

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

**COMMISSIONERS:**       **Jon Leibowitz, Chairman**  
                                   **J. Thomas Rosch**  
                                   **Edith Ramirez**  
                                   **Julie Brill**  
                                   **Maureen K. Ohlhausen**

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<b>In the Matter of</b>	)	
	)	
	)	
<b>TEVA PHARMACEUTICAL INDUSTRIES LTD.,</b>	)	<b>Docket No. C-4335</b>
<b>a corporation;</b>	)	
	)	
<b>and</b>	)	
	)	
	)	
<b>CEPHALON, INC,</b>	)	
<b>a corporation.</b>	)	
	)	

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

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Teva Pharmaceutical Industries Ltd. (“Teva”) of Respondent Cephalon, Inc. (“Cephalon”), and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments filed by interested persons, and having modified the Decision and Order in certain respects, 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, and its United States subsidiary, Barr Laboratories, Inc., located at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.
2. Respondent Cephalon is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its corporate head office and principal place of business located at 41 Moores Road, Frazer, Pennsylvania 19355.
3. The Commission has jurisdiction of the subject matter of this proceeding and of the 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, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Teva (including, but not limited to, Barr Pharmaceuticals, LLC), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Teva shall include Cephalon.
- B. “Cephalon” means Cephalon, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Cephalon (including, but not limited to, Cima Labs Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

- C. “Respondents” means Teva and Cephalon, individually and collectively.
- D. “Commission” means the Federal Trade Commission.
- E. “Acquirer(s)” means the following:
  - 1. a Person specified by name in this Order to acquire particular assets or rights that a Respondent is 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 and effective; or
  - 2. a Person approved by the Commission to acquire particular assets or rights that a Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- F. “Acquisition” means Respondent Teva’s acquisition of fifty percent (50%) or more of the voting securities of Respondent Cephalon.
- G. “Acquisition Date” means the date on which the Acquisition occurs.
- H. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”).
- I. “Amrix Patents” means the following United States patents: US 7387793, US 7544372, US 7790199, US 7820203, US 7829121, and any re-examinations and re-issues of the foregoing patents, and any patents claiming priority thereto.
- J. “Application(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SND A”), 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 a Respondent and the FDA related thereto. The term “Application” also includes an “Investigational New Drug Application” (“IND”) 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 a Respondent and the FDA related thereto.
- K. “Categorized Assets” means, for each specified Divestiture Product, all of the specified 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 Divestiture Product to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Divestiture Product, including, without limitation, the following:

1. all Product Intellectual Property related to the specified Divestiture Product;
2. all Product Approvals related to the specified Divestiture Product;
3. all Product Manufacturing Technology related to the specified Divestiture Product;
4. all Product Marketing Materials related to the specified Divestiture Product;
5. all Website(s) related exclusively to the specified Divestiture Product;
6. the content related exclusively to the specified Divestiture Product that is displayed on Website that is not dedicated exclusively to the specified Divestiture Product;
7. a list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by Law:
  - a. to require each Respondent to discontinue the use of those NDC Numbers in the sale or marketing of the specified Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Acquisition Date and *except* as may be required by applicable Law;
  - b. to prohibit each Respondent from seeking from any customer any type of cross-referencing of those NDC Numbers with any Retained Product(s);
  - c. to seek to change any cross-referencing by a customer of those NDC Numbers with a Retained Product (including the right to receive notification from the specified Respondent of any such cross-referencing that is discovered by any Respondent);
  - d. to seek cross-referencing from a customer of the specified Respondent's NDC Numbers related to such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;
  - e. to approve the timing of each Respondent's discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the Acquisition Date and *except* as may be required by applicable Law; and
  - f. to approve any notification(s) from each Respondent to any customer(s) regarding the use or discontinued use of such NDC numbers by that Respondent prior to such notification(s) being disseminated to the customer(s);

8. all rights to all of the specified Respondent's Applications related to the specified Divestiture Product;
9. all Product Development Reports related to the specified Divestiture Product;
10. at the option of the Acquirer of the specified Divestiture Product, all Product Assumed Contracts related to the specified Divestiture Product (copies to be provided to that Acquirer on or before the Closing Date);
11. all patient registries related to the specified Divestiture Product, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the specified Divestiture Product;
12. a list of all customers and targeted customers for the specified Divestiture Product and a listing of the net sales (in either units or dollars) of the specified Divestiture Product 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 the specified Divestiture Product on behalf of the High Volume Account and his or her business contact information;
13. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to the specified Divestiture Product;
14. copies of all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date, to be provided to the Acquirer of the specified Divestiture Product not later than five (5) days after the Closing Date;
15. at the option of the Acquirer of the specified Divestiture Product, all unfilled customer purchase orders for the specified Divestiture Product; and
16. all of the specified Respondent's books, records, and files directly related to the foregoing;

*provided, however,* that "Categorized Assets" shall not include: (1) documents relating to a 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 specified Divestiture Product; (2) administrative, financial, and accounting records; (3) quality control records that are determined not to be material to the manufacture of the specified

Divestiture Product by the Interim Monitor or the Acquirer of the specified Divestiture Product; (4) formulas used to determine the final pricing of any Divestiture Product and/or Retained Products to customers and competitively sensitive pricing information that is exclusively related to the Retained Products; (5) any real estate and the buildings and other permanent structures located on such real estate; and (6) all Product Licensed Intellectual Property;

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

- L. “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.
- M. “Clinical Trial(s)” means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.
- N. “Closing Date” means, as to each Divestiture Product, the date on which a Respondent (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.
- O. “Confidential Business Information” means all information owned by, or in the possession or control of, a Respondent that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support, or use of each of the Divestiture Products;

*provided, however,* that the restrictions contained in this Order regarding a Respondent’s use, conveyance, provision, or disclosure of “Confidential Business Information” shall not apply to the following:

- a. information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by a Respondent;
- b. information related to the Divestiture Products that Respondent Cephalon can demonstrate it obtained without the assistance of Respondent Teva prior to the Acquisition;
- c. information that is required by Law to be publicly disclosed;
- d. information relating to a Respondent's general business strategies or practices relating to research, Development, manufacture, marketing, or sales of Products that does not discuss with particularity the Divestiture Products;
- e. information specifically excluded from the Generic Fentanyl Product Assets or the Generic Cyclobenzaprine Product Assets;
- f. all intellectual property licensed on a non-exclusive basis to the Acquirer of the specified Divestiture Product; and
- g. information that is protected by the attorney work product, attorney-client, joint defense or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.

P. "Contract Manufacture" means:

1. to manufacture a Contract Manufacture Product by a Respondent on behalf of an Acquirer;
2. to manufacture a Product that is bioequivalent and in the identical dosage strength, formulation and presentation as a Contract Manufacture Product by a Respondent on behalf of an Acquirer;
3. to provide any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Contract Manufacture Product by a Respondent on behalf of an Acquirer.

Q. "Contract Manufacture Product(s)" means the following products:

1. Generic Fentanyl Products; and
2. Generic Cyclobenzaprine Products; and/or

any ingredient or component of any of the foregoing Divestiture Products, for which any part of the manufacturing process is performed by a Respondent prior to the Closing Date at a facility that is not subject to divestiture pursuant to this Order;

*provided however*, that with the consent of the affected Acquirer, a Respondent may substitute a bioequivalent form of such Products in performance of the Respondent's agreement to Contract Manufacture.

- R. "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.
- S. "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 a Respondent's 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.
- T. "Divestiture Products" means the Generic Fentanyl Products and the Generic Cyclobenzaprine Products, individually and collectively.
- U. "Divestiture Product Core Employee(s)" means the Product Research and Development Employees and the Product Manufacturing Employees related to each Divestiture Product.
- V. "Divestiture Product Releasee(s)" means the following Persons:
1. the Acquirer for the assets related to a particular Divestiture Product;
  2. any Person controlled by or under common control with that Acquirer; and
  3. any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.



- W. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- X. “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.
- Y. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- Z. “Generic Cyclobenzaprine Product(s)” means the following: all Products in Development, manufactured, marketed or sold by Respondent Teva pursuant to ANDA No. MR-090-864 and any supplements, amendments, or revisions thereto.
- AA. “Generic Cyclobenzaprine 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 each of the respective Generic Cyclobenzaprine Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of each such Generic Cyclobenzaprine Product, including, without limitation, the Categorized Assets related to the Generic Cyclobenzaprine Products; and
1. all of Respondent Teva’s rights and interests in any patent infringement suit in which Respondent Teva is alleged to infringe any Amrix Patent, including without limitation:
    - a. all rights to all documentation created by or for, or in the possession of, Respondent Teva that is related exclusively to any pending patent litigation related to the Generic Cyclobenzaprine Products;
    - b. a right of access to any employee of Respondent Teva for the purposes of the suit;
    - c. a right of access to any witness under the control of Respondent Teva identified in the suit;
    - d. a waiver of any conflicts-of-interests or non-disclosure agreement(s) sufficient to allow Respondent Teva’s outside legal counsel to represent the Acquirer in the suit, to share all information and opinions created by or for Respondent Teva related exclusively to the suit with the Acquirer, and to provide any information gathered in connection with the suit with the Acquirer; and
    - e. all rights to all of the litigation files and any related attorney work-product created by or for, or in the possession of, Respondent Teva or in the possession of Respondent Teva’s outside counsel relating exclusively to the Generic Cyclobenzaprine Product;

*provided however*, “Generic Cyclobenzaprine Product Assets” *excludes* the Amrix Patents.

BB. “Generic Cyclobenzaprine Product Divestiture Agreements” means all of the following agreements:

1. “Asset Purchase Agreement” between Barr Laboratories, Inc. and Par Pharmaceutical, Inc., dated as of September 16, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto; and,
2. “Supply Agreement” between Barr Laboratories, Inc. and Par Pharmaceutical, Inc., dated as of September 16, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto;

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

CC. “Generic Cyclobenzaprine Product License” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, or controlled by Respondent Teva prior to the Acquisition:

1. to research and Develop the Generic Cyclobenzaprine Products for marketing, distribution or sale within the Geographic Territory;
2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the Generic Cyclobenzaprine Products within the Geographic Territory;
3. to import or export the Generic Cyclobenzaprine Products to or from the Geographic Territory to the extent related to the marketing, distribution or sale of the Generic Cyclobenzaprine Products in the Geographic Territory; and
4. to have the Generic Cyclobenzaprine Products made anywhere in the World for distribution or sale within, or import into the Geographic Territory;

*provided however*, that for any Product Licensed Intellectual Property that is the subject of a license from a Third Party entered into by Respondent Teva prior to the Acquisition, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to Respondent Teva; *provided further however*, the Generic Cyclobenzaprine Product License *excludes* a grant of rights in or to the Amrix Patents.

- DD. “Generic Fentanyl Product(s)” means the following: all Products in Development, manufactured, marketed or sold by Respondent Teva pursuant to ANDA No. 77-312, and any supplements, amendments, or revisions thereto.
- EE. “Generic Fentanyl 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 each of the respective Generic Fentanyl 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 the Generic Fentanyl Products; and
1. an unlimited and unrestricted Right of Reference or Use to the Drug Master Files related to Oral Opioid Fentanyl granted by Respondent Cephalon to Barr Laboratories Inc. pursuant to the Commission Order C-4121 on a non-exclusive basis;
  2. all rights on a non-exclusive basis to Respondent Cephalon’s Risk Evaluation Mitigation Strategy related to NDA Number 20-747 (Actiq<sup>®</sup>, fentanyl citrate), and all strategic safety programs, submitted to an Agency related to Actiq<sup>®</sup> that are designed to decrease product risk by using one or more interventions or tools beyond the package insert;
  3. all rights granted by Respondent Cephalon to Barr Laboratories Inc. pursuant to the Commission Order C-4121, including, without limitation, all rights granted by Respondent Cephalon to Barr Laboratories Inc. pursuant to the “License and Supply Agreement” by and between Cephalon Inc. and Barr Laboratories, Inc. dated July 7, 2004, and all amendments, exhibits, attachments, agreements, and schedules thereto;
  4. at the Acquirer’s option, any of Respondent Teva’s equipment that is used in the manufacture of Generic Fentanyl Products; and
  5. Respondent Teva’s Risk MAP Program for the Generic Fentanyl Product.
- FF. “Generic Fentanyl Product Divestiture Agreements” means all of the following agreements:
1. “Asset Purchase Agreement” between Barr Laboratories, Inc. and Par Pharmaceutical, Inc., dated as of September 16, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto; and,
  2. “Manufacturing Agreement” between Barr Laboratories, Inc. and Par Pharmaceutical, Inc., dated as of September 16, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto;
  3. “REMS Program License Agreement” by and among Cephalon, Inc., and Par Pharmaceutical, Inc., dated as of September 13, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto;

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

GG. “Generic Fentanyl Product License” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was used by Respondent Teva to manufacture the Generic Fentanyl Products prior to the Acquisition, which license may be limited in scope for use for the following purposes:

1. to research and Develop the Generic Fentanyl Products for marketing, distribution or sale within the Geographic Territory;
2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the Generic Fentanyl Products within the Geographic Territory;
3. to import or export the Generic Fentanyl Products to or from the Geographic Territory to the extent related to the marketing, distribution or sale of the Generic Fentanyl Products in the Geographic Territory; and
4. to have the Generic Fentanyl Products made anywhere in the World for distribution or sale within, or import into the Geographic Territory;

*provided further however*, that for any Product Licensed Intellectual Property that is the subject of a license from a Third Party to Respondent Teva, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to Respondent Teva.

HH. “Generic Modafinil Products” means generic versions of all Products manufactured, marketed or sold by Respondent Cephalon prior to the Acquisition Date that contain the active pharmaceutical ingredient modafinil, including all dosage strengths, formulations and presentations of those Products. “Generic Modafinil Products” includes, without limitation, bioequivalent versions of all Products marketed or sold by Respondent Cephalon under the trademark Provigil<sup>®</sup>, but *excludes* the use of the Provigil<sup>®</sup> trademark on Product labels or packaging.

II. “Generic Modafinil Product Supply Agreement” means the “Modafinil Supply Agreement” between Barr Laboratories, Inc. and Par Pharmaceutical, Inc., dated as of September 16, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto; related to the Generic Modafinil Products that have been approved by the Commission to accomplish the requirements of this Order. The Generic Modafinil Product Supply Agreement is attached to this Order and contained in non-public Appendix III;

*provided, however,* that, with the consent of Par, the Respondents may substitute Products that are bioequivalent to the Generic Modafinil Products in performance of Respondents' obligations to supply Par under this Order.

- JJ. "Geographic Territory" shall mean the United States of America, including all of its territories and possessions, unless otherwise specified.
- KK. "Government Entity" means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.
- LL. "High Volume Account(s)" means any retailer, wholesaler or distributor whose annual or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States of America from the specified Respondent was, or is projected to be among the top twenty highest of such purchase amounts by the Respondent's U.S. customers on any of the following dates: (1) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (2) the end of the last quarter that immediately preceded the Acquisition Date; (3) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or (4) the end of the last quarter following the Acquisition or the Closing Date.
- MM. "Interim Monitor" means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- NN. "Law" means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- OO. "Manufacturing Designee" means any Person other than a Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- PP. "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.
- QQ. "Order Date" means the date on which this Decision and Order becomes final and effective.
- RR. "Order to Maintain Assets" means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- SS. "Par" means Par Pharmaceutical Companies, Inc., a corporation organized, existing and doing business under and by virtue of the laws of Delaware, with its headquarters address at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

- TT. “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 a Respondent as of the Closing Date (*except* where this Order specifies a different time).
- UU. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- VV. “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 and/or that is the subject of an Application.
- WW. “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.
- XX. “Product Assumed Contracts” means all of the following contracts or agreements (copies of each such contract to be provided to the Acquirer on or before the Closing Date and segregated in a manner that clearly identifies the purpose(s) of each such contract):
1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from a Respondent unless such contract applies generally to the Respondent’s sales of Products to that Third Party;
  2. pursuant to which a Respondent purchases the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party for use in connection with the manufacture of the specified Divestiture Product;
  3. relating to any Clinical Trials involving the specified Divestiture Product;
  4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;

5. relating to the particularized marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
6. pursuant to which a Third Party manufactures or packages the specified Divestiture Product on behalf of a Respondent;
7. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to a Respondent;
8. pursuant to which a Third Party is licensed by a Respondent to use the Product Manufacturing Technology;
9. constituting confidentiality agreements involving the specified Divestiture Product;
10. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;
11. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the specified Divestiture Product to a Respondent including, but not limited to, consultation arrangements; and/or
12. pursuant to which any Third Party collaborates with a Respondent in the performance of research, Development, marketing, distribution or selling of the specified Divestiture Product or the business related to such Divestiture Product;

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

YY. “Product Copyrights” means rights to all original works of authorship of any kind directly related to the specified Divestiture Product 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 such Divestiture Product or of any materials used in the research, Development, manufacture, marketing or sale of such Divestiture Product, including all copyrights in raw data relating to Clinical Trials of such Divestiture Product, 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 specified Divestiture Product 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 such Divestiture Product 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.

ZZ. “Product Development Reports” means:

1. Pharmacokinetic study reports related to the specified Divestiture Product;
2. Bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product;
3. Bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product;
4. all correspondence to a Respondent from the FDA and from a Respondent to the FDA relating to the Application(s) submitted by, on behalf of, or acquired by, the Respondent related to the specified Divestiture Product;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to the specified Divestiture Product;
7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Divestiture Product;
8. FDA approved patient circulars and information related to the specified Divestiture Product;
9. adverse event/serious adverse event summaries related to the specified Divestiture Product;
10. summary of Product complaints from physicians related to the specified Divestiture Product;
11. summary of Product complaints from customers related to the specified Divestiture Product;



12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;
14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including without limitation, identification and sources of impurities;
15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of the specified Divestiture Product;
16. analytical methods development records related to the specified Divestiture Product;
17. manufacturing batch records related to the specified Divestiture Product;
18. stability testing records related to the specified Divestiture Product;
19. change in control history related to the specified Divestiture Product; and
20. executed validation and qualification protocols and reports related to the specified Divestiture Product.

AAA. "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 Divestiture Product Core Employee (including former employees who were employed by the specified Respondent 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, the specified Respondent 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.

BBB. "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, trademarks, and copyrights and registrations thereof and to bring suit against a Third Party for the past, present or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing;

*provided, however*, "Product Intellectual Property" does not include the corporate names or corporate trade dress of "Teva" "Barr" or "Cephalon", or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by Respondents or the related corporate logos thereof, or general registered images or symbols by which Teva, Barr or Cephalon can be identified or defined.

CCC. "Product Licensed Intellectual Property" means the following:

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

have been routinely used, prior to the Acquisition Date, for Retained Product(s) that has been marketed or sold on an extensive basis by a Respondent within the two-year period immediately preceding the Acquisition.

DDD. “Product Manufacturing Employees” means all salaried employees of a Respondent who have directly participated in the planning, design, implementation or operational management of the Product Manufacturing Technology of the specified Divestiture Product (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.

EEE. “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 specified Divestiture Product, 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 specified Divestiture Product; 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 specified Divestiture Product.

FFF. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product 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 specified Divestiture Product.

GGG. “Product Research and Development Employees” means all salaried employees of a Respondent who directly have participated in the research, Development, or regulatory

approval process, or clinical studies of the specified Divestiture Product (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.

HHH. “Product Trade Dress” means the current trade dress of the specified Divestiture Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.

III. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for the specified Divestiture Product(s).

JJJ. “Proposed Acquirer” means a Person proposed by a Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets or rights required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by a Respondent pursuant to this Order.

KKK. “Remedial Agreement(s)” means the following:

1. any agreement between a Respondent and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final and effective;
2. any agreement between a Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to a Divestiture Product to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final and effective;
3. any agreement between a Respondent 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, including without limitation, any agreement by a Respondent to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or

4. any agreement between a Respondent and a Third Party to effect the assignment of assets or rights of a Respondent 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.

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

MMM. “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 or to defend an Application, including the ability to make available the underlying raw data from the investigation for FDA audit.

NNN. “Supply Cost” means a cost not to exceed the manufacturer’s average direct per unit cost in United States dollars of manufacturing the specified Divestiture Product for the twelve (12) month period immediately preceding the Acquisition 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.

OOO. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*,

- a. designating employees knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;
- b. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product 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 Manufacturing Designee; and

d. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:

- (1) manufacture the specified Divestiture Product in the quality and quantities achieved by the Respondent, or the manufacturer and/or developer of such Divestiture Product;
- (2) obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell the specified Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and
- (3) receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product.

PPP. “Third Party(ies)” means any non-governmental Person other than the following: a Respondent; or, the Acquirer of particular assets or rights pursuant to this Order.

QQQ. “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 a Respondent; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by a Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that a Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

## II.

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

- A. Not later than the earlier of: (1) ten (10) days after the Acquisition Date or (2) ten (10) days after the Order Date, Respondents shall divest the Generic Fentanyl Product Assets and grant the Generic Fentanyl Product License, absolutely and in good faith, to Par pursuant to, and in accordance with, the Generic Fentanyl Product Divestiture Agreements (which agreements shall not limit 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 Par or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Generic Fentanyl Product Assets is incorporated by reference into this Order and made a part hereof;

*provided, however*, that if Respondents have divested the Generic Fentanyl Product Assets and granted the Generic Fentanyl Product License to Par prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Par is not an acceptable purchaser of the Generic

Fentanyl Product Assets, then Respondents shall immediately rescind the transaction with Par, in whole or in part, as directed by the Commission, and shall divest the Generic Fentanyl Product Assets and grant the Generic Fentanyl Product License within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

*provided further* that if Respondents have divested the Generic Fentanyl Product Assets and granted the Generic Fentanyl Product License to Par prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, 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 Fentanyl Product Assets or grant of the Generic Fentanyl Product License, as applicable, to Par (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Not later than the earlier of: (1) ten (10) days after the Acquisition Date or (2) ten (10) days after the Order Date, Respondents shall divest the Generic Cyclobenzaprine Product Assets and grant the Generic Cyclobenzaprine Product License, absolutely and in good faith, to Par pursuant to, and in accordance with, the Generic Cyclobenzaprine Product Divestiture Agreements (which agreements shall not limit 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 Par or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Generic Cyclobenzaprine Product Assets is incorporated by reference into this Order and made a part hereof;

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

*provided further* that if Respondents have divested the Generic Cyclobenzaprine Product Assets and granted the Generic Cyclobenzaprine Product License to Par prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, 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 Cyclobenzaprine Product Assets or grant of the Generic Cyclobenzaprine Product License, as applicable, to Par (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- 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 an Acquirer, and to permit the relevant Acquirer to continue the research, Development, manufacture, sale, marketing or distribution of the Divestiture Product(s) being acquired by that Acquirer;

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

- D. Respondents shall provide, or cause to be provided to each Acquirer in a manner consistent with the Technology Transfer Standards the following:

1. all Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Product(s) being acquired by that Acquirer; and
2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed by a Respondent related to the Divestiture Products being acquired by that Acquirer.

Respondents shall obtain any consents from Third Parties required to comply with this provision.

- E. Respondents shall:

1. upon reasonable written notice and request from an Acquirer to Respondent, Contract Manufacture and deliver to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products related to the Divestiture Products acquired by that Acquirer at Respondent's Supply Cost, for a period of time sufficient to allow that Acquirer (or the Manufacturing Designee of the Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished drug product independently of Respondents and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in Respondent Teva's Application(s) for the Divestiture Product(s) acquired by that Acquirer from Persons other than the Respondents;



2. make representations and warranties to the Acquirer(s) that the Contract Manufacture Product(s) supplied by a Respondent pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract Manufacture Product(s) to be marketed or sold in the Geographic Territory, the Respondent 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 Contract Manufacture Product(s) supplied to the Acquirer pursuant to a Remedial Agreement by a Respondent to meet cGMP. This obligation may be made contingent upon the Acquirer giving the Respondent 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 claim, including the right to settle the claim, so long as such settlement is consistent with Respondents' responsibilities to supply the Contract Manufacture Products 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 a Respondent to the Acquirer;

*provided further* that in each instance where: (1) an agreement to divest relevant assets or to Contract Manufacture is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on a Respondent's aggregate liability resulting from the failure of the Contract Manufacture Products supplied to the Acquirer pursuant to such Remedial Agreement by a Respondent to meet cGMP;

3. give priority to supplying a Contract Manufacture Product to the relevant Acquirer over manufacturing and supplying of Products for Respondents' own use or sale;
4. make representations and warranties to each Acquirer that Respondents shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by Respondents to deliver the Contract Manufacture Products in a timely manner as required by the Remedial Agreement(s) unless Respondents can demonstrate that their failure was entirely beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents;

*provided, however*, that in each instance where: (1) an agreement to divest relevant assets or to Contract Manufacture is specifically referenced and attached to this Order and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on a Respondent's aggregate liability for such a failure;

5. during the term of any agreement to Contract Manufacture between a Respondent and an Acquirer, upon written request of that 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 agreement to Contract Manufacture between a Respondent 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. during the term of any agreement to Contract Manufacture between a Respondent and an Acquirer, provide consultation with knowledgeable employees of the Respondent and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all Product Approvals to manufacture the relevant Divestiture Products in the same quality achieved by, or on behalf of, a Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondents and sufficient to satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the relevant 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 Manufacturing Designee(s) of that Acquirer), respectively, is approved by the FDA to manufacture and sell such Divestiture Product in the United States and able to manufacture such Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents; (2) the date the Acquirer of a particular Divestiture Product notifies the Commission and the Respondents of its intention to abandon its efforts to manufacture such Divestiture Product; (3) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer of a particular Divestiture Product has abandoned its efforts to manufacture such Divestiture Product, or (4) the date 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 being acquired by that Acquirer;
2. deliver such Confidential Business Information to that 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 that Acquirer, provide that Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the relevant Divestiture 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. Respondent's obligations to the Acquirer of the Divestiture Product under the terms of any related Remedial Agreement; or
    - c. applicable Law;
  5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except the Acquirer of the Divestiture Product or other Persons specifically authorized by that 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 that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Products acquired by that Acquirer. 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 that Acquirer.

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

I. Respondents shall:

1. for each Divestiture Product, for a period of six (6) months from the Closing Date or until the hiring of twenty (20) Divestiture Product Core Employees by an Acquirer or its Manufacturing Designee, whichever occurs earlier, provide that Acquirer with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that 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 that 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 Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, Respondents shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

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

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, and manufacture the Divestiture Product consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Product and to ensure successful execution of the pre-Acquisition plans for that

Divestiture Product. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

*provided, however,* that this Paragraph II.H. does not require nor shall be construed to require Respondents to terminate the employment of any employee or to prevent Respondents from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition; and

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

- a. directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product (“Divestiture Product Employee”) to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or
- b. hire any Divestiture Product Employee;

*provided, however,* Respondents may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

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

- J. Respondents shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each Divestiture Product Core Employee retained by Respondent, the direct supervisor(s) of any such employee, and any other employee retained by Respondents and designated by the Interim Monitor (if applicable) sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that 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 and disclosure of the Confidential Business

Information related to the Divestiture Products by Respondent's personnel to all of Respondent's 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 the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondents shall provide a copy of the notification to the relevant Acquirer. Respondents shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Respondents shall provide the relevant Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.

- L. Until Respondents complete the divestitures required by this Order and fully provides, or causes to be provided, the Product Manufacturing Technology related to a particular Divestiture Product to the relevant Acquirer,
  1. Respondents shall take actions as are necessary to:
    - a. maintain the full economic viability and marketability of the businesses associated with that Divestiture Product;
    - b. minimize any risk of loss of competitive potential for that business;
    - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to that Divestiture Product;
    - d. ensure the assets related to each Divestiture Product are provided to the relevant 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 that Divestiture Product.

- M. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against an Acquirer or the Divestiture Product Releasee(s) of that Acquirer for the research, Development, manufacture, use, import, export, distribution, or sale of the Divestiture Product(s) acquired by that Acquirer under the following:
1. any Patent owned or licensed by Respondents as of the day after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claims a method of making, using, or administering, or a composition of matter, relating to the Divestiture Product(s) acquired by that Acquirer, or that claims a device relating to the use thereof;
  2. any Patent owned or licensed by Respondents at any time after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the Divestiture Product(s) acquired by that Acquirer;

if such suit would have the potential to interfere with that Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Product(s) anywhere in the World for the purposes of marketing or sale in the United States of America; or (2) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of a particular Divestiture Product. Respondents shall also covenant to that Acquirer that as a condition of any assignment, transfer, or license to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue that Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential to interfere with that Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Product(s) anywhere in the World for the purposes of marketing or sale in the United States of America; or (2) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of a particular Divestiture Product;

*provided however*, that, for the purposes of this Paragraph II.M. only, and only with respect to any suit filed by Respondent Cephalon prior to May 13, 2011 involving the Generic Cyclobenzaprine Products, the term "Patent" shall *exclude* the Amrix Patents.

- N. Upon reasonable written notice and request from an Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Products acquired by that Acquirer, if such litigation would have the potential to interfere with the Acquirer's freedom to practice

the following: (1) the research, Development, or manufacture of the Divestiture Product acquired by that Acquirer; or (2) the use, import, export, supply, distribution, or sale of that Divestiture Product within the Geographic Territory; *provided however*, these obligations do not apply to any matter involving the Amrix Patents.

- O. For any patent infringement suit in which a Respondent is alleged to have infringed a Patent of a Third Party prior to the Closing Date or for such suit as a Respondent has prepared or is preparing as of the Closing Date to defend against such infringement claim(s), and where such a suit would have the potential to interfere with the relevant Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Product(s) acquired by that Acquirer; or (2) the use, import, export, supply, distribution, or sale of that Divestiture Product(s), Respondents shall:
1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from Respondents in connection with obtaining resolution of any pending patent litigation involving that Divestiture Product;
  2. waive conflicts of interest, if any, to allow the Respondents' outside legal counsel to represent the relevant Acquirer in any ongoing patent litigation involving that Divestiture Product; and
  3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work-product in the possession of Respondents' outside counsel relating to that Divestiture Product;

*provided however*, these obligations do not apply to any matter involving the Amrix Patents.

P. Respondents shall not, in the Geographic Territory:

1. use the Product Trademarks contained in the Product Intellectual Property or any mark confusingly similar to such Product Trademarks, as a trademark, trade name, or service mark;
2. attempt to register such Product Trademarks;
3. attempt to register any mark confusingly similar to such Product Trademarks;
4. challenge or interfere with the relevant Acquirer's use and registration of such Product Trademarks; or
5. challenge or interfere with the relevant Acquirer's efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties;



*provided however*, that this paragraph shall not preclude Respondents from continuing to use all trademarks, tradenames, or service marks that have been in use in commerce on a Retained Product at any time prior to the Acquisition Date.

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

### **III.**

**IT IS FURTHER ORDERED** that:

- A. Not later than the earlier of: (1) ten (10) days after the Acquisition Date or (2) ten (10) days after the Order Date, Respondents shall supply Generic Modafinil Products to Par, in a timely manner, pursuant to, and in accordance with, the Generic Modafinil Supply Agreement (which agreement shall not limit 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 Par or to reduce any obligations of Respondents under such agreement) for a period of at least one (1) year, and at Par's option, up to two (2) years.

*provided, however*, that if Respondents have executed the Generic Modafinil Product Supply Agreement with Par prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Par is not acceptable for the purposes of the agreement to supply Generic Modafinil Products, then Respondents shall immediately rescind the Generic Modafinil Supply

Agreement and shall execute an agreement to supply Generic Modafinil Products within ninety (90) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

*provided further* that if Respondents have entered in to the Generic Modafinil Product Supply Agreement with Par prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the agreement to supply Generic Modafinil Products was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of the supply of Generic Modafinil Products, as applicable, with Par (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Respondents shall, in connection with any Remedial Agreement by Respondents to supply Generic Modafinil Products to an Acquirer,
1. manufacture and deliver, absolutely and in good faith, to that Acquirer sufficient commercial quantities of Generic Modafinil Products in final finished and packaged form suitable for sale to the ultimate consumer/patient by the Acquirer (including all Acquirer approved packaging) in sufficient time to allow the Acquirer to market, distribute and sell the Generic Modafinil Products in commercial quantities not later than April 6, 2012;
  2. continue to manufacture and deliver such Generic Modafinil Products to the Acquirer in such quantities and in a timely manner to allow such Acquirer to continue to market, distribute and sell Generic Modafinil Products at least until April 6, 2013, and, at the Acquirer's option, a one (1) year extension of this obligation;
  3. make representations and warranties to that Acquirer that the Generic Modafinil Products supplied by the Respondents meet the relevant Agency-approved specifications;
  4. indemnify, defend and hold that Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Generic Modafinil Products supplied to that Acquirer by a Respondent to meet cGMP. This obligation may be made contingent upon that Acquirer giving Respondents prompt written notice of such claim and cooperating fully in the defense of such claim;

*provided, however,* that Respondents may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with Respondents' responsibilities to supply the Generic Modafinil Products 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 a Respondent to the Acquirer;

*provided further* that in each instance where: (1) an agreement to supply Generic Modafinil Products is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for the Generic Modafinil Products, each such agreement may contain limits on Respondent's aggregate liability resulting from the failure of the Generic Modafinil Products supplied to the Acquirer by Respondent to meet cGMP;

5. give priority to supplying Generic Modafinil Products to the Acquirer over manufacturing and supplying of Products for Respondents' own use or sale;
  6. hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by Respondents to deliver the Generic Modafinil Products in a timely manner as required by the Remedial Agreement(s) unless Respondents can demonstrate that its failure was entirely beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents;
- C. Respondent shall maintain manufacturing facilities necessary to manufacture each of the Generic Modafinil Products for the term of the agreement to supply Generic Modafinil Products to the Acquirer of the agreement to supply Generic Modafinil Products.
- D. From September 26, 2012, Respondents shall not, directly or indirectly (i) enforce or seek to enforce against the FDA or any other Person, or (ii) seek to have the FDA enforce, any rights that Respondents may have to market on an exclusive basis any Product that is the subject of an ANDA that references or is based on Provigil (*i.e.*, Application Number N020717) as the Reference Listed Drug. Not later than ten (10) days after the Order Date, and at such time(s) as may be provided for under any applicable FDA rules or procedures, Respondents shall:
1. relinquish any and all claims to such exclusive marketing rights that Respondents may have after September 25, 2012;
  2. provide written notification to the FDA and the Commission that Respondents relinquish any and all such exclusive marketing rights that Respondents may have after September 25, 2012; and
  3. ensure that such notification(s) are made in a timely manner and in a manner consistent with all applicable FDA rules and procedures and sufficient to accomplish the requirements of this Paragraph of the Order;

*provided however*, this Paragraph shall not be interpreted to require Respondents to waive or relinquish their rights in the Provigil® trademark and copyrights.

- E. The purpose of requiring the Respondents to supply the Generic Modafinil Products and the related obligations imposed on the Respondents by this Order is to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

#### IV.

**IT IS FURTHER ORDERED** that:

- A. At any time after Respondent Teva signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondents expeditiously complies with all of their obligations and performs 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 the Respondents of the divestiture of all Divestiture 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 Divestiture Product, the date the Acquirer of such Divestiture Product (or that Acquirer's Manufacturing 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 the Respondents;
- b. with respect to each Divestiture Product, the date the Acquirer of that Divestiture Product notifies the Commission and the Respondents of its intention to abandon its efforts to manufacture such Divestiture Product; or
- c. with respect to each Divestiture Product, the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the relevant 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 Respondents' compliance with their obligations under the Order, including, but not limited to, their obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Order.
5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
6. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with

the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.

7. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Order;

*provided, however*, beginning ninety (90) days after Respondents have filed their final report pursuant to Paragraph IX.B., and every ninety (90) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by the relevant Acquirer toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents.

8. A Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
  - F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
  - G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
  - H. The Interim Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

V.

**IT IS FURTHER ORDERED** that:

- A. If Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent 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 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 the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent 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 Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in



connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of the Order to Maintain Assets in this matter.
  8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
  9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

## VI.

**IT IS FURTHER ORDERED** that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, Respondents shall assure that Respondents' counsel (including in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

- A. To assure Respondents' compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or

- B. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and businesses associated with those Divestiture Products;

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

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

## VII.

**IT IS FURTHER ORDERED** that:

- A. Any 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 or Generic Modafinil Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of the Respondents' obligations to the Acquirer pursuant to this Order.
- D. Respondents shall also include in each Remedial Agreement a representation from the Acquirer that that 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, as applicable, and to have any such manufacture to be independent of Respondents, all as soon as reasonably practicable.
- E. Respondents shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products or Generic Modafinil Products a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- F. Respondents shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission.

## VIII.

**IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondents have fully complied with the following: Paragraphs II.A , II.B., II.C., II.D., II.E.1.-3., II.F., II.H., II.I.1.- 4., II.K., II.L. and III.A., Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondents shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondents shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including a full description of all substantive contacts or negotiations related to the divestiture of the relevant assets and/or the agreement to supply relevant Products and the identity of all Persons contacted, including copies of all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning completing the obligations.
- C. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

## IX.

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

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

**X.**

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

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

**XI.**

**IT IS FURTHER ORDERED** that this Order shall terminate on July 2, 2022.

By the Commission, Commissioner Ohlhausen not participating.

Donald S. Clark  
Secretary

SEAL  
ISSUED: July 2, 2012

**NON-PUBLIC APPENDIX II.A.**  
**GENERIC FENTANYL PRODUCT DIVESTITURE AGREEMENTS**  
**[Redacted From the Public Record Version, But Incorporated By Reference]**

**NON-PUBLIC APPENDIX II.B.**  
**GENERIC CYCLOBENZAPRINE PRODUCT DIVESTITURE AGREEMENTS**  
**[Redacted From the Public Record Version, But Incorporated By Reference]**

**NON-PUBLIC APPENDIX III  
GENERIC MODAFINIL PRODUCT SUPPLY AGREEMENT  
[Redacted From the Public Record Version, But Incorporated By Reference]**