monitor appointed pursuant to this Order may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

## VII.

### **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 relevant assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver or otherwise convey the assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed pursuant to each of the relevant Paragraphs in a manner that satisfies the requirements of each such Paragraph. 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 the relevant assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent Teva, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent Teva has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent Teva 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*, 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 Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondent from among those approved by the Commission; and, *provided further, however*, that Respondent shall select such entity 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 Respondents, 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 the 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 misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
  7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of the Order to Maintain Assets in this matter.
  8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
  9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

## 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 date this Order becomes final, and every sixty (60) days thereafter until Respondents have fully complied with, the following:
  1. Paragraphs II.A, Paragraphs II.B. , III.A., IV.A. and V.A. (*i.e.*, has assigned, licensed, divested, transferred, delivered or otherwise conveyed all relevant assets to the relevant Commission-approved Acquirer in a manner that fully satisfies the requirements of the Order);
  2. Paragraphs II.F., II.G., and II.H; and
  3. and all of its responsibilities to render transitional services to the relevant Commission-approved Acquirer as provided by this Order and the Remedial Agreement(s),

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, if any Interim Monitor has been appointed. 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 any proposed (1) dissolution of such Respondent(s), (2) acquisition, merger or consolidation of Respondent(s), or (3) any other change in the Respondent(s) that may affect compliance obligations arising out of the Order, including, but not limited to, assignment and the creation or dissolution of subsidiaries.

**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 with reasonable notice to Respondents made to their principal United States offices, Respondents shall permit any duly authorized representative of the Commission:

- A. access, during business office hours of Respondent(s) and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondent related to compliance with this Order; and
- B. upon five (5) days' notice to Respondent(s) and without restraint or interference from Respondent, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

**XI.**

**IT IS FURTHER ORDERED** that this Order shall terminate ten (10) years from the date on which the Order becomes final.

By the Commission.

Donald S. Clark  
Secretary

SEAL  
ISSUED:

**PUBLIC  
APPENDIX I  
ORDER TO MAINTAIN ASSETS**

**NON-PUBLIC APPENDIX II.A.  
AGREEMENTS RELATED TO  
THE IVAX GENERIC DIVESTITURE PRODUCTS (GROUP 1) ASSETS  
AND  
THE TEVA GENERIC DIVESTITURE PRODUCTS (GROUP 1) ASSETS  
AND  
THE NOVOPHARM GENERIC DIVESTITURE PRODUCT ASSETS**

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

**NON-PUBLIC  
APPENDIX II.B.  
AGREEMENTS RELATED TO  
THE IVAX GENERIC DIVESTITURE PRODUCTS (GROUP 2) ASSETS  
AND  
THE TEVA GENERIC DIVESTITURE PRODUCTS (GROUP 2) ASSETS  
[Redacted From the Public Record Version But Incorporated By Reference]**

**NON PUBLIC  
APPENDIX III  
AGREEMENTS RELATED TO  
THE GSK AUTHORIZED GENERIC PRODUCTS**

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

**NON-PUBLIC  
APPENDIX IV  
AGREEMENTS RELATED TO  
GENZYME LEUPROLIDE PRODUCTS**

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

**NON-PUBLIC  
APPENDIX V  
AGREEMENTS RELATED TO  
THE GENIX CALCITRIOL PRODUCTS**

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