0710132

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Deborah Platt Majoras, Chairman**
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

In the Matter of	)	
	)	**Docket No. C-**
SCHERING-PLOUGH CORPORATION,	)	
a corporation	)	

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission ("Commission") having initiated an investigation of the acquisition by Respondent Schering-Plough Corporation ("Schering-Plough") of Organon Biosciences N.V. from Akzo Nobel N.V., and Respondent having been furnished thereafter with a copy of a draft of a 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 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 Order ("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 constitute an admission by Respondent that the law has been violated as alleged in such 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 Respondent has violated the said Acts, and that a Complaint should

issue stating its charges in that respect, 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 issues its Complaint, makes the following jurisdictional findings, and issues the following Decision and Order ("Order"):

1. Respondent Schering-Plough Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the State of New Jersey, with its headquarters address at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033-1310.

2. Akzo Nobel N.V. is a corporation organized, existing and doing business under and by virtue of the laws of The Netherlands, with its headquarters address at Velperweg 76, 6824 BM Arnhem, The Netherlands and its principal place of business in the U.S. at 120 White Plains Road, Suite 300, Tarrytown, New York 10591-5522.

3. Organon BioSciences N.V., with its headquarters address at Wethouder van Eschstraat 1, 5342 AV OSS, The Netherlands, includes Intervet.

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

ORDER

I.

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

A. "Schering-Plough" means Schering-Plough Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Schering-Plough Corporation, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Schering-Plough Corporation shall include Organon BioSciences and Intervet.

C. "Organon BioSciences" means Organon BioSciences N.V., a corporation organized, existing and doing business under and by virtue of the laws of The Netherlands, with its offices and principal place of business located at Wethouder van Eschstraat 1, 5342 AV Oss, The Netherlands. Organon Biosciences is a wholly owned subsidiary of Akzo Nobel.

D. "Intervet" means Intervet Inc, a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters located at 29160 Intervet Lane, Millsboro, Delaware 19966. Intervet is a wholly owned indirect subsidiary of Organon BioSciences.

E. "Respondent" means Schering-Plough.

F. "Commission" means the Federal Trade Commission.

G. "Acquirer" means the following:

1. Wyeth; or

2. an entity that is approved by the Commission to acquire particular assets that the Respondent is required to assign, grant, license, divest, transfer, deliver or otherwise convey pursuant to this Order. There may be one or more Acquirers under this Order.

H. "Acquisition" means the Respondent Schering-Plough's acquisition of one hundred percent (100%) of the voting stock of Organon BioSciences N.V. from Respondent Akzo Nobel N.V. pursuant to a letter of intent dated March 12, 2007.

I. "Agency(ies)" means any governmental regulatory authority or authorities 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 Divestiture Product in the Territory. The term "Agency" includes, but is not limited to, the United States Department of Agriculture ("USDA").

IB98 from January 1, 2000, through the Closing Date, and quality control histories pertaining to Avimune IB98 owned by, or in the possession or control of, Respondent, or to which Respondent has a right of access, in each case such as is in existence as of the Closing Date;

provided, however, that in cases in which documents or other materials included in the Avimune IB98 Assets contain information that (i) relates both to Avimune IB98 and to other Products or businesses of Respondent (including the business outside the Territory), and (ii) cannot be segregated in a manner that preserves the usefulness of the information as it relates to Avimune IB98, Respondent shall be required only to provide copies of the documents and materials containing this information. In instances where such copies are provided to the Acquirer, the Acquirer shall have access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that Respondent provide the Acquirer with the above-described information without requiring Respondent completely to divest itself of information that, in content, also relates to Products and businesses other than Avimune IB98;

provided further, however, the term "Avimune IB98 Assets" does not include: (i) Retained Master Seed; (ii) Retained Challenge Material; (iii) Retained Reagents; (iv) manufacturing equipment and facilities, business permits and licenses, research and Development expertise, professional services, trade and distribution networks, personnel, manufacturing facilities, factories, laboratories and other real property, administrative, systems and processing infrastructure, sales, promotion and marketing expertise, regulatory expertise, financing, and items of a similar nature generally necessary to

O. “CHOLERVAC PM-1 Assets” means all of Respondent’s rights, title and interest acquired in the Acquisition in and to all assets related to the business of Organon and Intervet in the

9. at the Acquirer’s option, each of the Product Assumed Contracts;

10. all Product Marketing Materials;

including, without limitation, clinical data, and sales force call activity, for CHOLERVAC PM-1 from January 1, 2000, through the Closing Date, and quality control histories pertaining to CHOLERVAC PM-1 owned by, or in the possession or control of, Respondent, or to which Respondent has a right of access, in each case such as is in existence as of the Closing Date;

provided, however, that in cases in which documents or other materials included in the CHOLERVAC PM-1 Assets contain information that (i) relates both to CHOLERVAC PM-1 and to other Products or businesses of Respondent (including the business outside the Territory), and (ii) cannot be segregated in a manner that preserves the usefulness of the information as it relates to CHOLERVAC PM-1, Respondent shall be required only to provide copies of the documents and materials containing this information. In instances where such copies are provided to the Acquirer, the Acquirer shall have access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that Respondent provide the Acquirer with the above-described information without requiring Respondent completely to divest itself of information that, in content, also relates to Products and businesses other than CHOLERVAC PM-1;

provided further, however, the term "CHOLERVAC PM-1 Assets" does not include: (i) Retained Master Seed; (ii) Retained Challenge Material; (iii) Retained Reagents; (iv) manufacturing equipment and facilities, business permits and licenses, research and Development expertise, professional services, trade and distribution networks, personnel, manufacturing facilities, factories, laboratories and other real property, administrative, systems and processing infrastructure, sales, promotion and marketing expertise, regulatory expertise, financing, and items of a similar nature generally necessary to conduct an animal health business; (v) those assets listed in 1-16 above as used in the conduct of Respondent's business outside the Territory.

P. "Closing Date" means the date on which Respondent (or a Divestiture Trustee) and an Acquirer close on a transaction to divest, license, or otherwise convey relevant assets pursuant to this Order.

Q. "Confidential Business Information" means all information owned by, or in the possession or control of, Respondent that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, distribution, importation, exportation, cost, pricing, supply, sales, sales support, or use of a Divestiture Product; *provided, however*, that the restrictions contained in this Order regarding the use, conveyance, provision, or disclosure of "Confidential Business Information" shall not apply to the following:

1. Information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such

Agreement for that Divestiture Product.

W. "Divestiture Assets" means the Avimune IB98 Assets, the CHOLERVAC PM-1 Assets, and the F VAX-MG Assets.

X. "Divestiture Product Core Employees" means the Product Manufacturing Employee(s), Product Marketing Employee(s), Product Sales Employee(s) and Product Research and Development Employee(s) related to each of the Divestiture Products.

Y. "Divestiture Products" means any one or more of the following Products: Avimune IB98, CHOLERVAC PM-1, and F VAX-MG.

Z. "Divestiture Trustee" means a trustee appointed by the Commission pursuant to the relevant provisions of this Order.

AA. "Effective Date" means the date the Respondent and Akzo Nobel close on the Acquisition.

BB. "Employee Access Period" means a period of twelve (12) months from the Closing Date.

CC. "Employee Notification" means the "Notice of Divestiture and Requirement for

Divestiture Product, in and into the Territory, which license(s) shall be perpetual, fully paid-up and royalty-free, and exclusive (even as to Respondent); and,

(iii) all of which licenses shall include the right to use to make improvements or modifications to such Divestiture Product (including, but not limited to, the preparation of new or modified Products by combining components, antigens, or ingredients of such Divestiture Product with one or more other components, antigens, ingredients, or Products);

3. the Master Seed;

4. the Challenge Material;

5. the Reagents;

6. the Product Regulatory File;

7. License(s) to use the Product Registrations to the extent required for the distribution, marketing, promoting, offering for sale and selling of the Divestiture Products in the Territory, which license(s) shall be royalty-free, non-exclusive, transferable and sublicensable; *provided however*, that such license(s) shall terminate upon Acquirer's receipt of all Divestiture Product approvals in accordance with Paragraph II.C.5 of this Order;

8. a list of all of the NDC Numbers related to the Product;

9. the existing lists of all current customers for the Divestiture Product and the pricing of the Divestiture Product for such customers;

10. at the Acquirer's option, each of the Product Assumed Contracts;

11. all Product Marketing Materials;

12. rights of reference (if such rights exist) to information similar to the Product Regulatory File submitted to any Agency other than the USDA and relating to the Divestiture Product except as may be retained by Respondent (1) in order to comply with its obligations to Contract Manufacture under Paragraph II.D.1 of this Order, or (2) for the purposes of conducting Respondent's business related to such Product outside the Territory;

13. Product Scientific and Regulatory Material;

14. all unfilled customer orders for the Divestiture Product as of the Closing Date (a list of

such orders is to be provided to the Acquirer within two days after the Closing Date);

15. license(s) to all Product Manufacturing Technology:

    (i) to make and have made the Divestiture Product anywhere in the world, which license(s) shall be perpetual, transferable, fully paid-up and royalty-free, and co-exclusive with Respondent within the Territory and non-exclusive outside the Territory, and;

    (ii) to use, distribute, offer for sale, promote, advertise, sell, or import, or to have used, distributed, offered for sale, promoted, advertised, sold, or imported such Divestiture Product, in and into the Territory, which license(s) shall be perpetual, fully paid-up and royalty-free, and exclusive (even as to Respondent); and,

    (iii) all of which licenses shall include the right to use to make improvements or modifications to such Divestiture Product (including, but not limited to, the preparation of new or modified Products by combining components, antigens, or ingredients of such Divestiture Product with one or more other components, antigens, ingredients, or Products);

16. at the Acquirer's option, all inventories for the Territory in existence as of the Closing Date, including, but not limited to, raw materials, goods in process, finished goods, and Divestiture Product specific packaging and labels, which shall include the grant of a license to use Product Trademar•eAnI*and'frgool inventopurpoc0 ofhe grant oProdetby for ;ed go Date)

purposes. The purpose of this proviso is to ensure that Respondent provide the Acquirer with the above-described information without requiring Respondent completely to divest itself of information that, in content, also relates to Products and businesses other than F VAX-MG;

provided further, however, the term "F VAX-MG Assets" does not include: (i) Retained Master Seed; (ii) Retained Challenge Material; (iii) Retained Reagents; (iv) manufacturing equipment and facilities, business permits and licenses, research and Development expertise, professional services, trade and distribution networks, personnel, manufacturing facilities, factories, laboratories and other real property, administrative, systems and processing infrastructure, sales, promotion and marketing expertise, regulatory expertise, financing, and items of a similar nature generally necessary to conduct an animal health business; (v) those assets listed in 1-17 above as used in the conduct of Respondent's business outside the Territory.

FF. "Government Entity" means any Federal, state, local or non-U.S. government or any court, legislature, government agency or government commission, or any judicial or regulatory authority of any government.

GG. "Interim Monitor" means a monitor appointed by the Commission pursuant to the relevant provisions of this Order.

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

LL. "Product" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically or genetically active ingredient.

MM. "Product Assumed Contracts" means all of the following contracts or agreements related to the Territory:

1. pursuant to which any Third Party purchases any Divestiture Product from the Respondent;

2. pursuant to which the Respondent purchases any materials from any Third Party for use in connection with the manufacture of any Divestiture Product;

3. relating to any clinical trial involving any Divestiture Product;

4. constituting the material transfer agreements involving the transfer of any Divestiture Product;

5. relating to the marketing of any Divestiture Product or educational matters relating to any Divestiture Product;

6. relating to the manufacture of any Divestiture Product;

7. constituting confidentiality agreements involving any Divestiture Product;

8. involving any royalty, licensing or similar arrangement involving any Divestiture Product;

9. pursuant to which any services are provided with respect to any Divestiture Product or any Divestiture Product business, including consultation arrangements; and/or

10. pursuant to which any Third Party collaborates with the Respondent in the performance of research or Development of any Divestiture Product or any Divestiture Product business.

provided, however, that where any such contract or agreement also relates to a Product of Respondent other than any Divestiture Product, Respondent shall assign the Acquirer all such rights in the Territory under the contract or agreement as are related to the Product required to be divested pursuant to this Order, but concurrently may retain similar rights for the purposes of the other Product.

NN. "Product Copyrights" means rights to all original works of authorship of any kind related to any Divestiture Product and any registrations and applications for registrations thereof,

including, but not limited to, the following: educational materials for the sales force; copyrights in all pre-clinical, clinical and process development data and reports relating to the research and Development of any Divestiture Product or of any materials used in the research, Development, manufacture, marketing or sale of any Divestiture Product, including all raw data relating to clinical trials of any Divestiture Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; customer information, promotional and marketing materials, any Divestiture Product sales forecasting models, medical education materials, sales training materials, website content and advertising and display materials; all records relating to employees that accept employment with the Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all records,

information, and all rights in the Territory to limit the use or disclosure thereof, that are related to a Divestiture Product that Respondent can demonstrate have been routinely used, prior to the Effective Date, by Respondent or Organon BioSciences or Intervet (whichever is relevant to such Divestiture Product) for a Retained Product(s).

RR. "Product Manufacturing Employee(s)" means all salaried employees of Respondent who directly participated (irrespective of the portion of working time involved) in the manufacture of the Divestiture Product for the Territory, including, but not limited to, those involved in the quality assurance and quality control of the Divestiture Product for the Territory, within the eighteen (18) month period immediately prior to the Closing Date.

SS. "Product Manufacturing Technology" means all technology, trade secrets, know-how, and proprietary information related to the manufacture, validation, packaging, release testing, stability and shelf life of the Divestiture Product, including the Divestiture Product's formulation, in existence and in the possession of Respondent as of the Closing Date, including, but not limited to, the percentages and specifications of ingredients, the manufacturing processes and flow diagrams thereof, the Production Outlines, specifications, technology, inventions, assays, quality control and testing procedures, know-how, trade secrets and trade art, whether tangible or intangible and used to manufacture, formulate, test and package the Divestiture Products for sale, marketing and distribution in the Territory.

TT. "Product Marketing Employee(s)" means all management level employees of Respondent who directly participated (irrespective of the portion of working time involved) in the marketing, contracting, or promotion of the Divestiture Product in the Territory within the eighteen (18) month period immediately prior to the Closing Date. These employees include, without limitation, all management level employees having any responsibilities in the areas of sales management, brand management, sales training and market research, but excluding administrative assistants.

UU. "Product Marketing Materials" means the content of all marketing materials used in the Territory related to the Divestiture Product as of the Closing Date, including, without limitation, all tangible copies of all advertising materials, training materials, product data, price lists, mailing lists, sales materials (e.g., detailing reports; vendor lists; sales data; reimbursement data), marketing information (e.g., competitor information; research data;

EEE. "Reagents" means all of the reagents (other than the Retained Reagents) that are proprietary or unavailable from commercial sources used in the research, Development, manufacture, distribution, marketing or sale of any one or more of the Divestiture Products to confirm the identification of the Master Seed and to perform the potency tests of the Divestiture Products, including the reference vaccine for each Divestiture Product for the Territory.

FFF. "Remedial Agreement(s)" mean:

1. The agreement between Respondent and Wyeth, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final;

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

3. Any agreement between Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of this Order; or,

4. Any agreement between Respondent and a Third Party to effect the assignment of assets or rights of Respondent related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

GGG. "Retained Challenge Material"means the quantities of materials used to confirm the immunogenicity of each Divestiture Product and the media formula to propagate the challenge organism, which are not conveyed to Acquirer as Divestiture Assets and are retained by Respondent for the conduct of its business outside the Territory.

HHH. "Retained Master Seed" means the quantities of isolated strain of organism selected and permanently stored by Respondent from which all other seed passages are derived within permitted levels for each Divestiture Product, which are not conveyed to Acquirer as Divestiture Assets and are retained by Respondent for the conduct of its business outside the Territory.

III. "Retained Product" means any Product(s) other than a Divestiture Product.

JJJ. "Retained Reagents" means the quantities of the reagents that are proprietary or unavailable from commercial sources used in the research, Development, manufacture, distribution, marketing or sale of any one or more of the Divestiture Products to confirm the identification of the Master Seed and to perform the potency tests of the Divestiture Products, including the reference vaccine for each Divestiture Product for the Territory, which are not conveyed to Acquirer as Divestiture Assets and are retained by Respondent for the conduct of its business outside the Territory.

KKK. "Supply Cost" means a cost not to exceed the manufacturer's average direct unit cost of manufacturing the Divestiture Product for the twelve (12) month period immediately preceding the Effective Date. "Supply Cost" shall expressly exclude any intracompany business transfer profit; *provided, however,* that in each instance where: (1) an agreement to Contact Manufacture is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, "Supply Cost" means the cost as specified in such Remedial Agreement for that Divestiture Product.

LLL. "Territory" means the United States of America and its territories and possessions.

MMM. "Third Party(ies)" means any private entity other than: (1) the Respondent, or (2) the Acquirer for the affected assets, rights and Divestiture Products.

NNN. "Wyeth" means Wyeth, a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at Five Giralda Farms, Madison, New Jersey 07940-0874.

II.

IT IS FURTHER ORDERED

the relevant Third Parties.

C. Respondent shall transfer the Product Manufacturing Technology related to each Divestiture Product to the Acquirer in an organized, comprehensive, complete, useful, timely, and meaningful manner. Respondent shall, *inter alia*:

1. Designate employees of Respondent knowledgeable with respect to Product Manufacturing Technology for each Divestiture Product to a committee for the purposes of communicating directly with the Acquirer and the Interim Monitor for the purposes of effecting such transfer;

2. Prepare technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the relevant Divestiture Product, such protocols and acceptance criteria to be subject to the approval of the Acquirer;

3. Prepare and implement a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all Product Manufacturing Technology to the Acquirer;

4. Upon reasonable notice and request from the Acquirer to Respondent, provide in a timely manner, at no greater than Direct Cost, assistance and advice to enable the Acquirer (or the Designee of the Acquirer) to:

    a. Manufacture the Divestiture Products in the same quality achieved by the Respondent and in commercial quantities;

    b. Obtain any product approvals necessary for the Acquirer to manufacture, sell, market or distribute the Divestiture Products; and,

    c. Receive, integrate, and use such Product Manufacturing Technology to achieve the Order's purposes; and,

5. Provide consultation with knowledgeable employees of Respondent and training, at the request of the Acquirer and at a facility chosen by the Acquirer, until the Acquirer (or the Designee of the Acquirer) obtains all Divestiture Product approvals to manufacture the Divestiture Products in the same quality achieved by the Respondent and in commercial quantities, and in a manner consistent with the rules and regulations set forth by USDA in the code of Federal Regulations Title 9 and current industry good manufacturing practices for animal health products, independently of Respondent and sufficient to satisfy the Acquirer that its personnel (or the Designee's personnel) are adequately trained in the manufacture of the Divestiture Products.

D. Respondent shall include in any Remedial Agreement related to the Divested Assets the following provisions:

1. At the option of the Acquirer, Respondent shall Contract Manufacture and deliver to the Acquirer, in a timely manner and under reasonable terms and conditions, a supply of any one or more of the Divestiture Products at Respondent's Supply Cost, for a period of time sufficient to allow the Acquirer (or the Designee of the Acquirer) to obtain any Agency or Government Entity approvals necessary to manufacture the Divestiture Products.

2. After Respondent commences delivery of any one or more of the Divestiture Products to the Acquirer pursuant to a Remedial Agreement to Contract Manufacture any one or more of the Divestiture Products, Respondent will make inventory of any one or more of the Divestiture Products available for sale or resale in the Territory only to the Acquirer.

3. Respondent shall make representations and warranties to the Acquirer that the Divestiture Products supplied through Contract Manufacture pursuant to the Remedial Agreement meet any Agency or Government Entity specifications. Respondent shall agree to indemnify, defend and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Divestiture Products supplied to the Acquirer pursuant to the Remedial Agreement by the Respondent to meet any Agency or Government Entity specifications. This obligation shall be contingent upon the Acquirer giving Respondent prompt, adequate notice of such claim and cooperating fully in the defense of such claim. The Remedial Agreement shall be consistent with the obligations assumed by Respondent under this Order; *provided, however*, Respondent may reserve the right to control the defense of any such litigation, including the right to settle the litigation, so long as such settlement is consistent with the Respondent's responsibilities to supply the Divestiture Products in the manner required by this Order; *provided further, however*, this obligation shall not require Respondent to be liable for any negligent act, omission or willful misconduct of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by the Respondent to the Acquirer.

4. Respondent shall make representations and warranties to the Acquirer that Respondent will hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by Respondent to deliver any one or more of the Divestiture Products in a timely manner as required by the Remedial Agreement unless Respondent can demonstrate that its failure was entirely beyond the control of the Respondent and in no part the result of negligence or willful misconduct by Respondent.

5. During the term of the Contract Manufacture between Respondent and the Acquirer, upon request of the Acquirer or Interim Monitor (if applicable), Respondent shall make

Business Information and facilitating the delivery in a manner consistent with this Order;

4. Not use, directly or indirectly, any such Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the Divestiture Products in the Territory other than as necessary to comply with the following:

   a. The requirements of this Order;

   b. Respondent's obligations to the Acquirer under the terms of the Remedial Agreement related to Divestiture Products; or

   c. Applicable Law;

5. Not disclose or convey any such Confidential Business Information, directly or indirectly, to any person except the Acquirer or other persons specifically authorized by the Acquirer to receive such information, and only if authorized to do so by Acquirer; and,

6. Not provide, disclose, or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the Divestiture Products in the Territory to the employees associated with business related to those ifically.deve such iDþosedrmation, anpecD⁅69eeEmpw)4 3ieee marketing or les or

Divestiture Product Employees, or (ii) a Divestiture Product Employee contacts

necessary to maintain the viability and marketability of the Divestiture Assets and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Assets except for ordinary wear and tear.

K. Respondent shall maintain manufacturing facilities for production of the Divestiture Products that are ready, validated, qualified and approved by the Agency and Government Entities, and fully capable of producing Divestiture Products for the Territory until the Acquirer (or the Designee of the Acquirer) is fully validated, qualified and approved by the Agency and Government Entities and able to manufacture Divestiture Products for the Territory independently of Respondent; *provided, however*, the Commission may eliminate, or limit the duration of, the Respondent's obligation under this provision should the Commission determine that the Acquirer is not using commercially reasonable best efforts to secure the Agency and Government Entities approvals necessary to manufacture Divestiture Products for the Territory independently of Respondent.

III.

IT IS FURTHER ORDERED that:

A. Any Remedial Agreement shall be deemed incorporated into this Order.

B. Any failure by Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order. Notwithstanding any paragraph, section, or other provision of the Remedial Agreement, any failure to meet any condition precedent to closing (whether waived or not) without the prior approval of the Commission shall constitute a failure to comply with this Order.

C. Respondent shall include in each Remedial Agreement related to a Divestiture Product, a specific reference to this Order, the remedial purposes thereof, and the provisions to reflect the full scope and breadth of Respondent's obligations to the Acquirer pursuant to this Order.

D. Respondent shall include in each Remedial Agreement a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure from Agencies all approvals necessary to manufacture, or to have manufactured by Third Parties, in commercial quantities, each Divestiture Product, and to have any such manufacture to be independent of Respondent, as soon as reasonably practicable.

E. Respondent shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission.

IV.

IT IS FURTHER ORDERED that the purpose of the divestiture of the Divestiture Assets, the transfer of the Product Manufacturing Technology related to the Divestiture Products, and the related obligations imposed on the Respondent by this Order, is:

A. To ensure the continued use of the Divestiture Assets in the research, Development, and manufacture of each of the Divestiture Products for the Territory;

B. To provide for the future use of the Divestiture Assets in the distribution, sale and marketing of each of the Divestiture Products in the Territory;

C. To create a viable and effective competitor, who is independent of the Respondent, in the research, Development, manufacture, distribution, sale, and marketing of each of the Divestiture Products in the Territory; and,

D. To remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

V.

IT IS FURTHER ORDERED that:

Respondent shall assure that, in any instance wherein counsel (including in-house counsel under appropriate confidentiality arrangements) either retains unredacted copies of documents or other materials provided to the Acquirer or accesses original documents (under circumstances where copies of documents are insufficient or otherwise unavailable) provided to the Acquirer, that Respondent's counsel does so only in order to do the following:

A. Comply with any Remedial Agreement, this Order, any Law (including, without limitation,

agreements with the Acquirer (but shall not be deemed to have violated this requirement if the Acquirer withholds such agreement unreasonably); and, (2) uses its best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication;

provided further, however, that Respondent may continue to use that portion of those documents retained by Respondent that does not relate to the Divestiture Products.

VI.

IT IS FURTHER ORDERED that:

A. Dr. David A. Espeseth of Espeseth Consulting shall serve as the monitor ("Interim Monitor") to assure that Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order and the Remedial Agreements. In lieu of or as a replacement to Dr. Espeseth, the Commission may appoint one or more Interim Monitors to assure Respondent's compliance with the requirements of the Order and the related Remedial Agreements.

B. If Dr. Espeseth fails to serve, or if a new Interim Monitor must be selected, the Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.

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

D. Respondent shall consent to the following terms and conr concessTw[B.)-5ni(0 Tw[yco)45.mTc0 TDf the c

aoncau6 -ridyequirconceart th8proutnterim Monitadud by aoncs as required by

3. The Interim Monitor shall serve until the later of:

    a. the completion by Respondent of the divestiture of all relevant assets required to be divested pursuant to this Order in a manner that fully satisfies the requirements of

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

B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by the Order.

D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent shall consent to the following terms and conditions regarding the

Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable best 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. Each divestiture shall be made in the manner and to an acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondent from among those approved by the Commission; *provided further, however*, that Respondent shall select such entity 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 and, in the case of a court-appointed Divestiture Trustee, by the court, 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 the 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 misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

Nonpublic Appendix I

Asset Purchase Agreement

[Redacted From Public Record Version But Incorporated By Reference]

Nonpublic Appendix II

Notice of Divestiture and Requirement for Confidentiality

[Redacted From Public Record Version But Incorporated By Reference]