



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, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Hikma (including, but not limited to, West-ward Pharmaceutical Corporation and Hikma (Maple) Limited), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Baxter” means Baxter Healthcare Corporation, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Baxter (including, but not limited to, Baxter International, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Commission” means the Federal Trade Commission.
- D. “Acquirer(s)” means the following:
  1. a Person specified by name in this Order to acquire particular assets or rights that Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective; or
  2. a Person approved by the Commission to acquire particular assets or rights that Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.

- 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);

*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, manufacture, marketing, or sales of Products that does not discuss with particularity the Generic Injectable Products;
- e. information specifically excluded from the Generic Injectable Product Assets;
- f. all intellectual property licensed to the Acquirer on a non-exclusive basis; and
- g. information that is protected by the attorney work product, attorney-client, joint defense or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.

M. "Contract Manufacture" means:

1. to manufacture a Generic Injectable Product or ingredient or component thereof, or
2. to provide of any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Generic Injectable Product,

by Respondent or Baxter to an Acquirer.

N. "Contract Manufacture Product(s)" means any Generic Injectable Product, or ingredient or component thereof, for which any part of the manufacturing process is performed by the Respondent prior to the Closing Date at a facility that is not subject to divestiture pursuant to this Order.

O. "Development" means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture,

use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.

- 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.

- 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 Technology related to any such Generic Injectable Product;
  4. all Product Marketing Materials related to any such Generic Injectable Product;
  5. all Website(s) related exclusively to any such Generic Injectable Product;
  6. a list of all of the NDC Numbers related to any such Generic Injectable Product, and rights, to the extent permitted by Law:
    - a. to require Respondent to discontinue the use of those NDC Numbers in the sale or marketing of the Generic Injectable Products *except* for returns, rebates, allowances, and adjustments for Generic Injectable Products sold prior to the Acquisition Date and *except* as may be required by applicable Law;
    - b. to prohibit Respondent from seeking from any customer any type of cross-referencing of those NDC Numbers with any Retained Product(s);
    - c. to seek to change any cross-referencing by a customer of those NDC Numbers with the Retained Product(s) (including the right to receive notification from Respondent of any such cross-referencing that is discovered by Respondent);
    - d. to seek cross-referencing from a customer of those NDC Numbers with the Acquirer’s NDC Numbers related to the Generic Injectable Product;
    - e. to approve the timing of Respondent’s discontinued use of those NDC Numbers in the sale or marketing of Generic Injectable Products *except* for returns, rebates, allowances, and adjustments for Generic Injectable Products sold prior to the Acquisition Date and *except* as may be required by applicable Law; and
    - f. to approve any notification(s) from Respondent to any customer(s) regarding the use or discontinued use of such NDC numbers by Respondent prior to such notification(s) being disseminated to the customer(s);
  7. all rights to all of Respondent’s Applications related to any such Generic Injectable Product;

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; or (4) the end of the last quarter following the Acquisition or the Closing Date.
- BB. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- CC. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- DD. “Manufacturing Designee” means any Person other than Respondent or Baxter that has been designated by an Acquirer to manufacture a Generic Injectable Product for that Acquirer.
- EE. “NDC Numbers” means the National Drug Code numbers, including both the labeler code assigned by the FDA and the additional numbers assigned by an Application holder as a product code for a specific Product.
- FF. “Order Date” means the date on which this Decision and Order becomes final and effective.
- GG. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.

- 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 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 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 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 specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Generic Injectable Product, “Supply Cost” means the cost as specified in such Remedial Agreement for that Generic Injectable Product.

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

- a. designating employees knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Generic Injectable Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;
- b. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Generic Injectable Product that are acceptable to the Acquirer;
- c. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee; and

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 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 grant of the Generic Injectable Product License, as applicable, to X-Gen (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Prior to the Closing Date, Respondent shall secure all consents and waivers from all Third Parties that are necessary to permit Respondent to divest the Generic Injectable Product

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 by Respondent to meet cGMP. This obligation may be made contingent upon the Acquirer giving Respondent prompt written notice of such claim and cooperating fully in the defense of such claim. The Remedial Agreement shall be consistent with the obligations assumed by Respondent under this Order;

*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 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:
    - a. the requirements of this Order;
    - b. Respondent's obligations to the Acquirer of the particular Generic Injectable Product under the terms of any Remedial Agreement related to any such Generic Injectable Product; or
    - c. applicable Law;
  5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except the Acquirer or other Persons specifically authorized by such Acquirer to receive such information; and
  6. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the Generic Injectable Products to the employees associated with business related to those Retained Products that contain the same active pharmaceutical ingredient as the Generic Injectable Products.
- F. Respondent shall not enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of such Acquirer to acquire or use the Product Manufacturing Technology (including all related intellectual property) related to the Generic Injectable Products acquired by such Acquirer from the Third Party. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology.
- G. Not later than ten (10) days after the Closing Date, Respondent shall grant a release to each Third Party that is subject to an agreement as described in Paragraph II.F. that allows the Third Party to provide the relevant Product Manufacturing Technology to the Acquirer. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to such Acquirer.
- H. Respondent shall:
1. for each Generic Injectable Product, for a period of six (6) months from the Closing Date or upon the hiring of twenty (20) Generic Injectable Product Core Employees by the Acquirer or its Manufacturing Designee, whichever occurs earlier, provide such Acquirer with the opportunity to enter into employment contracts with the Generic

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 or incentive of those individuals to be employed by such Acquirer or its Manufacturing Designee. In addition, Respondent shall not make any counteroffer to such a Generic Injectable Product Core Employee who has received a written offer of employment from such Acquirer or its Manufacturing Designee;

*provided, however,* that, subject to the conditions of continued employment prescribed in this Order, this Paragraph II.I.3. shall not prohibit Respondent from continuing to employ any Generic Injectable Product Core Employee under the terms of such employee’s employment with Respondent prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to such employee;

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

*provided, however,* that this Paragraph II.H. does not require nor shall be construed to require Respondent to terminate the employment of any employee or to prevent

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 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 provided, the related Product Manufacturing Technology to the Acquirer,

1. Respondent shall take such actions as are necessary to:
  - a. maintain the full economic viability and marketability of the businesses associated with each Generic Injectable Product;
  - b. minimize any risk of loss of competitive potential for such business;
  - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to each Generic Injectable Product;
  - d. ensure the Generic Injectable Product Assets are provided to the Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the business associated with each Generic Injectable Product;
  - e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and
2. Respondent shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the businesses associated with each Generic Injectable Product.

L. Respondent shall not join, file, prosecute or maintain any suit, in law or equity, against an Acquirer or the Generic Injectable Product Releasee(s) of that Acquirer for the research, Development, manufacture, use, import, export, distribution, or sale of the Generic Injectable Product(s) acquired by that Acquirer under the following:

1. any Patent owned or licensed by Respondent as of the day after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claims a method of making, using, or administering, or a composition of matter, relating to the 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 Animal Health 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 select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the

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

- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondent's compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.
  - D. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
    - 1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim 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 its Manufacturing Designee(s)) 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;
      - b. with respect to each Generic Injectable Product, the date the Acquirer notifies the Commission and the Respondent of its intention to abandon its efforts to manufacture such Generic Injectable Product; or
      - c. with respect to each Generic Injectable Product, the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture such Generic Injectable Product;
- provided, however, that, with respect to each Generic Injectable Product, the Interim Monitor's service shall not exceed five (5) years from the Order Date;*

*provided, further,* that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Order, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with the Order.
5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
6. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
7. Respondent shall report to the Interim Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order;

*provided, however,* beginning one hundred twenty (120) days after Respondent has filed its final report pursuant to Paragraph VIII.B., and every one hundred twenty (120) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by the Acquirer toward obtaining FDA approval to manufacture each Generic Injectable Product and obtaining the ability to manufacture each Generic Injectable Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent and Baxter.

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 action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent has not

opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.
  2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
  3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
  4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the

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

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of the Order to Maintain Assets in this matter.
8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

**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 into this Order.
- B. Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondent shall include in each Remedial Agreement related to each of the Generic Injectable Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligations to the Acquirer pursuant to this Order.
- D. Respondent shall also include in each Remedial Agreement a representation from the Acquirer that such Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Generic Injectable Product and to have any such manufacture to be independent of Respondent and Baxter, all as soon as reasonably practicable.
- E. Respondent shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Generic Injectable Products a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- F. Respondent shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission.

## VII.

**IT IS FURTHER ORDERED** that the purpose of the divestiture of the Generic Injectable Product Assets and the transfer and delivery of the related Product Manufacturing Technology and the related obligations imposed on the Respondent by this Order is:

- A. to ensure the continued use of such assets in the research, Development, and manufacture of each of the Generic Injectable Products and for the purposes of the business associated with each Generic Injectable Product within the Geographic Territory;
- B. to provide for the future use of such assets for the distribution, sale and marketing of each of the Generic Injectable Products in the Geographic Territory;

- 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**