

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

In the Matter of)	
)	
)	
MYLAN LABORATORIES INC.,)	
a corporation;)	
)	
and)	
)	
E. MERCK oHG,)	
a corporation.)	

Docket No. C-4200

ORDER TO MAINTAIN ASSETS

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 to accept the executed Consent Agreement and to place 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 issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

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 this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final, the Decision and Order), which are attached hereto as Appendix A and incorporated herein by reference and made a part hereof, 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. “Divestiture Assets” means the Acebutolol Product Assets, Flecainide Product Assets, Guanfacine Product Assets, Nicardipine Product Assets, and the Sotalol Product Assets, as defined in the attached Decision and Order.
- G. “Divestiture Product Business(es)” means the relevant Respondent’s business within the Geographic Territory specified in the Decision and Order related to each of the Divestiture Products, including the research, Development, manufacture, distribution, marketing, and sale of each Divestiture Product and the assets related to such business, including, but not limited to, the Divestiture Assets.
- H. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- I. “Orders” means the Decision and Order and this Order to Maintain Assets.
- J. “Pre-Acquisition Marketing Plan” means any marketing or sales plan that was planned or implemented within the period immediately prior to the Acquisition and without consideration of the influence of the pending Acquisition for the Divestiture Product Businesses

II.

IT IS FURTHER ORDERED that from the date this Order to Maintain Assets becomes final:

- A. Respondents shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses, to minimize any risk of loss of competitive potential for the Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of the Divestiture Product Businesses except for ordinary wear and tear. Respondents shall not sell, transfer, encumber or otherwise impair the Divestiture Assets (other than in the manner prescribed in the Decision and Order) nor take any action that lessens the full economic viability, marketability or competitiveness of the Divestiture Product Businesses.
- B. Respondents shall maintain the operations of the Divestiture Product Businesses in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such businesses) and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Divestiture Product Businesses and shall use their best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors, including, but not limited to, the High Volume Accounts; customers; Agencies; employees; and others having business relations with the Divestiture Product Businesses. Respondents' responsibilities shall include, but are not limited to, the following:
 1. providing the Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such businesses and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for the Divestiture Product Businesses;
 2. continuing, at least at their scheduled pace, any additional expenditures for the Divestiture Product Businesses authorized prior to the date the Consent Agreement was signed by Respondents including, but not limited to, all research, Development, manufacture, distribution, marketing and sales expenditures;
 3. provide such resources as may be necessary to respond to competition against the Divestiture Products and/or to prevent any diminution in sales of the Divestiture Products during and after the Acquisition process and prior to divestiture of the related Divestiture Assets;
 4. provide such resources as may be necessary to maintain the competitive strength and positioning of the Divestiture Products at the High Volume Accounts;

5. making available for use by the Divestiture Product Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such business, including the Divestiture Assets;
 6. providing the Divestiture Product Businesses with such funds as are necessary to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses; and
 7. providing such support services to the Divestiture Product Businesses as were being provided to these businesses by Respondents as of the date the Consent Agreement was signed by Respondents.
- C. Respondents shall maintain a work force at least as equivalent in size, training, and expertise to what has been associated with the Divestiture Products for the relevant Divestiture Product's most recent Pre-Acquisition Marketing Plan.
- D. Until the Closing Date for each respective set of Divestiture Assets, Respondents shall provide all the related Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, and manufacture the relevant Divestiture Products consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of such Divestiture Products pending divestiture and to ensure successful execution of the Pre-Acquisition Marketing Plans related to the relevant Divestiture Products. Such incentives shall include a continuation of all employee benefits offered by Respondents until the Closing Date for the divestiture of the respective Divestiture Assets has occurred, including regularly scheduled raises, bonuses, vesting of pension benefits (as permitted by Law), and additional incentives as may be necessary to prevent any diminution of the relevant Divestiture Product's competitiveness.
- E. Respondents shall:
1. for a period of at least six (6) months from the relevant Closing Date, provide the relevant Acquirer with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by such Acquirer. Each of these periods is hereinafter referred to as the "Divestiture Product Core Employee Access Period(s)"; and
 2. not later than the earlier of the following dates: (1) ten (10) days after notice by staff of the Commission to Respondents to provide the Product Employee Information; or (2) ten (10) days after the relevant Closing Date, provide the relevant Acquirer or the relevant Proposed Acquirer with the Product Employee Information related to the relevant Divestiture Product Core Employees. Failure by Respondents to provide the Product Employee Information for any Divestiture Product Core Employee within the time

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

3. during the Divestiture Product Core Employee Access Period, not interfere with the hiring or employing by the relevant Acquirer of Divestiture Product Core Employees, and shall remove any impediments within the control of Respondents that may deter these employees from accepting employment with such Acquirer, including, but not limited to, any noncompete provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by such Acquirer. In addition, Respondents shall not make any counteroffer to a Divestiture Product Core Employee who receives 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 I.E.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.

F. Pending divestiture of the relevant Divestiture Assets, Respondents shall:

1. 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 the Orders;
 - b. Respondents' obligations to the Acquirer under the terms of any Remedial Agreement related to relevant Divestiture Product(s); or
 - c. applicable Law;
2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any person except the relevant Acquirer or other persons specifically authorized by the Acquirer to receive such information;
3. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the relevant Divestiture Products to the employees associated with business related to those Retained Products that are approved by the FDA for the same or similar indications or purposes as the relevant Divestiture Products; and

4. institute procedures and requirements to ensure that the above-described employees:

- a. do not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Order to Maintain Assets; and
- b. do not solicit, access or use any Confidential Business Information that they are prohibited under this Order to Maintain Assets from receiving for any reason or purpose.

G. Not later than thirty (30) days after the Effective Date, Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to the Divestiture Products by Respondents' personnel to all of Respondents' employees who:

1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of each of the relevant Divestiture Products;
2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that are approved by the FDA for the same or similar indications as each of the relevant Divestiture Products prior to the Acquisition, and or that contain the same active pharmaceutical ingredient as the relevant Divestiture Products; and/or
3. may have Confidential Business Information related to the Divestiture Products.

Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the relevant Closing Date. Respondents shall provide a copy of such notification to the Acquirer. Respondents shall maintain complete records of all such agreements at Respondent Mylan's headquarters address 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.

H. Respondents shall adhere to and abide by the Remedial Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of the Orders, it being understood that the Orders shall not be construed to reduce any obligations of Respondents under such agreement(s)), which are incorporated by reference into this Order to Maintain Assets and made a part hereof.

I. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses through their respective transfer to the Acquirer(s), to minimize any risk of loss of competitive potential

for the Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Assets except for ordinary wear and tear.

III.

IT IS FURTHER ORDERED that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint an Interim Monitor to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by the Orders and the Remedial Agreements. The Commission may appoint one or more Interim Monitors to assure Respondents' compliance with the requirements of the Orders, and the related 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 Monitor within ten (10) days after notice by the staff of the Commission to Respondent Mylan 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, Respondent Mylan 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 Orders in a manner consistent with the purposes of the Orders.
- D. If one or more Interim Monitors are appointed pursuant to this Paragraph or pursuant to the relevant provisions of the Decision and Order in this matter, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of each 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 Orders, 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 Orders and in consultation with the Commission;

2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission;

3. The Interim Monitor shall serve until the date of completion by Respondents of the divestiture of all Divestiture Assets and the transfer of the Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and until the earliest of:

- (1) with respect to each Divestiture Product, 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) with respect to each Divestiture Product, 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) with respect to each Divestiture Product, 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;

provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders;

provided, further, that, with respect to each Divestiture Product, the Interim Monitor's service shall not exceed five (5) years from the Closing Date on the Remedial Agreement to Contract Manufacture such Divestiture Product.

E. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with their obligations under the Orders, including, but not limited to, their obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Orders.

F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and

responsibilities.

- G. 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 misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
- H. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order to Maintain Assets and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by the Acquirer with respect to the performance of Respondents' obligations under the Orders or the Remedial Agreement(s). Within one (1) month 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 Orders.
- I. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement;

provided, however, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- J. 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.
- K. 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 or the relevant provisions of the Decision and Order in this matter.
- L. 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 Orders.

- M. The Interim Monitor appointed pursuant to this Order to Maintain Assets or the relevant provisions of the Decision and Order in this matter may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets becomes final, and every thirty (30) days thereafter until Respondents have fully complied with their obligations to assign, grant, license, divest, transfer, deliver or otherwise convey relevant assets as required by Paragraph II.A., II.B., and II.C. of the related Decision and Order in this matter, 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 to Maintain Assets and the related Decision and Order; *provided, however,* that, after the Decision and Order in this matter becomes final, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondents pursuant to Paragraph VI of the Decision and Order.

V.

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 the Order.

VI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order to Maintain Assets, 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 headquarter's address, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of such Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondent related to compliance with this Order, which copying services shall be provided by Respondent at the request authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of such Respondent, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on the earlier of:

- A. Three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. The latter of:
 - 1. The day after the divestiture of all of the Divestiture Assets, as required by and described in the Decision and Order, has been completed and each Interim Monitor, in consultation with Commission staff and the Acquirer(s), notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers and other transitions related to such divestitures are complete, or the Commission otherwise directs that this Order to Maintain Assets is terminated; or
 - 2. the day the related Decision and Order becomes final.

By the Commission.

Donald S. Clark
Secretary

SEAL
ISSUED: September 26, 2007

**PUBLIC
APPENDIX A
TO THE ORDER TO MAINTAIN ASSETS
AGREEMENT CONTAINING CONSENT ORDER
AND
PROPOSED DECISION AND ORDER**