

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: Jon Leibowitz, Chairman
J. Thomas Rosch
Edith Ramirez
Julie Brill
Maureen K. Ohlhausen

_____)
In the Matter of)
)
NOVARTIS AG,) Docket No. C-4364
a corporation.)
_____)

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Novartis AG (“Respondent”) of the voting securities of Fougera Holdings Inc. (“Fougera”), and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

1. Respondent 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 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 this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. “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. “Decision and Order” means the:
 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
 2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission in this matter.
- E. “Divestiture Product Business(es)” means the business within the United States of America

of distributing, marketing, and selling each of the Divestiture Products.

- F. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- G. “New Commercialization Partner” means any Third Party(ies) designated by Tolmar to market, distribute or sell the Divestiture Products.
- H. “Orders” means the Decision and Order and this Order to Maintain Assets.
- I. “Transition Period” means, for each Marketed Divestiture Product, the period beginning on the date this 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.

II.

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

- A. Until the end of the Transition Period, Respondent shall take such actions as are necessary to maintain the ongoing economic viability, marketability and competitiveness of each of the related Divestiture Product Businesses, to minimize any risk of loss of competitive potential for such Divestiture Product Businesses, and to prevent the deterioration, or impairment of such Divestiture Product Businesses.
- B. Other than in the manner as prescribed in the Orders, Respondent shall not sell, transfer, encumber or otherwise impair the Divestiture Product Assets.
- C. Until the end of the Transition Period, Respondent shall maintain the operations of the Divestiture Product Businesses in the regular and ordinary course of business and in accordance with past practice and/or as may be necessary to preserve the marketability, viability, and competitiveness of such Divestiture Product Businesses and as may be necessary to facilitate the transfer of such business to the New Commercialization Partner on behalf of Tolmar. During the Transition Period, Respondent shall use its best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; the High Volume Accounts; customers; Agencies; employees; and others having business relations with each of the respective Divestiture Product Businesses. Respondent’s responsibilities shall include, but are not limited to, the following:

1. providing each of the respective Divestiture Product Businesses with funds to operate at least at current rates of operation, to carry on, at least at their scheduled pace, all business plans, distribution, marketing and promotional activities for such Divestiture Product Businesses;
2. providing such resources as may be necessary to respond to competition against each of the Marketed Divestiture Products and/or to prevent any diminution in sales of each of the Marketed Divestiture Products during the Transition Period; *provided however*, that in determining how to respond to competition, including pricing decisions, Respondent shall consult with Tolmar and follow decision made by Tolmar with respect thereto;
3. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Marketed Divestiture Products at the related High Volume Accounts;
4. providing each of the respective Divestiture Product Businesses with such funds as are necessary to maintain the ongoing economic viability, marketability and competitiveness of such Divestiture Product Business;
5. providing such support services to each of the respective Divestiture Product Businesses as have been provided to such businesses by Respondent (prior to Respondent's decision to make the Acquisition) under the terms of the Collaboration, Development and Supply Agreement, including without limitation:
 - a. receiving, fulfilling and processing customer orders for the Marketed Divestiture Products, consistent with past practice, including without limitation, direct order entry capability and processing;
 - b. coordinating with Tolmar on matters related to supply and demand for the Marketed Divestiture Products consistent with past practice, including without limitation, maintaining inventory levels adequate to serve the market;
 - c. providing field sales force, telemarketing staff, and distribution centers, for the Marketed Divestiture Products;
 - d. coordinating with Tolmar on matters related to advertising and marketing support materials; and
 - e. advising Tolmar in a timely manner of any issues that may materially or adversely affect Respondent's ability to market a Marketed Divestiture Product; and
6. maintaining a work force at least as equivalent in size, training, and expertise to what has been associated with the Marketed Divestiture Products for the relevant Marketed Divestiture Product's last fiscal year.

- D. During the Transition Period, Respondent, in consultation with Tolmar, for the purposes of ensuring an orderly transition to the New Commercialization Partner, shall:
1. develop and implement a detailed transition plan to ensure that the commencement of the marketing, distribution and sale of the Marketed Divestiture Products by the New Commercialization Partner is not delayed or impaired by the Respondent;
 2. designate employees of Respondent knowledgeable about the marketing, distribution and sale related to each of the Marketed Divestiture Products who will be responsible for communicating directly with Tolmar and/or Tolmar's New Commercialization Partner, and the Interim Monitor (if one has been appointed), for the purpose of assisting in the transfer of the Divestiture Product Businesses to the New Commercialization Partner;
 3. subject to delivery of sufficient levels of supply by Tolmar, maintain and manage inventory levels of the Marketed Divestiture Products in consideration of the transition;
 4. negotiate in good faith with Tolmar and/or its New Commercialization Partner (in consultation with the Interim Monitor, if one has been appointed) to provide a non-exclusive fully paid up and royalty free license on commercially reasonable terms that are customary for the transition of product ownership to Tolmar and/or its New Commercialization Partner to use Respondent's existing product packaging and/or labeling (including Respondent's corporate name(s) and logo(s)) for a period of time sufficient to allow Tolmar and/or its New Commercialization Partner to commence the distribution, marketing and sale of that Divestiture Product (including without limitation, obtaining the authorization by the FDA of new product labeling and/or packaging for each of the Marketed Divestiture Products); *provided however*, nothing in this sub-paragraph shall require that Respondent and Tolmar and/or its New Commercialization Partner enter into such a license if Respondent negotiates in good faith as required above but notwithstanding such good faith negotiations, the parties are unable to agree to acceptable terms and conditions for such a license;
 5. continue to market, distribute and sell the Marketed Divestiture Product on behalf of Tolmar;
 6. ensure that all Confidential Business Information is delivered to Tolmar:
 - a. in good faith;
 - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
 - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;

7. allow Tolmar access at reasonable business hours to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products that contain such Confidential Business Information pending the complete delivery of such Confidential Business Information to Tolmar;
8. establish projected time lines for accomplishing all tasks necessary to effect the transition in an efficient and timely manner;
9. provide Tolmar with a listing of the inventory levels (weeks of supply) for each customer on a regular basis and in a timely manner;
10. provide Tolmar with anticipated reorder dates for each customer on a regular basis and in a timely manner; and
11. enter into any agreements with Tolmar and/or its New Commercialization Partner, on customary and commercially reasonable terms for the type of transaction or arrangement, to the extent such agreements are necessary to effectuate the foregoing.

E. During the Transition Period, Respondent shall:

1. not use, directly or indirectly, any such Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the Divestiture Products other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondent's obligations to Tolmar under the terms of any related Remedial Agreement; or
 - c. applicable Law;
2. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except Tolmar or other Persons specifically authorized by Tolmar to receive such information;
3. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Marketed Divestiture Products to Respondent's employees responsible for making pricing decisions related to those Retained Products that are prescription pharmaceuticals for the treatment of the same disease as the Marketed Divestiture Products; and
4. 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 to Maintain Assets 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 and/or its New Commercialization Partner.

- F. Not later than thirty (30) days from the date that this Order to Maintain Assets becomes final and effective, Respondent shall provide to all of Respondent's employees and other personnel who may have access to Confidential Business Information related to the Divestiture Products notification of the restrictions on the use of such information by Respondent's personnel. Respondent shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the date this Order to Maintain Assets is issued by the Commission to become final and effective. Respondent shall provide a copy of such notification to Tolmar. Respondent shall maintain complete records of all such agreements at Respondent's registered office within the United States and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondent shall provide Tolmar with copies of all certifications, notifications and reminders sent to Respondent's personnel.
- G. Respondent shall monitor the implementation by its employees and other personnel of all applicable restrictions, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets. Respondent shall provide Tolmar with copies of all certifications, notifications and reminders sent to Respondent's employees and other personnel.
- H. Respondent shall adhere to and abide by the Remedial Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of the Orders, it being understood that nothing in the Orders shall be construed to reduce any obligations of Respondent to Tolmar under such agreement(s)), which are incorporated by reference into this Order to Maintain Assets and made a part hereof.

- I. The purpose of this Order to Maintain Assets is to maintain the ongoing economic viability, marketability and competitiveness of the Divestiture Product Businesses within the Geographic Territory through the Transition Period, to minimize any risk of loss of competitive potential for the Divestiture Product Businesses within the Geographic
- J. Territory, and to prevent the destruction, deterioration, or impairment of any of the Divestiture Assets.

III.

IT IS FURTHER ORDERED that:

- A. At any time after Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor (“Interim Monitor”) to assure that Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by the Orders and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondent’s compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
 - 1. The Interim Monitor shall have the power and authority to monitor Respondent’s compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.
 - 2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
 - 3. The Interim Monitor shall serve until the 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 Orders, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with the Orders.
5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
6. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
7. Respondent shall report to the Interim Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondent's obligations under the Orders or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Orders.
8. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.

- E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
- G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- H. The Interim Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets is issued by the Commission to become final and effective, and every thirty (30) days thereafter until the end of the Transition 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.

provided, however, that, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondent pursuant to Paragraph VI of the Decision and Order.

V.

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

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

VI.

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

- A. access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on the earlier of:

- A. Three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. The day after the end of the Transition Period and the Interim Monitor, in consultation with Commission staff and Tolmar, notifies the Commission that all transitional services related to the Marketed Divestiture Products have been completed by the Respondent, or the Commission otherwise directs that this Order to Maintain Assets is terminated.

Janice Podoll Frankle
Acting Secretary

SEAL

ISSUED: July 13, 2012