Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

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B. "Claris" means: Claris Lifesciences Limited; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Claris Lifesciences Limited, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "Arjun Handa" means: (i) Arjun S. Handa, a natural person; (ii) all employees, agents, representatives, successors, and assigns of Arjun S. Handa; and (iii) all partnerships, joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Arjun S. Handa, and the respective partners, directors, officers, employees, agents, representatives, successors, and assigns of each.

D. "Commission" means the Federal Trade Commission.

E. "Respondent(s)" means Baxter, Claris and Arjun Handa, individually and collectively.

J. “Agency(ies)”

10. for each specified Divestiture Product that has been marketed or sold by the specified Respondent prior to the Closing Date, a list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by Law:

    a. to require Respondents to discontinue the use of those NDC Numbers in the sale or marketing of the specified Divestiture Product except for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and except as may be required by applicable Law and except as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement;

    b. to prohibit Respondents from seeking from any customer any type of cross-referencing of those NDC Numbers with any Retained Product(s) except for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and except as may be required by applicable Law;

    c. to seek to change any cross-referencing by a customer of those NDC Numbers with a Retained Product (including the right to receive notification from the Respondents of any such cross-referencing that is discovered by a Respondent);

    d. to seek cross-referencing from a customer of the specified Respondent's NDC Numbers related to such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;

    e. to approve the timing of Respondents' discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product except for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the Closing Date and except as may be required by applicable Law and except as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement; and

    f. to approve any notification(s) from Respondents to any customer(s) regarding the use or discontinued use of such NDC numbers by the Respondents prior to such notification(s) being disseminated to the customer(s);

11. all Product Development Reports related to the specified Divestiture Product;

12. at the option of the Acquirer of the specified Divestiture Product, all Product Contracts related to the specified Divestiture Product;

13. all patient registries related to the specified Divestiture 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 the specified Divestiture Product (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);

specified Respondent, the employees (whether current or former) responsible for taking such corrective actions;

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

    a. to the extent known or available to the specified Respondent, a list of the inventory levels (weeks of supply) in the possession of each customer (i.e., healthcare provider, hospital, group purchasing organization, wholesaler, or distributor) as of the date prior to and closest to the Closing Date as is available; and

    b. to the extent known by the specified Respondent, any pending reorder dates for a customer as of the Closing Date;

18. at the option of the Acquirer of the specified Divestiture Product and to the extent

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

S. "Contract Manufacture" means the following:

1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer (including, without limitation, for the purposes of Clinical Trials and/or commercial sales);

2. to manufacture, or to cause to be manufactured, a Product that is the Therapeutic Equivalent of, and in the identical dosage strength, formulation, and presentation as, a Contract Manufacture Product on behalf of an Acquirer; or

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

T. "Co nufacture Product(s)" means the Divestiture Products, individually and colle d any ingredient, material, or component use, or to ca81 5n(c)4(t)-fd((eco m) 3 3(a)4(MC

2. Supply Agreement among Baxter International Inc., Claris Injectables Limited and Renaissance Lakewood, LLC to be executed on or before the Closing Date;

3. Technology Sublicense Agreement between Claris Pharmaservices and Renaissance Lakewood, LLC to be executed on or before the Closing Date (which agreement shall provide, inter alia, that, in the event this Technology Sublicense Agreement terminates, Respondents shall not retain any reversionary rights or interests in the Milrinone Assets); and

4. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreements.

The Divestiture Agreements are contained in Non-Public Appendix II.A. The 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.

X. "Divestiture Product(s)" means the following, individually and collectively:

1. "Fluconazole Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Claris pursuant to the following Application: ANDA No. 077909, and any supplements, amendments, or revisions to this ANDA. These Products are administered by injection (packaged in plastic containers) containing, as an active pharmaceutical ingredient, fluconazole (in sodium chloride 0.9%), at the following strengths: 200 MG/100ML (2MG/ML); 400MG/200ML (2MG/ML); and 100MG/50ML (2MG/ML).

2. "Milrinone Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Claris pursuant to the following Application: ANDA No. 077151, and any supplements, amendments, or revisions to this ANDA. These Products are administered by injection (packaged in plastic containers) containing, as an active pharmaceutical ingredient, milrinone lactate (in dextrose 5%), at the following strengths: EQ 20 MG BASE/100ML (EQ 0.2MG BASE/ML); and EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML).

Y. "Divestiture Product Assets" means the following, individually and collectively:

1. "Fluconazole Product Assets" means all rights, title, and interest in and to all assets related to the Business of Claris within the United States of America related to each of the Fluconazole Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Fluconazole Products.

2. "Milrinone Product Assets" means all rights, title, and interest in and to all assets related to the Business of Claris within the United States of America related to each of the Milrinone Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Milrinone Products.

Z. "Divestiture Product Core Employees" means the Product Research and Development Employees and the Product Manufacturing Employees related to each Contract Manufacture Product.

AA. “

GG. "High Volume Account(s)" means any retailer, wholesaler, or distributor whose annual or projected annual purchase amounts, in units or in dollars, of a Divestiture Product in the United States of America from a Respondent, was or was forecasted (prior to the public announcement of the Acquisition and subsequent divestiture) to be among the top twenty (20) highest such purchase amounts of that Respondent's total sales of that Divestiture Product to 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) for forecasts of purchases of the Divestiture Product, the quarter immediately following the Closing Date.

HH. "Law" means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.

II. "Manufacturing Designee" means any Person other than a 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 Decision and Order in this matter is issued by the Commission.

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

OO. "Patent(s)" means all patents and patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention, and statutory invention registrations, in each case filed, or in existence, on or before the Closing Date (except where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.

PP. "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.

QQ. "Product(s)" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.

RR. “Product Approval(s)”

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

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

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

TT. "Product Copyrights" means rights to all original works of authorship of any kind directly related to a Divestiture

UU. "Product Development Reports" means:

1. pharmacokinetic study reports related to the specified Divestiture Product;
2. bioavailability study reports (including Reference Listed Drug information) related to the specified Divestiture Product;
3. bioequivalence study reports (including Reference Listed Drug information) related to the specified Divestiture Product;
4. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from, or otherwise conducted with the FDA relating to the Application(s) related to the specified Divestiture Product;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to the specified Divestiture Product;
7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Divestiture Product;
8. FDA approved patient circulars and information related to the specified Divestiture Product;
9. adverse event reports, adverse experience information, and descriptions of material events and matters concerning safety or lack of efficacy related to the specified Divestiture Product;
10. summary of Product complaints from physicians or clinicians related to the specified Divestiture Product;
11. summary of Product complaints from customers related to the specified Divestiture Product;
12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies, and other documents related to such recalls;
13. investigation reports and

16. analytical methods development records related to the specified Divestiture Product;

17. manufacturing batch or lot records related to the specified Divestiture Product;

18. stability testing records related to the specified Divestiture Product;

19. change in control history related to the specified Divestiture Product; and

20. executed validation and qualification protocols and reports related to the specified Divestiture Product.

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

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

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

   a. direct contact information for the employee, including telephone number;

   b. the date of hire and effective service date;

   c. job title or position held;

   d. a specific description of the employee's responsibilities related to the relevant Divestiture Product; provided, however, in lieu of this description, a 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.

WW. "Product Intellectual Property" means all of the following

3.

performance qualification protocol, (iv) controlling

BBB. “Product Research and Development Employees” means all salaried employees of a Respondent who have directly participated in the research, Development, regulatory

only if the "Supply Cost" specified in such Remedial Agreement during the first twelve (12) month period of a Respondent supplying the Contract Manufacture Product does not exceed a Respondent's lowest net price (i.e., the final price per SKU or NDC Number charged by a Respondent net of all discounts, rebates, or promotions) of the relevant Divestiture Product to any of a Respondent's top 5 High Volume Accounts (as measured in units of the Divestiture Product purchased by those customers) for the relevant Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date.

MMM. "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:

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

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

NNN. "Therapeutic Equivalent" means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product.

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

PPP. "United States of America" means the United States of America, and its territories, districts, commonwealths and possessions.

QQQ. "Website" means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by a Respondent; provided, however, "Website" shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by a Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), except to the extent that a Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

II.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Divestiture Product Assets and grant the Divestiture Product Licenses, absolutely and in good faith, to Renaissance pursuant to, and in accordance with, the Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefind gnd82 0 0ti bes ance

Commission, and only in a manner that receives the prior approval of the Commission;

provided further, that if Respondents have divested the Divestiture 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 Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Divestiture 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. Prior to the Closing Date for each respective Divestiture Product, Respondents shall provide the Acquirer with the opportunity to review all contracts or agreements that are Product Contracts related to the Divestiture Products being acquired by that Acquirer for the purposes of the Acquirer's determination whether to assume such contracts or agreements.

C. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the Divestiture Product Assets to an Acquirer, and to permit the Acquirer to continue the Business of the Divestiture Product(s) being acquired by that Acquirer;

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

D. Respondents shall:

1. submit to the Acquirer, at Respondents' expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;
2. deliver all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer to that Acquirer:
    a. in good faith;

a.

exceed the representations and warranties made by the supplying Respondent to the Acquirer in an agreement to Contract Manufacture;

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

5. agree to hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure of the Contract Manufacture Products to be delivered in a timely manner unless (i) Respondent Baxter can demonstrate that the failure was beyond the control of Respondent Baxter and in no p [(a(l)-6(u)no p [(a)-1(a))-6(ont)

ANDA: provide Product that is the Therapeutic Equivalent of such Contract Manufacture Product from the facility(ies) that Respondent Baxter 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;

11. 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;

12. not be entitled to terminate any agreement to Contract Manufacture due to an Acquirer filing a petition in bankruptcy, or entering into an agreement with its creditors, or applying for or consenting to appointment of a receiver or trustee, or making an assignment for the benefit of creditors, or becoming subject to involuntary proceedings under any bankruptcy or insolvency Law;

13. shall notify the Commission at least sixty (60) days prior to terminating any agreement with an Acquirer to Contract Manufacture for any reason, and shall submit at the same time a copy of such notice to the Monitor; and

14. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of Respondent Baxter 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, a Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent 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 Contract Manufacture Products.

The foregoing requirements to Contract Manufacture shall remain in effect with respect to each Contract Manufacture Product until the earliest of: (i) the date the Acquirer (or the Manufacturi

H. Respondent Baxter shall designate employees of Respondent Baxter knowledgeable about the marketing, distribution, warehousing, and sale (including administrative logistics of sales to the respective High Volume Accounts) related to each of the Divestiture Products to assist the Acquirer, in the transfer and integration of the Business related to the Divestiture Products into the Acquirer's business.

I. Respondents shall require, as a condition of continued employment post-divestiture of the Divestiture Product Assets, that each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one (1) year period prior to the Closing Date, and each employee that has responsibilities related to the marketing or sales of those Retained Products that are the Therapeutic Equivalent of the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee, sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of the Respondents (other than as necessary to comply with the requirements of this Order).

J. Not later than thirty (30) days after the Closing Date, each Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by that Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Each Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Each Respondent shall provide a copy of the notification to the Acquirer. Each Respondent shall maintain complete records of all such notifications at that Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Each Respondent shall provide the Acquirer with copies of all certifications, notifications, and reminders sent to that Respondent's personnel.

K. Respondents shall:

1. for a period of twelve (12) months after the Closing Date, provide that Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and Divestiture Product Assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the "Divestiture Product Core Employee Access Period(s);"

2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to the relevant Respondent to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by that

connection with the Acquisition; and

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

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

provided further, however, that a 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 a Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from that Respondent.

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

1. Respondents shall take actions as are necessary to:

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

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

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

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

   e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and

2. Respondents shall not sell, transfer, encumber, or otherwise impair the Divestiture Product Assets (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 related to that Divestiture Product.

Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date;

O. Upon reasonable written notice and request from an Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States of America.

P. For any patent infringement suit filed prior to the Closing Date in which a Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that a Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States of America, that Respondent shall:

1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from that Respondent in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;

2. waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent that Acquirer in any ongoing patent litigation related to that Divestiture Product; and

3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work product in the possession of that Respondent's outside counsel related to that Divestiture Product.

Q. The purpose of the divestiture of the Divestiture Product Assets and the provision of the related Product Manufacturing Technology (for

2. to create a viable and effective competitor that is independent of Respondent Baxter in the Business of each Divestiture Product within the United States of America;

form Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent Baxter;

b. the date the Acquirer of that Divestiture Product notifies the Commission and Respondent Baxter of its intention to abandon its efforts to manuf5re4e4pondee

provided, however, beginning ninety (90) days after Respondent Baxter has filed its final report pursuant to Paragraph VII.C., and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by the Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent Baxter.

I.

Order.

B.

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 Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture(s) 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 Respondents from among those approved by the Commission; provided further, however, that Respondents 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 Respondents, 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 Respondents, 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 Respondents, 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. Respondents 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 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 Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; provided, however, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

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

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

G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture(s) required by this Order.

V.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, each Respondent shall assure that its own counsel ((ne)4(s)5.9(o)-4(O)2(r)3(diS3(de)4(.97 0 Td ( )Tj /TT0 1 -3(onfv-2(i)-2(s)442(i

provided further, however, that pursuant to this Paragraph V, a 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 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 a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.

C. Respondents 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. For each Divestiture Product that is a Contract Manufacture Product, Respondents shall include in the Remedial Agreement(s) related to that Divestiture Product a representation from the Acquirer that the 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 Divestiture Product, as applicable, and to have any such manufacture to be independent of Respondent Baxter, all as soon as reasonably practicable.

E. No Respondent shall seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products, a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.

F. No Respondent shall modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

VII.

IT IS FURTHER ORDERED that:

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

B. Within five (5) days of each Closing Date, Respondent Baxter shall submit to the Commission a letter certifying the date on which that particular divestiture occurred.

C. Within thirty (30) days after the Order Date, and every ninety (90) days thereafter until Respondent Baxter has (i) completed its obligations to Contract Manufacture the Contract Manufacture Products for an Acquirer, and (ii) fully provided the Product Manufacturing Technology related to the Divestiture Products to each Acquirer, Respondent Baxter 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 these requirements of this Order. Respondent Baxter 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 Baxter 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 Orders, 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 Respondent Baxter to the Acquirer, and (iii) the agreement(s) to Contract Manufacture; and

2. a detailed description of the timing for the completion of such obligations.

D. 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, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which they have complied and are complying with the Order. In addition to the foregoing, Respondent Baxter shall include in these reports a list containing (i) all of the Retained Products that are the Therapeutic Equivalent of a Divestiture Product and (ii) total sales in units and dollars in the United States of each of these Retained Products by Respondent Baxter for either the one-year period immediately preceding the report or the full calendar or fiscal year that immediately precedes the report.

VIII.

IT IS FURTHER ORDERED that each 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

3. secured all consents and waivers from all Third Parties that are necessary to divest the Divestiture Assets to an Acquirer or certified that the Acquirer has executed all such agreements directly with each of the relevant Third Parties;

D. with respect to any Product Licensed Intellectual Property, Respondent Claris has granted or otherwise provided the rights to use such intellectual property either directly to the Acquirer, or to Respondent Baxter for the purposes of providing such rights to the Acquirer; and

E. both Respondent Claris and Respondent Arjun Handa certify to the Commission that all of the above-described acquisitions and transfers have occurred and all of the above-described consents and waivers from Third Parties have been provided to the Acquirer.

XI.

IT IS FURTHER ORDERED that this Order shall terminate on August 25, 2027.

By the Commission.

Donald S. Clark
Secretary

SEAL:
ISSUED: August 25, 2017

NON-PUBLIC APPENDIX I
ACQUISITION AGREEMENTS

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

NON-PUBLIC APPENDIX II.A
AGREEMENTS RELATED TO THE DIVESTITURES

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