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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-4320**
a corporation,	)	**[Public Record Version]**

DECISION AND ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Hikma Pharmaceuticals PLC ("Hikma") of certain assets relating to the business of generic injectable pharmaceutical products of Baxter Healthcare Corporation ("Baxter"), and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federa4 d.ycd Commission Act, as amended, 15 U.S.C. § 45; and

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

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and

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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 Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

ORDER

I.

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

A. "Hikma" or "Respondent" means Hikma Pharmaceuticals PLC, its directors, officers, [illegible] employees, agents, representatives, successors, and assigns; and its joint ventures, [illegible] subsidiaries, divisions, groups and affiliates in each case controlle[illegible]

E. “Acquisition” means the acquisition contemplated by the “Asset Purchase Agreement” by and among West-ward Pharmaceutical Corpora

provided, however, that the restrictions contained in this Order regarding the Respondent's use, conveyance, provision, or disclosure of "Confidential Business Information" shall not apply to the following:

a. information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by Respondent;

b. information related to the Generic Injectable Products that Baxter can demonstrate it obtained without the assistance of Respondent prior to the Acquisition;

c. information that is required by Law to be publicly disclosed;

d. information relating to the Respondent's general business strategies or practices relating to research, Development, man d

U. “Generic Injectable Product Assets” means all of the Respondent’s rights, title and interest in and to all assets related to the Respondent’s business within the Geographic Territory related to each of the respective Generic Injectable Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of each such Product, including, without limitation, the following:

1. all Product Intellectual Property related to any such Generic Injectable Product;

2. all Product Approvals related to any such Generic Injectable Product;

3. all Product Manufacturing

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

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 doc

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 hainging a

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 collaborac

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 adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA.

NN. "Product Development Reports" means:

1. Pharmacokinetic study reports related to the specified Generic Injectable Product;

2. Bioavailability study reports (including reference listed drug information) related to the specified Generic Injectable Product;

3. Bioequivalence study reports (including reference listed drug information) related to the specified Generic Injectable Product;

4. all correspondence to the Respondent from the FDA and from the Respondent to the FDA relating to the Application(s) submitted by, on behalf of, or acquired by, the Respondent related to the specified Generic Injectable Product;

5. annual and periodic reports related to the above-described Application(s), including any safety update reports;

6. FDA approved Product labeling related to the specified Generic Injectable Product;

7. currently used product package inserts (including historical change of controls summaries) related to the specified Generic Injectable Product;

8. FDA approved patient circulars and information related to the specified Generic Injectable Product;

9. adverse event/serious adverse event summaries related to the specified Generic Injectable Product;

10. summary of Product complaints from physicians related to the specified Generic Injectable Product;

11. summary of Product complaints from customers related to the specified Generic Injectable Product; and

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 a

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 Products and such a license to Respondent may be perpetual, fully paid-up and royalty-free license(s) with rights to sublicense.

RR. "Product Manufacturing Employees" means all salaried employees of Respondent who have directly participated in the planning, design, implementation or operational management of the Product Manufacturing Technology of the specified Generic Injectable Product (irrespective of the portion of working time involved unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

SS. "Product Manufacturing Technology" means:

1. all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of the Generic Injectable Product, including, but not limited to, the following: all product specifications, processes, 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 active pharmaceutical ingredients related to the Generic Injectable Product; 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 the Generic Injectable Product.

TT. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of a Generic Injectable 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 Generic Injectable Product; *provided however*, that for any generic Product, "Product Marketing Materials" excludes final pricing and formulas that determine the final pricing of

each of the Generic Injectable Products and/or Retained Products to customers and competitively sensitive information that is exclusively related to the Retained Products.

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

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

WW. "Product Trademark(s)" means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for the specified Product(s).

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

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

1. any agreement between Respondent and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, 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 Respondent and a Third Party to effect the assignment of assets or rights of Respondent related to a Generic Injectable 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 Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned,

granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of this Order; and/or

4. any agreement between Respondent and a Third Party to effect the assignment of assets or rights of Respondent related to a Generic Injectable 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.

ZZ. "Retained Product" means any Product(s) other than a Generic Injectable Product.

AAA. "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, including the ability to make available the underlying raw data from the investigation for FDA audit.

BBB. "Supply Cost" means a cost not to exceed the manufacturer's average direct per unit cost in United States dollars of manufacturing the Generic Injectable 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: (1) an agreement to Contract Manufacture is specif(omp)Tj21.3600 0.004

d. providing, in a time

related to the Generic Injectable Product Assets that have been approved by the Commission to accomplish the requirements of this Order. The X-Gen 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 reduce any obligations of Respondent under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Generic Injectable Product Assets is incorporated by reference into this Order and made a part hereof;

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

provided further that if Respondent has divested the Generic Injectable Product Assets and granted the Generic Injectable Product License to X-Gen prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Generic Injectable Product Assets or g

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

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 Generic Injectable Product, each such agreement may contain limits on Respondent's aggregate liability resulting from the failure of the Contract Manufacture Products supplied to the Acquirer pursuant to such Remedial Agreement by Respondent to meet cGMP;

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

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

   provided, however, that in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order or to supply Contract Manufacture Products, and (2) such agreement becomes a Remedial Agreement for a Generic Injectable Product, each such agreement may contain limits on Respondent's aggregate liability for such a failure;

5. during the term of any agreement to Contract Manufacture between Respondent and an Acquirer, upon written request of such 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 Manufacture between Respondent and an Acquirer, maintain manufacturing facilities necessary to manufacture each of the relevant Contract Manufacture Products in finished form, *i.e.*, suitable for sale to the ultimate consumer/patient; and

7. during the term of any agreement to Contract Manufacture between Respondent and an

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Business Information and facilitating the delivery in a manner consistent with this Order;

4. not use, directly or indirectly, any

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 earlier of the following dates: (1) ten (10) days after notice by staff of the Commission to Respondent to provide the Product Employee Information; or (2) ten (10) days after written request by an Acquirer, provide such Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Generic Injectable Product Core Employees. Failure by Respondent to provide the Product Employee Information for any Generic Injectable Product Core Employee within the time provided herein shall extend the Generic Injectable Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay;

3. during the Generic Injectable Product Core Employee Access Period(s), not interfere with the hiring or employing by the Acquirer or its Manufacturing Designee of the Generic Injectable Product Core Employees, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with such Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Generic Injectable Product or other contracts with Respondent that would affect the ability

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 hereon

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 Generic Injectable Products.

Respondent shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondent shall provide a copy of such notification to the Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondent shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.

K. Until Respondent completes the divestiture required by Paragraphs II.A. and fully provides, or causes to be provide

minders sent to Responde

1. any Patent owned or licensed by Respondent as of the day after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claims a method of making, using, or administering, or a composition of matter, relating to the Generic Injectable Product(s) acquired by that Acquirer, or that claims a device relating to the use thereof;

2. any Patents owned or licensed by Respondent at any time after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the Generic Injectable Product(s) acquired by that Acquirer;

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

M. Upon reasonable written notice and request from an Acquirer to Respondent, Respondent shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Product Intellectual Property related to any of the Generic Injectable Products, if such litigation would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Generic Injectable Product acquired by that Acquirer; or (2) the use, import, export, supply, distribution, or sale of such Generic Injectable Product within the Geographic Territory.

N. For any patent infringement suit in which the Respondent is alleged to have infringed a Patent of a Third Party prior to the Closing Date or for such suit as the Respondent has prepared or is preparing as of the Closing Date to defend against such infringement claim(s), and where such a suit would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Generic Injectable Product(s) acquired by that Acquirer; or (2) the use, import, export, supply, distribution, or sale of such Generic Injectable Product(s), Respondent shall:

1. cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from Respondent in connection with obtaining resolution of any pending patent litigation involving such Generic Injectable Product;

2. waive conflicts of interest, if any, to allow the Respondent's outside legal counsel to represent the relevant Acquirer in any ongoing patent litigation involving such Generic Injectable Product; and

3. permit the transfer to the Acquirer of all of the litigation files and any related attorney work-product in the possession of Respondent's outside counsel relating to such Generic Injectable Product.

O. Respondent shall not, in the Geographic Territory:

1. use the Product Trademarks contained in the Product Intellectual Property or any mark confusingly similar to such Product Trademarks, as a trademark, trade name, or service mark;

2. attempt to register such Product Trademarks;

3. attempt to register any mark confusingly similar to such Product Trademarks;

4. challenge or interfere with the relevant Acquirer's use and registration of such Product Trademarks; or

5. challenge or interfere with the relevant Acquirer's efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties;

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

III.

IT IS FURTHER ORDERED that:

A. At any time after Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements.

B. The Commission shall se000 TD(5.)Tj130 TD6400 0.eTj11.2800 0.0000 TD(ri)Tj7.3200 0.0000 TD(c")Tj

identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.

C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondent's compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.

D. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:

1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim 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 Respondent of the divestiture of all Generic Injectable 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 until the earliest of:

    a. with respect to each Generic Injectable Product, the date the Acquirer (or

provided, *further*, that the Commission may extend or modify this period as may be necessary or appropriate to accomp

8. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.

E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.

F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.

G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.

H. The Interim Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

IV.

IT IS FURTHER ORDERED that:

A. If Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Generic Injectable Product Assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an acnt,restbaing at to th0e eve

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 a

Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring

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;

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;

NON-PUBLIC APPENDIX II.A.
X-GEN GENERIC INJECTABLE PRODUCT DIVESTITURE AGREEMENTS

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