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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright
Terrell McSweeny

In the Matter of	)	
NOVARTIS AG **a corporation.**	)	**DOCKET NO. C-**

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed joint venture between Respondent Novartis AG ("Novartis" or "Respondent") and GlaxoSmithKline PLC ("GSK"), and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent and GSK with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not cgrtthad reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and 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"):

1. Respondent Novartis is a corporation organized, existing and doing business under and by virtue of the laws of the Swiss Confederation with its headquarters address located at Lichtstrasse 35, Basel, Switzerland, CH 4056, and the address of its United States subsidiary, Novartis Corporation, located at 230 Park Avenue, New York, New York 10169.

2. GSK is a corporation organized, existing and doing business under and by virtue of the laws of the United Kingdom of Great Britain and Northern Ireland, with its headquarters address located at 980 Great West Road, Brentford Middlesex TW8 9GS, England.

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

ORDER

I.

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

A. "Novartis" or "Respondent" means: Novartis AG, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Novartis AG (including, without limitation, Novartis Consumer Health, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

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

C. "Commission" means the Federal Trade Commission.

D. "Acquirer(s)" means the following:

1. a Person specified by name in this Order to acquire particular assets or rights that the Respondent is required

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 a Respondent and the FDA related thereto. The term "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 a Respondent and the FDA related thereto.

H. "Business" means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement and sale of a Product.

I. "cGMP" means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.

J. "Clinical Trial(s)" means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.

K. "Closing Date" means the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Habitrol Assets to the Acquirer pursuant to this Order.

L. "Confidential Business Information" means all information owned by, or in the possession or control of, the Respondent prior to the Acquisition Date that is not in the public domain and that is directly related to the conduct of the Business related to

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.

M. "Development" means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, scale-up, development-stage , quality assurance/qu

1. all rights to all of the Applications related to Habitrol bearing NDA No. 020076;
2. all Product Intellectual Property related to Habitrol that is not Product Licensed Intellectual Property;
3. all Product Approvals related to Habitrol;
4. all Product Marketing Materials related to Habitrol;
5. all Product Scientific and Regulatory Material related to Habitrol;
6. all Website(s) related exclusively to Habitrol;
7. the content related exclusively to Habitrol that is displayed on any Website that is not dedicated exclusively to Habitrol;
8. a list of all of the NDC Numbers related to Habitrol, and rights, to the extent permitted by Law:
    a. to

9. all Product Development Reports related to Habitrol;

10. at the option of the Acquirer of Habitrol, all Product Assumed Contracts related to Habitrol (copies to be provided to the Acquirer on or before the Closing Date);

11. a list of all customers and targeted customers for Habitrol and a listing of the net sales (in either units or dollars) of Habitrol to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of Habitrol on behalf of the High Volume Account and his or her business contact information;

12. at the option of the Acquirer of Habitrol and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, and finished goods related to Habitrol;

13. copies of all unfilled customer purchase orders for Habitrol as of the Closing Date, to be provided to the Acquirer of Habitrol not later than five (5) days after the Closing Date;

14. at the option of the Acquirer of Habitrol, all unfilled customer purchase orders for Habitrol; and

15. all of the Respondent's books, records, and files to the extent directly related to the foregoing;

provided, however, that "Habitrol Assets" shall not include: (i) documents relating to the Respondent's general business strategies or practices relating to the conduct of its Business of marketing over-the-counter pharmaceutical Products, where such documents do not discuss with particularity Habitrol; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of Habitrol by the Intel tobi(t)-2(u5(ay)22)-20(I)15(n)2(t)(I004 Tc 0.004

GG. "Order Date" means the date on which the final Decision and Order in this matter is issued by the Commission.

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

II. "Patent(s)" means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case 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.

JJ. "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.

KK. "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.

LL. "Product Approval(s)" means any approvals, registrations, permits, licenses, cons an aomTd (.)Tj 191

5. pursuant to which a Third Party provides any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of Habitrol on behalf of Respondent;

6. constituting confidentiality agreements involving Habitrol (other than confidentiality agreements entered into in connection with the process conducted to find a purchaser for the Habitrol Assets as contemplated by this Order);

7. involving any royalty, licensing, covenant not to sue, or similar arrangement involving Habitrol;

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

9. pursuant to which any Third Party collaborates with Respondent in the performance of research, Development, marketing, distribution or selling of Habitrol or the Business related to Habitrol;

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

NN. "Product Copyrights" means rights to all original works of authorship of any kind directly related to Habitrol and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and educational materials for the sales force; copyrights in all preclinical, clinical and process development data and reports relating to the research and Development of 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 Clinical Trials of that Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references))ed i6(h)-,h.2le(,)-4(cl)-6(i)-6(n)-4(c)-10(add i6(hd)-4(act)-6(

experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA or any other Agency.

OO. "Product Development Reports" means:

1. Pharmacokinetic study reports related to Habitrol;
2. Bioavailability study reports (including reference listed drug information) related to Habitrol;
3. Bioequivalence study reports (including reference listed drug information) related to Habitrol;
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 Habitrol;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to Habitrol;
7. currently used or planned product package inserts (including historical change of controls summaries) related to Habitrol;
8. FDA approved patient circulars and information related to Habitrol;
9. adverse event reports, adverse experience information, descriptions of material events and matters concerning safety or lack of efficacy related to Habitrol;
10. summary of Product complaints from physicians related to Habitrol;
11. summary of Product complaints from customers related to Habitrol;
12. Product recall reports filed with the FDA related to Habitrol, and all reports, studies and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities found in Habitrol;
14. reports related to Habitrol from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including without limitation, identification and sources of impurities;
15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce Habitrol that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of Habitrol;
16. analytical methods development records related to Habitrol;
17. manufacturing batch records related to Habitrol;
18. stability testing records related to Habitrol;

19. change in control history related to Habitrol; and

20. executed validation and qualification protocols and reports related to Habitrol.

PP. "Product Intellectual Property" means all of the following related to Habitrol (other than Product Licensed Intellectual Property):

1. Patents;

2. Product Copyrights;

3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and

4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof and to bring suit against a Third Party for the past, present or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing;

SS.

WW. "Retained Product" means any Product(s) other than Habitrol.

XX. "Third Party(ies)" means any non-governmental Person other than the following: the Respondent; the Joint Venture; or, the Acquirer.

YY. "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 Intellectual Property not owned by the Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), except to the extent that the Respondent can convey its rights, if any, therein; or (2) content unrelated to Habitrol.

II.

IT IS FURTHER ORDERED that:

A. Not later than the earlier of: (i) ten (10) days after the Acquisition Date or (ii) ten (10) days after the Order Date, Respondent shall divest the Habitrol Assets and grant the related Divestiture Product License, absolutely and in good faith, to Dr. Reddy's pursuant to, and in accordance with, the Habitrol Divestiture Agreement(s) (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 benefits of Dr. Reddy's or to reduce any obligations of Respondent under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Habitrol Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent has dives t

B. Prior to the Closing Date, Respondent shall secure all consents and waivers from all Third Parties that are necessary to permit Respondent to divest the assets required to be divested pursuant to this Order to the Acquirer, and to permit the Acquirer to continue the Business of Habitrol;

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

C. Respondent shall:

1. submit to the Acquirer, at Respondent's expense, all Confidential Business Information;

2. deliver all Confidential Business Information to the Acquirer:

   a. in good faith;

   b. in a timely manner, i.e., a Tc 0 T3(e)4(s)dd to b(r)5(-0.C /H4 <</MCID 5 a-pe 1 Tfpc)-2(

D. Respondent

G. From the Closing Date, neither the

I. For any patent infringement suit filed prior to the Closing Date in which Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that 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 Habitrol for the purposes of marketing, sale or offer for sale within the United States of America of Habitrol; or (ii) the use within, import into, or the supply, distribution, or sale or offer for sale within, the United States of America of Habitrol, Respondent shall:

1. cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from the Respondent in connection with obtaining resolution of any pending patent litigation related to Habitrol;
2. waive conflicts of interest, if any, to allow the Respondent's outside legal counsel to represent the Acquirer in any ongoing patent litigation related to Habitrol; and
3. permit the transfer to the Acquirer of all of the litigation files and any related attorney work-product in the possession of the Respondent's outside counsel related to Habitrol.

J. The purpose of the divestiture of the Habitrol Assets and the related obligations imposed on the Respondent by this Order is:

1. to ensure the continued use of such assets for the purposes of the Business associated with Habitrol within the Geographic Territory; and

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

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

1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.

2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.

3. The Interim Monitor shall serve until the date of completion by the Respondent of the divestiture of all Habitrol Assets in a manner that fully satisfies the requirements of the Orders;

provided, however, that the Interim Monitor's service shall not exceed five (5) years from 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 Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the Habitrol Assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with the Orders.

F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.

G. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all

reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.

H. Respondent shall report to the Interim Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by each Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order.

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

J. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality 9Td ( )Tj EAbpr(e)4(t)-2(e)4(nt((e)dTj /TT0 110(t)-2

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transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.

B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of a 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.

for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to the Acquirer as required by this Order; provided, however, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondent from among those approved by the Commission; provided further, however, that Respondent shall select such Person within five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; provided, however, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.

8.

1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, and (ii) transitional services being provided by the Respondent to the Acquirer; 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 (9) 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.

IX.

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 the Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, the Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

A. access, during business office hours of the Respondent and in the pres

X.

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

By the Commission.

Donald S. Clark
Secretary

SEAL
ISSUED:

NON-PUBLIC APPENDIX I
AGREEMENTS RELATED TO THE DIVESTITURE

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