

Complaint

IN THE MATTER OF

NOVARTIS AGCONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT

Docket No. C-4364; File No. 121 0144
Complaint, July 13, 2012 – Decision, September 4, 2012

This consent order addresses the \$1.525 billion acquisition by Novartis AG of certain assets of Fougere Holdings Inc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by substantially lessening competition in the U.S. markets for generic calcipotriene topical solution, generic lidocaine-prilocaine cream, generic metronidazole topical gel, and diclofenac sodium gel. The consent order requires Novartis to: (1) terminate Novartis's marketing agreement with Tolmar, Inc. with respect to the currently marketed products generic calcipotriene topical solution, generic lidocaine-prilocaine cream, and generic metronidazole topical gel ("Marketed Divestiture Products") and return all of Novartis's rights to distribute, market, and sell the Marketed Divestiture Products to Tolmar; and (2) return all rights to develop, distribute, market, and sell the development product generic diclofenac sodium gel to Tolmar.

Participants

For the *Commission*: Christine Tasso and David Von Nirschl.

For the *Respondent*: Claudia Higgins and Saul Morgenstern,
Kaye Scholar LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Respondent Novartis AG ("Novartis"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Fougere Holdings Inc. ("Fougere"), a corporation subject to the jurisdiction of the Commission, in violation of Section 5 of the Federal Trade Commission Act ("FTC Act"), as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the of the Clayton Act, as amended, 15 U.S.C. § 18,

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and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENT

1. Respondent Novartis 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, NY 10169.

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

II. THE ACQUIRED COMPANY

3. 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, NY 11747. The ultimate parent entity of Fougera Holdings Inc. is Fougera S.C.A. SICAR.

III. THE PROPOSED ACQUISITION

4. Pursuant to an Agreement and Plan of Merger (“Acquisition Agreement”) dated May 1, 2012, Novartis, through its subsidiary, Sandoz Inc., proposes to acquire Fougera for approximately \$1.525 billion (the “Acquisition”).

IV. THE RELEVANT MARKETS

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

- a. generic calcipotriene topical solution;

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- b. generic lidocaine-prilocaine cream;
- c. generic metronidazole topical gel; and
- d. generic diclofenac sodium gel.

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

V. THE STRUCTURE OF THE MARKETS

7. Generic calcipotriene topical solution is used to treat chronic, moderately severe scalp psoriasis. Only three companies offer generic calcipotriene topical solution in the United States: Novartis, Fougera, and G & W Laboratories (“G & W”). Novartis leads the market with a 67 percent share. G & W accounts for 22 percent, while Fougera represents an 11 percent share. The Acquisition would increase the Herfindahl-Hirschman Index concentration by 1,474 points to 6,568 points.

8. Generic lidocaine-prilocaine cream is used as a local anesthetic to treat intact skin and to relieve pain from injections and surgery. Lidocaine-prilocaine is available in both 30 gram tubes and packages containing five 5 gram tubes (“5-5 tubes”). The 5-5 tubes are used only in hospitals, while the 30 gram tubes are prescribed directly to patients for home use. Fougera, Hi-Tech Pharmaceutical Co. (“Hi-Tech”), and Novartis are the only U.S. suppliers of 30 gram tubes, with market shares of approximately 50 percent, 47 percent, and 3 percent, respectively. The Acquisition would increase the Herfindahl-Hirschman Index concentration in that market by 300 points to 5,018 points, and leave Hi-Tech as the only competitor to the combined Novartis/Fougera. Only Fougera and Novartis offer the 5-5 tubes, with respective market shares of approximately 83 percent and 17 percent. The Acquisition would therefore create a monopoly in that market.

9. Generic metronidazole topical gel is used to treat inflamed papules and pustules of rosacea, a condition that causes chronic redness of facial skin. Taro Pharmaceutical Industries (“Taro”) is the market leader with approximately 43 percent market share,

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Fougera has approximately 36 percent market share, Novartis has approximately 19 percent market share, and G & W has approximately 2 percent market share. The Acquisition would increase the Herfindahl-Hirschman Index concentration by 1,368 points to 4,878 points.

10. Solaraze is a branded drug sold by Fougera that is used to treat actinic keratosis. No companies currently market a generic version of the drug, diclofenac sodium gel, in the United States. Novartis is best positioned to be the first generic entrant into this market.

VI. ENTRY CONDITIONS

11. Entry into the relevant markets described in Paragraphs 5 and 6 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Entry would not take place in a timely manner because the combination of drug development times and U.S. Food and Drug Administration approval requirements are likely to take at least two years.

VII. EFFECTS OF THE ACQUISITION

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

- a. by eliminating actual, direct, and substantial competition between Novartis and Fougera and reducing the number of competitors in the markets for the sales of generic calcipotriene topical solution, generic lidocaine-prilocaine cream, and generic metronidazole topical gel, thereby: (1) increasing the likelihood that Novartis will be able to unilaterally exercise market power in these markets; (2) increasing the likelihood and degree of coordinated interaction between or among the remaining competitors; and (3) increasing the likelihood that customers would be forced to pay higher prices;

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- b. by eliminating potential competition between Novartis and Fougera in the market for the sale of diclofenac sodium gel and reducing the number of competitors in the future, thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of a generic diclofenac sodium gel product; and (2) increasing the likelihood that the combined entity would delay or eliminate the substantial price competition that would have resulted from an additional supplier of a diclofenac sodium gel product.

VIII. VIOLATIONS CHARGED

13. The Acquisition Agreement described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

14. The Acquisition described in Paragraph 4, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirteenth day of July, 2012 issues its Complaint against said Respondent.

By the Commission.

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,

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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.

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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

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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

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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

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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;

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- 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;

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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

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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;

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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 Fougere, or (ii) are responsible for making business decisions related to those Retained Products 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

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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

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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

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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

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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

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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

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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

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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.

Decision and Order

DECISION AND ORDER
[Redacted Public Version]

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 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, 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 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,

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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.

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- 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 acquisition of fifty percent (50%) or more of the voting securities of Fougera. The Acquisition is contemplated by the Agreement and Plan of Merger by and among Sandoz Inc., Jet Merger Sub Inc., and Fougera Holdings Inc., dated as of May 1, 2012, submitted to the Commission.
- F. “Acquisition Date” means the date on which the Acquisition is consummated.
- G. “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”).
- H. “Application(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDA”), or “Marketing Authorization

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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.

- I. “Collaboration, Development, and Supply Agreement” means the Collaboration, Development, and Supply Agreement between Atrix Laboratories, Inc., and Geneva Pharmaceuticals, Inc., dated August 28, 2000, and the following amendments to the Collaboration and Development and Supply Agreement:
1. Amendment No. 1, effective July 17, 2003;
 2. Amendment No. 2, effective November 11, 2004;
 3. Amendment No. 3, effective March 15, 2007;
 4. Amendment No. 4, effective February 28, 2012;
and
 5. the amendments thereto that constitute the Divestiture Product Agreements.

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

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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),

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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.
- The Divestiture Product Agreements are contained in Non-Public Appendix A attached to this Order.
- P. “Divestiture Product Assets” means, the following:
1. for each Divestiture Product, all of Respondent’s rights to import, Develop, manufacture, process, commercialize, distribute, sell, advertise, market, promote, out-license, or offer for sale, any of the

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Divestiture Products. Such rights include, without limitation, all of the foregoing rights acquired or held by Respondent as a result of the Collaboration, Development, and Supply Agreement and all rights to any and all improvements to the Divestiture Products;

2. a perpetual, non-exclusive, fully paid-up and royalty-free license(s) with rights to sublicense under the Development Divestiture Product Patents to research, Develop, manufacture, distribute, market, sell, store and transport the Development Divestiture Product within the United States;
3. rights to require the Respondent to withdraw from, seek the dismissal (with prejudice) of, and not participate in, any existing patent infringement litigation related to the Development Divestiture Product in which the Respondent is a party and that is directed against Tolmar or any Divestiture Product Releasee and rights to prohibit Respondent from providing assistance to any party adverse to Tolmar in any existing or future patent infringement litigation related to the Development Divestiture Product;
4. all rights to all Product Marketing Materials related to each Divestiture Product;
5. all rights to all Website(s) related exclusively to each Divestiture Product;
6. all content related exclusively to each Divestiture Product that is displayed on any Website that is not dedicated exclusively to the specified Divestiture Product;
7. rights, to the extent permitted by Law:
 - a. to require Respondent to discontinue the use of the NDC Numbers related to each Divestiture Product in the sale or marketing of the

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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 seeking from any customer any type of cross- referencing of those NDC Numbers with any Retained Product(s) *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;
 - c. to approve the timing of Respondent's discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the end of the Transition Period and *except* as may be required by applicable Law; and
 - d. to approve any notification(s) from Respondent to any customer(s) regarding the use or discontinued use of such NDC numbers by the Respondent prior to such notification(s) being disseminated to the customer(s);
8. a list of all customers and targeted customers for each Divestiture Product and, the following:
- a. a listing of the net sales (in either units or dollars) of the 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 Divestiture

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Product on behalf of the High Volume Account and his or her business contact information;

- b. a listing of the inventory levels (weeks of supply) for each customer as of the date the Order to Maintain Assets is issued to become final and effective; and
 - c. anticipated reorder dates for each customer as of the date the Order to Maintain Assets is issued to become final and effective.
9. at the option of Tolmar, copies of all unfilled customer purchase orders for the specified Divestiture Product at any date during the Transition Period;
10. at the option of Tolmar, all unfilled customer purchase orders for the specified Divestiture Product; and
11. copies of all of the Respondent's books, records, and files directly related to the foregoing;

provided, however, that "Divestiture Product Assets" shall not include: (i) 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 Divestiture Product(s); (ii) administrative, financial, and accounting records; (iii) quality control records that are determined by the Interim Monitor or Tolmar not to be material to the marketing, distribution or sale of the specified Divestiture Product; (iv) formulas used to determine the final pricing of any Divestiture Product and/or Retained Products to customers; (v) competitively sensitive pricing information to the extent that it is related to the Retained Products; (vi) rights to the corporate names or corporate trade dress of "Novartis" or "Sandoz", or the related corporate logos

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thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by Respondent or the related corporate logos thereof, or general registered images or symbols by which Novartis or Sandoz can be identified or defined; and (vii) 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);

provided further, however, the Respondent shall provide Tolmar access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes and Respondent may require Tolmar to enter into an agreement to return such original documents under terms that are customary and reasonable for such purposes.

- Q. “Divestiture Product(s)” means the Marketed Divestiture Products and the Development Divestiture Product, individually and collectively.
- R. “Divestiture Product Releasee(s)” means the following Persons:
1. Tolmar;
 2. any Person controlled by or under common control with Tolmar; and
 3. any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Tolmar, or of such Acquirer-affiliated entities, including, without limitation, the New Commercialization Partner.
- S. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.

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- T. “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.
- 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);

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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 all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case existing as of the Acquisition Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any Product of or owned by the Respondent as of the Acquisition Date (*except* where this Order specifies a different time).
- FF. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust,

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unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.

- GG. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.
- HH. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage or transport of the Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application.
- II. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of the specified Marketed Divestiture Product in the Geographic Territory pursuant to the Collaboration, Development and Supply Agreement, 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

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masters and other similar materials related to the specified Divestiture Product.

- JJ. “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).
- KK. “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, (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;

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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.

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- 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.

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

- A. Not later than the earlier of: (i) ten (10) days after the Acquisition Date or (ii) ten (10) days after the Order Date, Respondent shall divest the 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

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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 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 Divestiture Product Assets to Tolmar (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. Prior to the Acquisition Date, Respondent shall secure all consents and waivers from all Third Parties that are necessary to permit Respondent to divest the Divestiture Product Assets to Tolmar; *provided, however*, Respondent may satisfy this requirement by certifying 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, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and

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- c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
- 3. pending complete delivery of all such Confidential Business Information to Tolmar, provide Tolmar and the Interim Monitor (if any has been appointed) with 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 that contain Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
- 4. not use, directly or indirectly, any such Confidential Business Information 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;
- 5. except as otherwise permitted by the Orders, 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;
- 6. 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

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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 Fougere, or (ii) are responsible for making business decisions related to those Retained Products 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 necessary to comply with the requirements of the Orders).

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- E. Not later than thirty (30) days after the Acquisition Date, Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondent's personnel to all of Respondent's employees who are covered by Paragraph II.C.6 and II.C.7. 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 date the Order to Maintain Assets is issued by the Commission to become final and effective. Respondent shall provide a copy of the notification to Tolmar. 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 Tolmar with copies of all certifications, notifications and reminders sent to Respondent's personnel.
- F. Respondent shall:
1. until the end of the Transition Period, take such actions with respect to the marketing, sales or distribution of the Marketed Divestiture Products as are necessary to:
 - a. maintain the ongoing economic viability and marketability of the businesses associated with that Marketed Divestiture Product;
 - b. minimize any risk of loss of competitive potential for that business;
 2. until the end of the Transition Period, not take any action that lessens the ongoing economic viability, marketability, or competitiveness of businesses related to the Marketed Divestiture Products; and

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3. other than as in the manner prescribed in this Order, not sell, transfer, encumber or impair the Divestiture Product Assets.

G. Respondent shall not join, file, prosecute or maintain any suit, in law or equity, against Tolmar or the Divestiture Product Releasee(s) for the research, Development, manufacture, use, import, export, distribution, marketing or sale of the Divestiture Product(s) under the following:

1. any Patent owned or licensed by Respondent as of the day after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claims a method of making, using, or administering, or a composition of matter, relating to the Divestiture Product(s), or that claims a device relating to the use thereof;
2. any Patent owned or licensed by Respondent at any time after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the Divestiture Product(s);

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

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Product Releasee(s) under such Patents, if the suit would have the potential to interfere with that Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Product(s) anywhere in the World for the purposes of marketing or sale in the United States of America; or (2) the use within, import into, export from, or the supply, distribution, marketing, or sale within, the United States of America of a particular Divestiture Product.

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

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I. Respondent shall not, in the Geographic Territory:

1. use the Product Trademarks 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 such Product Trademarks;
4. challenge or interfere with Tolmar's use and registration of such Product Trademarks; or
5. challenge or interfere with Tolmar's efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties;

provided however, that this paragraph shall not preclude Respondents from continuing to use all trademarks, tradenames, or service marks that have been in use in commerce on a Retained Product at any time prior to the Acquisition Date.

J. The purpose of the divestiture of the Divestiture Product Assets and the related obligations imposed on the Respondent by this Order is:

1. to provide for the future use of such assets for the distribution, sale and marketing of each Divestiture Product in the Geographic Territory;
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.

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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

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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.

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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

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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 Divestiture Product Assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief

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available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- 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

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agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission

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determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondent from among those approved by the Commission; *provided further, however*, that Respondent shall select such Person within five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether

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or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.
 8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
 9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

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

- G. Any Remedial Agreement shall be deemed incorporated into this Order.
- H. Any failure by the Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- I. 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.
- J. 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.
- K. 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

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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.

Decision and 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, 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.

IX.

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

By the Commission.

Analysis to Aid Public Comment

NON-PUBLIC APPENDIX A

**THE COLLABORATION, DEVELOPMENT AND SUPPLY
AGREEMENT**

AND

THE DIVESTITURE AGREEMENTS

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

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Novartis AG (“Novartis”) that is designed to remedy the anticompetitive effects of Novartis’s acquisition of Fougere Holdings Inc. (“Fougere”) in several generic pharmaceutical markets. Under the terms of the proposed Consent Agreement, Novartis is required to: (1) terminate Novartis’s marketing agreement with Tolmar, Inc. (“Tolmar”) with respect to the currently marketed products generic calcipotriene topical solution, generic lidocaine-prilocaine cream, and generic metronidazole topical gel (“Marketed Divestiture Products”) and return all of Novartis’s rights to distribute, market, and sell the Marketed Divestiture Products to Tolmar; and (2) return all rights to develop, distribute, market, and sell the development product generic diclofenac sodium gel to Tolmar.

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

Analysis to Aid Public Comment

withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (“Order”).

Pursuant to an Agreement and Plan of Merger executed on May 1, 2012, Novartis proposes to acquire Fougera in a transaction valued at approximately \$1.525 billion (the “Proposed Acquisition” or “Acquisition”). The Commission’s Complaint alleges that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in the U.S. markets for generic calcipotriene topical solution, generic lidocaine-prilocaine cream, generic metronidazole topical gel, and diclofenac sodium gel. The proposed Consent Agreement will remedy the alleged violations by replacing the competition that would otherwise be eliminated by the Acquisition.

The Products and Structure of the Markets

The Acquisition would reduce the number of generic suppliers in three current generic drug markets with likely anticompetitive consequences. In human pharmaceutical product markets with generic competition, price generally decreases as the number of generic competitors increases. Accordingly, the reduction in the limited number of suppliers within each relevant market has a direct and substantial effect on pricing.

Generic calcipotriene topical solution is used to treat chronic, moderately severe scalp psoriasis. Only three companies offer generic calcipotriene topical solution in the United States: Novartis, Fougera, and G & W Laboratories (“G & W”). Novartis leads the market with a 67 percent share. G & W accounts for 22 percent, while Fougera represents an 11 percent share.

Generic lidocaine-prilocaine cream is used as a local anesthetic to treat intact skin and to relieve pain from injections and surgery. Lidocaine-prilocaine is available in both 30 gram tubes and packages containing five 5 gram tubes (“5-5 tubes”). The 5-5 tubes are used only in hospitals, while the 30 gram tubes are prescribed directly to patients for home use. Fougera, Hi-Tech Pharmaceutical Co. (“Hi-Tech”), and Novartis are the only U.S. suppliers of 30 gram tubes. The market for the generic 5-5

Analysis to Aid Public Comment

tubes is even more concentrated as only Fougera and Novartis offer them. The Acquisition would therefore create a monopoly in the generic lidocaine-prilocaine 5-5 tube market.

Generic metronidazole topical gel is used to treat inflamed papules and pustules of rosacea, a condition that causes chronic redness of facial skin. Taro Pharmaceutical Industries (“Taro”) is the market leader with approximately 43 percent market share, Fougera has approximately 36 percent market share, Novartis has approximately 19 percent market share, and G & W has approximately 2 percent market share.

Furthermore, the Acquisition could inhibit significant future competition by reducing the number of potential suppliers in the diclofenac sodium gel market. Solaraze is a branded drug sold by Fougera that is used to treat actinic keratosis. No companies currently market a generic version of the drug, diclofenac sodium gel, in the United States. Novartis is best positioned to be the first generic entrant into this market.

Entry

Entry into the relevant markets for the sale of the products would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Entry would not take place in a timely manner because the combination of drug development times and U.S. Food and Drug Administration (“FDA”) approval requirements are likely to take at least two years.

Effects

In each of the relevant product markets, the Proposed Acquisition likely would eliminate one of a limited number of suppliers and cause significant competitive harm by facilitating price increases – or eliminating decreases – after the transaction is consummated.

In generic pharmaceuticals markets, pricing is heavily influenced by the number of competitors with sufficient supply that participate in the market. Market participants consistently characterize generic drug markets as commodity markets in which

Analysis to Aid Public Comment

the number of generic suppliers has a direct impact on pricing. Customers and competitors alike have confirmed that the price of a generic pharmaceutical product decreases with the entry of the second, third, and even fourth and fifth generic competitor. Further, customers generally believe that having at least four suppliers in a generic pharmaceutical market produces the most competitive prices.

Evidence gathered during our investigation indicates that anticompetitive effects are likely to result from a decrease in the number of independent competitors in the markets at issue. The Proposed Acquisition, by reducing an already limited number of competitors or potential competitors in each of these markets, would cause anticompetitive harm to U.S. consumers by increasing the likelihood of higher post-acquisition prices. In the market for generic calcipotriene topical solution, Novartis and Fougera are two of only three suppliers. In the lidocaine-prilocaine cream 30 gram tube market, Novartis and Fougera are two of only three suppliers of the product, and the Proposed Acquisition would eliminate Fougera as an independent competitor to Novartis leaving only Hi-Tech. In the generic lidocaine-prilocaine cream 5-5 gram tubes market, the Acquisition would result in a merger to monopoly. In the generic metronidazole gel market, Novartis and Fougera are two of four competitors, and combined, Novartis and Fougera represent 55 percent of the market. In all of these markets, industry participants have indicated that the presence of Fougera as a competitor has allowed them to negotiate lower prices.

Finally, the Acquisition would eliminate significant potential competition between Novartis and Fougera in the market for the sale of diclofenac sodium gel. Novartis, through its agreement with Tolmar, was the first to file for an approval of a generic form of Solaraze with the FDA. Thus, Fougera's brand, Solaraze, is likely to face competition solely from Novartis for a significant period of time when generic competition is introduced into this market. As a result, the Acquisition would increase the likelihood that the launch of a generic diclofenac sodium gel product would be delayed or abandoned altogether and increase the likelihood that the combined entity would delay or eliminate the substantial price competition that would have resulted from the entry of a supplier of a generic diclofenac sodium gel product.

Analysis to Aid Public Comment

The Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the relevant product markets. Pursuant to the Consent Agreement, Novartis is required to return certain rights related to the relevant products to Tolmar no later than ten (10) days after the Acquisition. Specifically, the proposed Consent Agreement requires that Novartis: (1) terminate its marketing agreement with Tolmar, thereby returning all of its rights to distribute, market, and sell the Marketed Divestiture Products back to Tolmar; and (2) return all rights to develop, distribute, market, and sell generic diclofenac sodium gel to Tolmar. Tolmar is the Colorado-based developer and manufacturer of the relevant generic products.

If Novartis does not fully comply with its obligations to return all rights to generic calcipotriene topical solution, generic lidocaine-prilocaine cream, generic metronidazole topical gel, and generic diclofenac sodium gel, the Commission may appoint a trustee to effect the return of such rights.

The proposed remedy contains several provisions to ensure that the transfer of rights back to Tolmar is successful. The Consent Agreement contains an Order to Maintain Assets that requires Novartis to continue to market the Marketed Divestiture Products in a manner that maintains the full economic viability and marketability of the businesses until Tolmar directs Novartis to cease marketing the Marketed Divestiture Products or Tolmar's new marketing partner commences the distribution, marketing, and sale of the Marketed Divestiture Products.

The Commission appointed William Rahe of Quantic Regulatory Services, LLC to act as an interim monitor to assure that Novartis expeditiously complies with all of its obligations and performs all of its responsibilities as required by the Consent Agreement. In order to ensure that the Commission remains informed about the status of the returned rights and assets, the Consent Agreement requires Novartis to file reports with the interim monitor who will report in writing to the Commission concerning performance by Novartis of its obligation under the Consent Agreement.

Analysis to Aid Public Comment

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

Complaint

IN THE MATTER OF

FRANKLIN'S BUDGET CAR SALES, INC.
DBA
FRANKLIN TOYOTA/SCION

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND THE
GRAMM-LEACH-BLILEY ACT

Docket No. C-4371; File No. 102 3094
Complaint, October 3, 2012 – Decision, October 3, 2012

This consent order addresses Franklin's Budget Car Sales, Inc.'s practices that, taken together, failed to provide reasonable and appropriate security for personal information on its computers and networks. The complaint alleges that Franklin Toyota misrepresented that it implements reasonable and appropriate measures to protect consumers' personal information from unauthorized access, in violation of Section 5 of the Federal Trade Commission Act; and violated the Gramm-Leach-Bliley Privacy Rule by failing to send consumers annual privacy notices and by failing to provide a mechanism by which consumers could opt out of information sharing with nonaffiliated third parties. The consent order prohibits Franklin Toyota from violating any provision of the Gramm-Leach-Bliley Act's Standards for Safeguarding Consumer Information Rule ("Safeguards Rule") and making misrepresentations about the privacy, security, confidentiality, and integrity of any personal information collected from or about consumers.

Participants

For the *Commission*: Karen Jagielski.

For the *Respondent*: Michael A. Goodman, Hudson Cook, LLP.

COMPLAINT

The Federal Trade Commission ("FTC" or "Commission"), having reason to believe that Franklin's Budget Car Sales, Inc., also dba Franklin Toyota/Scion ("Franklin Toyota" or "respondent") has violated Section 5(a) of the FTC Act, 15 U.S.C. § 45(a); the provisions of the Commission's Standards for Safeguarding Customer Information Rule ("Safeguards Rule"), 16 C.F.R. Part 314, issued pursuant to Title V, Subtitle A of the Gramm-Leach-Bliley Act ("GLB Act") (codified at 15 U.S.C. §§