

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

In the Matter of)	
)	
HIKMA PHARMACEUTICALS PLC,)	Docket No. C-4320
a corporation.)	
)	

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Hikma Pharmaceuticals PLC (“Hikma”) of certain assets relating to the business of generic injectable pharmaceutical products of Baxter Healthcare Corporation (“Baxter”), and Respondent 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 Respondent 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

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent 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 Respondent 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 Hikma is a corporation organized, existing and doing business under and by virtue of the laws of England and Wales, with its headquarters address at 13 Hanover Square, London W1S 1HW, United Kingdom and the address of its United States subsidiary, West-Ward Pharmaceutical Corporation, located at 465 Industrial Way West, Eatontown, New Jersey 07724-2209.
2. Baxter is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at One Baxter Parkway, Deerfield, Illinois 60015-4633.
3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, 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 and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. “Hikma” or “Respondent” means Hikma Pharmaceuticals PLC, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Hikma (including, but not limited to, West-Ward Pharmaceutical Corporation and Hikma (Maple) Limited), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Baxter” means Baxter Healthcare Corporation, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Baxter (including, but not limited to, Baxter International, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Commission” means the Federal Trade Commission.
- D. “Decision and Order” means the:
 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
 2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission in this matter.

- E. “Divestiture Assets” means the Generic Injectable Product Assets, as defined in the Decision and Order.
- F. “Divestiture Product Business(es)” means the business of the Respondent 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, without limitation, the Divestiture Assets.
- G. “Divestiture Product Core Employees” means the Generic Injectable Product Core Employees, as defined in the Decision and Order.
- H. “Divestiture Products” means the Generic Injectable Products, as defined in the Decision and Order
- I. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- J. “Orders” means the Decision and Order and this Order to Maintain Assets.

II.

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

- A. Until Respondent fully transfers and delivers each of the respective Divestiture Assets to an Acquirer, Respondent shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of each of the related Divestiture Product Businesses, to minimize any risk of loss of competitive potential for such Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of such Divestiture Product Businesses except for ordinary wear and tear. Respondent shall not sell, transfer, encumber or otherwise impair such 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 related Divestiture Product Businesses.
- B. Until Respondent fully transfers and delivers each of the respective Divestiture Assets to an Acquirer, Respondent shall maintain the operations of the related 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 business) and/or as may be necessary to preserve the marketability, viability, and competitiveness of such Divestiture Product Businesses and shall use their best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; the High Volume Accounts; customers; Agencies; employees; and others having business relations with each

of the respective Divestiture Product Businesses. Respondent's responsibilities shall include, but are not limited to, the following:

1. providing each of the respective 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 business and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for such Divestiture Product Business;
 2. continuing, at least at their scheduled pace, any additional expenditures for each of the respective Divestiture Product Businesses authorized prior to the date the Consent Agreement was signed by Respondent including, but not limited to, all research, Development, manufacturing, distribution, marketing and sales expenditures;
 3. providing such resources as may be necessary to respond to competition against each of the Divestiture Products and/or to prevent any diminution in sales of each of the Divestiture Products during and after the Acquisition process and prior to the complete transfer and delivery of the related Divestiture Assets to an Acquirer;
 4. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Divestiture Products at the related High Volume Accounts;
 5. making available for use by each of the respective 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 without limitation, the Divestiture Assets;
 6. providing each of the respective Divestiture Product Businesses with such funds as are necessary to maintain the full economic viability, marketability and competitiveness of such Divestiture Product Business; and
 7. providing such support services to each of the respective Divestiture Product Businesses as were being provided to such business by Respondent as of the date the Consent Agreement was signed by Respondent.
- C. Until Respondent fully transfers and delivers the Divestiture Assets to the Acquirer, Respondent 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 last fiscal year.
- D. Until the Closing Date for the Divestiture Assets, Respondent 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 as may be necessary to preserve the marketability, viability and competitiveness of such Divestiture Products pending divestiture. Such incentives shall include a continuation of all employee benefits offered by Respondent until the Closing Date

for the divestiture of the 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. Respondent shall:

1. for each Divestiture Product, for a period of six (6) months from the Closing Date or upon the hiring of twenty (20) Divestiture Product Core Employees by the Acquirer, whichever occurs earlier, provide the 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)";
2. not later than the earlier of the following dates: (1) ten (10) days after notice by staff of the Commission to Respondent to provide the Product Employee Information; or (2) ten (10) days after written request by an Acquirer, provide such Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by Respondent 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 Employee Access Period, not interfere with the hiring or employing by the Acquirer of Divestiture Product Core Employees, and shall remove any impediments within the control of Respondent 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 Respondent that would affect the ability or incentive of those individuals to be employed by such Acquirer. In addition, Respondent shall not make any counteroffer to a Divestiture Product Core Employee who receives a written offer of employment from the Acquirer;

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

F. Pending divestiture of the Divestiture Assets, Respondent shall:

1. 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 particular Generic Injectable Product under the terms of any Remedial Agreement related to such Generic Injectable Product; or
 - c. applicable Law;
 - 2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except the Acquirer or other Persons specifically authorized by such 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 Generic Injectable Products to the employees associated with business related to those Retained Products that contain the same active pharmaceutical ingredient as the Generic Injectable 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 from receiving for any reason or purpose.
- G. Not later than thirty (30) days from the earlier of the Closing Date or the date that this Order to Maintain Assets becomes final and effective, Respondent shall provide to all of Respondent's employees and other personnel who may have access to Confidential Business Information related to the Divestiture Products notification of the restrictions on the use of such information by Respondent's personnel. Respondent shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondent shall provide a copy of such notification to the Acquirer. Respondent shall maintain complete records of all such agreements at Respondent's registered office within the United States and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondent shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.
- H. Respondent shall monitor the implementation by its employees and other personnel of all applicable restrictions, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets. Respondent shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondent's employees and other personnel.

- I. Respondent shall adhere to and abide by the Remedial Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of the Orders, it being understood that nothing in the Orders shall be construed to reduce any obligations of Respondent to the Acquirer under such agreement(s)), which are incorporated by reference into this Order to Maintain Assets and made a part hereof.
- J. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses within the Geographic Territory through their full transfer and delivery to an Acquirer, to minimize any risk of loss of competitive potential for the Divestiture Product Businesses within the Geographic Territory, 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 Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor (“Interim Monitor”) to assure that Respondent expeditiously complies with all of its obligations and perform all of its responsibilities as required by the Orders and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent 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 of the identity of any proposed Interim Monitor, Respondent 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 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 Respondent’s compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. If an Interim Monitor is appointed, Respondent 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 Respondent’s 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 Respondent of the divestiture of all Generic Injectable Product Assets and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of the Decision and Order and until the earliest of:
 - a. with respect to each Generic Injectable Product, the date the Acquirer (or its Designee(s)) is approved by the FDA to manufacture such Generic Injectable Product and able to manufacture such Generic Injectable Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent and Baxter;
 - b. with respect to each Generic Injectable Product, the date the Acquirer notifies the Commission and the Respondent of its intention to abandon its efforts to manufacture such Generic Injectable Product; or
 - c. with respect to each Generic Injectable Product, the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture such Generic Injectable Product;

provided, however, that, with respect to each Generic Injectable Product, the Interim Monitor's service shall not exceed five (5) years from the Order Date;

provided, further, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.
4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Order, including, but not limited to, its obligations related to the relevant assets. Respondent 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 Respondent's compliance with the Order.
5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, 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 Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.

6. Respondent 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. Respondent shall report to the Interim Monitor in accordance with the requirements of this Orders 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 Respondent of its obligations under the Order;

provided, however, beginning one hundred twenty (120) days after Respondent has filed its final report pursuant to Paragraph VIII.B. of the Decision and Order, and every one hundred twenty (120) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by the Acquirer toward obtaining FDA approval to manufacture each Generic Injectable Product and obtaining the ability to manufacture each Generic Injectable Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent and Baxter.
8. 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 Orders.

- H. The Interim Monitor appointed pursuant to this Order to Maintain Assets 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 effective, and every thirty (30) days thereafter until Respondent has fully complied with their obligations to assign, grant, license, divest, transfer, deliver or otherwise convey relevant assets as required by Paragraph II.A. of the related Decision and Order in this matter, Respondent 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 and effective, 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 Respondent pursuant to Paragraph VIII of the Decision and Order.

V.

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

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

VI.

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

- A. access, during business office hours of such Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of

such Respondent related to compliance with this Order, which copying services shall be provided by such Respondent at the request of the authorized representative(s) of the Commission and at the expense of such Respondent; and

- B. to interview officers, directors, or employees of such Respondent, who may have counsel present, regarding such matters.

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 later 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 the 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 after the day the related Decision and Order becomes final and effective.

By the Commission.

Donald S. Clark
Secretary

SEAL
ISSUED: April 25, 2011