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UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

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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 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, Bridg

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” (“SNDA”), 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”) 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

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 Retained Product (including the right to receive notification from the Respondent of any such cross-referencing a customer may be wi re s

10. 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);

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

12. 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;

13. 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;

14. 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;

15. at the option of the Acquirer of the specified Divestiture Product, all unfilled customer purchase orders for the specified Divestiture Product; and

16. all of the Respondent's books, records, and files directly related to the foregoing;

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 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 there

O. “Closing Date” mea

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

any ingredient or component of any of the Flourouracil 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.

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) 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, d of r ir,

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 Flouroucil Product Assets, individually and collectively.

Y. "Divestiture Product Releasee(s)" means the following Persons:

1. the Acquirer for the assets related to a particular Divestiture Product;

2. any Person controlled by or under common control with that Acquirer; and

3. any 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 Flourouracil Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of each such 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.

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 Acquisiti

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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 Acquireactur

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;

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 an

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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;

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;

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;

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:

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;

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 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, 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 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 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:

(1) manufacture the specified Divestiture Product in the quality and quantities achieved by the Respondent, or the manufacturer and/or developer of such Divestiture Product;

(2) 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

(3) 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 rig

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 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 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

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

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cooperating fully in the defense of such claim. The Remedial 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 agree

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 effects from any failure to h steps as swith the Ireuiremyapsof theis Para

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 Pr

Information related to the Divestiture Products by Respondent's personnel to all of Respondent's employees who:

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;

   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. a

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.

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 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;

thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order.

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

the Interim Monitor and each of the

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.

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 shall be

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 suc

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

B. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture orre insuff

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 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.

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

X.

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

By the Commission.

Donald S. Clark
Secretary

SEAL
ISSUED: February 21, 2012

NON-PUBLIC APPENDIX I
DIVESTITURE AGREEMENTS

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

NON-PUBLIC APPENDIX II
BUILD-UP INVENTORY

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