UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

In the Matter of	)	
TEVA PHARMACEUTICAL INDUSTRIES LTD., a corporation,	)	**Docket No.**
and	)	
BARR PHARMACEUTICALS, INC., a corporation.	)	

DECISION AND ORDER

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

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

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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 marke

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 [illegible] customer()Tj86.(c

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 informa

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 "Desmospressin 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 [illegible] 60.00 0.00 0.00

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 Conceptive 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 0.025 mg/0.35 mg strength, pursuant to ANDA No. 76-334;

2. Norgestimate/Ethinyl Estradiol Tablets ("Tri-Previfem"), USP 0.018 mg/0.35 mg, 0.215

mg/ 0.35 mg, and 0.25 mg/0.35 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, and 1.0 mg/0.02 mg/75 mg strengths, 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.

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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: Cyclaf

manufactured, marketed or sold by Respondent Barr pursuant to the following ANDAs:

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.

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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 researc

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 tf.00000 0r8l0.3600 360jn0000200 ea2Aise TD(76)'31.8000 0.0000 n TD(ea)Tj20.5200 0.0000all

3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, Tj12.0000 0.0000 TD(ecm0.00 0.00 0.00 rgBT99.0000 708.8400 TD()Tj0.0000 0

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 recor

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 Da

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 table

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 Desig

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 O

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 12.96000 1.0000gpe

(including, but not limited to, entering into additional agreements or arrangements) as the

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 in this Order, to jET1.09gBT1 thed b

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

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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

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 rela20e8.00000 1.00000 0.02

2. any Patents owned or licensed at any time after the Effective Date by Respondents that claim any aspect of the research,

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(

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 In[illegible]

consistent with cGMP, independently of Respondents (and, in the case of the Generic Oral Contraceptive Products, independently of Respondents and Watson/Andrx).

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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 confidentialit8afi

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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 Trustee7(ion;000 0.00000 1.00

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 fails act 12.0 failac

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 the remedial (GATE18 1200 T70000 0.05 20
0000 and 8400 TD0.0600 Tc-0.0600 Tw(a)Tj5.2800

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 ten (10) years from the Order Date.

By the Commission.

Donald S. Clark
Secretary

SEAL

ISSUED: _____

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]