

FEL TRADE COMMI

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

Commission Rule 2.34, 16 C.F.R. § 2.34, the Com

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” (“SNDAs”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed.

5. the amendments thereto that constitute the Divestitur

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 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 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 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 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.

- 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 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*

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;
3. any agreement between the Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, (i) any agreement to supply specified products or components thereof, or (ii) any agreement to provide transitional services related to the business being transferred to the Acquirer, and that has been approved by the Commission to accomplish the requirements of this Order; and/or
4. any agreement between the Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

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

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

- NN. “Tolmar” means Tolmar Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address located at 701 Centre Avenue, Fort Collins, Colorado 80526. Tolmar was formerly known as Atrix Laboratories, Inc., the party to the Collaboration, Development and Supply Agreement.
- OO. “Transition Period” means, for each Marketed Divestiture Product, the period beginning on the date the Order to Maintain Assets becomes final and effective and ending, with respect to each Marketed Divestiture Product, on the earlier of the following dates: (i) the date on which Tolmar directs the Respondent to cease the distribution, marketing and sale of that Marketed Divestiture Product; or (ii) the date on which the New Commercialization Partner commences the distribution, marketing, and sale of that Marketed Divestiture Product; *provided however*, the Transition Period shall end not later than six (6) months from the Order Date.
- PP. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by the Respondent; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by the Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that the Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

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 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

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

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
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 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

I. Respondent shall not, in the Geographic Territory:

1. use the Product Trademarks or 4a11c3d7., 0.0000 TD(og)Tj12.0000 0.00017gn9.0200 0.0000 TDu P00

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

duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.

2.

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 restri

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

- 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 neces

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 require

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 ten (10) years from the Order Date.

By the Commission.

Donald S. Clark
Secretary

SEAL

ISSUED: _____

NON-PUBLIC APPENDIX A

THE COLLABORATION, DEVELOPMENT AND SUPPLY AGREEMENT

AND

THE DIVESTITURE AGREEMENTS