

**UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION**

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

In the Matter of)
)
)
VALEANT PHARMACEUTICALS INTERNATIONAL, INC.,) **Docket No. C-4343**
a corporation.)
)

DECISION AND ORDER
[Public Record Ver

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. Johnson & Johnson is a corporation organized, existing and doing business under and by virtue of the laws of New Jersey, with its headquarters address located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and the address of its wholly owned subsidiary, Janssen Pharmaceuticals, Inc., located at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.
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.

International (Barbados) SRL, and Valeant Pharmaceuticals North America LLC, dated as of July 15, 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” (“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, 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~~ ~~Application~~

- 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 Refissa Products;
- d. information specifically excluded from the Refissa Product Assets; and
- e. 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.

K. "Development" means all preclinical and clinical drug development activities (including

4. constituting confidentiality agreements involving the Refissa Products;
5. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the Refissa Products;
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 specialized services necessary to the research, Development, manufacture or distribution of the Refissa Products to the Respondent including, but not limited to, consultation arrangements; and/or
8. pursuant to which any Third Party collaborates with the Respondent in the performance of research, Development, marketing, distribution or selling of the Refissa Products or the business related to the Refissa Products;

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 Refissa Products, but concurrently may retain similar rights for the purposes of the Retained Product(s).

- Z. "Product Copyrights" means rights to all original works of authorship of any kind directly related to the Divestiture Products 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 or distribution of such Divestiture Product.

experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA.

AA. “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.

BB. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of the Divestiture Products 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 Divestiture Products.

CC. “Product Trade Dress” means the current trade dress of the Divestiture Products, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.

DD. “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 Divestiture Product(s);

provided, however, “Product Trademarks” 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.

- EE. “Refissa Co-Marketing Agreement” means the “Co-Marketing Agreement” by and between Valeant Pharmaceuticals North America and Spear Pharmaceuticals, Inc., dated February 28, 2010, and all amendments, exhibits, attachments, agreements, and schedules thereto. The Refissa Co-Marketing Agreement is attached to this Order and contained in Non-Public Appendix I.
- FF. “Refissa Product(s)” means all products that are the subject of the Refissa Co-Marketing Agreement. “Refissa Products” includes all products marketed under the ANDA No. 76-498.
- GG. “Refissa Product Assets” means all rights, title and interest in and to all assets related to the research, Development, manufacture, distribution, marketing, and sale of the Refissa Products that are owned or controlled by, or licensed to Respondent on or before the Acquisition Date, to the extent legally transferable, including, without limitation, the following:
1. all rights, economic benefits, or other interests conveyed to Respondent pursuant to the Refissa Co-Marketing Agreement;
 2. all Product Intellectual Property related to the Refissa Products;
 3. all Product Marketing Materials related to the Refissa Products;
 4. all Website(s) related exclusively to the Refissa Products;
 5. the content related exclusively to the Refissa Products that is displayed on any Website that is not dedicated exclusively to the Refissa Products;
 6. at the option of Spear, all Product Assumed Contracts related to the Refissa Products;
 7. a list of all customers and targeted customers for the Refissa Products and a listing of the net sales (in either units or dollars) of the Refissa Products to such customers on either an annual, quarterly, or monthly basis;
 8. a list of all physician sales calls related to Refissa Product made pursuant to the Refissa Product Co-Marketing Agreement;

9. a list of all prescribers of the Refissa Products;
10. at the option of Spear, 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 Refissa Products; and
11. all of the Respondent's books, records, and files directly related to the foregoing;

provided, however, that "Refissa Product 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 pharmaceutical Products, where such documents do not discuss with particularity the Refissa Products; (2) administrative, financial, and accounting records;

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 Refissa Products 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 Refissa Products; 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 Spear, the Respondent shall provide Spear 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 Spear with the above-described information without requiring the Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

HH. "Refissa Product Co-Marketing Termination Agreement" means the "Termination and Release Agreement" between Valeant Pharmaceuticals North America LLC, Spear Pharmaceuticals, Inc. and Spear Dermatology Products, Inc., dated as of November 22, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto; related to the Refissa Product Assets that have been approved by the Commission to accomplish the requirements of this Order. The Refissa Product Co-Marketing Termination Agreement is attached to this Order and contained in non-public Appendix I.

II. "Remedial Agreement(s)" means the following:

1. any agreement between the Respondent and the 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 the Acquirer that is specifically referenced ~~in~~ ~~the~~ ~~Order~~ ~~is~~ ~~specifically~~ ~~referenc~~

II.

IT IS FURTHER ORDERED that:

3. pending complete delivery of all Confidential Business Information to Spear, provide Spear a

G. Respondent shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each

- c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to the Refissa Products;
 - d. ensure the Refissa Product Assets are provided to Spear in a manner without disruption, delay, or impairment of the regulatory approval processes related to the business associated with the Refissa Products; 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 the Refissa Products.

J. Respondent shall not, in the United States of America:

- 1. use the Product Trademarks related to the Refissa Products or any mark confusingly similar to such Product Trademarks, as a trademark, trade name, or service mark;
- 2. attempt to register such Product Trademarks;
- 3. attempt to register any mark confusingly similar to or resulting in dilution of such Product Trademarks;
- 4. challenge or interfere with Spear's use and registration of such Product Trademarks; or
- 5. challenge or interfere with Spear's efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties;

provided however, this Paragraph shall only apply to those Product Trademarks conceived, registered, or developed prior to the Acquisition Date.

K. Respondent shall not join, file, prosecute or maintain any suit, in law or equity, against Spear or the Divestiture Product Releasee(s) under the following:

- 1. any Patent owned or licensed by Respondent as of the day after the Acquisition Date

(excluding the Patent(s) owned or licensed by Respondent as of the day after the Acquisition Date that are owned or licensed to Respondent by a Third Party)

if such suit would have the potential to interfere with Spear's freedom to practice the following: (1) the research, Development, or manufacture of the Refissa Products 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 Refissa Product. Respondent shall also covenant to Spear 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 Spear or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential to interfere with Spear's freedom to practice the following: (1) the research, Development, or manufacture of the Refissa 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 Refissa Product.

- L. The purpose of the divestiture of the Refissa Product Assets, the termination of the Refissa Product Co-Marketing Agreement and the related obligations imposed on the Respondent by this Order is to ensure the continued research, Development, manufacture, distribution, sale and marketing of the Refissa Products independently of Respondent and for the purposes of the business associated with each Re

D. If an I

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 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. The 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.

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 Refissa Product Assets or to terminate the Refissa Product Co-Marketing Agreement as required by this Osi0000 0.0000 TD(ir)Tj7.3200 0.0000 TD(e)Tj5.28

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

caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the court.

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.
9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and a

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 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 Spear pursuant to this Order.
- D. 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 Refissa Products a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- E. 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 Paragraphs II.A, and II.C.1.-3

- 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:

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

B. to interview officers, director

**NON-PUBLIC APPENDIX I
REFISSA CO-MARKETING AGREEMENT
AND
REFISSA PRODUCT CO-MARKETING TERMINATION AGREEMENT**

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