

UNITED STATES OF AMERICA  
BEFORE FEDERAL TRADE COMMISSION

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

<p>In the Matter of</p> <p style="text-align: center;">TEVA PHARMACEUTICAL INDUSTRIES LTD., a corporation,</p> <p style="text-align: center;">and</p> <p style="text-align: center;">BARR PHARMACEUTICALS, INC., a corporation.</p>	<p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p>	<p>Docket No. C-4242</p>
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**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 Barr Pharmaceuticals, Inc. (“Barr”), and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), 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, 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 corporate head office and principal place of business located at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131 Israel and the address of its United States subsidiary, Teva Pharmaceuticals USA, Inc., located at 1090 Horsham Road, P.O.B. 1090, North Wales, Pennsylvania 19454.
2. Respondent Barr is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.
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, Teva Pharmaceuticals USA, Inc., Barr Acquisition Corp., Barr Acquisition, LLC, and IVAX Corporation), and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each. After the Acquisition, Teva shall include Barr.
- B. “Barr” means Barr Pharmaceuticals, Inc., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Barr (including, but not limited to, Barr Laboratories, Inc., and PLIVA d.d. ), and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.
- C. “Respondent(s)” means Teva and Barr, individually and collectively.
- D. “Commission” means the Federal Trade Commission.

- E. “Acquirer(s)” means the following:
1. a Person specified by name in this Order to acquire particular assets or rights that 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. a Person approved by the Commission to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- F. “Acquisition” means the acquisition contemplated by the “Agreement and Plan of Merger” by and among Barr Pharmaceuticals, Inc., Teva Pharmaceutical Industries LTD. and Boron Acquisition Corp., dated as of July 17, 2008.
- G. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”).
- H. “Application(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDA”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Respondent(s) and the FDA related thereto. The term “Application” also includes an “Investigational New Drug Application” (“IND”) for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Respondent(s) and the FDA related thereto.
- I. “Carboplatin Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Teva pursuant to the following ANDA:
1. Carboplatin (Paraplatin) for injection, USP 50mg; 150mg; and 450mg strengths, pursuant to ANDA No. 76-162; and
  2. any supplements, amendments, or revisions thereto;
- provided, however,* that for the purposes of the Contract Manufacture provisions of this Order, the term “Carboplatin Products” shall include all presentations of any Retained

Product that, as of the Effective Date, are being, or will be, manufactured, marketed or sold by either Respondent for sale within the United States that contain the active pharmaceutical ingredient carboplatin in the dosage strengths and presentations specified above.

- J. “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, non-exclusive, 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 Approvals 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. all Website(s) related to such Divestiture Product(s);
  7. 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 Respondent(s) 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 Respondent(s) 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 Respondent(s) of any such cross-referencing that is discovered by Respondent(s));
    - d. to seek cross-referencing from a customer of those NDC Numbers with the 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; and

- f. to approve any notification(s) from Respondent(s) to any customer(s) regarding the use or discontinued use of such NDC numbers by Respondent(s) prior to such notification(s) being disseminated to the customer(s);
8. all rights to all of Respondents' Applications related to such Divestiture Product(s);
9. 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);
10. all Product Development Reports related to such Divestiture Product(s);
11. at the Acquirer's option, all Product Assumed Contracts related to such Divestiture Product(s) (copies to be provided to the Acquirer on or before the Closing Date);
12. all strategic safety programs submitted to the FDA related to such Divestiture Product(s) that are designed to decrease product risk by using one or more interventions or tools beyond the package insert;
13. 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 such Divestiture Product(s);
14. a 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;
15. at the 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);
16. copies of all unfilled customer purchase orders for such Divestiture Product(s) as of the Closing Date, to be provided to the Acquirer not later than five (5) days after the Closing Date;
17. at the Acquirer's option, subject to any rights of the customer, all unfilled customer purchase orders for such Divestiture Products; and

18. all of the relevant 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: (1) documents relating to either Respondent's 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; (2) shall not include administrative, financial, and accounting records; (3) quality control records that are determined by the Interim Monitor or the Acquirer not to be material to the manufacture of the Divestiture Product(s); and (4) any real estate and the buildings and other permanent structures located on such real estate;

*provided further, however,* 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 Respondent(s) 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 Respondent(s) has a legal obligation to retain the original copies, the Respondent(s) shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer, the Respondent(s) shall provide such 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 Respondent(s) provides the Acquirer with the above-described information without requiring Respondent(s) completely to divest itself of information that, in content, also relates to Retained Product(s).

- K. "cGMP" means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.
- L. "Chlorzoxazone Products" means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Teva pursuant to the following ANDA:
1. Chlorzoxazone tablet, USP 500mg strength, pursuant to ANDA No. 89-859; and
  2. any supplements, amendments, or revisions thereto;

*provided, however,* that for the purposes of the Contract Manufacture provisions of this Order, the term "Chlorzoxazone Products" shall include all presentations of any Retained Product that, as of the Effective Date, are being, or will be, manufactured, marketed or sold by either Respondent for sale within the United States that contain the active pharmaceutical ingredient chlorzoxazone in the dosage strengths and presentations specified above.

- M. “Closing Date” means, as to each Divestiture Product, the date on which Respondent(s) (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.
- N. “Confidential Business Information” means all information owned by, or in the possession or control of, a Respondent that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support, or use of the Divestiture Product(s);
- provided however*, that the restrictions contained in this Order regarding the Respondents’ use, conveyance, provision, or disclosure of “Confidential Business Information” shall not apply to the following:
1. information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by Respondent(s);
  2. information related to the Divestiture Products that were researched, Developed, manufactured, marketed, or sold by Respondent Teva that Respondent Barr can demonstrate it obtained without the assistance of Respondent Teva prior to the Acquisition;
  3. information related to the Divestiture Products that were researched, Developed, manufactured, marketed, or sold by Respondent Barr that Respondent Teva can demonstrate it obtained without the assistance of Respondent Barr 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 Products;
  6. information relating to either Respondent’s 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 Products; or
  7. information specifically excluded from the Categorized Assets.
- O. “Contract Manufacture” means the manufacture of a Divestiture Product to be supplied by Respondent Teva, Respondent Barr, or a Designee to an Acquirer.
- P. “Contract Manufacture Product” means any Divestiture Product *except* a Generic Pipeline Oral Contraceptive Product, an Epoprostenol Product, or a Fluoxetine Product.

Q. “Cyclosporine Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Barr pursuant to the following of Respondent Barr’s ANDAs:

1. Cyclosporine capsules, USP 25mg and 100mg strengths, pursuant to ANDA No. 65-044;
2. Cyclosporine liquid, USP 100mg/ml strengths, pursuant to ANDA No. 65-054; and
3. any supplements, amendments, or revisions thereto;

*provided, however,* that for the purposes of the Contract Manufacture provisions of this Order, the term “Cyclosporine Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being, or will be, manufactured, marketed or sold by either Respondent for sale within the United States that contain the active pharmaceutical ingredient cyclosporine in the dosage strengths and presentations specified above.

R. “Deferoxamine Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Teva pursuant to the following ANDA:

1. Deferoxamine for injection, USP 500mg and 2000mg strengths, pursuant to Teva Parenteral ANDA No. 76-806; and
2. any supplements, amendments, or revisions thereto;

*provided, however,* that for the purposes of the Contract Manufacture provisions of this Order, the term “Deferoxamine Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being, or will be, manufactured, marketed or sold by either Respondent for sale within the United States that contain the active pharmaceutical ingredient deferoxamine in the dosage strengths and presentations specified above.

S. “Designee” means any Person other than Respondent Teva or Respondent Barr that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer *provided however,* that the term “Designee” shall exclude Watson/Andrx for the manufacture of the Generic Oral Contraceptive Products.

T. “Desmopressin Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Barr pursuant to the following ANDA:

1. Desmopressin Acetate tablets, USP 0.1mg and 0.2mg strengths, pursuant to ANDA No. 76-470; and
2. any supplements, amendments, or revisions thereto;



*provided, however,* that for the purposes of the Contract Manufacture provisions of this Order, the term “Desmopressin Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being, or will be, manufactured, marketed or sold by either Respondent for sale within the United States that contain the active pharmaceutical ingredient desmopressin acetate in the dosage strengths and presentations specified above.

- U. “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.
- V. “Direct Cost” means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of Respondents’ employees’ labor shall not exceed the average hourly wage rate for such employee;  
  
*provided, however,* 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, “Direct Cost” means such cost as is provided in such Remedial Agreement for that Divestiture Product.
- W. “Divestiture Product(s)” means the following: the Generic Assorted Indication Products, the Generic Oral Contraceptive Products, and the Trazodone Products, individually and collectively.
- X. “Divestiture Product Core Employee(s)” means the Product Research and Development Employees and the Product Manufacturing Employees related to each Divestiture Product.
- Y. “Divestiture Product Releasee(s)” means the Acquirer for the assets related to a particular Divestiture Product or any Person controlled by or under common control with such Acquirer, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of such Acquirer, or of such Acquirer-affiliated entities.
- Z. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- AA. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the

domain name registration. “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.

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

CC. “Effective Date” means the earliest of the following dates:

1. the date the Respondents close on the Acquisition pursuant to the Agreement and Plan of Merger;
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 Delaware; or
3. the date on which Respondent Teva acquires, directly or indirectly, fifty (50)% or more of the voting securities of Respondent Barr.

DD. “Epoprostenol Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Barr pursuant to the following ANDA:

1. Epoprostenol Sodium freeze dried powder + diluent, USP 0.5mg strength dry vial, USP 1.5mg strength dry vial (freeze-dried powder) strengths, pursuant to ANDA No. 78-397; and
2. any supplements, amendments, or revisions thereto;

*provided, however,* that for the purposes of the Contract Manufacture provisions of this Order, the term “Epoprostenol Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being, or will be, manufactured, marketed or sold by either Respondent for sale within the United States that contain the active pharmaceutical ingredient epoprostenol sodium in the dosage strengths and presentations specified above.

EE. “Fluoxetine Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Teva pursuant to the following ANDA:

1. Fluoxetine capsules, USP 90mg strength, pursuant to ANDA No. 77-664; and
2. any supplements, amendments, or revisions thereto;

*provided, however,* that for the purposes of the Contract Manufacture provisions of this Order, the term “Fluoxetine Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being, or will be, manufactured, marketed or sold by either Respondent for sale within the United States that contain the active

pharmaceutical ingredient fluoxetine in the dosage strengths and presentations specified above.

FF. “Flutamide Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Barr pursuant to the following ANDA:

1. Flutamide, USP 125mg strength, pursuant to ANDA No. 75-820; and
2. any supplements, amendments, or revisions thereto;

*provided, however,* that for the purposes of the Contract Manufacture provisions of this Order, the term “Flutamide Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being, or will be, manufactured, marketed or sold by either Respondent for sale within the United States that contain the active pharmaceutical ingredient flutamide in the dosage strengths and presentations specified above.

GG. “Generic Assorted Indication Products” means the following products: Carboplatin Products, Chlorzoxazone Products, Cyclosporine Products, Deferoxamine Products, Desmopressin Products, Epoprostenol Products, Flutamide Products, Fluoxetine Products, Glipizide/Metformin Products, Metoclopramide Products, Metronidazole Products, Mirtazapine Products, Tamoxifen Products, and the Tetracycline Products.

HH. “Generic Assorted Indication Product Assets” means all of the specified Respondent’s rights, title and interest in and to all assets related to such Respondent’s business within the Geographic Territory related to each of the respective Generic Assorted Indication Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of each such Product, including, without limitation, the Categorized Assets related to each of the Generic Assorted Indication Products.

II. “Generic Oral Contraceptive Product Assets” means all of the specified Respondent’s rights, title and interest in and to all assets related to such Respondent’s business within the Geographic Territory related to each of the respective Generic Oral Contraceptive Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of each such Product, including, without limitation, the Categorized Assets related to each of the Generic Oral Contraceptive Products.

JJ. “Generic Oral Contraceptive Products” means all Products in Development, manufactured, marketed or sold by Respondent Teva pursuant to the following of Respondent Teva’s ANDAs and/or pre-ANDA Products in Development:

1. Norgestimate/Ethinyl Estradiol Tablets (“Previfem”), USP 0.25 mg/0.035 mg strength, pursuant to ANDA No. 76-334;

2. Norgestimate/Ethinyl Estradiol Tablets (“Tri-Previfem”), USP 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, and 0.25 mg/0.035 mg strengths, pursuant to ANDA No. 76-335;
3. Norethindrone/Ethinyl Estradiol Tablets (“Cyclafem 1/35”), USP 1 mg/0.035 mg strength, pursuant to ANDA No. 76-337;
4. Norethindrone/Ethinyl Estradiol Tablets (“Cyclafem 7/7/7”), USP 0.5 mg/0.035 mg, 0.75 mg/0.035 mg, 1 mg/0.035 mg strengths, pursuant to ANDA No. 76-338;
5. Desogestrel/Ethinyl Estradiol Tablets (“Emoquette”), USP 0.15 mg/0.03 mg strength, pursuant to ANDA No. 76-675;
6. Desogestrel/Ethinyl Estradiol Tablets (“Belisma”), USP 0.15 mg/0.02 mg strength, and Ethinyl Estradiol Tablets USP 0.01 mg strength, pursuant to ANDA No. 76-681;
7. Norethindrone Acetate/Ethinyl Estradiol/Ferrous Fumarate Tablets (“Gildess Fe 1.5”), 1.5 mg/0.03 mg/75 mg strength, pursuant to ANDA No. 77-075;
8. Norethindrone Acetate/Ethinyl Estradiol/Ferrous Fumarate Tablets (“Gildess Fe 1/20”), USP 0.1 mg/0.02 mg/75 mg strength, pursuant to ANDA No. 77-077;
9. Levonorgestrel/Ethinyl Estradiol Tablets (“Monavi”), USP 0.10 mg/0.02 mg strength, pursuant to ANDA No. 77-099;
10. Levonorgestrel/Ethinyl Estradiol Tablets (“Iantha”), USP 0.05 mg/0.03 mg, 0.075 mg/0.04 mg, and 0.125 mg/0.03 mg strengths, pursuant to ANDA No. 77-502;
11. Norethindrone Acetate/Ethinyl Estradiol Tablets (“Genliet 35”), USP 0.4 mg/0.035 mg strength, pursuant to ANDA No. 78-376;
12. Norethindrone Acetate/Ethinyl Estradiol/Ferrous Fumarate Tablets (“Gildess Fe 24”), USP 1 mg/0.02 mg strength, pursuant to ANDA 90-293;
13. Norgestimate/Ethinyl Estradiol Tablets (generic Product in Development for Ortho Tri-Cyclen® Lo 28), USP 0.180 mg/0.025 mg, 0.215 mg/0.025 mg, and 0.250 mg/0.025 mg strengths, for which no ANDA has been filed; and
14. any supplements, amendments, or revisions thereto;

*provided, however,* that for the purposes of the Contract Manufacture provisions of this Order, the term “Generic Oral Contraceptive Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being, or will be, manufactured, marketed or sold by either Respondent for sale within the United States that contain the same active pharmaceutical ingredients specified above in the dosage strengths and presentations specified above.

- KK. “Generic Pipeline Oral Contraceptive Products” means the following Products in Development by Respondent Teva pursuant to the following of Respondent Teva’s ANDAs and/or pre-ANDA Products in Development: Cyclofem 1/35, Cyclofem 7/7/7, Emoquette, Belisma, Gildess Fe 1.5, Gildess Fe 1/20, Monavi, Iantha, Genliet 35, Gildess Fe 24, and a generic Product in Development for Ortho Tri-Cyclen Lo 28.
- LL. “Geographic Territory” shall mean the United States of America (including all of the territories within its jurisdiction or control) unless otherwise specified.
- MM. “Glipizide/Metformin Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Barr pursuant to the following ANDA:
1. Glipizide/Metformin HCl tablets, USP 2.5/250mg, 2.5/500mg and 5/500mg strengths, pursuant to ANDA No. 77-347; and
  2. any supplements, amendments, or revisions thereto;
- provided, however, that for the purposes of the Contract Manufacture provisions of this Order, the term “Glipizide/Metformin Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being, or will be, manufactured, marketed or sold by either Respondent for sale within the United States that contain the active pharmaceutical ingredients glipizide and metformin in the dosage strengths and presentations specified above.*
- NN. “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.
- OO. “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 Respondent was, or is projected to be among the top twenty highest of such purchase amounts by the 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.
- PP. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- QQ. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.

RR. “Metoclopramide Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Barr pursuant to the following ANDAs:

1. Metoclopramide HCl tablets, USP 5mg strength, pursuant to ANDA No. 72-750;
2. Metoclopramide HCl tablets, USP 10mg strength, pursuant to ANDA No. 71-250 and
3. any supplements, amendments, or revisions thereto;

*provided, however,* that for the purposes of the Contract Manufacture provisions of this Order, the term “Metoclopramide Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being, or will be, manufactured, marketed or sold by either Respondent for sale within the United States that contain the active pharmaceutical ingredients metoclopramide in the dosage strengths and presentations specified above.

SS. “Metronidazole Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Teva pursuant to the following ANDAs:

1. Metronidazole tablets, USP 250mg strength, pursuant to ANDA No. 70-035;
2. Metronidazole tablets, USP 500mg strength, pursuant to ANDA No. 70-044 and
3. any supplements, amendments, or revisions thereto;

*provided, however,* that for the purposes of the Contract Manufacture provisions of this Order, the term “Metronidazole Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being, or will be, manufactured, marketed or sold by either Respondent for sale within the United States that contain the active pharmaceutical ingredients metronidazole in the dosage strengths and presentations specified above.

TT. “Mirtazapine Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Barr pursuant to the following ANDA:

1. Mirtazapine orally disintegrating tablets, USP 15mg and 30mg strengths, pursuant to ANDA No. 76-307; and
2. any supplements, amendments, or revisions thereto;

*provided, however,* that for the purposes of the Contract Manufacture provisions of this Order, the term “Mirtazapine Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being, or will be, manufactured, marketed or sold by either Respondent for sale within the United States that contain the active

pharmaceutical ingredients mirtazapine in the dosage strengths and presentations specified above.

- UU. “NDC Numbers” means the National Drug Code numbers, including both the labeler code assigned by the FDA and the additional numbers assigned by an Application holder as a product code for a specific Product.
- VV. “Order Date” means the date on which this Decision and Order becomes final.
- WW. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- XX. “Patent(s)” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case existing as of the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any Product of or owned by Respondent(s) as of the Closing Date (*except* where this Order specifies a different time).
- YY. “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.
- ZZ. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient.
- AAA. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage or transport of the Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application.
- BBB. “Product Assumed Contracts” means all of the following contracts or agreements (copies of each such contract to be provided to the Acquirer on or before the Closing Date and segregated in a manner that clearly identifies the purpose(s) of each such contract):
  1. that make specific reference to the Divestiture Product(s) and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the Divestiture Product(s) from the Respondent(s) unless such contract applies generally to the Respondent’s sales of Products to that Third Party;

2. pursuant to which Respondent(s) purchases the active pharmaceutical ingredient(s) or other necessary ingredient(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary 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 or packages the Divestiture Product(s) on behalf of Respondent(s);
7. pursuant to which a Third Party provides the Product Manufacturing Technology related to the Divestiture Product(s) to Respondent(s);
8. pursuant to which a Third Party is licensed by Respondent(s) to use the Product Manufacturing Technology;
9. constituting confidentiality agreements involving the Divestiture Product(s);
10. involving any royalty, licensing, or similar arrangement involving the Divestiture Product(s);
11. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the Divestiture Products to Respondent(s) including, but not limited to, consultation arrangements; and/or
12. pursuant to which any Third Party collaborates with Respondent(s) in the performance of research, Development, marketing, distribution 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 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).

CCC. “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, and educational materials for the sales force; copyrights in all preclinical, clinical and process development data and reports relating to the research and Development of the Divestiture Product(s) or of any materials used in the research, Development, manufacture, marketing or sale of the Divestiture Product(s), including all copyrights in 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; all copyrights in 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 Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to the Divestiture Product(s) or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA.

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

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

1. a complete and accurate list containing the name of each 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 relevant Respondent's last fiscal year and current target or guaranteed bonus, if any;
  - f. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and
  - g. any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
3. at the Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.

FFF. “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 corporate names or corporate trade dress of “Teva” or “Barr”, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by Respondents or the related logos thereof.

GGG. “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, for a Retained Product(s) that:
  - a. has been marketed or sold on an extensive basis by a Respondent within the two-year period immediately preceding the Acquisition; or
  - b. 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 a Respondent; and
2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to a Divestiture Product and that Respondent(s) can demonstrate have been routinely used, prior to the Effective Date, for a Retained Product(s) that:
  - a. has been marketed or sold on an extensive basis by the Respondent(s) within the two-year period immediately preceding the Acquisition; or
  - b. 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 a Respondent;

*provided however*, that, in cases where the aggregate retail sales of a Retained Product(s) in dollars within the two-year period immediately preceding the Acquisition collectively

are less than the aggregate retail sales in dollars within the same period of the Divestiture Product(s) collectively being divested to a particular Acquirer, the above-described intellectual property shall be considered, at the such Acquirer's option, to be Product Intellectual Property and, thereby, subject to assignment to such Acquirer;

*provided further, however*, that in such cases, Respondents may take a license back from such Acquirer for such intellectual property for use in connection with the Retained Products and such a license to Respondents may be perpetual, fully paid-up and royalty-free license(s) with rights to sublicense.

HHH. "Product Manufacturing Employees" means all salaried employees of Respondents who have directly participated in the planning, design, implementation or operational management 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.

III. "Product Manufacturing Technology" means:

1. all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of the 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 cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;
2. all active pharmaceutical ingredients related to the Divestiture Product(s); and,
3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer's option, all such equipment used to manufacture the Divestiture Product(s).

JJJ. "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 purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational

materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the Divestiture Product(s); *provided however*, that for any generic Product, “Product Marketing Materials” excludes the pricing of each of the Divestiture Products to customers.

- KKK. “Product Research and Development Employees” means all salaried employees of Respondents 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.
- LLL. “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.
- MMM. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for the Divestiture Product(s).
- NNN. “Proposed Acquirer” means a Person proposed by Respondents (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 Respondents pursuant to this Order.
- OOO. “Remedial Agreement(s)” means the following:
1. any agreement between Respondent(s) and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final;
  2. any agreement between Respondent(s) and a Third Party to effect the assignment of assets or rights of Respondent(s) related to a Divestiture Product to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final;

3. any agreement between Respondent(s) and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of this Order; and/or
4. any agreement between Respondent(s) and a Third Party to effect the assignment of assets or rights of Respondent(s) related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

PPP. “Retained Product” means any Product(s) other than a Divestiture Product.

QQQ. “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.

RRR. “Supply Cost” means a cost not to exceed the manufacturer’s average direct per unit cost in United States dollars 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; *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” means the cost as specified in such Remedial Agreement for that Divestiture Product.

SSS. “Tamoxifen Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Barr pursuant to the following ANDA:

1. Tamoxifen citrate tablet, USP 10mg and 20mg strengths, pursuant to ANDA No. 70-929; and
2. any supplements, amendments, or revisions thereto;

*provided, however*, that for the purposes of the Contract Manufacture provisions of this Order, the term “Tamoxifen Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being, or will be, manufactured, marketed or sold by either Respondent for sale within the United States that contain the active pharmaceutical ingredients tamoxifen in the dosage strengths and presentations specified above.

TTT. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered pursuant to this Order are delivered

in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*,

- a. designating employees knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer and/or its Designee, and the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;
- b. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product(s) that are acceptable to the Acquirer;
- c. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Designee; and
- d. providing, in a timely manner, assistance and advice to enable the Acquirer or its Designee to:
  - (1) manufacture the specified Divestiture Product(s) in the quality and quantities achieved by the Respondent(s), or the manufacturer and/or developer of such Divestiture Product;
  - (2) obtain any Product Approvals necessary for the Acquirer or its Designee, to manufacture, distribute, market, and sell the specified Divestiture Product(s) in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product(s); and
  - (3) receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product(s).

UUU. “Tetracycline Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Barr pursuant to the following ANDA:

1. Tetracycline HCl capsules, USP 250mg and 500mg strengths, pursuant to ANDA No. 61-837; and
2. any supplements, amendments, or revisions thereto;

*provided, however*, that for the purposes of the Contract Manufacture provisions of this Order, the term “Tetracycline Products” shall include all presentations of any Retained

Product that, as of the Effective Date, are being, or will be, manufactured, marketed or sold by either Respondent for sale within the United States that contain the active pharmaceutical ingredients tetracycline in the dosage strengths and presentations specified above.

- VVV. “Third Party(ies)” means any non-governmental Person other than the following: Respondent Teva, Respondent Barr, or the Acquirer for the affected assets, rights and Divestiture Product(s).
- WWW. “Trazodone 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 Trazodone Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Trazodone Products, including, without limitation, the Categorized Assets related to the Trazodone Products.
- XXX. “Trazodone Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Teva pursuant to the following ANDAs:
1. Trazodone HCl tablets, USP 50mg strength, pursuant to ANDA No. 72-192;
  2. Trazodone HCl tablets, USP 100mg strength, pursuant to ANDA No. 72-193; and
  3. any supplements, amendments, or revisions thereto;
- provided, however,* that for the purposes of the Contract Manufacture provisions of this Order, the term “Trazodone Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being, or will be, manufactured, marketed or sold by either Respondent for sale within the United States that contain the active pharmaceutical ingredients trazodone in the dosage strengths and presentations specified above.
- YYY. “Vintage” means Vintage Pharmaceuticals LLC, a limited liability company organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 130 Vintage Drive, Huntsville, Alabama 35811.
- ZZZ. “Vintage Generic Divestiture Product Agreement(s)” means the following agreements:
1. “Asset Purchase Agreements” between Teva Pharmaceuticals USA, Inc. and Vintage Pharmaceuticals LLC, dated as of November 20, 2008, and all amendments, exhibits, attachments, agreements, and schedules thereto, including:
    - a. The Asset Purchase Agreement related to the Generic Oral Contraceptive Products that is between Teva Pharmaceuticals USA, Inc. and Vintage Pharmaceuticals LLC, dated as of November 20, 2008, and all amendments, exhibits, attachments, agreements, and schedules thereto;



- b. The Asset Purchase Agreement related to the Trazodone Products that is between Teva Pharmaceuticals USA, Inc. and Vintage Pharmaceuticals LLC, dated as of November 20, 2008, and all amendments, exhibits, attachments, agreements, and schedules thereto;
2. “Supply Agreement” related to the Trazodone Product that is between Teva Pharmaceuticals USA, Inc. and Vintage Pharmaceuticals LLC, dated as of November 20, 2008, and all amendments, exhibits, attachments, agreements, and schedules thereto; and
3. the following agreements assigned from Respondent Teva to Vintage:
  - a. “Manufacturing Services Agreement” between Patheon Inc. and Andrx Pharmaceuticals, Inc. dated as of October 3, 2006, and all amendments, exhibits, attachments, agreements, and schedules thereto, and to the full extent that such agreement(s) relate to any Generic Oral Contraceptive Product to be marketed or sold in the United States; and
  - b. “Marketing and Distribution Agreement” by and among Teva Pharmaceuticals USA, Inc., Novopharm Limited, Andrx Pharmaceuticals, Inc., and Andrx Pharmaceuticals, LLC, dated as of December 10, 2003, and all amendments, exhibits, attachments, agreements, and schedules thereto, and to the full extent that such agreement(s) relate to any Generic Oral Contraceptive Product to be marketed or sold in the United States;

related to the Generic Oral Contraceptive Product Assets and/or the Trazodone Product Assets that have been approved by the Commission to accomplish the requirements of this Order. The Vintage Generic Divestiture Product Agreements are attached to this Order and contained in non-public Appendix II.A.

- AAAA. “Watson/Andrx” means Watson Pharmaceuticals, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Watson (including, but not limited to, Watson Laboratories, Inc., Andrx Corporation, Andrx Pharmaceuticals, Inc., and Andrx Pharmaceuticals, LLC), and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.
- BBBB. “Watson” means Watson Laboratories, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Nevada, with its headquarters address at 311 Bonnie Circle, Corona, California 92880.
- CCCC. “Watson Generic Divestiture Product Agreement(s)” means the following agreements:

1. "Asset Purchase Agreement" between Teva Pharmaceuticals USA, Inc. and Watson Laboratories, Inc., dated as of November 24, 2008, and all amendments, exhibits, attachments, agreements, and schedules thereto;
2. "Supply Agreement" between Teva Pharmaceuticals USA, Inc. and Watson Laboratories, Inc., dated as of November 24, 2008, and all amendments, exhibits, attachments, agreements, and schedules thereto;
3. the following agreements assigned from Respondent Barr to Watson:
  - a. "Material Supply Agreement" between Johnson Matthey PLC and Barr Laboratories, Inc., dated as of September 30, 2003, and all amendments, exhibits, attachments, agreements, and schedules thereto, to the full extent that such agreement(s) relate to the Epoprostenol Product; and
  - b. "Supply Agreement" between Hollister-Stier Laboratories LLC and Barr Laboratories, Inc., dated as of December 15, 2004, and all amendments, exhibits, attachments, agreements, and schedules thereto; and
  - c. "Joint Venture Agreement" between Sidmark Laboratories, Inc. and Banner Pharmacaps Inc., dated as of May 29, 2002, and all amendments, exhibits, attachments, agreements, and schedules thereto, to the full extent that such agreement(s) relate to the Cyclosporine Products;

related to the Generic Assorted Indication Product Assets that have been approved by the Commission to accomplish the requirements of this Order. The Watson Generic Divestiture Product Agreements are attached to this Order and contained in non-public Appendix II.B.

DDDD. "Website" means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by Respondents; *provided, however*, "Website" shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by Respondents that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that Respondents can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Product(s).

## II.

**IT IS FURTHER ORDERED** that:

- A. Not later than the earlier of: (1) ten (10) days after the Effective Date or (2) ten (10) days after the Order Date, Respondents shall divest the Generic Oral Contraceptive Product

Assets and the Trazodone Product Assets, absolutely and in good faith, to Vintage pursuant to, and in accordance with, the Vintage Generic Divestiture Product Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Vintage or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Generic Oral Contraceptive Product Assets and the Trazodone Product Assets is incorporated by reference into this Order and made a part hereof;

*provided, however,* that if Respondents have divested the Generic Oral Contraceptive Product Assets and the Trazodone Product Assets to Vintage prior to the Order Date, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Vintage is not an acceptable purchaser of either the Generic Oral Contraceptive Product Assets or the Trazodone Product Assets, then Respondents shall immediately rescind the transaction with Vintage, in whole or in part, as directed by the Commission, and shall divest the Generic Oral Contraceptive Product Assets and/or the Trazodone Product Assets, as applicable, within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer or Acquirers that receive(s) the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

*provided further* that if Respondents have divested the Generic Oral Contraceptive Product Assets and the Trazodone Product Assets to Vintage prior to the Order Date, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Generic Oral Contraceptive Product Assets and/or the Trazodone Product Assets, as applicable, to Vintage (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 the earlier of: (1) ten (10) days after the Effective Date or (2) ten (10) days after the Order Date, Respondents shall divest the Generic Assorted Indication Product Assets, absolutely and in good faith, to Watson pursuant to, and in accordance with, the Watson Generic Divestiture Product Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Watson or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Generic Assorted Indication Product Assets is incorporated by reference into this Order and made a part hereof;

*provided, however,* that if Respondents have divested the Generic Assorted Indication Product Assets to Watson prior to the Order Date, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Watson is

not an acceptable purchaser of the Generic Assorted Indication Product Assets, then Respondents shall immediately rescind the transaction with Watson, in whole or in part, as directed by the Commission, and shall divest the Generic Assorted Indication Product Assets within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer or Acquirers that receive(s) the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

*provided further* that if Respondents have divested the Generic Assorted Indication Product Assets to Watson prior to Order Date, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Generic Assorted Indication Product Assets to Watson (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- C. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the assets required to be divested pursuant to this Order to each of the relevant Acquirers, and/or to permit each such 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 each such Acquirer has executed all such agreements directly with each of the relevant Third Parties.

- D. Respondents shall transfer and deliver, or cause to be transferred and delivered, all Product Manufacturing Technology (including all related intellectual property) related to the specified Divestiture Products that either Respondent owns, and shall transfer and deliver, or cause to be transferred and delivered, all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed by either Respondent related to the specified Divestiture Products, to each of the relevant Acquirers in a manner consistent with the Technology Transfer Standards. Respondents shall obtain any consents from Third Parties required to comply with this provision.

- E. Respondents shall:

1. upon reasonable written notice and request from an Acquirer to Respondents, Contract Manufacture and deliver to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products at Respondents' Supply Cost, for a period of time sufficient to allow such Acquirer (or the Designee of the Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the

finished drug product independently of Respondents and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and/or necessary components listed in the specified Respondent's Application(s) for the Product from Persons other than the Respondents;

2. make representations and warranties to the Acquirer(s) that the Contract Manufacture Product(s) supplied through Contract Manufacture pursuant to a 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 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 Acquirer pursuant to a Remedial Agreement by Respondents to meet cGMP. This obligation may be made contingent upon the Acquirer giving Respondents prompt written notice of such claim and cooperating fully in the defense of such claim. The Remedial Agreement shall be consistent with the obligations assumed by Respondents under this Order;

*provided, however,* that Respondents may reserve the right to control the defense of any such litigation, including the right to settle the litigation, so long as such settlement is consistent with Respondents' responsibilities to supply the ingredients and/or components 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 Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by Respondents to the 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 Acquirer pursuant to such Remedial Agreement by Respondents to meet cGMP;

3. give priority to supplying a Contract Manufacture Product to the Acquirer over manufacturing and supplying of Products for Respondents' own use or sale;
4. make representations and warranties to the Acquirer(s) that Respondents shall hold harmless and indemnify the Acquirer(s) for any liabilities or loss of profits resulting from the failure by Respondents to deliver the Contract Manufacture Products in a timely manner as required by the Remedial Agreement(s) unless Respondents can demonstrate that its failure was entirely beyond the control of 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;

5. during the term of any Contract Manufacture between Respondent(s) and an Acquirer, upon written request of such Acquirer or the Interim Monitor (if any has been appointed), make available to the Acquirer and the Interim Monitor (if any has been appointed) all records that relate to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;
6. during the term of any Contract Manufacture between Respondent(s) and an Acquirer, maintain manufacturing facilities necessary to manufacture each of the relevant Contract Manufacture Products in finished form, *i.e.*, suitable for sale to the ultimate consumer/patient; and
7. pending FDA approval of any Divestiture Product that has not yet been approved for commercial scale-up manufacturing and during the term of any Contract Manufacture between Respondent(s) and an Acquirer, provide consultation with knowledgeable employees of Respondents and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling such Acquirer (or the Designee of such Acquirer) to obtain all Product Approvals to manufacture the Divestiture Products in the same quality achieved by, or on behalf of, the Respondents and in commercial quantities, and in a manner consistent with cGMP, independently of Respondents (and, in the case of the Generic Oral Contraceptive Products, independently of Respondents and Watson/Andrx), and sufficient to satisfy management of the Acquirer that its personnel (or the Designee's personnel) are adequately trained in the manufacture of the Divestiture Products;

The foregoing provisions, II.E.1. - 7., shall remain in effect with respect to each Divestiture Product until the earliest of: (1) the date each Acquirer (or the Designee(s) of such Acquirer), respectively, is approved by the FDA to manufacture such Divestiture Product and able to manufacture such Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents (and, in the case of the Generic Oral Contraceptive Products, independently of Respondents and Watson/Andrx); (2) the date the Acquirer of a particular Divestiture Product notifies the Commission and the Respondents of its intention to abandon its efforts to manufacture such Divestiture Product; (3) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer of a particular Divestiture Product has abandoned its efforts to manufacture such Divestiture Product, or (4) four (4) years from the Closing Date.

F. Respondents shall:

1. submit to each Acquirer, at Respondents' expense, all Confidential Business Information related to the Divestiture Products;

2. deliver such Confidential Business Information to such Acquirer:
    - a. in good faith;
    - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
    - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
  3. pending complete delivery of all such Confidential Business Information to each respective Acquirer, provide each such 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 Divestiture Products 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 Divestiture Products other than as necessary to comply with the following:
    - a. the requirements of this Order;
    - b. Respondents' obligations to the Acquirer of the particular Divestiture Product(s) under the terms of any Remedial Agreement related to such Divestiture Product(s); or
    - c. applicable Law;
  5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except the relevant Acquirer or other Persons specifically authorized by such Acquirer to receive such information; and
  6. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the Divestiture Products to the employees associated with business related to those Retained Products that contain the same active pharmaceutical ingredient as the Divestiture Products.
- G. Respondents shall not enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of such Acquirer to acquire or use the Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Products acquired by such Acquirer from the Third

Party. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology.

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 to the relevant Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to such Acquirer.

I. Respondents shall:

1. for each Divestiture Product, for a period of six (6) months from the Closing Date or upon the hiring of twenty (20) Divestiture Product Core Employees by each of the relevant Acquirers, whichever occurs earlier, provide each 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 Acquirer. Each of these periods is hereinafter referred to as the “Divestiture Product Core 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 Respondents to provide the Product Employee Information; or (2) ten (10) days after written request by an Acquirer, provide such Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the 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 Core Employee Access Period(s) with respect to that employee in an amount equal to the delay;
3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by the relevant Acquirer of the Divestiture Product Core Employees related to the particular Divestiture Products and assets acquired by such Acquirer, and remove any impediments within the control of Respondent(s) that may deter these employees from accepting employment with such Acquirer, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondent(s) that would affect the ability or incentive of those individuals to be employed by such 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 such Acquirer;

*provided, however,* that, subject to the conditions of continued employment prescribed in this Order, this Paragraph II.I.3. shall not prohibit Respondents from continuing to employ any Divestiture Product Core Employee under the terms of such employee’s employment with Respondent(s) prior to the date of the written offer of employment from the Acquirer to such employee;



4. 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, subject to those conditions of continued employment prescribed in this Order, this Order does not require nor shall be construed to require Respondents to terminate the employment of any employee or to prevent Respondents from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition; and

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

- a. directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer with any amount of responsibility related to a Divestiture Product (“Divestiture Product Employee”) to terminate his or her employment relationship with the 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 Acquirer or who independently applies for employment with Respondents, as long as such employee was not solicited in violation of the nonsolicitation requirements contained herein;

*provided further, however,* that 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 Respondents.

- J. 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).

- K. Not later than thirty (30) days after the Closing Date, Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to the Divestiture Products by Respondent's personnel to all of Respondents' employees who:
1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of any of the Divestiture Products;
  2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that contain the same active pharmaceutical ingredient as the Divestiture Products; 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 Closing Date. Respondents shall provide a copy of such notification to the Acquirer.

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

- L. Until Respondents complete the divestitures required by Paragraphs II.A. and II.B., and fully transfer and deliver, or cause to be transferred and delivered, the related Product Manufacturing Technology, to each of the relevant Acquirers,
1. Respondents shall take such actions as are necessary to:
    - a. maintain the full economic viability and marketability of the businesses associated with each Divestiture Product;
    - b. minimize any risk of loss of competitive potential for such business;
    - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to each Divestiture Product;
    - d. ensure the assets required to be divested are transferred and delivered to each Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the business associated with each Divestiture Product;

- e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and
  - 2. Respondents shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the businesses associated with each Divestiture Product.
- M. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against an Acquirer or the Divestiture Product Releasee(s) of that Acquirer for the research, Development, manufacture, use, import, export, distribution, or sale of the Divestiture Product(s) acquired by that Acquirer under the following:
- 1. any Patent owned or licensed by Respondents as of the day after the Effective Date that claims a method of making, using, or administering, or a composition of matter, relating to the Divestiture Product(s) acquired by that Acquirer, or that claims a device relating to the use thereof;
  - 2. any 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 Divestiture Product(s) acquired by that Acquirer, other than such Patents that claim inventions conceived by and reduced to practice after the Effective Date;
- if such suit would have the potential to interfere with such Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Products acquired by that Acquirer; or (2) the use, import, export, supply, distribution, or sale of such Divestiture Product(s) within the Geographic Territory. Respondents shall also covenant to such Acquirer that as a condition of any assignment, transfer, or license to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue such Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential to interfere with that Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Product(s) acquired by that Acquirer; or (2) the use, import, export, supply, distribution, or sale of such Divestiture Product(s) within the Geographic Territory.
- N. Upon reasonable written notice and request from an Acquirer to Respondent(s), Respondent(s) shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Product Intellectual Property related to any of the Divestiture Products, if such litigation would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Product(s) acquired by that Acquirer; or (2)

the use, import, export, supply, distribution, or sale of such Divestiture Product(s) within the Geographic Territory.

- O. For any patent infringement suit in which either Respondent is alleged to have infringed a Patent of a Third Party prior to the Closing Date or for such suit as such Respondent has prepared or is preparing as of the Closing Date to defend against such infringement claim(s), and where such a suit would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Product(s) acquired by that Acquirer; or (2) the use, import, export, supply, distribution, or sale of such Divestiture Product(s), Respondents shall:
1. cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from Respondent(s) in connection with obtaining resolution of any pending patent litigation involving such Divestiture Product(s);
  2. waive conflicts of interest, if any, to allow either Respondent's outside legal counsel to represent the relevant Acquirer in any ongoing patent litigation involving such Divestiture Product(s); and
  3. permit the transfer to the relevant Acquirer of all of the litigation files and any related attorney work-product in the possession of either Respondent's outside counsel relating to such Divestiture Product(s).
- P. 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 relevant Acquirer's use and registration of such Product Trademarks; or
  5. challenge or interfere with the relevant Acquirer's efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties;
- provided however*, that this paragraph shall not preclude Respondents from continuing to use all trademarks, tradenames, or service marks that have been in use in commerce on a Retained Product at any time prior to the Effective Date.
- Q. Respondents shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of

the Divestiture Products a decision the result of which would be inconsistent with the terms of this Order and/or the remedial purposes thereof.

### III.

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

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor (“Interim Monitor”) to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, 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 date of completion by Respondents of the divestiture of all Generic Assorted Indication Product Assets, Generic Oral Contraceptive Assets, and the Trazodone Product Assets, and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and until the earliest of:

- a. with respect to each Generic Assorted Indication Product and the Trazodone Products, the date the Acquirer (or its Designee(s)) is approved by the FDA to manufacture such Divestiture Product and able to manufacture such Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents;
- b. with respect to each Generic Oral Contraceptive Product, the date the Acquirer (or its Designee(s)) is approved by the FDA to manufacture such Divestiture Product and able to manufacture such Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents and Watson/Andrx;
- c. with respect to each Divestiture Product, the date the Acquirer notifies the Commission and the Respondents of its intention to abandon its efforts to manufacture such Divestiture Product; or
- d. with respect to each Divestiture Product, the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture such Divestiture Product;

*provided, however,* that, with respect to each Divestiture Product, the Interim Monitor's service shall not exceed five (5) years from the Order Date;

*provided, further,* 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 ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Order, including, but not limited to, its 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 Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.

6. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
  7. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Order;

*provided, however,* beginning one hundred twenty (120) days after Respondents have filed their final report pursuant to Paragraph IX.B., and every one hundred twenty (120) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by the Acquirer toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents (and, in the case of the Generic Oral Contraceptive Products, independently of Respondents and Watson/Andrx).
  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.

#### IV.

**IT IS FURTHER ORDERED** that:

- A. If Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Generic Assorted Indication Product Assets, the Generic Oral Contraceptive Product Assets, and/or the Trazodone Product Assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*l*), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(*l*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent 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 Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission; *provided further, however*, that Respondents shall select such Person within five (5) days after receiving notification of the Commission's approval.
  5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to

employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
  7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to 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.

## V.

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

With respect to Confidential Business Information, Respondents shall assure that, in any instance wherein Respondents' counsel (including in-house counsel under appropriate confidentiality arrangements) either retains unredacted copies of documents or other materials provided to an Acquirer or accesses original documents (under circumstances where copies of documents are insufficient or otherwise unavailable) provided to an Acquirer, Respondents' counsel does so only in order to do the following:

- A. comply with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- B. defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or assets and businesses associated with those Divestiture Products;

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

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

## VI.

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

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondents shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligations to the Acquirer pursuant to this Order.

- D. Respondents shall also include in each Remedial Agreement a representation from the Acquirer that such Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product and to have any such manufacture to be independent of Respondents, all as soon as reasonably practicable.
- E. Respondents shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission.

## VII.

**IT IS FURTHER ORDERED** that the purpose of the divestiture of the Generic Assorted Indication Product Assets, the Generic Oral Contraceptive Product Assets, and the Trazodone Product Assets and the transfer and delivery of the related Product Manufacturing Technology and the related obligations imposed on the Respondents by this Order is:

- A. to ensure the continued use of such assets in the research, Development, and manufacture of each of the Divestiture Products and for the purposes of the business associated with each Divestiture Product within the Geographic Territory;
- B. to provide for the future use of such assets for the distribution, sale and marketing of each of the Divestiture Products in the Geographic Territory;
- C. to create a viable and effective competitor, that is independent of the Respondents:
  - 1. in the research, Development, and manufacture of each of the Divestiture Products for the purposes of the business associated with each Divestiture Product within the Geographic Territory; and
  - 2. the distribution, sale and marketing of the each of the Divestiture Products in the Geographic Territory; and,
- D. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

## VIII.

**IT IS FURTHER ORDERED** that this Order shall not reduce or limit or be construed to reduce or limit the obligations of Watson/Andrx pursuant to the Order issued by the Commission *In the Matter of Watson Pharmaceuticals, Inc., and Andrx Corporation*, Docket Number C-4172.

## **IX.**

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

- A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondents have fully complied with the following: Paragraphs II.A , II.B., II.C., II.D., II.F. 1.-3., II.H., II.I.1.-4., II.K., and II.L., 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 Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which they have complied and are complying with the Order.

## **X.**

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

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

**XI.**

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

- A. access, during business office hours of such Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of such Respondent related to compliance with this Order, which copying services shall be provided by such Respondent at the request of the authorized representative(s) of the Commission and at the expense of such Respondent; and
- B. to interview officers, directors, or employees of such Respondent, who may have counsel present, regarding such matters.

**XII.**

**IT IS FURTHER ORDERED** that this Order shall terminate on February 9, 2019.

By the Commission.

Donald S. Clark  
Secretary

SEAL  
ISSUED: February 9, 2009

**NON-PUBLIC APPENDIX II.A.  
VINTAGE GENERIC DIVESTITURE PRODUCT AGREEMENTS**

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

**NON-PUBLIC APPENDIX II.B.  
WATSON GENERIC DIVESTITURE PRODUCT AGREEMENTS**

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