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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright

In the Matter of	)	
MYLAN INC., **a corporation;**	)	
AGILA SPECIALTIES GLOBAL PTE. LIMITED, **a corporation;**	)	
AGILA SPECIALTIES PRIVATE LIMITED, **a corporation;**	)	**Docket No. C-4413**
and	)	
STRIDES ARCOLAB LIMITED, **a corporation.**	)	

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Mylan Inc. ("Mylan") of the voting securities of Respondents Agila Specialties Global Pte. Limited and Agila Specialties Private Limited (collectively "Agila") from Respondent Strides Arcolab Limited, and Respondents 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 Respondents 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

ORDER

I.

IT IS ORDERED that, as used in the Order, the following definitions shall apply:

A. "Mylan" means Mylan Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Mylan Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Mylan shall include Agila.

B. "Agila" means: (i) Agila Specialties Global Pte. Limited, its directors, officers,

H. "Acquisition" means Respondent Mylan's acquisition of the voting securities of Agila. The acquisition is contemplated pursuant to a *Sale and Purchase Agreement* among Agila Specialties Asia Pte. Limited, Mylan Inc., Arun Kumar and Pronomz Ventures LLP, dated as of February 27, 2013, and a *Sale and Purchase Agreement* among Strides Arcolab Limited, Mylan Inc., Arun Kumar and Pronomz Ventures LLP, dated as of February 27, 2013, submitted to the Commission.

I. "Acquisition Date" means the date on which the Acquisition is consummated.

J. "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 (AFDA").

K. "Amiodarone Products" means the following: all Products in Development, manufactured, marketed, sold, owned or controlled by Respondent Agila pursuant to ANDA No. 076394, and any supplements, amendments, or revisions thereto.

L. "Application(s)" means all of the following: "New Drug Application" (ANDA"), "Abbreviated New Drug Application" (AANDA"), "Supplemental New Drug Application" ("SNDA"), or AMarketing Authorization 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, registration dossier, 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, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the Respondent and the FDA related thereto.

M. "Business" means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement and sale of a Product.

N. "Categorized Assets"

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FDA to facilitate the investigation of adverse effects related to the specified Divestiture Product (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);

13. for any specified Divestiture Product that has been marketed or sold by a Respondent prior to the Closing Date, a list of all customers and targeted customers for the specified Divestiture Product and a listing of the net sales (in either units or dollars) of the specified 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 specified Divestiture Product on behalf of the High Volume Account and his or her business contact information;

14. for each specified Divestiture Product that is a Contract Manufacture Product:

    a. a list of the inventory levels (weeks of supply) for each customer (*i.e.*, retailer, group purchasing organization, wholesaler or distributor) as of the Closing Date; and

    b. anticipated reorder dates for each customer as of the Closing Date;

15. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to the specified Divestiture Product;

16. copies of all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date, to be provided to the Acquirer of the specified Divestiture Product not later than five (5) days after the Closing Date;

17. at the option of the Acquirer of the specified Divestiture Product, all unfilled customer purchase orders for the specified Divestiture Product; and

18. all of the Respondent's books, records, and files directly related to the foregoing;

provided, however, that "Categorized Assets" shall not include: (i) documents relating to the specified Respondent's general business strategies or practices relating to the conduct of its Business s gener EMC /H3 <</MCI(d)7(u)2(c)1(t,)2(a)1((l

provided further, however, that in cases in which documents or other materials included in the assets to be divested contain information: (i) that relates both to the specified Divestiture Product and to Retained Products or Businesses of the specified Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Divestiture Product; or (ii) for which the specified Respondent has a legal obligation to retain the original copies, the Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the specified Divestiture Product, the Respondent shall provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the specified Respondent provides the Acquirer with the above-described information without requiring the Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

O. "cGMP" means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.

P. "Clinical Trial(s)" means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.

Q. "Closing Date" means, as to each Divestiture Product, the date on which a Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.

R. "Confidential Business Information" means all information owned by, or in the possession or control of, any Respondent that is not in the public rs isseo sPrnReny t ey ern02 Tc -7.001

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4. 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.

S. "Contract Manufacture" means, the following:

1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer;

2. to manufacture, or to cause to be manufactured, a Product that is the therapeutic equivalent (as that term is defined by the FDA) and in the identical dosage strength, formulation and presentation as a Contract Manufacture Product on behalf of an Acquirer;

3. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Contract Manufacture Product on behalf of an Acquirer.

T. "Contract Manufacture Product(s)" means:

1. the Acetylcysteine Products;

2. the Amiodarone Products;

3. the Etomidate Products; and

4. the Fomepizole Products;

5. the Mesna Products; and

6. any ingredient, material, or component used in the manufacture of any of the foregoing Products including the active pharmaceutical ingredient, excipients or packaging materials;

provided however, that with the consent of the Acquirer of the specified Product, a Respondent may substitute a therapeutic equivalent (as that term is defined by the FDA) form of such Product in performance of that Respondent's agreement to Contract Manufacture.

U. "Development" means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. "Develop" means to engage in Development.

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GG. "Fomepizole Products" means the following: all Products in Development, manufactured, marketed, sold, owned or controlled by Respondent Agila pursuant to ANDA No. 205283, and any supplements, amendments, or revisions thereto.

HH. "Ganciclovir Products" means the following: all Products in Development, manufactured, marketed, sold, owned or controlled by Respondent Mylan pursuant to ANDA No. 204950, and any supplements, amendments, or revisions thereto.

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

JJ. "Gland" means Gland Pharma Limited, a corporation organized, existing and doing business under and by virtue of the laws of the Republic of India, with its headquarters address located at 6-3-862, Ameerpet, Hyderabad 500 016 India.

KK. "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.

LL. "Group A Divestiture Products" means:

1. the Flourouracil Products; and
2. the Methotrexate Products.

MM. "Group A Divestiture Product Agreement(s)" means, the following:

1. the *Asset Purchase Agreement* among Mylan Inc., Accord Healthcare, Inc. and Intas Pharmaceuticals Limited, dated as of August 30, 2013;
2. the *Disclosure Letter to the Asset Purchase Agreement* among Mylan Inc., Accord Healthcare, Inc. and Intas Pharmaceuticals Limited, dated as of August 30, 2013;
3. *Amendment No. 3 to Supply Agreement* (to that certain the Supply Agreement, dated as of April 28, 2005, between GeneraMedix and Intas Pharmaceuticals, Ltd.) by and between Vinovia Enterprises Limited and Intas Pharmaceuticals, Ltd., which is to be executed on the Closing Date for the Group A Divestiture Assets;
4. *Termination of Technical/ Quality Agreement* (in respect of that certain Technical/Quality Agreement effective as of June 28, 2013, by and between Intas Pharmaceuticals Ltd. and Mylan Teoranta d/b/a Mylan Institutional) by and between Intas Pharmaceuticals Ltd. and Mylan Institutional, which is to be executed on the Closing Date for the Group A Divestiture Assets; and
5. all amendments, exhibits, attachments, agreements, and schedules thereto,

related to the Group A Divestiture Assets that have been approved by the Commission to accomplish the requirements of this Order. The Group A Divestiture Product Agreements are contained in Non-Public Appendix I.

NN. "Group A Divestiture Product Assets" means all rights, title and interest in and to all assets related to the Business within the Geographic Territory of the specified Respondent (as that Respondent is identified in the definition of the respective Divestiture Product) related to each of the respective Group A Divestiture Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Group A Divestiture Products.

OO. "Group B Divestiture Products" means the following:

1. the Amiodarone Products;
2. the Etomidate Products;
3. the Fomepizole Products;

RR. “Group C Divestiture Products” means:

1. the Acetylcysteine Products; and
2. the Mesna Products.

SS. “Group C Divestiture Product Agreement(s)” means, the following

Date; (iii) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or (iv) the end of the last quarter following the Acquisition or the Closing Date.

VV.

DDD. "Meropenem Products" means the following: all Products in Development, manufactured, marketed, sold, owned or controlled by Respondent Mylan pursuant to ANDA No. 204139, and any supplements, amendments, or revisions thereto.

EEE. "Mesna Products" means the following: all Products in Development, manufactured, marketed, sold, owned or controlled by Respondent Agila pursuant to ANDA No. 090913, and any supplements, amendments, or revisions thereto.

FFF. "Methotrexate Products" means the following: all Products in Development, manufactured, marketed, sold, owned or controlled by Respondent Mylan pursuant to the following ANDAs:

1. ANDA No. 040716;
2. ANDA No. 040767;
3. ANDA No. 040768; and,
4. any supplements, amendments, or revisions thereto.

GGG. "Mycophenolate Mofetil Products" means the following: all Products in Development, manufactured, marketed, sold, owned or controlled by Respondent Mylan pursuant to ANDA No. 203575, and any supplements, amendments, or revisions thereto.

HHH. "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.

III. "Orders" means this Decision and Order and the related Order to Maintain Assets.

JJJ. "Order Date" means the date on which the final Decision and Order in this matter is issued by the Commission.

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

LLL. "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 filed, or in existence, on or before the Closing 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.

MMM. "Person" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.

NNN. “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.

OOO. “Product Approval(s)” means any approvals, registrations,

11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;

12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the specified Divestiture Product to the Respondent including, but not limited to, consultation arrangements; and/or

13. pursuant to which any Third Party collaborates with the Respondent in the performance of research, Development, marketing, distribution or selling of the specified Divestiture Product or the Business related to such Divestiture Product;

provided, however, that where any such contract or agreement also relates to a Retained Product(s), the Respondent shall assign the Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

QQQ. "Product Copyrights" means rights to all original works of authorship of any kind directly related to a Divestiture Product and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and educational materials for the sales force; copyrights in all preclinical, clinical and process development data and reports relating to the research and Development of that Product or of any materials used in the research, Development, manufacture, marketing or sale of that Product, including all copyrights in raw data relating to Clinical Trials of that Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, that Product's sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees of a Respondent who accept employment with an Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to that Product or relating to its biology; all copyrights in adverse experience reports and fi(c)-1i0 Tw ye1(t)-2(e)2ti toa2(i)3(e)y hifiednsfe e

RRR. "Product Development Reports" means:

1. Pharmacokinetic study reports related to the specified Divestiture Product;
2. Bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product;
3. Bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product;
4. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from or otherwise conducted with the FDA relating to the Application(s) related to the specified Divestiture Product;
5. annual and periodic reports related to the above-described Application(s), including

16.

3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques,

WWW. "Product Manufacturing Technology" means all of the following related to a Divestiture Product:

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of that Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;
2. all ingredients, materials, or components used in the manufacture of any that Product including the active pharmaceutical ingredient, excipients or packaging materials; and,
3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer's option, all such equipment used to manufacture that Product.

XXX. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g*., detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the specified Divestiture Product.

YYY. "Product Research and Development Employees" means all salaried employees of a Respondent who have directly participated in the research, Development, regulatory approval process, or clinical studies of the specified Divestiture Product (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) with the eighteen (18) month period immediately prior to the Closing Date.

ZZZ. "Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and Clinical Trial materials and information.

AAAA. "Product Trade Dress" means the current trade dress of a Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.

BBBB. "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 a Product.

CCCC. "Proposed Acquirer" means a Person proposed by a Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets or rights required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed pursuant to this Order.

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

1. any agreement between a Respondent(s) 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, any agreement to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;

2. any agreement between a Respondent(s) and a Third Party to effect the assignment of assets or rights of that Respondent(s) 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 a Respondent(s) 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, any agreement by that Respondent(s) to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or

4. any agreement between a Respondent(s) and a Third Party to effect the assignment of assets or rights of that Respondent(s) 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.

EEEE. "Retained Product" means any Product(s) other than a Divestiture Product.

FFFF. "Right of Reference or Use" means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an Application or to defend an Application, including the ability to make available the underlying raw data from the investigation for FDA audit.

GGGG. "Sagent" means Sagent Pharmaceuticals, 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 1901 N. Roselle Road, Suite 700, Schaumburg, Illinois 60195.

HHHH. "Supply Cost" means a cost not to exceed the Respondent's (as that Respondent is identified in the definition of the respective Divestiture Product) average direct per unit cost in United States dollars of manufacturing the specified Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date. "Supply Cost" shall expressly exclude any intracompany business transfer profit; *provided, however*, that in each instance where: (i) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, "Supply Cost" means the cost as specified in such Remedial Agreement for that Divestiture Product.

IIII. "Technology Transfer Standards" means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*,

1. designating employees of the Respondent(s) nn

4. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:

   a. manufacture the specified Divestiture Product in the quality and quantities achieved by the specified Respondent (as that Respondent is identified in the definition of the specified Divestiture Product), or the manufacturer and/or developer of such Divestiture Product;

   b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell the specified Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and

   c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product.

JJJJ. "Third Party(ies)" means any non-governmental Person other than the following: the Respondents; or, the Acquirer of particular assets or rights pursuant to this Order.

KKKK. "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 a Respondent; *provided, however*, "Website" shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by a Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that a 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 Mylan shall divest the Group A Divestiture Product Assets and grant the related Divestiture Product License, absolutely and in good faith, to Intas pursuant to, and in accordance with, the Group A Divestiture Product Agreement(s) (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

provided, however, that if Respondent Mylan has divested the Group A Divestiture Product Assets to Intas prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent Mylan that Intas is not an acceptable purchaser of the Group A Divestiture Product Assets, then Respondent Mylan shall immediately rescind the transaction with Intas, in whole or in part, as directed by the Commission, and shall divest the Group A Divestiture Product Assets within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further that if Respondent Mylan has divested thedivested the Group A

D. Not later than the earlier of: (i) ten (10) days after the Acquisition Date or (ii) ten (10) days after the Order Date, Respondent Mylan shall divest the Labetalol Product Assets (to the extent that such assets are not already owned, controlled or in the possession of Gland), absolutely and in good faith, to Gland pursuant to, and in accordance with, the Labetalol Product Divestiture 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 Gland or to reduce any obligations of Respondent Mylan under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Labetalol Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent Mylan has divested the Labetalol Divestiture Product Assets to Gland prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent Mylan that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent Mylan, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Labetalol Divestiture Product Assets to Gland (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.

E. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the assets required to be divested pursuant to this Order to an Acquirer, and to permit the relevant Acquirer to continue the Business of the Divestiture Product(s) being acquired by that Acquirer;

provided, however, Respondents may satisfy this requirement by certifying that the relevant Acquirer for the Divestiture Product has executed all such agreements directly with each of the relevant Third Parties.

F. Respondents shall:

1. submit to each Acquirer, at Respondents' expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;

2. deliver all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer to that Acquirer:

    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;

3. pending complete delivery of all such Confidential Business Information to the relevant Acquirer, provide that Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of

3. give priority to supplying a Contract Manufacture Product to the relevant Acquirer over manufacturing and supplying of Products for Respondents' own use or sale;

4. make representations and warranties to each Acquirer that Respondents shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure of the Contract Manufacture Products to be delivered in a timely manner as required by the Remedial Agreement(s) unless Respondents can demonstrate that the failure was beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents;

   provided, however, that in each instance where: (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on a Respondent's aggregate liability for such a failure;

5. during the term of any agreement to Contract Manufacture, upon written request of that Acquirer or the Interim Monitor (if any has been appointed), make available to the Acquirer and the Interim Monitor (if any has been appointed) all records that relate to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;

6. during the term of any agreement to Contract, Respondent Mylan shall take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);

7. in the event Respondent Mylan becomes unable to supply or produce a Contract Manufacture Product from the facility or facilities originally contemplated under a Remedial Agreement with an Acquirer, then Respondent Mylan shall provide a therapeutically equivalent (as that term is defined by the FDA) Product from another of Respondent Mylan's facility or facilities in those instances where such facilities are being used or have previously been used, and are able to be used, by Respondents to manufacture such Product(s);

8. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Interim Monitor to monitor compliance with the obligations to Contract Manufacture;

9. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of the Respondents and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all Product Approvals to manufacture the Contract Manufacture Products acquired by that Acquirer in the same quality achieved by, or on behalf of, the relevant Respondent (as that Respondent is identified in the definition of the respective Divestiture Product) and in commercial quantities, and in a manner consistent with

cGMP, independently of Respondent Mylan and sufficient to satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the Contract Manufacture Products;

The foregoing provisions, II.H.1. - 9., shall remain in effect with respect to each Contract Manufacture Product until the earliest of: (i) the date the Acquirer of that Contract Manufacture Product (or the Manufacturing Designee(s) of that Acquirer), respectively, is approved by the FDA to manufacture and sell such Contract Manufacture Product in the United States and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent Mylan; (ii) the date the Acquirer of a particular Contract Manufacture Product notifies the Commission and Respondent Mylan of its intention to abandon its efforts to manufacture such Contract Manufacture Product; (iii) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer of a particular Contract Manufacture Product has abandoned its efforts to manufacture such Contract Manufacture Product, or (iv) the date five (v) years from the Closing Date.

I. Respondent Mylan shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one (1) year period prior to the Closing Date and each employee that has responsibilities related to the marketing or sales of those Retained Products that are the therapeutic equivalent (as that term is defined by the FDA) of the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee 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 Mylan (other than as necessary to comply with the requirements of this Order).

J. Not later than thirty (30) days after the Closing Date, Respondent Mylan shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondent Mylan's

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, and manufacture the Divestiture Product consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Product and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

provided, however, that this Paragraph does not require nor shall be construed to require Respondents to terminate the employment of any employee or to prevent Respondents from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition; and

5. for a period of one (1) year from the Closing Date, not, directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product ("Divestiture Product Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or hire any Divestiture Product Employee;

provided, however, Respondents may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with a Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided further, *however*, that any Respondent may do the following: (i) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product Employee who contacts any Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from any Respondent.

L. Until Respondents complete the divestitures required by this Order and fully provide, or cause to be provided, the Product Manufacturing Technology related to a particular Divestiture Product to the relevant Acquirer,

1. Respondents shall take actions as are necessary to:

   a. maintain the full economic viability and marketability of the Businesses associated with that Divestiture Product;

   b. minimize any risk of loss of competitive potential for that Business;

   c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to that Divestiture Product;

d. ensure the assets related to each Divestiture Product are provided to the relevant Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Business associated with each Divestiture Product;

e.

N. Upon reasonable written notice and request from an Acquirer to Respondent Mylan, Respondent Mylan shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent Mylan to assist that Acquirer to

3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

III.

IT IS FURTHER ORDERED that:

A. At any time after the Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that the Respondents expeditiously comply with all of their obligations and perform all of their 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 Respondents, which consent shall not be unreasonably withheld. If Respondent Mylan 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 Mylan of the identity of any proposed Interim Monitor, Respondents 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 Mylan 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 Respondents' 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, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:

1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.

2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.

3. The Interim Monitor shall serve until the date of completion by the Respondents of the divestiture of all Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and, with respect to each Divestiture Product that is a Contract Manufacture Product, until the earliest of:

a. the date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell that Divestiture Product and able to manufacture the Divestiture Product in commercial quantities, in a manner consistent with cGMP,

independently of Respondent Mylan;

b. the date the Acquirer of that Divestiture Product notifies the Commission and Respondent Mylan of its intention to abandon its efforts to manufacture that Divestiture Product; or

c. the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture that Divestiture Product;

provided, however, that, the Interim Monitor's service shall not exceed five (5) years 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.

E. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' 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 Respondents' compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondents 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 Respondents' compliance with the Orders.

F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent Mylan, 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 Mylan, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.

G. Respondents 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.

H. Respondents 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 Respondents, and any reports submitted by each Acquirer with respect to the performance of Respondents' obligations under the Order or the Remedial Agreement(s).

Within thirty (

under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(*l*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.

B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent Mylan, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent Mylan

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

9. Respondents 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,* that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee'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 Divestiture Trustee's duties.

F. 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.

G. 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.

V.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, each Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

A. To assure such Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or

B. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and Businesses associated with those Divestiture Products;

VII.

IT IS FURTHER ORDERED that:

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

B.

IX.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that 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

NON-PUBLIC APPENDIX I
AGREEMENTS RELATED TO THE DIVESTITURES

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