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UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
William E. Kovacic
J. Thomas Rosch
Edith Ramirez
Julie Brill

In the Matter of	)	
HIKMA PHARMACEUTICALS PLC,	)	**Docket No. C-**
a corporation,	)	

1. Respondent Hikma is a corporation organized, existing and doing business under and by virtue of the laws of England and Wales, with its headquarters address at 13 Hanover Square, London W1S 1HW, United Kingdom and the address of its United States subsidiary, West-ward Pharmaceutical Corp., located at 465 Industrial Way West, Eatontown, New Jersey 07724-2209.

2. Baxter is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at One Baxter Parkway, Deerfield, Illinois 60015-4633.

3. The Com

E. "Acquisition" means the acquisition contemplated by the "Asset Purchase Agreement" by and among West-ward Pharmaceutical Corporation, Hikma (Maple) Limited, and Baxter, dated as of October 29, 2010.

F. "Acquisition Date" means the date the Respondent closes on the Acquisition pursuant to the Asset Purchase Agreement, by and among West-ward Pharmaceutical Corporation, Hikma (Maple) Limited and Baxter, dated as of October 29, 2010.

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 Application" ("MAA"), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Respondent and the FDA related thereto. The term "Application" also includes an "Investigational New Drug Application" ("IND") for a Product 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 Respondent and the FDA related thereto.

I. "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.

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

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

L. "Confidential Business Information" means all information owned by, or in the possession or control of, a 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 the Generic Injectable Product(s);

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.

P. "Direct Cost" means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. "Direct Cost" to the Acquirer for its use of any of Respondent's employees' labor shall not exceed the average hourly wage rate for such employee;

provided, however, in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Generic Injectable Product, "Direct Cost" means such cost as is provided in such Remedial Agreement for that Generic Injectable Product.

Q. "Divestiture Trustee" means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.

R. "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. "Domain Name" shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.

S. "Drug Master Files" means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.

T. "Generic Injectable Product(s)" means the following: all Products in Development, manufactured, marketed or sold by Respondent Hikma pursuant to the following ANDAs:

1. Phenytoin, in 2mL vials and 10 mL vials with a dosage strength of 50mg/mL pursuant to ANDA No. A040573;

2. Promethazine, in 1mL ampoules with dosage strengths of 25mg/mL or 50mg/mL pursuant to ANDA No. A040737; and

3. any supplements, amendments, or revisions thereto;

provided, however, that for the purposes of the Contract Manufacture provisions of this Order, the term "Generic Injectable Products" shall include all presentations of any Retained Product that, as of the Acquisition Date, are being, or will be, manufactured, marketed or sold by the Respondent for sale within the United States that contain the same active pharmaceutical ingredients in the dosage strengths and presentations specified above.

8. Right of Reference or Use to the Drug Master Files related to the above-described Applications including, but not limited to, the pharmacology and toxicology data contained in all Application(s);

9. all Product Development Reports related to any such Generic Injectable Product;

10. at the Acquirer's option, all Product Assumed Contracts related to any such Generic Injectable Product (copies to be provided to the Acquirer on or before the Closing Date);

11. all strategic safety programs submitted to the FDA related to any such Generic Injectable Product that are designed to decrease product risk by using one or more interventions or tools beyond the package insert;

12. all patient registries related to any such Generic Injectable Product, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to any such Generic Injectable Product;

13. a list of all customers and targeted customers for such Generic Injectable Product and a listing of the net sales (in either units or dollars) of such Generic Injectable Products 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 such Generic Injectable Products on behalf of the High Volume Account and his or her business contact information;

14. at the Acquirer's option 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 any such Generic Injectable Product;

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

16. at the Acquirer's option, subject to any rights of the customer, all unfilled customer purchase orders for such Generic Injectable Product; and

17. all of the Respondent's books, records, and files directly related to the foregoing or to any such Generic Injectable Product;

provided, however, that "Generic Injectable Product Assets" shall not include: (1) documents relating to 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 Generic Injectable Products; (2) shall not include administrative, financial, and accounting records; (3) quality control records that are determined by the Interim Monitor or the Acquirer not to be material to the manufacture of the Generic Injectable Product; and (4) any real estate and the buildings and other permanent structures located on such real estate;

provided further, however, that in cases in which documents or other materials included in the relevant assets to be divested contain information: (1) that relates both to a Generic Injectable Product and to other Products or businesses of the Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to any such Generic Injectable Product; or (2) for which the 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, the Respondent shall provide such Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that Respondent provides the Acquirer with the above-described information without requiring Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

V. "Generic Injectable Product Core Employee(s)" means the Product Research and Development Employees and the Product Manufacturing Employees related to each Generic Injectable Product.

W. "Generic Injectable Product License" means all of the following related to the Generic Injectable Products:

1. a perpetual, non-exclusive, fully paid-up and royalty-free license(s) with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how:

   a. to research and Develop the Generic Injectable Products for marketing, distribution or sale within the United States of America;

   b. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the Generic Injectable Products within the United States of America;

   c. to import or export the Generic Injectable Products to or from the United States of America to the extent related to the marketing, distribution or sale of the Generic Injectable Products in the United States of America; and

   d. to have the Generic Injectable Products made anywhere in the World for distribution or sale within, or import into the United States of America;

provided further however, that for any Product Licensed Intellectual Property that is the subject of a license from a Third Party to the Respondent, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to the Respondent.

X. "Generic Injectable Product Releasee(s)" means the Acquirer for the assets related to a particular Generic Injectable Product or any Person controlled by or under common control with such Acquirer, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of such Acquirer, or of such Acquirer-affiliated entities.

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

Z. "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.

AA. "High Volume Account(s)" means any retailer, wholesaler or distributor whose annual or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Generic Injectable Product in the United States of America from the Respondent was, or is projected to be among the top twenty highest of such purchase amounts by the Respondent's U.S. customers on any of the following dates: (1) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (2) the end of the last quarter that immediately preceded the Acquisition Date; (3) the end of the last quarter that immediately preceded the Closing Date for the relevant assets

HH. "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 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, related to any Product of or owned by Respondent as of the Closing Date (*except* where this Order specifies a different time).

II. "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.

JJ. "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.

KK. "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.

LL. "Product Assumed Contracts" means all of the following contracts or agreements (copies of each such contract to be provided to the Acquirer on or before the Closing Date and segregated in a manner that clearly identifies the purpose(s) of each such contract):

1. that make specific reference to the Generic Injectable Product(s) and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the Generic Injectable Product(s) from the Respondent unless such contract applies generally to the Respondent's sales of Products to that Third Party;

2. pursuant to which Respondent purchases the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party for use in connection with the manufacture of the Generic Injectable Product(s);

3. relating to any Clinical Trials involving the Generic Injectable Product(s);

4. with universities or other research institutions for the use of the Generic Injectable Product(s) in scientific research;

5. relating to the particularized marketing of the Generic Injectable Product(s) or educational matters relating solely to the Generic Injectable Product(s);

6. pursuant to which a Third Party manufactures or packages the Generic Injectable Product(s) on behalf of Respondent;

7. pursuant to which a Third Party provides the Product Manufacturing Technology related to the Generic Injectable Product(s) to Respondent;

8. pursuant to which a Third Party is licensed by Respondent to use the Product Manufacturing Technology;

9. constituting confidentiality agreements involving the Generic Injectable Product(s);

10. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the Generic Injectable Product(s);

11. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the Generic Injectable Products to Respondent including, but not limited to, consultation arrangements; and/or

12. pursuant to which any Third Party collaborates with Respondent in the performance of research, Development, marketing, distribution or selling of the Generic Injectable Product or the Generic Injectable Product business;

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

MM. "Product Copyrights" means rights to all original works of authorship of any kind directly related to the Generic Injectable 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 the Generic Injectable Product or of any materials used in the research, Development, manufacture, marketing or sale of the Generic Injectable Product, including all copyrights in raw data relating to Clinical Trials of the Generic Injectable 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, the Generic Injectable Product sales forecasting models, medical education materials, sales training

materials, and advertising and display materials; all records relating to employees who accept employment with the 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 the Generic Injectable Product or relating to its biology; all copyrights in Advertising Materials and all copyrights in periodic adverse experien(e d)Tj14.3400 0.0000 hyi70 0.0000 source documentation) and all copyrights in periodic adverse experien(e d)Tj14.3400 0.0000 hyi70 0.0000

12. Product recall reports filed with the FDA related to the specified Generic Injectable Product.

OO. "Product Employee Information" means the following, for each Generic Injectable Product Core Employee, as and to the extent permitted by Law:

1. a complete and accurate list containing the name of each Generic Injectable Product Core Employee (including former employees who were employed by Respondent within ninety (90) days of the execution date of any Remedial Agreement);

2. with respect to each such employee, the following information:

   a. the date of hire and effective service date;

   b. job title or position held;

   c. a specific description of the employee's responsibilities related to the relevant Generic Injectable Product; *provided, however*, in lieu of this description, Respondent may provide the employee's most recent performance appraisal;

   d. the base salary or current wages;

   e. the most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year and current target or guaranteed bonus, if any;

   f. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and

   g. any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and

3. at the Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.

PP. "Product Intellectual Property" means all of the following related to a Generic Injectable Product (other than Product Licensed Intellectual Property):

1. Patents;

2. Product Copyrights;

3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and

4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof and to bring suit against a Third Party for the past, present or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing;

   provided, however, "Product Intellectual Property" does not include the corporate names or corporate trade dress of "Hikma" or "West-ward", 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 Hikma or West-ward can be identified or defined.

QQ. "Product Licensed Intellectual Property" means the following:

1. Patents that are related to a Generic Injectable Product that Respondent can demonstrate have been routinely used, prior to the Acquisition Date, for a Retained Product(s) that:

   a. has been marketed or sold on an extensive basis by a Respondent within the two-year period immediately preceding the Acquisition; or

   b. for which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell such a Retained Product on an extensive basis by a Respondent; and

2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to a Generic Injectable Product and that Respondent can demonstrate have been routinely used, prior to the Acquisition Date, for a Retained Product(s) that:

   a. has been marketed or sold on an extensive basis by the Respondent within the two-year period immediately preceding the Acquisition; or

   b. for which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell such a Retained Product on an extensive basis by a Respondent;

provided however, that, in cases where the aggregate retail sales of a Retained Product(s) in dollars within the two-year period immediately preceding the Acquisition collectively are less than the aggregate retail sales in dollars within the same period of the Generic Injectable Product collectively being divested to a particular Acquirer, the above-described intellectual property shall be considered, at the such Acquirer's option, to be Product Intellectual Property and, thereby, subject to assignment to such Acquirer;

provided further, however, that in such cases, Respondent may take a license back from such Acquirer for such intellectual property for use in connection with the Retained

each of the Generic Injectable Products and/or Retained Products to customers and competitively sen

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

(1) manufacture the specified Generic Injectable Product in the quality and quantities achieved by the Respondent, or the manufacturer and/or developer of such Generic Injectable Product;

(2) obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell the specified Generic Injectable Product in commercial quantities and to meet all Agency-approved specifications for such Generic Injectable Product; and

(3) receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Generic Injectable Product.

DDD. "Third Party(ies)" means any non-governmental Person other than the following: Respondent; Baxter; or, the Acquirer for the Generic Injectable Product Assets.

EEE. "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 Respondent; *provided, however*, "Website" shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Generic Injectable Products.

FFF. "X-Gen" means X-Gen Pharmaceuticals, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York, with its headquarters address at 300 Daniel Zenker Drive, Horseheads, NY 14845-1014.

GGG. "X-Gen Generic Injectable Product Divestiture Agreements" means all of the following agreements:

1. "Asset Purchase Agreement" by and among X-Gen Pharmaceuticals, Inc., West-ward Pharmaceutical Corp. and Hikma Farmacêutica, S.A., dated as of March 28, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto;

2. "Manufacturing Agreement" between X-Gen Pharmaceuticals, Inc. and Hikma Farmacêutica, S.A., dated as of March 28, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto; and

3. Letter Agreement to X-Gen Pharmaceuticals, Inc. from Hikma Farmacêutica, S.A., dated as of March 29, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto;

related to the Generic Injectable Product Assets that have been approved by the Commission to accomplish the requirements of this Order. The Generic Injectable Product Divestiture Agreements are attached to this Order and contained in non-public Appendix II.A.

II.

IT IS FURTHER ORDERED that:

A. Not later than the earlier of: (1) ten (10) days after the Acquisition Date or (2) ten (10) days after the Order Date, Respondent shall divest the Generic Injectable Product Assets and grant the Generic Injectable Product License, absolutely and in good faith, to X-Gen pursuant to, and in accordance with, the X-Gen Generic Injectable Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of X-Gen or to re.0000 tTDur86b.nqp000 7h9.f0000 TDur86b.nqp000 7h00

Assets and grant the Generic Injectable Product License to the Acquirer, and to permit the Acquirer to continue the research, Development, manufacture, sale, marketing or distribution of the Generic Injectable Products;

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

C. Respondent shall provide, or cause to be provided to the Acquirer in a manner consistent with the Technology Transfer Standards the following:

1. all Product Manufacturing Technology (including all related intellectual property) related to the Generic Injectable Products; and

2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed by Respondent related to the specified Generic Injectable Products.

Respondent shall obtain any consents from Third Parties required to comply with this provision.

D. Respondent shall:

1. upon reasonable written notice and request from an Acquirer to Respondent, Contract Manufacture and deliver to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products at Respondent's Supply Cost, for a period of time sufficient to allow the Acquirer (or the Manufacturing Designee of the Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished drug product independently of Respondent and Baxter and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in the specified Respondent's Application(s) for the respective Generic Injectable Product from Persons other than the Respondent;

2. make representations and warranties to the Acquirer(s) that the Contract Manufacture Product(s) supplied by the Respondent pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract Manufacture Product(s) to be marketed or sold in the Geographic Territory, Respondent shall agree to indemnify, defend and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Contract Manufacture Product(s) supplied to the Acquirer pursuant to a Remedial Agreement t wt Ma tf tw b15.3600 0.000dt0

provided, however, that Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with Respondent's responsibilities to supply the ingredients and/or components in the manner required by this Order; *provided further* that this obligation shall not require Respondent to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by Respondent to the Acquirer;

provided further that in each instance where: (1) an agreement to divest relevant assets or supply Contract Manufacture Products is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a

7. during the term of any agreement to Contract Manufacture between Respondent and an Acquirer, provide consultation with knowledgeable employees of Respondent and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling such Acquirer (or the Manufacturing Designee of such Acquirer) to obtain all Product Approvals to manufacture the Generic Injectable Products in the same quality achieved by, or on behalf of, the Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent and Baxter 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 Generic Injectable Products;

The foregoing provisions, II.D.1. - 7., shall remain in effect with respect to each Generic Injectable Product until the earliest of: (1) the date each Acquirer (or the Manufacturing Designee(s) of such Acquirer), respectively, is approved by the FDA to manufacture such Generic Injectable Product and able to manufacture such Generic Injectable Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent and Baxter; (2) the date the Acquirer of a particular Generic Injectable Product notifies the Commission and the Respondent of its intention to abandon its efforts to manufacture such Generic Injectable Product; (3) 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 Generic Injectable Product has abandoned its efforts to manufacture such Generic Injectable Product, or (4) the date four (4) years from the Closing Date.

E. Respondent shall:

1. submit to each Acquirer, at Respondent's expense, all Confidential Business Information related to the Generic Injectable Products;

2. deliver such Confidential Business Information to such 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 Acquirer, provide the 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 identifying the books, records, and files directly related to the Generic Injectable Products that contain such 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 related to the research, Development, manufacturing, marketing, or sale of the Generic Injectable Products other than as necessary to comply with the following

Injectable Product Core Employees related to the Generic Injectable Products and assets acquired by such Acquirer. Each of these periods is hereinafter referred to as the "Generic Injectable Product Core Employee Access Period(s)"; and

2. not later than the ear

Respondent from continuing to employ the Generic Injectable Product Core Employees in connection with the Acquisition; and

5. for a period of one (1) year from the Closing Date, not:

   a. 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 Generic Injectable Product ("Generic Injectable Product Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or

   b. hire any Generic Injectable Product Employee;

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

   provided further, however, that Respondent may do the following: (1) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Generic Injectable Product Employees; or (2) hire a Generic Injectable Product Employee who contacts Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from Respondent.

I. Respondent shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each Generic Injectable Product Core Employee retained by Respondent, the direct supervisor(s) of any such employee, and any other employee retained by Respondent and designated by the Interim Monitor (if applicable) sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Confidential Business Information related to the Generic Injectable Products as strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order).

J. Not later than thirty (30) days after the Closing Date, Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Generic Injectable Products by Respondent's personnel to all of Respondent's employees who:

   1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of any of the Generic Injectable Products;

2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that contain the same active pharmaceutical ingredient as the Generic Injectable Products; and/or

3. may have Confidential Business Information related to the Generi

1. any Patent owned or licensed by Respondent as of the day after the Ac

1. cooperate with the Acquirer an

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 Mo

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

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

Commission 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,

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.

V.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, Respondent shall assure that Respondent's counsel (including 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 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 Generic Injectable Products or the assets and businesses associated with those Generic Injectable Products;

provided, however, that Respondent may disclose such information as necessary for the purposes set forth in this Paragraph V pursuant to an appropriate confidentiality order, agreement or arrangement;

provided further, however, that pursuant to this Paragraph V, Respondent shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if such Acquirer withholds such agreement unreasonably); and (2) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VI.

IT IS FURTHER ORDERED that:

A. Any Remedial Agreement shall be deemed incorporated int

C. to create a viable and effective competitor, that is independent of the Respondent and Baxter:

1. in the research, Development, and manufacture of each of the Generic Injectable Products for the purposes of the business associated with each Generic Injectable Product within the Geographic Territory; and

2. the distribution, sale and marketing of the each of the Generic Injectable Products in the Geographic Territory; and,

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

VIII.

IT IS FURTHER ORDERED that:

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

B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondent has fully complied with the following: Paragraphs II.A , II.B., II.C., II.E.1.-3., II.G., II.H.1.-4., II.J., and II.K., Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. 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 full description of the efforts being made to comply with the relevant paragraphs of the Order, including a full description of all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all Persons contacted, including copies of all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning completing the obligations.

C. One (1) year after the Order Date, annually for the next nine 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.

IX.

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

A. any proposed dissolution of a Respondent;

B. any proposed acquisition, merger or consolidation of a Respondent; or

C. any other change in a 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.

X.

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, such Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

A. access, during business office hours of such 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 such Respondent related to compliance with this Order, which copying services shall be provided by such Respondent at the request of the authorized representative(s) of the Commission and at the expense of such Respondent; and

B. to interview officers, directors, or employees of such Respondent, who may have counsel present, regarding such matters.

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 II.A.
X-GEN GENERIC INJECTABLE PRODUCT AGREEMENTS