

Complaint

IN THE MATTER OF

**VALEANT PHARMACEUTICALS
INTERNATIONAL, INC.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT*Docket No. C-4342; File No. 111 0215**Complaint, December 9, 2011 – Decision, February 21, 2012*

This consent order addresses the \$425 million acquisition by Valeant Pharmaceuticals International, Inc. of certain assets of Sanofi. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the FTC Act by significantly reducing competition in the markets for BenzaClin and topical fluorouracil cream. The consent order requires Valeant to (1) divest all rights and assets related to generic BenzaClin, and (2) grant a perpetual, unrestricted license for the authorized generic of Efudex.

Participants

For the *Commission*: *Jacqueline K. Mendel, Catherine M. Sanchez, and David Von Nirschl.*

For the *Respondent*: *Michael Buchwald, Maria Raptis and Steven C. Sunshine, Skadden, Arps, Meagher & Flom LLP.*

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Valeant Pharmaceuticals International, Inc. (“Respondent”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire certain assets from Sanofi, a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

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I. RESPONDENT

1. Respondent is a corporation organized, existing, and doing business under and by virtue of the laws of Canada, with its headquarters address at 7150 Mississauga Road, Mississauga, Ontario L5N 8M5 Canada. Respondent has offices in the United States at 14 Main Street, Suite 140, Madison, NJ 07940 and 700 Route 202/206, Bridgewater, NJ 08807, as well as locations in Irvine, CA, Petaluma, CA, Chantilly, VA and Durham, NC. Respondent develops, manufactures and markets branded, generic and over-the-counter (“OTC”) pharmaceutical products, with an emphasis on dermatologic and neurologic therapeutic areas. Respondent employs approximately 3700 employees worldwide and had worldwide 2010 revenues of \$1.1 billion, the majority of which derived from U.S. sales.

2. Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED ACQUISITION

3. Pursuant to an Asset Purchase Agreement (“the Acquisition Agreement”) dated July 8, 2011, Respondent proposes to acquire certain assets of Sanofi’s dermatology unit, Dermik, in a transaction valued at approximately \$425 million (“the Acquisition”).

III. THE RELEVANT MARKETS

4. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the manufacture and sale of:

- a. BenzaClin; and
- b. Topical fluorouracil cream (“topical 5FU”).

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5. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant lines of commerce.

IV. THE STRUCTURE OF THE MARKETS

6. Sanofi's Dermik unit manufactures and markets BenzaClin, a topical pharmaceutical product used to treat acne vulgaris, commonly known as acne. Respondent owns the only Abbreviated New Drug Application ("ANDA") for the generic version of BenzaClin, which it licenses to Mylan, Inc. ("Mylan"). Pursuant to this licensing agreement, Mylan sells the only generic of BenzaClin and Respondent receives royalties from those sales. Currently Dermik's BenzaClin sales account for approximately 50 per cent of unit sales in the BenzaClin market, while Mylan's generic version accounts for the other approximate 50 per cent. The Acquisition would create a monopoly in this market.

7. Topical 5FU products are used to treat actinic keratosis, a pre-cancerous lesion that can result from years of repeated sun exposure. There are three branded topical 5FUs currently on the market: (1) Respondent's Efudex; (2) Dermik's Carac; and (3) Allergan, Inc.'s Fluoroplex. Two generic companies, Spear Pharmaceuticals and Taro Pharmaceuticals U.S.A., Inc., market generic equivalents of Efudex, and Respondent also markets an authorized generic of the drug. Efudex sales have been almost completely displaced by sales of the three generic versions of the drug. Branded Carac is priced directly against the three generics of branded Efudex. Post-acquisition, Respondent's market share in the topical 5FU market would be over 50 per cent.

V. ENTRY CONDITIONS

8. Entry into the relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Entry would not take place in a timely manner because the combination of topical drug development times and U.S. Food and Drug Administration approval requirements take more than two years. Furthermore, entry would not be likely because the markets are relatively small, so the limited sales opportunities available to a

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new entrant would likely be insufficient to justify the time and investment necessary to enter.

VI. EFFECTS OF THE ACQUISITION

9. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. by eliminating actual, direct, and substantial competition between Respondent and Sanofi and creating a monopoly in the market for BenzaClin thereby: (1) increasing the likelihood that Respondent will be able to exercise unilaterally market power in this market; and (2) increasing the likelihood that customers would be forced to pay higher prices; and
- b. by eliminating actual, direct, and substantial competition between Respondent and Sanofi in the market for topical 5FUs and reducing the number of competitors in the market for topical 5FUs thereby: (1) increasing the likelihood that Respondent will be able to exercise unilaterally market power in this market; and (2) increasing the likelihood that customers would be forced to pay higher prices.

VII. VIOLATIONS CHARGED

10. The Acquisition Agreement described in Paragraph 3 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

11. The Acquisition described in Paragraph 3, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this ninth day of December, 2011, issues its Complaint against said Respondent.

Order to Maintain Assets

By the Commission.

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Valeant Pharmaceuticals International, Inc. (“Respondent”) of the assets relating to the business of Sanofi’s dermatology unit, Dermik, 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:

Order to Maintain Assets

1. Respondent Valeant is a corporation organized, existing and doing business under and by virtue of the laws of Canada, with its corporate head office and principal place of business located at 7150 Mississauga Road, Mississauga, Ontario L5N 8M5, Canada.
2. Sanofi is a corporation organized, existing and doing business under and by virtue of the laws of the French Republic, with its global headquarters located at 174 Avenue de France, 75013 Paris, France and the address of its United States subsidiary, Sanofi-Aventis US LLC, located at 55 Corporate Drive, Bridgewater, New Jersey 08807.
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. “Valeant” or “Respondent” means Valeant Pharmaceuticals International Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Valeant, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Commission” means the Federal Trade Commission.

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- C. “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.
- D. “Divestiture Assets” means the Clindamycin-Benzoyl Peroxide Product Assets and the Fluorouracil Product Assets, as defined in the Decision and Order.
- E. “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.
- F. “Divestiture Products” means the Clindamycin-Benzoyl Products and the Fluorouracil Products, individually and collectively, as defined in the Decision and Order.
- G. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- H. “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:

Order to Maintain Assets

- 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 its 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

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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

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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. 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 Clindamycin-Benzoyl Peroxide 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 the Clindamycin-Benzoyl Peroxide Products under the terms of any related Remedial Agreement; or
 - c. applicable Law;
 - 2. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except the Acquirer of the Clindamycin-Benzoyl Peroxide Products or other Persons specifically authorized by that Acquirer to receive such information; and
 - 3. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the the Clindamycin-Benzoyl Peroxide Products to the employees associated with business related to those Retained Products that contain the same

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active pharmaceutical ingredient as the
Clindamycin-Benzoyl Peroxide Products.

- E. 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.
- F. 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.
- G. During the term of any agreement to Contract Manufacture between the Respondent and an Acquirer, Respondent shall take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s), including, without limitation, such actions as are necessary to ensure the production of the Build-Up Inventory.

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- H. 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.
- I. 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 performs 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.

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- 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 the Respondent of the divestiture of all Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and until the earliest of:
 - a. with respect to the Fluorouracil Products, the date the Acquirer of the Fluorouracil Products (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell the Fluorouracil Products and able to manufacture the Fluorouracil Products in commercial quantities, in a manner consistent with cGMP, independently of the Respondent;

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- b. with respect to the Fluorouracil Products, the date the Acquirer of the Fluorouracil Products notifies the Commission and the Respondent of its intention to abandon its efforts to manufacture the Fluorouracil Products; or
- c. with respect to the Fluorouracil Products, 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 the Fluorouracil Products;

provided, however, that, with respect to the Fluorouracil Products, 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 Orders, 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 Orders.
- 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

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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 the 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 Orders 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 Orders.
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

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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 its obligations to assign, grant, license, divest, transfer, deliver or otherwise convey relevant assets as required by Paragraph II.A. and II.B. 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

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with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondent pursuant to Paragraph VII 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 the Respondent;
- B. any proposed acquisition, merger or consolidation of the Respondent; or
- C. any other change in the 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 the Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, the Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of the 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 the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and

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- B. to interview officers, directors, or employees of the 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.

Decision and Order

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Valeant Pharmaceuticals International, Inc. (“Respondent”) of the assets relating to the business of Sanofi’s dermatology unit, Dermik, 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 that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having modified the Decision and Order in certain respects, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Valeant is a corporation organized, existing and doing business under and by virtue of the

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laws of Canada, with its corporate head office and principal place of business located at 7150 Mississauga Road, Mississauga, Ontario L5N 8M5, Canada.

2. Sanofi is a corporation organized, existing and doing business under and by virtue of the laws of the French Republic, with its global headquarters located at 174 Avenue de France, 75013 Paris, France and the address of its United States subsidiary, Sanofi-Aventis US LLC, located at 55 Corporate Drive, Bridgewater, New Jersey 08807.
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 the Order, the following definitions shall apply:

- A. “Valeant” or “Respondent” means Valeant Pharmaceuticals International Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Valeant, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Commission” means the Federal Trade Commission.
- C. “Acquirer(s)” means the following:
 1. a Person specified by name in this Order to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to

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accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective; or

2. a Person approved by the Commission to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- D. "Acquisition" means Respondent's acquisition of the assets relating to Sanofi's dermatology unit, Dermik. The acquisition is contemplated pursuant to an Asset Purchase Agreement among Sanofi, Valeant International (Barbados) SRL and Valeant Pharmaceuticals International, Inc., dated as of July 8, 2011, submitted to the Commission.
- E. "Acquisition Date" means the date on which the Acquisition is consummated.
- F. "Agency(ies)" means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term "Agency" includes, without limitation, the United States Food and Drug Administration ("FDA").
- G. "Application(s)" means all of the following: "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug Application" ("SNDAs"), or "Marketing Authorization Application" ("MAA"), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between the Respondent and the FDA related thereto. The term "Application" also includes an "Investigational New Drug Application" ("IND")

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filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between the Respondent and the FDA related thereto.

- H. “Build-Up Inventory” has the meaning set forth in Appendix II. The purpose of the Build Up Inventory is to ensure that there is a sufficient number of units of saleable inventory of a Contract Manufacture Product available to supply the Acquirer with all of the Acquirer’s requirements of the Contract Manufacture Products until the earlier of the following dates:
1. the date the Respondent establishes a facility (other than the Legacy Facility) that is approved by the FDA to manufacture each of the Contract Manufacture Products in finished form (*i.e.*, suitable for sale to the ultimate customer/patient) and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP for the purposes of sale within the United States; or
 2. the date the Acquirer of that Contract Manufacture Product (or the Manufacturing Designee(s) of that Acquirer), respectively, is approved by the FDA to manufacture each of the Contract Manufacture Products in finished form (*i.e.*, suitable for sale to the ultimate customer/patient) and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP for the purposes of sale within the United States, independently of Respondent.
- I. “Categorized Assets” means, for each specified Divestiture Product, all of Respondent Valeant’s rights, title and interest in and to all assets related to Respondent Valeant’s business within the Geographic Territory related to the Divestiture Product to the extent legally transferable, including the research,

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Development, manufacture, distribution, marketing, and sale of the Divestiture Product, including, without limitation, the following:

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

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Retained Product (including the right to receive notification from the Respondent of any such cross-referencing that is discovered by Respondent);

- d. to seek cross-referencing from a customer of the Respondent's NDC Numbers related to such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;
 - e. to approve the timing of Respondent's discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the Acquisition Date and *except* as may be required by applicable Law; and
 - f. to approve any notification(s) from Respondent to any customer(s) regarding the use or discontinued use of such NDC numbers by the Respondent prior to such notification(s) being disseminated to the customer(s);
 - g. all rights to all of the Respondent's Applications related to the specified Divestiture Product;
- 8. all Product Development Reports related to the specified Divestiture Product;
 - 9. at the option of the Acquirer of the specified Divestiture Product, all Product Assumed Contracts related to the specified Divestiture Product (copies to be provided to that Acquirer on or before the Closing Date);
 - 10. all patient registries related to the specified Divestiture Product, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and

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identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the specified Divestiture Product;

11. a list of all customers and targeted customers for the specified Divestiture Product and a listing of the net sales (in either units or dollars) of the specified Divestiture Product to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of the specified Divestiture Product on behalf of the High Volume Account and his or her business contact information;
12. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to the specified Divestiture Product;
13. copies of all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date, to be provided to the Acquirer of the specified Divestiture Product not later than five (5) days after the Closing Date;
14. at the option of the Acquirer of the specified Divestiture Product, all unfilled customer purchase orders for the specified Divestiture Product; and
15. all of the Respondent's books, records, and files directly related to the foregoing;

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provided, however, that “Categorized Assets” shall not include: (1) documents relating to the Respondent’s general business strategies or practices relating to research, Development, manufacture, marketing or sales of generic pharmaceutical Products, where such documents do not discuss with particularity the specified Divestiture Product; (2) administrative, financial, and accounting records; (3) quality control records that are determined not to be material to the manufacture of the specified Divestiture Product by the Interim Monitor or the Acquirer of the specified Divestiture Product; (4) formulas used to determine the final pricing of any Divestiture Product and/or Retained Products to customers and competitively sensitive pricing information that is exclusively related to the Retained Products; (5) any real estate and the buildings and other permanent structures located on such real estate; and (6) all Product Licensed Intellectual Property;

provided further, however, that in cases in which documents or other materials included in the assets to be divested contain information: (1) that relates both to the specified Divestiture Product and to Retained Products or businesses of the Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Divestiture Product; or (2) for which the Respondent has a legal obligation to retain the original copies, the Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the specified Divestiture Product, the Respondent shall provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that the Respondent provides the Acquirer with the above-described information without requiring the

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Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

- J. “cGMP” means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.
- K. “Clinical Trial(s)” means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.
- L. “Clindamycin-Benzoyl Peroxide Products” means the following: all Products in Development, manufactured, marketed, sold, owned or controlled by Respondent Valeant pursuant to ANDA No. 065443, and any supplements, amendments, or revisions thereto.
- M. “Clindamycin-Benzoyl Peroxide Product Assets” means all of Respondent Valeant’s rights, title and interest in and to all assets related to Respondent Valeant’s business within the Geographic Territory related to each of the respective Clindamycin-Benzoyl Peroxide Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of each such Clindamycin-Benzoyl Peroxide Product, including, without limitation, the Categorized Assets related to the Clindamycin-Benzoyl Peroxide Products.
- N. “Clindamycin-Benzoyl Peroxide Product Divestiture Agreements” means “Asset Purchase Agreement” between Valeant Pharmaceuticals International, Valeant Pharmaceuticals North America, LLC, Mylan Pharmaceuticals Inc. and solely for the purposes set forth herein Dow Pharmaceutical Sciences, Inc., dated as of November 28, 2011, and all amendments,

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exhibits, attachments, agreements, and schedules thereto; related to the Clindamycin-Benzoyl Peroxide Product Assets that have been approved by the Commission to accomplish the requirements of this Order, including the “First Amendment To Asset Purchase Agreement,” dated as of February 3, 2012.

- O. “Closing Date” means, as to each Divestiture Product, the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.
- P. “Confidential Business Information” means all information owned by, or in the possession or control of, the Respondent that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support, or use of each of the Divestiture Products;

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

- a. information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by the Respondent;
- b. information that is required by Law to be publicly disclosed;
- c. information relating to the Respondent’s general business strategies or practices relating to research, Development, manufacture, marketing, or sales of Products that does not discuss with particularity the Divestiture Products;

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- d. information specifically excluded from the Divestiture Product Assets;
- e. all intellectual property licensed on a non-exclusive basis to the Acquirer of the specified Divestiture Product; and
- f. information that is protected by the attorney work product, attorney-client, joint defense or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.

Q. “Contract Manufacture” means:

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

R. “Contract Manufacture Product(s)” means the Fluorouracil Products; and/or

any ingredient or component of any of the Fluorouracil Products;

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

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- S. “Development” means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.
- T. “Direct Cost” means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of the Respondent’s employees’ labor shall not exceed the average hourly wage rate for such employee;
- provided, however, in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, “Direct Cost” means such cost as is provided in such Remedial Agreement for that Divestiture Product.*
- U. “Divestiture Agreements” means the Clindamycin-Benzoyl Peroxide Product Divestiture Agreements and the Fluorouracil Product Divestiture Agreements, individually and collectively. The Divestiture Agreements are attached to this Order and contained in non-public Appendix I.
- V. “Divestiture Product License” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s)

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with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, or controlled by Respondent Valeant prior to the Acquisition:

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

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

- W. “Divestiture Products” means the Clindamycin-Benzoyl Peroxide Products and the Fluorouracil Products, individually and collectively.
- X. “Divestiture Product Assets” means the Clindamycin-Benzoyl Peroxide Product Assets and the Fluorouracil Product Assets, individually and collectively.
- Y. “Divestiture Product Releasee(s)” means the following Persons:

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1. the Acquirer for the assets related to a particular Divestiture Product;
 2. any Person controlled by or under common control with that Acquirer; and
 3. any Manufacturing Designees, licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.
- Z. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- AA. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration. “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- BB. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- CC. “Fluorouracil Product(s)” means the following: all Products in Development, manufactured, marketed or sold by Respondent Valeant pursuant to NDA No. 016831, and any supplements, amendments, or revisions thereto.
- DD. “Fluorouracil Product Assets” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) with rights to sublicense to all of Respondent Valeant’s rights, title and interest in and to all assets related to Respondent Valeant’s business within the Geographic Territory related to each of the respective Fluorouracil Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of each such

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Fluorouracil Product, including, without limitation, a perpetual, non-exclusive, fully paid-up and royalty-free license(s) with rights to sublicense to the Categorized Assets related to the Fluorouracil Products, and an unlimited and unrestricted Right of Reference or Use to the Drug Master Files related to NDA 016831; *provided however*, “Fluorouracil Product Assets” excludes all rights to the Efudex[®] trademark.

EE. “Fluorouracil Product Divestiture Agreements” means, the following agreements:

1. “Asset Purchase Agreement” between Valeant Pharmaceuticals International, Valeant Pharmaceuticals North America, LLC, Mylan Pharmaceuticals Inc. and solely for the purposes set forth herein Dow Pharmaceutical Sciences, Inc., dated as of November 28, 2011; and
2. “Supply Agreement” between Mylan Pharmaceuticals Inc. and Valeant Pharmaceuticals International, Inc., as entered into as of February 3, 2012; and

all amendments, exhibits, attachments, agreements, and schedules thereto; related to the Fluorouracil Product Assets that have been approved by the Commission to accomplish the requirements of this Order, including the “First Amendment To Asset Purchase Agreement,” dated as of February 3, 2012.

FF. “Geographic Territory” shall mean the United States of America, including all of its territories and possessions, unless otherwise specified.

GG. “Government Entity” means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.

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- HH. “High Volume Account(s)” means any retailer, wholesaler or distributor whose annual or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States of America from the Respondent was, or is projected to be among the top twenty highest of such purchase amounts by the Respondent’s U.S. customers on any of the following dates: (1) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (2) the end of the last quarter that immediately preceded the Acquisition Date; (3) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or (4) the end of the last quarter following the Acquisition or the Closing Date.
- II. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- JJ. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- KK. “Legacy Facility” means the facility operated by Legacy Pharmaceuticals Puerto Rico, LLC, that supplies Fluorouracil Products and Efudex to Respondent.
- LL. “Manufacturing Designee” means any Person other than the Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- MM. “Mylan” means Mylan Laboratories Inc., 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.

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- NN. “NDC Numbers” means the National Drug Code numbers, including both the labeler code assigned by the FDA and the additional numbers assigned by an Application holder as a product code for a specific Product.
- OO. “Order Date” means the date on which this Decision and Order becomes final and effective.
- PP. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- QQ. “Patent(s)” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case existing as of the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any Product of or owned by the Respondent as of the Closing Date (*except* where this Order specifies a different time).
- RR. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- SS. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.
- TT. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents,

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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.

UU. “Product Assumed Contracts” means all of the following contracts or agreements (copies of each such contract to be provided to the Acquirer on or before the Closing Date and segregated in a manner that clearly identifies the purpose(s) of each such contract):

1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from the Respondent unless such contract applies generally to the Respondent’s sales of Products to that Third Party;
2. pursuant to which the Respondent purchases the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party for use in connection with the manufacture of the specified Divestiture Product;
3. relating to any Clinical Trials involving the specified Divestiture Product;
4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;

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5. relating to the particularized marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
6. pursuant to which a Third Party manufactures the specified Divestiture Product on behalf of the Respondent;
7. pursuant to which a Third Party provides any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of the specified Divestiture Product on behalf of Respondent;
8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to the Respondent;
9. pursuant to which a Third Party is licensed by the Respondent to use the Product Manufacturing Technology;
10. constituting confidentiality agreements involving the specified Divestiture Product;
11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;
12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the specified Divestiture Product to the Respondent including, but not limited to, consultation arrangements; and/or
13. pursuant to which any Third Party collaborates with the Respondent in the performance of research, Development, marketing, distribution or selling of the specified Divestiture Product or the business related to such Divestiture Product;

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

- VV. “Product Copyrights” means rights to all original works of authorship of any kind directly related to the specified Divestiture Product and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and educational materials for the sales force; copyrights in all preclinical, clinical and process development data and reports relating to the research and Development of such Divestiture Product or of any materials used in the research, Development, manufacture, marketing or sale of such Divestiture Product, including all copyrights in raw data relating to Clinical Trials of such Divestiture Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, the specified Divestiture Product sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees who accept employment with the Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing

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processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to such Divestiture Product or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA.

WW. “Product Development Reports” means:

1. Pharmacokinetic study reports related to the specified Divestiture Product;
2. Bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product;
3. Bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product;
4. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from or otherwise conducted with the FDA relating to the Application(s) related to the specified Divestiture Product;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to the specified Divestiture Product;
7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Divestiture Product;

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8. FDA approved patient circulars and information related to the specified Divestiture Product;
9. adverse event reports, adverse experience information, descriptions of material events and matters concerning safety or lack of efficacy related to the specified Divestiture Product;
10. summary of Product complaints from physicians related to the specified Divestiture Product;
11. summary of Product complaints from customers related to the specified Divestiture Product;
12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;
14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including without limitation, identification and sources of impurities;
15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of the specified Divestiture Product;
16. analytical methods development records related to the specified Divestiture Product;

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17. manufacturing batch records related to the specified Divestiture Product;
 18. stability testing records related to the specified Divestiture Product;
 19. change in control history related to the specified Divestiture Product; and
 20. executed validation and qualification protocols and reports related to the specified Divestiture Product.
- XX. “Product Intellectual Property” means all of the following related to a Divestiture Product (other than Product Licensed Intellectual Property):
1. Patents;
 2. Product Copyrights;
 3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and
 4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof and to bring suit against a Third Party for the past, present or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing;
- provided, however, “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Valeant”, or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondent or the related corporate logos thereof, or general registered images or symbols by which Valeant can be identified or defined.*
- YY. “Product Licensed Intellectual Property” means the following:

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

ZZ. “Product Manufacturing Technology” means:

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of the specified Divestiture Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;

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2. all active pharmaceutical ingredients related to the specified Divestiture Product; and,
3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer's option, all such equipment used to manufacture the specified Divestiture Product.

AAA. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the specified Divestiture Product.

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

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

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associated therewith, for the specified Divestiture Product(s);

provided, however, “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Valeant”, or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondent or the related corporate logos thereof, or general registered images or symbols by which Valeant can be identified or defined.

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

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

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

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agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;

3. any agreement between the Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement by the Respondent to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or
4. any agreement between the Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

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

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

HHH. "Supply Cost" means a cost not to exceed the manufacturer's average direct per unit cost in United

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States dollars of manufacturing the specified Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date. “Supply Cost” shall expressly exclude any intracompany business transfer profit; *provided, however*, that in each instance where: (1) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, “Supply Cost” means the cost as specified in such Remedial Agreement for that Divestiture Product.

- III. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*,
- a. designating employees knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;
 - b. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product that are acceptable to the Acquirer;
 - c. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all

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such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee; and

- d. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:
 - i. manufacture the specified Divestiture Product in the quality and quantities achieved by the Respondent, or the manufacturer and/or developer of such Divestiture Product;
 - ii. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell the specified Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and
 - iii. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product.

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

KKK. “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 the Respondent; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by the Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that the Respondent

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can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

II.**IT IS FURTHER ORDERED** that:

- A. Not later than the earlier of: (i) ten (10) days after the Acquisition Date or (ii) ten (10) days after the Order Date, Respondent shall divest the Clindamycin-Benzoyl Peroxide Product Assets (to the extent that such assets are not already owned, controlled or in the possession of Mylan) and grant the related Divestiture Product License, absolutely and in good faith, to Mylan pursuant to, and in accordance with, the Clindamycin-Benzoyl Peroxide Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Mylan or to reduce any obligations of Respondent under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Clindamycin-Benzoyl Peroxide Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent has divested the Clindamycin-Benzoyl Peroxide Product Assets and granted the related Divestiture Product License to Mylan prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that Mylan is not an acceptable purchaser of the Clindamycin-Benzoyl Peroxide Product Assets, then Respondent shall immediately rescind the transaction with Mylan, in whole or in part, as directed by the Commission, and shall divest the Clindamycin-Benzoyl Peroxide Product Assets and grant the related Divestiture Product License within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that

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receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further that if Respondent has divested the Clindamycin-Benzoyl Peroxide Product Assets and granted the related Divestiture Product License to Mylan prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Clindamycin-Benzoyl Peroxide Product Assets or grant of the related Divestiture Product License, as applicable, to Mylan (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Not later than the earlier of: (i) ten (10) days after the Acquisition Date or (ii) ten (10) days after the Order Date, Respondent shall divest the Fluorouracil Product Assets and grant the related Divestiture Product License, absolutely and in good faith, to Mylan pursuant to, and in accordance with, the Fluorouracil Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Mylan or to reduce any obligations of Respondent under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Fluorouracil Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent has divested the Fluorouracil Product Assets and granted the related Divestiture Product License to Mylan prior to the Order Date, and if, at the time the Commission

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determines to make this Order final and effective, the Commission notifies Respondent that Mylan is not an acceptable purchaser of the Fluorouracil Product Assets, then Respondent shall immediately rescind the transaction with Mylan, in whole or in part, as directed by the Commission, and shall divest the Fluorouracil Product Assets and grant the related Divestiture Product License within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further that if Respondent has divested the Fluorouracil Product Assets and granted the related Divestiture Product License to Mylan prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Fluorouracil Product Assets or grant of the related Divestiture Product License, as applicable, to Mylan (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- C. Prior to the Closing Date, Respondent shall secure all consents and waivers from all Third Parties that are necessary to permit Respondent to divest the assets required to be divested pursuant to this Order to an Acquirer, and to permit the relevant Acquirer to continue the research, Development, manufacture, sale, marketing or distribution of the Divestiture Product(s) being acquired by that Acquirer;

provided, however, Respondent may satisfy this requirement by certifying that the relevant Acquirer

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for the Divestiture Product has executed all such agreements directly with each of the relevant Third Parties.

- D. Respondent shall provide, or cause to be provided to each Acquirer in a manner consistent with the Technology Transfer Standards the following:
1. all Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Product(s) being acquired by that Acquirer; and
 2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed by the Respondent related to the Divestiture Products being acquired by that Acquirer.

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

- E. Respondent shall:
1. submit to each Acquirer, at Respondent's expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;
 2. deliver all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer to that Acquirer:
 - a. in good faith;
 - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
 - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;

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3. pending complete delivery of all such Confidential Business Information to the relevant Acquirer, provide that Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the relevant Divestiture Products that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
4. not use, directly or indirectly, any such Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the Clindamycin-Benzoyl Peroxide 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 Clindamycin-Benzoyl Peroxide Products under the terms of any related Remedial Agreement; or
 - c. applicable Law;
5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except the Acquirer of the Clindamycin-Benzoyl Peroxide Products or other Persons specifically authorized by that Acquirer to receive such information; and
6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the the Clindamycin-Benzoyl Peroxide Products to the employees associated with business related to those Retained Products that contain the same

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active pharmaceutical ingredient as the
Clindamycin-Benzoyl Peroxide Products.

F. Respondent shall:

1. upon reasonable written notice and request from an Acquirer to the Respondent, Contract Manufacture and deliver to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products related to the Divestiture Products acquired by that Acquirer at Respondent's Supply Cost, for a period of time sufficient to allow that Acquirer (or the Manufacturing Designee of the Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished drug product independently of Respondent and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in Respondent's Application(s) for the Divestiture Product(s) acquired by that Acquirer from Persons other than the Respondent;
2. make representations and warranties to the Acquirer(s) that the Contract Manufacture Product(s) supplied by the Respondent pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract Manufacture Product(s) to be marketed or sold in the Geographic Territory, the Respondent shall agree to indemnify, defend and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Contract Manufacture Product(s) supplied to the Acquirer pursuant to a Remedial Agreement by the Respondent to meet cGMP. This obligation may be made contingent upon the Acquirer giving the Respondent prompt written notice of such claim and cooperating fully in the defense of such claim. The Remedial

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Agreement shall be consistent with the obligations assumed by Respondent under this Order;

provided, however, that Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with Respondent's responsibilities to supply the Contract Manufacture Products in the manner required by this Order; *provided further* that this obligation shall not require Respondent 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 the Respondent to the Acquirer;

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

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

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

5. during the term of any agreement to Contract Manufacture between the Respondent and an Acquirer, upon written request of that Acquirer or the Interim Monitor (if any has been appointed), make available to the Acquirer and the Interim Monitor (if any has been appointed) all records that relate to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;
6. during the term of any agreement to Contract Manufacture between the Respondent and an Acquirer, Respondent shall take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);
7. produce or cause to be produced the Build-Up Inventory and ensure that, within ten (10) days of March 9, 2012, at least the number of units of Contract Manufacture Products in finished form (*i.e.*, suitable for sale to the ultimate consumer/patient) specified as the Build-Up Inventory is physically in existence and available for supply to the Acquirer;

provided however, that if the Respondent or the Interim Monitor notifies the Commission that, due to circumstances beyond the control of the Respondent, the Build-Up Inventory will be deficient in any respect, then the Respondent shall: (i) in consultation with the Interim Monitor and staff of the Commission, take such steps as are reasonably necessary to address the effects of any deficiency in Build-Up Inventory and otherwise mitigate the competitive and other

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effects from any failure to comply with the requirements of this Paragraph II.F.7.; and (ii) bear the burden of establishing to the Commission that any failure to comply with the requirements of this Paragraph II.F.7. was beyond the control of Respondent and in no part the result of negligence or willful misconduct by Respondent;

8. on January 15, 2012, February 1, 2012, February 15, 2012, March 1, 2012, and March 15, 2012, respectively, notify the Commission of the number of units of Build Up Inventory that is physically in existence and available for supply to the Acquirer;
9. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Interim Monitor to monitor Respondent's compliance with its obligations pursuant to Paragraph II.F.7;
10. not later than June 30, 2013, and for the purposes of supplying the Acquirer, establish a facility that is approved by the FDA to manufacture each of the Contract Manufacture Products in finished form (*i.e.*, suitable for sale to the ultimate consumer/patient) in commercial quantities, in a manner consistent with cGMP for the purposes of sale of the Contract Manufacture Products within the United States; the obligation to establish a manufacturing facility, shall include, without limitation, ensuring that, at all times after June 30, 2013, there is a facility fully capable of manufacturing in commercial quantities, and in a manner consistent with cGMP, the Contract Manufacture Products in finished form;
11. within (10) days of the Order Date, absolutely and in good faith, begin the technical transfer and other processes that are necessary for Respondent to obtain all Product Approvals that are required to ensure that Respondent can comply with the requirements of Paragraph II.A.10;

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12. during the term of any agreement to Contract Manufacture between the Respondent and an Acquirer, provide consultation with knowledgeable employees of the Respondent and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all Product Approvals to manufacture the relevant Divestiture Products in the same quality achieved by, or on behalf of, the Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent and sufficient to satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the relevant Divestiture Products;

The foregoing provisions, II.F.1. - 12., shall remain in effect with respect to each Divestiture Product that is a Contract Manufacture Product until the earliest of: (1) the date the Acquirer of that Divestiture Product (or the Manufacturing Designee(s) of that Acquirer), respectively, is approved by the FDA to manufacture and sell such Divestiture Product in the United States and able to manufacture such Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent; (2) the date the Acquirer of a particular Divestiture Product notifies the Commission and the Respondent of its intention to abandon its efforts to manufacture such Divestiture Product; (3) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer of a particular Divestiture Product has abandoned its efforts to manufacture such Divestiture Product, or (4) the date four (4) years from the Closing Date.

- G. Respondent shall not enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of

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that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Products acquired by that Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology.

- H. Not later than ten (10) days after the Closing Date, Respondent shall grant a release to each Third Party that is subject to an agreement as described in Paragraph II.G. that allows the Third Party to provide the relevant Product Manufacturing Technology to that Acquirer. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to that Acquirer.
- I. Respondent shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one (1) year period prior to the Closing Date and each employee that has responsibilities to those Retained Products that contain the same active pharmaceutical ingredient as the Divestiture Products and the direct supervisor(s) of any such employee sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order).
- J. Not later than thirty (30) days after the Closing Date, Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondent's personnel to all of Respondent's employees who:

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1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of any of the Divestiture Products;
2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that contain the same active pharmaceutical ingredient as the Divestiture Products; and/or
3. may have Confidential Business Information related to the Divestiture Products.

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

- K. Until Respondent completes the divestitures required by this Order and fully provides, or causes to be provided, the Product Manufacturing Technology related to a particular Divestiture Product to the relevant Acquirer,
1. Respondent shall take actions as are necessary to:
 - a. maintain the full economic viability and marketability of the businesses associated with that Divestiture Product;
 - b. minimize any risk of loss of competitive potential for that business;

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- c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to that Divestiture Product;
 - d. ensure the assets related to each Divestiture Product are provided to the relevant Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the business associated with each Divestiture Product;
 - e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and
 2. Respondent shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the businesses associated with that Divestiture Product.
- L. Respondent shall not join, file, prosecute or maintain any suit, in law or equity, against an Acquirer or the Divestiture Product Releasee(s) of that Acquirer for the research, Development, manufacture, use, import, export, distribution, or sale of the Divestiture Product(s) acquired by that Acquirer under the following:
1. any Patent owned or licensed by Respondent as of the day after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claims a method of making, using, or administering, or a composition of matter, relating to the Divestiture Product(s) acquired by that Acquirer, or that claims a device relating to the use thereof;

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2. any Patent owned or licensed by Respondent at any time after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the Divestiture Product(s) acquired by that Acquirer;

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

- M. Upon reasonable written notice and request from an Acquirer to Respondent, Respondent shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Products acquired by

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that Acquirer, if such litigation would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Product acquired by that Acquirer; or (2) the use, import, export, supply, distribution, or sale of that Divestiture Product within the Geographic Territory.

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

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related obligations imposed on the Respondent by this Order is:

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

III.

IT IS FURTHER ORDERED that:

- A. At any time after the Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that the Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements.

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- 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 Order in a manner consistent with the purposes of the Order.
- 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 Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.
 - 2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
 - 3. The Interim Monitor shall serve until the date of completion by the Respondent of the divestiture of all Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing

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Technology in a manner that fully satisfies the requirements of this Order and until the earliest of:

- a. with respect to the Fluorouracil Products, the date the Acquirer of the Fluorouracil Products (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell the Fluorouracil Products and able to manufacture the Fluorouracil Products in commercial quantities, in a manner consistent with cGMP, independently of the Respondent;
- b. with respect to the Fluorouracil Products, the date the Acquirer of the Fluorouracil Products notifies the Commission and the Respondent of its intention to abandon its efforts to manufacture the Fluorouracil Products; or
- c. with respect to the Fluorouracil Products, 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 the Fluorouracil Products;

provided, however, that, with respect to the Fluorouracil Products, 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

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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 Order and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days

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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.

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 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.

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IV.**IT IS FURTHER ORDERED** that:

- A. If Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

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- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
 - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.
 - 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
 - 3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall

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develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondent from among those approved by the Commission; *provided further, however*, that Respondent shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of 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

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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. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.
8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

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

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

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

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

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

VI.**IT IS FURTHER ORDERED** that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by the Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondent shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of the Respondent's obligations to the Acquirer pursuant to this Order.
- D. Respondent shall also include in each Remedial Agreement a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to

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secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product, as applicable, and to have any such manufacture to be independent of Respondent, all as soon as reasonably practicable.

- E. Respondent 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 or the remedial purposes thereof.
- F. Respondent shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission.

VII.**IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondent has fully complied with the following: Paragraphs II.A , II.B., II.C., II.D. II.E.1.-3., II.F., and II.K., 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. Respondent shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondent 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

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all substantive contacts or negotiations related to the divestiture of the relevant assets and/or the agreement to supply relevant Products and the identity of all Persons contacted, including copies of all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning completing the obligations.

- C. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondent 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.

VIII.

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

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

IX.

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 the Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, the Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

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

X.

IT IS FURTHER ORDERED that this Order shall terminate on February 21, 2022.

By the Commission.

NON-PUBLIC APPENDIX I

DIVESTITURE AGREEMENTS

**[Redacted From the Public Record Version But Incorporated
By Reference]**

Analysis to Aid Public Comment

NON-PUBLIC APPENDIX II

BUILD-UP INVENTORY

**[Redacted From the Public Record Version But Incorporated
By Reference]**

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

I. Introduction

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from Valeant Pharmaceuticals International, Inc. (“Valeant”), which is designed to remedy the anticompetitive effects of Valeant’s acquisition of certain assets of Sanofi’s dermatology unit, Dermik (“Dermik”)

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (“Order”).

Valeant proposes to acquire certain assets of Sanofi’s dermatology unit, Dermik, in a transaction valued at approximately \$425 million (“the Acquisition”). Both parties sell topical pharmaceutical products in the United States. The Commission’s Complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the markets for 1) BenzaClin and 2) topical fluorouracil cream (“topical 5FU”). The proposed

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Consent Agreement remedies the loss of competition in these markets that would result from the Acquisition. Specifically, under the terms of the Consent Agreement, Valeant would be required to (1) divest all rights and assets related to generic BenzaClin, and (2) grant a perpetual, unrestricted license for the authorized generic of Efudex (“AG Efudex”). Valeant has proposed Mylan Inc. (“Mylan”) as the buyer of generic BenzaClin and AG Efudex assets.

II. The Products and the Structure of the Market

Valeant’s proposed acquisition of Dermik from Sanofi would create a monopoly in the BenzaClin market. Dermik manufactures and markets BenzaClin, which is a topical pharmaceutical product used to treat acne vulgaris, commonly known as acne. BenzaClin is a combination of clindamycin, an antibiotic, and benzoyl peroxide, an antimicrobial. Valeant owns the only Abbreviated New Drug Application (“ANDA”) for the generic version of BenzaClin, which it licenses to Mylan. Pursuant to that license, Mylan sells the only generic equivalent of BenzaClin in the United States and Valeant receives the vast majority of royalties from those sales. Currently Dermik’s BenzaClin sales account for approximately 50 per cent of sales, while sales of Mylan’s generic version account for the other approximate 50 per cent. The Acquisition would create a monopoly in this market.

In addition, Valeant’s proposed acquisition of Dermik is likely to result in anticompetitive effects in the market for topical 5FU products. Topical 5FU products are used to treat actinic keratosis (“AK”), which is a pre-cancerous lesion that can result from years of repeated sun exposure. Three branded topical 5FUs are currently on the market, including Valeant’s Efudex and Dermik’s Carac. There are also two generic versions of Efudex, as well as an “authorized” generic, also sold by Valeant. The price of the generic drugs in this market determines the pricing of branded Carac. Post-acquisition, Valeant’s market share in the topical 5FU market would be over 50 per cent. Other treatments for AKs are not viable substitutes for topical 5FUs because they are more costly, less efficacious or impracticable.

Analysis to Aid Public Comment

III. Entry

Entry into the manufacture and sale of both BenzaClin and topical 5FU products is difficult, expensive and time consuming. Developing and obtaining U.S. Food and Drug Administration approval for the manufacture and sale of topical pharmaceuticals takes over two years due to substantial regulatory, technological and intellectual property barriers. Furthermore, entry would not be likely because the markets are relatively small, so the limited sales opportunities available to a new entrant would likely be insufficient to justify the time and investment necessary to enter.

IV. Effects of the Acquisition

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for the manufacture and sale of both BenzaClin and topical 5FU products by eliminating actual, direct and substantial competition between Valeant and Sanofi in those markets. With respect to the BenzaClin market, the transaction would combine BenzaClin and its only generic equivalent, eliminating BenzaClin's closest competitor and creating a monopoly. The impact of eliminating the competition between BenzaClin and its only currently-marketed generic equivalent, is highly likely to result in consumers paying higher prices.

In the topical 5FU market, the transaction would give Valeant control over three linked treatments for AK – Dermik's branded Carac and Valeant's branded and AG Efudex products. The combination of these products at Valeant would eliminate head to head competition between Carac and the Efudex AG and is thus likely to result in higher prices for topical 5FUs.

V. The Consent Agreement

The proposed Consent Agreement effectively remedies the acquisition's anticompetitive effects in the relevant markets by requiring Valeant to (1) divest its ANDA for generic BenzaClin to Mylan, and (2) supply an authorized generic of Efudex, pursuant to a license to Mylan. If approved, Mylan will acquire all rights and assets currently held by Valeant, including any existing

Analysis to Aid Public Comment

inventory. The assets to be transferred include all manufacturing and research and development rights in the divested products.

Mylan is a particularly well-suited acquirer of generic BenzaClin because it has been manufacturing and marketing the product, pursuant to an agreement with Valeant, since it was introduced in August 2009. Mylan is the second-largest generic pharmaceutical manufacturer in the United States, and is well-positioned to replicate the competition that would be lost with the proposed Valeant/Dermik acquisition. Headquartered in Pittsburgh, Pennsylvania, Mylan employs more than 18,000 employees and generated approximately \$5.45 billion in revenue in 2010. Mylan sells approximately 270 products and has a manufacturing facility where BenzaClin is manufactured. It is in the process of upgrading that facility to handle compounds such as 5FU.

Mylan expects to begin manufacturing generic Efudex at that facility in 2013. Until that time, the proposed Consent Agreement contemplates Mylan's purchase of topical 5FU from Valeant pursuant to a supply agreement. In order to ensure that there is no supply interruption, the proposed Consent Agreement would require that Valeant build up a two-year inventory and establish its own manufacturing as a back-up supply until Mylan is able to manufacture Efudex commercially. Valeant would also be required to assist Mylan with developing its manufacturing capabilities and securing the necessary FDA approvals. With these provisions, Mylan will be able to compete in the 5FU market immediately following the divestiture and establish independent manufacturing as soon as practicable.

The Commission has appointed Francis J. Civile as the Interim Monitor to oversee the asset transfer and to ensure Valeant's compliance with the provisions of the proposed Consent Agreement. Mr. Civile has over 27 years of experience in the pharmaceutical industry. He has extensive experience in areas such as pharmaceutical research and development, regulatory approval, manufacturing and supply, and marketing. Mr. Civile will oversee the transfer of Efudex manufacturing technology to the acquirer and ensure that Valeant is diligent in building up the required inventory of the product and establishing its own back-up supply capabilities. In order to ensure that the Commission

Analysis to Aid Public Comment

remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Agreement requires the parties to file reports with the Commission periodically until the divestitures and transfers are accomplished.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

Complaint

IN THE MATTER OF

OMNICARE, INC.COMPLAINT AND FINAL ORDER IN REGARD TO ALLEGED
VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION
ACT AND SECTION 7 OF THE CLAYTON ACT*Docket No. 9352; File No. 111 0239**Complaint, January 27, 2012 – Decision, February 22, 2012*

This case addresses the \$760 million acquisition by Omnicare, Inc. of certain assets of PharMerica Corporation. The complaint alleges that the acquisition, if consummated, would violate Section 5 of the Federal Trade Commission Act and Section 7 of the Clayton Act by substantially increasing Omnicare's bargaining leverage and otherwise reducing competition in the sale of long term care pharmacy services to Plan Sponsors. The Order dismisses the Administrative Complaint without prejudice, because Respondent has announced that it is abandoning the proposed acquisition of PharMerica, and has withdrawn its Hart-Scott-Rodino Notification and Report Form filed for the proposed transaction.

Participants

For the *Commission*: Jordan S. Andrew, Stephanie C. Bovee, Gerald A. Stein, Lore Unt, Mark Seidman, Christine L. White, and Daniel Zach.

For the *Respondent*: John D. Harkrider and Michael L. Keeley, Axinn, Veltrop & Harkrider, LLP, and Jacqueline I. Grise and Roxann E. Henry, Dewey & LeBoeuf.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by the Act, the Federal Trade Commission, having reason to believe that Respondent Omnicare, Inc.'s ("Omnicare") cash tender offer to acquire PharMerica Corporation ("PharMerica"), if consummated, would violate Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows: