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UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: Jon Leibowitz, Chairman
J. Thomas Rosch
Edith Ramirez
Julie Brill

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

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 has jurisdiction

issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent Teva is a corporation organized, existing and doing business under and by virtue of the laws of the State of Israel, with its corporate head office and principal place of business located at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131 Israel and the address of its United States subsidiary, Teva Pharmaceuticals USA, Inc., located at 1090 Horsham Road, P.O.B. 1090, North Wales, Pennsylvania 19454, 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 e Aca

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 a 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 Applica

any real estate and the buildings and other permanent structures located on such real estate; and (6) all Product Licensed Intellectual Property;

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

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.org

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

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 and Mitigation Strategy related to NDA Number 20-747 (Actiq®, fentanyl citrate), and all strategic safety programs, submitted to an Agency related to Actiq® 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, and Par P

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 Licensed Intellectual Property trademark Provigil® that contain the active pharmaceutical ingredient modafinil, including all

ducts within 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 Licensed Intellectual Property trademark Provigil® that contain the active pharmaceutical ingredient modafinil, including all

KK. "Government Entity" means any Federal, state, local or non-U.S. governme

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 [illegible]

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

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 re

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 of 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

Product in commerc

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 Fentany

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 exercise 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 Manufactured 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 (1) an a

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 Infor

2. not later than the earlier of the following dates: (1) ten (10) days after notice by staff of

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 submit to the Commission a verified written report setting forth in detail the manner in which Respondents have complied with the requirements of this Order.

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 Release(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;

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, trade names, or service marks that have been in use in commerce on a Retained Product at anytime prior to the Acquisition Date.

Q. The purpose of the divestiture of the Divestiture Product Assets and the transfer and

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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.

B. Respondents shall, in connection with any Remedial Agreement by Respondents to supply

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. The purpose of the 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 commA

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 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

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 a

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, or 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 any 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 Thir

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 II.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 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

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]