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UNITED STATES OF AMERICA

BEFORE FEDERAL TRADE COMMA0.0881.000 12.0 F13 12.0000 Tf26.7000 Tc-2

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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 Novartis AG is a corporation organized, existing and doing business under and by virtue of the laws of the Swiss Confederation, with its headquarters address located at Lichtstrasse 35, Basel, Switzerland, V8 CH4056, and the address of its United States subsidiary, Novartis Corporation, located at 230 Park Avenue, New York, New York 10169.

2. Fougera Holdings Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address located at 60 Baylis Road, Melville, New York, 11747. The ultimate parent entity of Fougera Holdings Inc. is Fougera S.C.A. SICAR.

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. "Novartis" or "Respondent" means Novartis AG, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Novartis AG (including, without limitation, Sandoz Inc. f.k.a. Geneva Pharmaceuticals, Inc., and Jet Merger Sub Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Novartis shall include Fougera.

B. "Fougera" means Fougera Holdings Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Fougera Holdings Inc. (including, without limitation, Fougera Pharmaceuticals Inc. and Nycomed US Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "Commission" means the Federal Trade Commission.

D. "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 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.

E. “Acquisition” means Respondent’s ac

The Collaboration, Development, and Supply Agreement is contained in Non-Public Appendix A attached to this Order.

J. "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.

K. "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. The term "Confidential Business Information" *excludes* (i) 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, (ii) 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, and (iii) information that is contained in documents, records, or books of the Respondent provided to the Acquirer by the Respondent that is unrelated to the Divestiture Products or that is exclusively related to Retained Product(s).

L. "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.

M. "Development Divestiture Product" means the following Product Developed or in Development: Tolmar's gel containing 3% diclofenac sodium and any such Product that is the subject of ANDA No. 20-936.

N. "Development Divestiture Product Patents" means the following United States Patents:

1. U.S. Patent No. 5,639,738;

2. U.S. Patent No. 5,852,002;

3. U.S. Patent No. 5,929,048;

4. U.S. Patent No. 5,792,753;

5. U.S. Patent No. 5,985,850; and

6. U.S. Patent No. 5,914,322.

O. "Divestiture Product Agreements" mean:

1. Amendment No. 5 to the Collaboration, Development, and Supply Agreement; and,

2. Amendment No. 6 to the Collaboration, Development, and Supply Agreement, dated as of July 5, 2012.

a. to require Respondent to discontinue the use of the NDC Numbers related to each Divestiture Product in the sale or marketing of the specified Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the end of the Transition Period and *except* as may be required by applicable Law;

b. to prohibit Respondent from seekin

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

V. "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.

W. "High Volume Account(s)" means any retailer, wholesaler or distributor whose annual aggregate purchase volumes, in units or in dollars, of a Marketed Divestiture Product from Respondent were among the largest customers of the Respondent for that Marketed Divestiture Product in the United States of America and which customers, when aggregated together, represent at least 80% of Respondent's sales of that Marketed Divestiture Product during 2011.

X. "Interim Monitor" means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.

Y. "Law" means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.

Z. "Marketed Divestiture Products" means all Products marketed, distributed, or sold, pursuant to the following ANDAs:

1. No. A077029, and any supplements, amendments, or revisions thereto (Calcipotriene Topical Solution);

2. No. A076320, and any supplements, amendments, or revisions thereto (Lidocaine/Prilocaine Cream); and

3. No. A077547, and any supplements, amendments, or revisions thereto (Metronidazole Topical Gel).

AA. "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.

BB. "New Commercialization Partner" means any Third Party(ies) designated by Tolmar to market, distribute or sell the Divestiture Products.

CC. "Order Date" means the date on which this Decision and Order is issued by the Commission to become final and effective.

DD. "Order to Maintain Assets" means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.

EE. “Patent(s)” means

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, (i) any agreement to supply specified products or components thereof, or (ii) any agreement to provide transitional services related to the business being transferred to the Acquirer, 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, (i) any agreement to supply specified products or components thereof, or (ii) any agreement to provide transitional services related to the business being transferred to the Acquirer, 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.

LL. "Retained Product" means any Product(s) of Respondent other than a Divestiture Product, including any such Product(s) acquired by the Respondent as a result of the Acquisition.

MM. "Third Party(ies)" means any non-governmental Person other than the following: the Respondent; or, Tolmar.

NN. "Tolmar" means Tolmar Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address located at 701 Centre Avenue, Fort Collins, Colorado 80526. Tolmar was formerly known as Atrix Laboratories, Inc., the party to the Collaboration, Development and Supply Agreement.

OO. "Transition Period" means, for each Marketed Divestiture Product, the period beginning on the date the Order to Maintain Assets becomes final and effective and ending, with respect to each Marketed Divestiture Product, on the earlier of the following dates: (i) the date on which Tolmar directs the Respondent to cease the distribution, marketing and sale of that Marketed Divestiture Product; or (ii) the date on which the New Commercialization Partner commences the distribution, marketing, and sale of that Marketed Divestiture Product; *provided however*, the Transition Period shall end not later than six (6) months from the Order Date.

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

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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 Divestiture Product Assets (to the extent that such assets are not already owned, controlled or in the possession of Tolmar), absolutely and in good faith, to Tolmar pursuant to, and in accordance with, the Divestiture Product Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Tolmar or to reduce any obligations of Respondent under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Divestiture Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent has divested the Divestiture Product Assets to Tolmar prior to the Order Date, and if, at the time the Commission determines to make this Order final and effectivel0.0000 0.00000 0.00000 cm0.0i00 0.00 rgBT94.44toei3ed by

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that Tolmar has executed all such agreements directly with each of the relevant Third Parties.

C. Respondent shall:

1. submit to Tolmar, at Respondent's expense, all Confidential Business Information;

2. deliver all Confidential Business Information to Tolmar:

a. in good faith;

b. in a timely manner,

7. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support, or use of each of the Development Divestiture Product to any of Respondent's employees that (i) prior to the Acquisition, were employees or agents of Fougera, or (ii) are responsible for making business decisions related to those Retained Products that that are prescription pharmaceuticals for the treatment of the same disease as the Development Divestiture Product;

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: (i) oral antibiotics; (ii) 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; (iii) information that is required by Law or rules of an applicable stock exchange to be publicly disclosed; (iv) information specifically excluded from the Divestiture Product Assets; and (v) all intellectual property licensed on a non-exclusive basis to Tolmar.

D. Respondent shall require that each of Respondent's employees that has had access to Confidential Business Information within the one (1) year period prior to the Acquisition Date 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 necessaryit to complyg

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2. to create a viable and effective competitor, that is independent of the Respondent in the distribution, sale and marketing of the each Divestiture Product in the Geographic Territory; and,

3. 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.

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 end of the Transition Period; *provided, however,* that the Interim Monitor's service shall not exceed one (1) year from the Order

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

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

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

6. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.

7. Respondent shall report to the Interim Monitor in accordance with the requirements of this 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. 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

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 se

V.

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 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.

E. Respondent shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission.

VI.

IT IS FURTHER ORDERED that:

A. Within five (5) days of the Acquisition Date, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition occurred.

B. Within thirty (30) days after the date the Order to Maintain Assets is issued, and every thirty (30) days thereafter until Respondent has fully complied with Paragraphs II.A , II.B., II.C. of this Order, and until the end of the Transitional Period, 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 the Orders. 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 detailed description of the efforts being made to comply with the relevant paragraphs of the Orders, including a detailed description of all substantive contacts, negotiations, or recommendations related to the transitional services being provided by the Respondent to Tolmar and/or the New Commercialization Partner, and a detailed description the timing for the completion of such obligations.

C. One (1) year after the Order Date, and annually for three (3) 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.

VII.

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.

VIII.

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, pe

IX.

IT IS FURTHER ORDERED that this Order shall terminate on September 4, 2022.

By the Commission.

Donald S. Clark
Secretary

SEAL
ISSUED: September 4, 2012

NON-PUBLIC APPENDIX A

THE COLLABORATION, DEVELOPMENT AND SUPPLY AGREEMENT

AND

THE DIVESTITURE AGREEMENTS

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