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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.,))) Docket No. C-4242
a corporation,	CECTICAL INDUSTRIES LTD.,) DOCKET NO. C-4242)
and)
BARR PHARMA a corporation.	CEUTICALS, INC.,)))
)

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 Responsible and the communication of the c

- 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 preparatory for the preparatory is 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 Respondence between Respo
- 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);
 - 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 prohibid Revebsite(s) re.0000 cme 3make, distribute, off(e)Tj5.280ioo p

- 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);
- 15. at the Acquirer's option and to the ext
 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 topption another the ext

s ivestiture Product(s), and any othe

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).

- 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

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 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.

- 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 r

KK. "Generic Pipeline Oral Contraceptive Products" means the following Products in Development by Respondent Teva pursuant to the following RR. "Metoclopramide Products" means all of the following: all Products in Development, manufactured, marketed or sold by Responde

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 suc

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. Edvadea)TSjEffilt@0000 0.00/c0.0000 m5e9gTD(e)T0au000 TD(ty)Tj9.0000 0.0500 225.8400 TD0.0600 T

- 8. FDA approved patient circulars and information related to the specified Divestiture Product(s);
- adverse event/serious adverse event summaries related to the specified Divestiture Product(s);
- 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, pritio

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. integrability of the Divestiture Products to 11.3trade0dr0000 TD(esea)Tj20.5200 149

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, accountingivestissfecPriveuth.2000 0e0000e0000 TD(reg)Tj18.120en0 018.0000 T3D(t Marketing)

- 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 or

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

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 sun; 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 is 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 Manufac

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 dayiating Mt ACONTED http://www.asportantein10(sear)Tj19

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

- 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. Respondents shall take no action to interfere 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 ma

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

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 circ

- 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

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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 repor

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

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

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