

**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

**COMMISSIONERS: Maureen K. Ohlhausen, Acting Chairman
 Terrell McSweeney**

In the Matter of)	
)	
BAXTER INTERNATIONAL INC.,)	
a corporation;)	
)	
CLARIS LIFESCIENCES LIMITED,)	Docket No. C-4620
a corporation;)	
and)	
)	
ARJUN HANDA,)	
an individual.)	

- 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.
- F. “Decision and Order” means the:
1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
 2. Final Decision and Order following its issuance and service by the Commission in this matter.
- G. “Divestiture Product Business(es)” means the Business of Respondent (as that Respondent is specified in the definition of each Divestiture Product) within the Geographic Territory specified in the Decision and Order related to each of the Divestiture Products to the extent that such Business is owned, controlled, or managed by the Respondent and the assets related to such Business to the extent such assets are owned by, controlled by, managed by, or licensed to, the Respondent.
- H. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- I. “Transition Period” means, for each Divestiture Product that is marketed or sold in the United States before the Closing Date, the period beginning on the date this Order to Maintain Assets is issued and ending on the earlier of the following dates: (i) the date on which the Acquirer directs the Respondent(s) to cease the marketing, distribution, and sale of such Divestiture Product(s); (ii) the date on which the Acquirer commences the marketing, distribution, and sale of such Divestiture Product(s); or (iii) the date four (4) months after the Closing Date for such Divestiture Product(s).

Divestiture Products during and after the Acquisition process and prior to the complete transfer and delivery of the related Divestiture Product Assets to an Acquirer;

4. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Divestiture Products that were marketed or sold by Respondents prior to the date the Respondents entered the agreement to effect the Acquisition (as such agreement is identified in the definition of Acquisition), at the related High Volume Accounts;
 5. making available for use by each of the respective Divestiture Product Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such Divestiture Product Business; and
 6. providing such support services to each of the respective Divestiture Product Businesses as were being provided to such Divestiture Product Business by Respondents as of the date the Consent Agreement was signed by Respondents.
- C. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall maintain a work force that is (i) at least as large in size (as measured in full time equivalents) as, and (ii) comparable in training, and expertise to, what has been associated with the Divestiture Products for the relevant Divestiture Product's last fiscal year.
- D. Not later than one (1) day after the date this Order to Maintain Assets is issued by the Commission, for each Divestiture Product that has been marketed or sold prior to the Closing Date, Respondents shall provide to the Proposed Acquirer of that Divestiture Product, for each High Volume Account, a list by either SKU or NDC Number containing the current net price per SKU or NDC Number, *i.e.*, the final price per SKU or NDC Number, charged by the relevant Respondent (as that Respondent is identified in the definition of each Divestiture Product) net of all customer-level discounts, rebates, or promotions, for that Divestiture Product, as of five (5) business days or less prior to the date this Order to Maintain Assets is issued.

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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 Respondent to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; *provided, however,* that the provision of such information may be conditioned upon the Acquirer's or Proposed Acquirer's written confirmation that it will (i) treat the information as confidential and, (ii) use the information solely in connection with considering whether to provide or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, and (iii) restrict access to the information to such of the Acquirer's or Proposed Acquirer's employees who need such access in connection with the specified and permitted use;
3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees related to the Divestiture Products and Divestiture Product Assets acquired by that Acquirer, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with a Respondent that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, a Respondent shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit a Respondent from continuing to employ any Divestiture Product Core Employee under the terms of that employee's employment with a Respondent prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture, and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall

3. maintain and manage inventory levels of the Divestiture Products in consideration of the marketing and distribution transition to the Acquirer;
4. continue to market, distribute, and sell the Divestiture Products;
5. allow the Acquirer access at reasonable business hours to all Confidential Business Information related to the Divestiture Products 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 Divestiture Products that contain such Confidential Business Information pending the completed delivery of such Confidential Business Information to the Acquirer;
6. to the extent known or available to the specified Respondent, provide the Acquirer with 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) by stock keeping unit or NDA Number on a regular basis and in a timely manner;
7. to the extent known by the specified Respondent, provide the Acquirer with anticipated reorder dates for each customer by stock keeping unit or NDC Number on a regular basis and in a timely manner; and
8. establish projected time lines for accomplishing all tasks necessary to effect the marketing and distribution transition to the Acquirer in an efficient and timely manner.

G. Pending divestiture of the Divestiture Product Assets, Respondents shall:

- to receive such information (*e.g.*, employees of the Respondents responsible for the Contract Manufacture or continued Development of a Divestiture Product on behalf of an Acquirer), (iii) the Commission, or (iv) the Monitor (if any has been appointed) and *except* to the extent necessary to comply with applicable Law;
3. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing, sales or Development of the Divestiture Products to the employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products;
 4. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the research and Development of the Development Divestiture Products to any employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products *unless* authorized by the Acquirer of the particular Divestiture Product to do so; and
 5. institute procedures and requirements to ensure that the above-described employees:
 - a. do not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Order to Maintain Assets; and
 - b. do not solicit, access or use any Confidential Business Information that they are prohibited from receiving for any reason or purpose.
- H. Not later than thirty (30) days from the earlier of (i) the Closing Date or (ii) the date this Order to Maintain Assets is issued by the Commission, 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.

- J. Each Respondent shall monitor the implementation by its employees and other personnel of all applicable restrictions with respect to Confidential Business Information, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets.

- K. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses within the

2. The Monitor shall act in a fiduciary capacity fo

- G. Each 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 performance of the 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 Monitor.
- H. Each Respondent shall report to the Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by a Respondent, and any reports submitted by each Acquirer with respect to the performance of a Respondent's obligations under the Orders or the Remedial Agreement(s). Within thirty (30) days from the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by each Respondent of its obligations under the Orders; *provided, however*, beginning ninety (90) days after Respondent Baxter has filed its final report pursuant to Paragraph VII.C. of the Decision and Order, and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by each 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. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other professionals, beginning ninety (90) days after Respondent Baxter has filed its final report pursuant to Paragraph VII.C. of the Decision and Order, and ninety (90) days thereafter, to report in writing to the Commission concerning progress by each 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.

- N. The Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets is issued by the Commission, and every sixty (60) days thereafter until Respondents have fully complied with this Order to Maintain Assets, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with the Orders. Each Respondent shall submit at the same time a copy of its report concerning compliance with the Orders to the Monitor, if any Monitor has been appointed. Each Respondent shall include in its reports, among other things that are required from time to time, a detailed description of its efforts to comply with the relevant paragraphs of the Orders, including:

- A. 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 relevant Respondent to the Acquirer, and (iii) the agreement(s) to Contract Manufacture; and

- B. a detailed description of the timing for the completion of such obligations,

provided, however, that, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission on the same timing as, the reports of compliance required to be submitted by Respondents pursuant to the Decision and Order.

V.

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
- 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 the Orders.

VI.

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

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

VII.

IT IS FURTHER ORDERED that Respondent Claris's and Respondent Arjun Handa's obligations under this Order to Maintain Assets, shall terminate on the date on which all of the following have occurred:

- A. Respondent Baxter has acquired over fifty (50) percent of the voting securities or equity interests of each of the Claris Generic Pharmaceutical Entities;
- B. the Divestiture Assets are completely owned and controlled either by Respondent Baxter or an Acquirer;
- C. with respect to any Divestiture Product or related Product Intellectual Property or Manufacturing Technology, that is owned or controlled by Respondent Claris prior to the Acquisition, Respondent Claris has:
 - 1. transferred all rights and assets that were owned or controlled by Respondent Claris prior to the Acquisition and necessary to effect the related divestitures to either Respondent Baxter or the Acquirer;
 - 2. transferred or otherwise provided all rights, assets or other resources that were owned or controlled by Respondent Claris prior to the Acquisition and necessary for Respondent Baxter to provide the services and assistance to the Acquirer described in this Order to Respondent Baxter; and
 - 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.

VIII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate as to Respondent Baxter on the later of:

- A. three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. the day after the divestiture of all of the Divestiture Product Assets, as required by and described in the Decision and Order, has been completed;
- C. the day after the Product Manufacturing Technology related to each Divestiture Product that is a Contract Manufacture Product or a Pipeline Product has been provided to the Acquirer in a manner consistent with the Technology Transfer Standards and the Monitor, in consultation with Commission staff and the Acquirer(s), notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers, and other transitions related to the provision of the Product Manufacturing Technology are complete; or
- D. the day the Commission otherwise directs that this Order to Maintain Assets is terminated.

By the Commission.

April J. Tabor
Acting Secretary

SEAL
ISSUED: July 20, 2017