1510198

UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION

Edith Ramirez, Chairwoman Julie Brill **COMMISSIONERS:**

Maureen K. Ohlhausen

jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent Hikma is a corporation organized, existing, and doing business under and by virtue of the laws of England and Wales with its principal executive offices located

- the 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 the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- D. "Acquisition" means Respondent Hikma's acquisition of fifty percent (50%) or more of the voting securities of Roxane Laboratories, Inc. and Boehringer Ingelheim Roxane, Inc. Respondent entered a *Stock Agreement and Plan of Merger* dated July 28, 2015, among Hikma Pharmaceuticals PLC, Eurohealth (U.S.A.), Inc., and Boehringer Ingelheim Corporation, that was submitted to the Commission.
- E. "Acquisition Date" means the date on which the Acquisition is consummated.
- F. "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").
- G. "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 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto. "Application" also includes an "Investigational New Drug Application" ("IND") filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.
- H. "Business" means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement, and sale of a Product.
- I. "Categorized Assets" means the following assets and rights of the Respondent, as such assets and rights are in existence as of the date the Respondent signs the Agreement Containing Consent Orders in this matter and as are maintained by the Respondent in accordance with the Order to Maintain Assets until the Closing Date for each Divestiture Product:
 - 1. all rights to all of the Applications related to the specified Divestiture Product;
 - 2. all Product Intellectual Property related to the specified Divestiture Product that is not Product Licensed Intellectual Property;

- 3. all Product Approvals related to the specified Divestiture Product;
- 4. all Product Manufacturing Technology related to the specified Divestiture Product that is not Product Licensed Intellectual Property;

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expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.

- L. "Closing Date" means, as to each Divestiture Product, the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.
- M. "Confidential Business Information" means all information owned by, or in the possession or control of, the Respondent that is not in the public domain and that is directly related to the conduct of the Business related to a Divestiture Product(s). The term "Confidential Business Information" *excludes* the following:
 - 1. information relating to the Respondent's general business strategies or practices that does not discuss with particularity the Divestiture Products;
 - 2. information specifically excluded from the Divestiture Product Assets conveyed to the Acquirer of the related Divestiture Product(s);
 - 3. information that is contained in documents, records, or books of the Respondent that is provided to an Acquirer by the Respondent that is unrelated to the Divestiture Products acquired by that Acquirer or that is exclusively related to Retained Product(s); and
 - 4. information that is protected by the attorney work product, attorney-client, joint defense, or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.
- N. "Contract Manufacture" means the following:
 - 1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer;
 - 2. to manufacture, or to cause to be manufactured, a Product that is the Therapeutic Equivalent of,

- provided, however, that with the consent of the Acquirer of the specified Product, the Respondent may substitute a Therapeutic Equivalent form of such Product in performance of that Respondent's agreement to Contract Manufacture.
- P. "Development" means all preclinical and clinical drug development activities, 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.
- Q. "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 the Respondent's employees' labor shall not exceed the average hourly wage rate for such employee; provided, however

- 2. Termination of Share Subscription and Shareholder's Agreement from Hikma Pharmaceuticals LLC to Unimark Remedies Limited, dated as of February 18, 2016;
- 3. Termination of Product Development, Manufacturing, Supply and Marketing Agreement from West-Ward Pharmaceutical Corporation to Unimark Remedies, dated as of February 18, 2016;
- 4. *Share Purchase Agreement* amongst Mehul J. Parekh and Hikma Pharmaceuticals LLC and Unimark Remedies Limited, dated as of February 18, 2016; and
- 5. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted with the foregoing listed agreements.

The Flecainide Product Divestiture Agreements are contained in Non-Public Appendix II. The Flecainide Product Divestiture Agreements that have 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 are Remedial Agreements.

- DD. "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.
- EE. "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 Divestiture 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: (i) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (ii) the end of the last quarter that immediately preceded the Acquisition Date; (iii) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or (iv) the end of the last quarter following the Acquisition or the Closing Date.
- FF. "Law" means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- GG. "Lithium Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Hikma pursuant to the following Applications:
 - 1. ANDA No. 76243; and
 - 2. ANDA No. 78763;

and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, lithium carbonate, at the following strengths: 150mg, 300mg, and 600mg.

HH. "Lithium Product Assets" means all rights, title, and interest in and to all assets related to the Business of Hikma within the Geographic Territory related to each of the Lithium

- Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Lithium Products.
- II. "Manufacturing Designee" means any Person other than the Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- JJ. "Monitor" means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- KK. "NDC Number(s)" means the National Drug Code number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code for a specific Product.
- LL. "Orders" means this Decision and Order and the related Order to Maintain Assets.
- MM. "Order Date" means the date on which the final Decisioy the Faerl Tc7rl T*IsMai(e)-9(r)4(-0.001 Tw -37.

- 3. Supply Agreement (Lithium Carbonate) between West-Ward Pharmaceuticals Corp. and Delcor Asset Corporation, attached to the Asset Purchase Agreement and to be executed on or before the Closing Date; and
- 4. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted with the foregoing listed agreements.

The Prednisone/Lithium Product Divestiture Agreements are contained in Non-Public Appendix I. The Prednisone/Lithium Product Divestiture Agreements that have 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 are Remedial Agreements.

- SS. "Prednisone Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Hikma pursuant to the following Applications:
 - 1. ANDA No. 80292;
 - 2. ANDA No. 88832; and
 - 3. ANDA No. 83677;

and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, prednisone, at the following strengths: 5mg, 10mg, and 20mg.

- TT. "Prednisone Product Assets" means all rights, title, and interest in and to all assets related to the Business of Hikma within the Geographic Territory related to each of the Prednisone Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Prednisone Products.
- UU. "Product(s)" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically,

following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and all educational materials for the sales force; copyrights in all preclinical, clinical, and process development data and reports relating to the research and Development of that Product or of any materials used in the research, Development, manufacture, marketing, or sale of that Product, including all copyrights in raw data relating to Clin

- the Respondent may provide the employee's most recent performance appraisal;
- e. the base salary or current wages;
- f. the most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year, and current target or guaranteed bonus, if any;
- g. employment status (*i.e.*, active or on leave or disability; full-time or part-time);
- h. all 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.
- AAA. "Product Intellectual Property" means all of the following intellectual property related to a Divestiture Product (other than Product Licensed Intellectual Property) that is owned, licensed, or controlled by the Respondent as of the Closing Date:
 - 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 violation of any of the foregoing;

provided, however, that "Product Intellectual Property" does not include the corporate names or corporate trade dress of "Hikma" or the related corporate logos thereof; or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondent or the related corporate logos thereof; or general registered images or symbols by which Hikma can be identified or defined.

- BBB. "Product Licensed Intellectual Property" means the following:
 - 1. all of the following intellectual property related to a Divestiture Product that is owned, licensed, or controlled by Respondent as of the Closing Date, as follows:
 - a. Patents that are related to a Divestiture Product that the Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date; and

- 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 Divestiture Product and that the Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date; and
- 2. in those instances in which (i) the Respondent is the holder of an NDA for a

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,

of assets or rights of that Respondent related to a Divestiture Product to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;

- 3. any agreement between the Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including, without limitation, any agreement by that Respondent to supply specified Products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or
- 4. any agreement between the Respondent and a Third Party to effect the assignment of assets or rights of that Respondent related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules theretoeduytts or ri ri riso8 T (a)4(lgr)3(a)4(nt)-2(e)4(s)-5(t)-5.ndmts (y)

- PPP. "Technology Transfer Standards" means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*:
 - 1. designating employees of the Respondent knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who Q /H2 -2(i)-2(ot)-po no un sa

- TTT. "Unimark Product Development Agreement" means the *Product Development*,

 Manufacturing, Supply and Marketing Agreement by and between Unimark Remedies
 Limited and West-Ward Pharmaceutical Corporation dated as of May 3, 2011. The
 Unimark Product Development Agreement is contained in Non-Public Appendix II.
- UUU. "Unimark Supplementary Agreement" means the *Supplementary Agreement* between Unimark Remedies Limited and West-Ward Pharmaceutical Corporation, dated as of February 18, 2016. The Unimark Supplementary Agreement relates and refers to the Unimark Product Development Agreement. The Unimark Supplementary Agreement is contained in Non-Public Appendix II.
- VVV. "Unimark Share Subscription and Shareholders' Agreement" means the *Share Subscription and Shareholders' Agreement* between Hikma Pharmaceuticals LLC and Unimark Remedies Limited and The Promoters of Unimark Remedies Limited, dated as of April 13, 2011. The Unimark Share Subscription and Shareholders' Agreement is contained in Non-Public Appendix II.
- WWW. "Website" means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by the Respondent; *provided, however*, "Website" shall not include the following: (1) content owned by Third Parties and other Product Intelle

shall divest the Lithium Product Assets within one hundred eighty (180) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that if Respondent has divested the Prednisone Product Assets and the Lithium Product Assets to Renaissance 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 Prednisone Product Assets and the Lithium Product Assets to Renaissance (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. Not later than ten (10) days after the Acquisition Date, Respondent shall:
 - 1. divest, absolutely and in good faith, all of its Ownership Interest in Unimark to Mr. Mehul J. Parekh (founder and Managing Director of Unimark), Mr. Parekh's spouse, Mr. Parekh's daughter, as designated in the *Share Purchase Agreement* (as identified in the definition of Flecainide Divestiture Agreements), or to any company designated by Mr. Parekh that is wholly owned jointly or singly by the aforementioned three individuals, pursuant to the *Share Purchase Agreement*;
 - 2. divest all rights it may have in the Flecainide Product Assets to Unimark pursuant to the *Flecainide Agreement* (as identified in the definition of Flecainide Divestiture Agreements); *provided, however*, if Respondent has divested the Flecainide Product Assets to Unimark 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 Flecainide

Divestiture Products to the marketing or sales employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products.

- F. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent shall provide, or cause to be provided, to that 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 Divestiture Product(s) being acquired by that Acquirer; and
 - 2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to the Respondent related to the Divestiture Products being acquired by that Acquirer.

Respondent shall obtain any consents from Third Parties required to comply with this provision. 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 that Pacquires in the last agreement may limit or otherwise impair the ability of that Pacquires in the last agreement may limit or otherwise impair the ability of that Pacquires and Indiana and Indiana and Indiana agreement against a Third Party or an Acquire ability of the Indiana agreement against a Third Party or an Acquire ability of the Indiana agreement against a Third Party or an Acquire ability of the Indiana agreement against a Third Party or an Acquire ability of the Indiana agreement against a Third Party or an Acquire against a Third Party or an Acquire ability of the Indiana against a Third Party or an Acquire the ability of the Indiana against a Third Party or an Acquire against a Third Party or an Acquire the ability of the Indiana against a Third Party or an Acquire against a Third Party or an Acquire the Acquire ability of the Indiana against a Third Party or an Acquire against a Third Party or a

any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to

- 6. during the term of any agreement to Contract Manufacture, take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);
- 7. in the event Respondent becomes (i) unable to supply or produce a Contract Manufacture Product from the facility or facilities originally contemplated under a Remedial Agreement with an Acquirer and (ii) that Product is the subject of an ANDA: provide Product that is the Therapeutic Equivalent of such Contract Manufacture Product from the facility(ies) that Respondent uses or has used to source its own supply of the Product that is the Therapeutic Equivalent of the Contract Manufacture Product, where such facility(ies) is still suitable for use for such manufacturing;
- 8. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Monitor to monitor compliance with the obligations to Contract Manufacture; and
- 9. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of the Respondent and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all Product Approvals to manufacture the Contract Manufacture Products acquired by that Acquirer in the same quality achieved by, or on behalf of, the Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent and sufficient to satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the Contract Manufacture Products.

The foregoing provisions, II.G.1. - 9., shall remain in effect with respect to each Contract Manufacture Product until the earliest of: (i) the date the Acquirer (or the Manufacturing Designee(s) of that Acquirer) is approved by the FDA to manufacture and sell such Contract Manufacture Product in the United States and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent; (ii) the date the Acquirer notifies the Commission and Respondent of its intention to abandon its efforts to manufacture the relevant Contract Manufacture Product; (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the relevant Contract Manufacture Product; or (iv) five (5) years after the Closing Date.

Information, and the direct supervisor(s) of any such employee sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential

whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with the Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

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

- K. Until Respondent completes the divestitures required by this Order and fully provides, or causes to be provided, the Product Manufacturing Technology related to a particular Divestiture Product to the relevant Acquirer:
 - 1. Respondent shall take actions as are necessary to:
 - a. maintain the full economic viability and marketability of the Businesses associated with that Divestiture Product;

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regarding the powers, duties, authorities, and responsibilities of the Monitor:

- 1. The 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 Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.
- 2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
- 3. The Monitor shall serve until the date of completion by the Respondent of the divestiture of all Divestiture Product Assets, and the transfer and delivery of the related Product Manufacturing Technology, in a manner that fully satisfies the requirements of this Order, and, with respect to each Divestiture Product that is Contract Manufacture Product, until the earliest of: (i) the date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell that Divestiture Product and is able to manufacture the final finished Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent; (ii) the date the Acquirer of that Divestiture Product notifies the Commission and Respondent of its intention to abandon its efforts to manufacture that Divestiture Product; or (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture that Divestiture Product:

provided, however, that the Monitor's service shall not extend more than five (5) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- E. Subject to any demonstrated legally recognized privilege, the 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 Monitor may reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent's compliance with the Orders.
- F. The 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 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 Monitor's duties and responsibilities.
- G. Respondent shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the

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 $\S 5(l)$ of the Federal Trade Commission Act, 15 U.S.C. $\S 45(l)$, 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 $\S 5(l)$ 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 the Commission believes that the divestiture can be achieved within a reasonable

divested, delivered,

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 Monitor pursuant to the relevant provisions of this Order or 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*, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

V.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibiti

Divestiture Products;

provided, *however*, that the 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, the Respondent needing such access to original documents shall: (i) 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 that Acquirer withholds such agreement unreasonably); and (ii) 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 the 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 Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligation to the Acquirer pursuant to this Order.
- D. FoCID 1(ed)-4(t)-6(o)-isbmedial purposes ts u(pur02 -12.97 0 Tw 21.if-0]TJ dia C)-6(h)-14elat ic eou1-

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 Paragraphs II.A., II.B., II.C., II.D., II.E.1, II.E.2., II.E.3, II.F., II.G., II.H., II.I., 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 Monitor, if any 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:
 - 1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondent to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
 - 2. a detailed description of the timing for the completion of such 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.

VIII.

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

- A. any proposed dissolution of the Respondent;
- B. any proposed acquisition, merger, or consolidation of the Respondent; or
- C. any other change in the 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.

Commission:

- A. access, during business office hours of the 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 the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

X.

IT IS FURTHER ORDERED that this Order shall terminate on the date ten (10) years after the Order Date.

By the Commission.

NON-PUBLIC APPENDIX I AGREEMENTS RELATED TO THE DIVESTITURES OF THE LITHIUM PRODUCTS AND THE PREDNISONE PRODUCTS

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