

UNITED STATES OF AMERICA  
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: Deborah Platt Majoras, Chairman  
Pamela J. Hanft  
John Leibowitz  
William E. Katt  
J. Thomas Rhee

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In the Matter of )  
 MYLAN LABORATORIES INC., )  
 a corporation ; ) Docket No. C-  
 and )  
 E. MERCK OHG, )  
 a corporation . )

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DECISION AND ORDER  
[Public Record Verifiable]

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

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

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should

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

1. Respondent Mylan Laboratories Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the Commonwealth of Pennsylvania, with its headquarters address at 1500 Corporate Drive, Suite 400, Canonburg, Pennsylvania 15317.
2. Respondent E. Merck oHG is a corporation organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany, with its headquarters address at Frankfurter Strasse 250, D-64293, Germany and the address of the principal place of business of its United States subsidiary, EMD, Inc. at 2751 Napa Valley Corporate Drive, Napa, CA 94558.
3. Merck Generic Business includes the following: Merck dura GmbH, Merck Generics Group B.V., EMD, Inc., Merck Generics Belgium B.V.B.A. and Merck Genericos S.L.
4. The Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

## **ORDER**

### **I.**

**IT IS ORDERED** that, as used in the Order, the following definitions shall apply:

- A. "Mylan" means Mylan Laboratories, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Mylan and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Mylan shall include the Merck Generics Business of Respondent Merck.
- B. "Merck" means E. Merck oHG, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Merck (including, but not limited to, the Merck Generics Business), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

- C. “Merck Generics Business” means the generic pharmaceutical business operated by Merck KgaA including, the following: Merck dura GmbH (Alsfelder Str. 19, 64289, Darmstadt, Germany); Merck Generics Group B.V. (Rokin 55, Amsterdam, Netherlands 1012 KK); EMD, Inc. (2751 Napa Valley Corporate Drive, Napa, CA 94558); Merck Generics Belgium B.V.B.A. (3090 Overijse, Brusselsesteenweg 288); Merck Genericos S.L. (Poligono Merck, Mollet de Valles Spain 8100; and all other such entities as are listed item 6(a) of the *Notification and Report Form for Certain Mergers and Acquisitions* filed by Respondent Merck dated June 5, 2007, in connection with the Acquisition, and the directors, officers, employees, agents, representatives, predecessors, successors, and assigns of the foregoing entities; and the joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by the foregoing entities, and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.
- D. “Respondents” means Mylan and Merck, individually and collectively.
- E. “Commission” means the Federal Trade Commission.
- F. “Acebutolol Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Merck pursuant to the following of





10. all Product Development Reports related to such Divestiture Product(s);
11. at the relevant Acquirer's option, all Product Assumed Contracts related to such Divestiture Product(s) (copies to be provided to the relevant Acquirer on or before the Closing Date);
12. all strategic safety program(s) submitted to the FDA related to such Divestiture Product(s) that is designed to decrease product risk by using one or more interventions or tools beyond the package insert;
13. all patient registries related to such Divestiture Product(s), and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to such Divestiture Product(s);
14. a list of all customers and/or targeted customers for such Divestiture Product(s) and the net sales (in either units or dollars) of such Divestiture Products to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of such Divestiture Products on behalf of the High Volume Account and his or her business contact information;
15. at the relevant Acquirer's option and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to such Divestiture Product(s);
16. copies of all unfilled customer purchase orders for such Divestiture Product(s) as of the Closing Date, to be provided to the relevant Acquirer not later than two (2) days after the Closing Date;
17. at the relevant Acquirer's option, subject to any rights of the customer, all unfilled customer purchase orders for such Divestiture Products; and
18. all of the Respondents' books, records, and files directly related to the foregoing or to such Divestiture Product(s);

*provided, however*, that "Categorized Assets" shall not include: (1) documents relating to Respondents' general business strategies or practices relating to research, Development, manufacture, marketing or sales of generic pharmaceutical Products, where such documents do not discuss with particularity the Divestiture Products; (2) shall not include administrative, financial, and accounting records; (3) quality control

records that are determined by the Interim Monitor or the Acquirer not to be material to the manufacture of the Divestiture Product(s); and (4) any real estate and the buildings and other permanent structures located on such real estate;

*provided further*, that in cases in which documents or other materials included in the relevant assets to be divested contain information: (1) that relates both to such

3. information that is required by Law to be publicly disclosed;
  4. information that does not directly relate to the Divestiture Product(s);
  5. information relating to Respondents' general business strategies or practices relating to research, Development, manufacture, marketing or sales of generic pharmaceutical Products that does not discuss with particularity the Divestiture Product(s); or
  6. information specifically excluded from the Categorized Assets.
- Q. "Contract Manufacture" means the manufacture of a Divestiture Product to be supplied by Respondents or a Designee to an Acquirer.
- R. "Designee" means any entity other than Respondents that will manufacture a Divestiture Product for an Acquirer.
- S. "Development" means all preclinical and clinical drug development activities (including







in dollars, of a Divestiture Product in the United States from either Respondent (whichever Respondent is relevant to such Divestiture Product) was, is, or is projected to be among the top twenty highest of such purchase amounts by that Respondent's (whichever Respondent is relevant to such Divestiture Product) U.S. customers on any of the following dates: (1) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (2) the end of the last quarter that immediately preceded the Effective Date; (3) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or 4) the end of the last quarter following the Acquisition and/or the Closing Date.

JJ. "Interim Monitor" means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.

KK. "Law" means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.

LL. "NDC Numbers" means the National Drug Code number(s), including both the labeler code assigned by the FDA and the additional numbers assigned by the Application holder as a product code for a specific Product.

MM. "Nicardipine Products" means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Merck pursuant to the following of Respondent Merck's ANDAs:

1. ANDA No. 74-928 (Nicardipine in 20 mg and 30 mg dosage strengths); and
2. any supplements, amendments, or revisions thereto;

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

NN. "Nicardipine Product Assets" means all of Respondent Merck's rights, title and interest in and to all assets related to Respondent Merck's business within the Geographic Territory related to the Nicardipine Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Nicardipine Products, including, without limitation, the Categorized Assets related to the Nicardipine Products.

OO. "Order to Maintain Assets" means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.

- PP. “Patents” 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 Respondents as of the Closing Date (*except* where this Order specifies a different time).
- QQ. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, joint venture, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- RR. “Product” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient.
- SS. “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.
- TT. “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 relevant Closing Date and segregated in a manner that clearly identifies the purpose(s) of each such contract):
1. that make specific reference to the Divestiture Product(s) and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the Divestiture Product(s) from Respondent (whichever Respondent is relevant to such Divestiture Product) unless such contract applies generally to the divesting entity’s sales of Products to that Third Party;
  2. pursuant to which Respondent (whichever Respondent is relevant to such Divestiture Product) purchases the active pharmaceutical ingredient(s) or other necessary ingredient(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) from any Third Party for use in connection with the manufacture of the Divestiture Product(s);
  3. relating to any clinical trials involving the Divestiture Product(s);
  4. with universities or other research institutions for the use of the Divestiture Product(s) in

scientific research;

5. relating to the particularized marketing of the Divestiture Product(s) or educational matters relating solely to the Divestiture Product(s);
6. pursuant to which a Third Party manufactures or packages the Divestiture Product(s) on behalf of Respondent (whichever Respondent is relevant to such Divestiture Product);
7. pursuant to which a Third Party provides the Product Manufacturing Technology related to the Divestiture Product(s) to Respondent (whichever Respondent is relevant to such Divestiture Product);
8. pursuant to which a Third Party is licensed by Respondent (whichever Respondent is relevant to such Divestiture Product) to use the Product Manufacturing Technology;
9. constituting confidentiality agreements involving the Divestiture Product(s);
10. involving any royalty, licensing, or similar arrangement involving the Divestiture Product(s);
11. pursuant to which a Third Party provides any specialized services necessary to the

copyrights in raw data relating to clinical trials of the Divestiture Product(s), all case report

Product(s);

9. adverse event/serious adverse event summaries related to the specified Divestiture Product(s);
10. summary of Product complaints from physicians related to the specified Divestiture Product(s);
11. summary of Product complaints from customers related to the specified Divestiture Product(s); and
12. Product recall reports filed with the FDA related to the specified Divestiture Product(s).

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

1. a complete and accurate list containing the name of each relevant employee (including former employees who were employed by Respondents 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, Respondents 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 Respondents’ 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 request, the Acquirer shall provide to the Respondents, as applicable, copies of g





- b. for which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell such a Retained Product on an extensive basis by either Respondent;

*provided however*, that, in cases where the aggregate retail sales in dollars within the two-year period immediately preceding the Acquisition of the Retained Product(s) collectively are less than the aggregate retail sales in dollars within the same period of the Divestiture Product(s) collectively, the above-described intellectual property shall be considered, at the Acquirer's option, to be Product Intellectual Property and, thereby, subject to assignment to the Acquirer; *provided further, however*, that in such cases, Respondents may take a license back from the Acquirer for such intellectual property for use in connection with the Retained Products and such a license to Respondents may be perpetual, fully paid-up and royalty-free license(s) with rights to sublicense.

ZZ. "Product Manufacturing Employees" means all salaried employees of Respondents who have directly participated in the planning, design, implementation or operational management of the Product Manufacturing Technology of the specified Divestiture Product(s) (irrespective of the portion of working time involved unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

AAA. "Product Manufacturing Technology" means:

1. all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of the Divestiture Product(s), including, but not limited to, the following: all product specifications, processes, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and



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

HHH. "Retained Product" means any Product(s) other than a Divestiture Product.

III. "Right of Reference or Use" means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an Application, including the ability to make available the underlying raw data from the investigation for FDA audit.

JJJ. "Sotalol Products" means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Merck pursuant to the following of Respondent Merck's ANDAs:

limitation, the Categorized Assets related to the Sotalol Products.

- LLL. “Supply Cost” means a cost not to exceed the manufacturer’s average direct per unit cost in United States dollars of manufacturing the Divestiture Product for the twelve (12) month period immediately preceding the Effective Date. “Supply Cost” shall expressly exclude any intracompany business transfer profit; *provided, however*, that in each instance where: (1) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, “Supply Cost” means the cost as specified in such Remedial Agreement for that Divestiture Product.
- MMM. “Third Party(ies)” means any private entity other than the following: Respondents or the relevant Acquirer for the affected assets, rights and Divestiture Product(s).
- NNN. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by Respondents; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by Respondents that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that Respondents can convey their rights, if any, therein; or (2) content unrelated to the Product(s).

## II.

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

- A. Not later than ten (10) days after the Effective Date, Respondents shall divest the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets, absolutely and in good faith, to Amneal pursuant to, and in accordance with, the Generic Divestiture Product Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Amneal or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets, respectively, is incorporated by reference into this Order and made a part hereof;

*provided, however*, that if Respondents have divested the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets to Amneal prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the

Commission notifies Respondents that Amneal is not an acceptable purchaser of the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets then Respondents shall immediately rescind the transaction with Amneal, in whole or in part, as directed by the Commission, and shall divest the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets, as is relevant, within one hundred eighty (180) days from the date the Order becomes final, absolutely and in good faith, at no minimum price, to a(n) Acquirer(s) and only in a manner that receives the prior approval of the Commission;

*provided further* that if Respondents have divested the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets to Amneal prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets to Amneal (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. 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 the relevant Acquirer(s), and/or to permit such Acquirer to continue the research, Development, manufacture, sale, marketing or distribution of the Divestiture Products;

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

- C. Respondents shall transfer the Product Manufacturing Technology related to the relevant Divestiture Product to the relevant Acquirer in an organized, comprehensive, complete, useful, timely, and meaningful manner. Respondents shall, *inter alia*:

1. designate employees of Respondents knowledgeable with respect to such Product Manufacturing Technology to a committee for the purposes of communicating directly with such Acquirer and the Interim Monitor (if any has been appointed) for the purposes of effecting such transfer;



Remedial Agreement shall be consistent with the obligations assumed by Respondents under this Order; *provided, however*, that Respondents may reserve the right to control the defense of any such litigation, including the right to settle the litigation, so long as such settlement is consistent with Respondents' responsibilities to supply the ingredients and/or components in the manner required by this Order; *provided further* that this obligation shall not require Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by Respondents to the Acquirer; *provided further* that in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on Respondents' aggregate liability resulting from the failure of the Products supplied to the Acquirer pursuant to such Remedial Agreement by Respondents to meet cGMP;

3. Respondents shall make representations and warranties to the 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 Products in a timely manner as required by a Remedial Agreement 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 is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on Respondents' aggregate liability for such a breach;
4. during the term of the Contract Manufacture between Respondents and the Acquirer, upon request of the Acquirer or Interim Monitor (if any has been appointed), Respondents shall make available to the Acquirer and the Interim Monitor (if any has been appointed) all records that relate to the manufacture of the relevant Divestiture Products that are generated or created after the Closing Date;
5. during the term of the Contract Manufacture between Respondents and the Acquirer, maintain manufacturing facilities necessary to manufacture each of the Divestiture Products in finished form (suitable for sale to the ultimate consumer/patient); and
6. during the term of the Contract Manufacture between Respondents and the Acquirer, provide consultation with knowledgeable employees of Respondents and training, at the request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling the Acquirer (or the Designee of the Acquirer) to obtain all Product Approvals to manufacture the relevant Divestiture Products in the same quality achieved by the Respondents 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 Designee's personnel) are adequately trained in the manufacture of the relevant Divestiture Products;

The foregoing provisions, II.D.1. - 6., shall remain in effect with respect to each Divestiture Product until the earliest of: (1) the date the relevant Acquirer (or the Designee(s) of such Acquirer) is approved by the FDA to manufacture such Divestiture Product and able to manufacture such Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents; (2) the date the relevant Acquirer notifies the Commission and the Respondents of its intention to abandon its efforts to manufacture such Divestiture Product; or (3) the date of written notification from staff of the Commission that the relevant Interim Monitor, in consultation with staff of the Commission, has determined that the relevant Acquirer has abandoned its efforts to manufacture such Divestiture Product.

E. Respondents shall:

1. submit to the Acquirer, at Respondents' expense, all Confidential Business Information related to the relevant Divestiture Product(s);
2. deliver such Confidential Business Information as follows:
  - 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 the Acquirer, provide the 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 Product(s) 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 relevant Divestiture Product(s) other than as necessary to comply with the following:
  - a. the requirements of this Order;
  - b. Respondents' obligations to the Acquirer under the terms of any Remedial





provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay;

3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by the relevant Acquirer of the Divestiture Product Core Employees related to the particular Divestiture Products and assets acquired by such Acquirer, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with the relevant Acquirer, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondent (whichever Respondent is relevant to such Divestiture Product) that would affect the ability or incentive of those individuals to be employed by the relevant Acquirer. In addition, Respondents shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from the relevant Acquirer;

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

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, and manufacture the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for such Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent (whichever Respondent is relevant to such Divestiture Product) until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product(s) has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

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

5. for a period of one (1) year from the relevant Closing Date, not:
  - a. directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer with any amount of responsibility related to a Divestiture Product ("Divestiture Product Employee") to terminate his or her employment relationship



principal place of business within the United States and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondents shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

- K. Until Respondents complete the divestitures required by Paragraph II.A. and fully transfer the related Product Manufacturing Technology,
1. Respondents shall take such actions as are necessary to:
    - a. maintain the full economic viability and marketability of the businesses associated with each Divestiture Product;
    - b. minimize any risk of loss of competitive potential for such business;
    - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to each Divestiture Product;
    - d. ensure the assets required to be divested are transferred 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 of the Product Manufacturing Technology; and
  2. Respondents shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the businesses associated with each Divestiture Product.
- L. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the relevant Acquirer(s) or the Divestiture Product Releasee(s) for the research, Development, manufacture, use, import, export, distribution, or sale of the Divestiture Product(s) under the following:
1. any Patent owned or licensed by Respondents as of the Effective Date that claims a method of making, using, or administering, or a composition of matter, relating to the respective Divestiture Product, or that claims a device relating to the use thereof;
  2. any Patents owned or licensed at any time after the Effective Date by Respondents that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the respective Divestiture Products, other than such Patents that claim inventions conceived by and reduced to practice after the Effective Date;



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 Acquirer(s)'s use and registration of such Product Trademarks; or
5. challenge or interfere with the Acquirer(s)'s efforts to enforce their trademark registrations for and trademark rights in such Product Trademarks against Third Parties;

*provided however*, that this Order shall not preclude Respondents from continuing to use those trademarks, tradenames, or service marks related to the Retained Products as of the Effective Date.

- P. Respondents shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products a decision the result of which would be inconsistent with the terms of this Order and/or the remedial purposes thereof.

### **III.**

**IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent Mylan, which consent shall not be unreasonably withheld. If Respondent Mylan has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim

conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:





- F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
- G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- H. The Interim Monitor appointed pursuant to this Order may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

#### IV.

**IT IS FURTHER ORDERED** that:

- A. If Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey relevant assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver or otherwise convey the assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed pursuant to each of the relevant Paragraphs in a manner that satisfies the requirements of each such Paragraph. 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 the relevant assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent Mylan, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent Mylan 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 Mylan 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.

Commission; and, *provided further, however*, that Respondents shall select such entity within five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, 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 Respondent, 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 misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
  7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of the Order to Maintain Assets in this matter.
  8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
  9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner

as provided in this Paragraph.

- F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

## V.

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

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

- A. comply with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- B. defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or assets and businesses associated with those Products; *provided, however*, that Respondents may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement or arrangement;

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

## VI.

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

- A. Within five (5) days of the Acquisition, Respondent Mylan shall submit to the Commission a letter certifying the date on which the Acquisition occurred.

B. Within thirty (30) days after the date this Order becomes final, and every sixty (60) days thereafter until Respondents have fully complied with the following:

1. Paragraphs II.A , II.B., II.C., II.D., II.E., II.G., II.H., II.J., and II.K.; and
2. all of their responsibilities to render transitional services to the relevant Acquirer as provided by this Order and the Remedial Agreement(s),

Respondent Mylan shall submit to the Commission a verified written report setting forth in detail the manner and form in which Respondents intend to comply, are complying, and have complied with this Order. Respondent Mylan shall submit at the same time a copy of their report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondent Mylan 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 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 date this Order becomes final, annually for the next nine years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, Respondent Mylan 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.

## VII.

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

- A. any proposed dissolution of Respondent Mylan;
- B. any proposed acquisition, merger or consolidation of Respondent Mylan; or
- C. any other change in Respondents 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.

**VIII.**

**X.**

**IT IS FURTHER ORDERED** that the purpose of the divestiture of the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets, the transfer of the Product Manufacturing Technology related to the Acebutolol Products, the Flecainide Products, the Guanfacine Products, the Nicardipine Products, and the Sotalol Products, respectively, and the related obligations imposed on the Respondents by this Order is:

- A. to ensure the continued use of the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets in the research, Development, and manufacture of each of the respective Divestiture Products;
- B. to provide for the future use of the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets in the distribution, sale and marketing of each of the respective Divestiture Products;
- C. to create a viable and effective competitor, who is independent of the Respondents, in the research, Development, manufacture, distribution, sale and marketing of each of the respective Divestiture Products; and,
- D. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

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

[Redacted From the Public Record Via the B I C Act and B Reference]