0910075

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

In the Matter of	)	
SCHERING-PLOUGH CORPORATION, a corporation,	)	Docket No. C-4268
and	)	
MERCK & CO., INC., a corporation.	)	

clinical trial, or Phase III clinical trial, for the purposes of obtaining any and all Applications and/or Product Approvals in the United States for the use of Products containing SCH 619734 (Rolapitant) for CINV and/or PONV; or

2. for Animal Health Products, means a controlled study in animals, including the target species with respect to a particular Product, 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 animal study used in research and Development of Animal Health Products.

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

P. "Confidential Business Information" means:

1. all information owned by, or in the possession or control of, a Respondent that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support, or use of the Rolapitant Product(s); and

2. all information owned by, or in the possession or control of, a Respondent that is not in the public domain and that is related to any of the business conducted by Merial, including without limitation, the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support, or use of Animal Health Products; TD (lth H(bli)Tj 0.0000 TD (od)Tj 12.0000 0.0000 TD (uc)Tj o)Tj 15.0

d. information relating to the Respondents' general business strategies or practices relating to research, Development, manufacture, marketing, or sales of Products that does not discuss with particularity the Rolapitant Products or the proprietary business interests of Merial;

e. information specifically excluded from the Rolapitant Product Assets (other than the NK-1 Know How exclusively licensed to the Acquirer);

1 Know How ex

V. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to the relevant provisions of this Order

W. “Domain Name” means the domain name(s) (universal resource locators (“URLs”)

Pvt. Ltd; Intervet (Italia) S.R.L.; Intervet Innovation GmbH; Intervet International B.V.; Intervet International GmbH; Intervet Korea Ltd.; Intervet Mexico S.A. de C.V.; Intervet Nederlands B.V.; Intervet Pharma R&D S.A.; Intervet Productions SA; Intervet Productions Srl; Intervet SA; Intervet South Africa (Pty) Limited; Intervet UK Ltd; Intervet UK Production Ltd; Intervet Venezolana SA; Laboratorios Intervet S.A.; Schering-Plough Animal Health Kabushiki Kaisha; Schering-Plough Animal Health Limited; Schering-Plough Animal Health Limited; Schering-Plough Sante Animale S.A.S.; Schering-Plough Saude Animal Industria E Comercio Ltda.; Schering-Plough Tibbi Urunler Ticaret Anonim Sirketi and the respective directors, officers, employees, agents, representatives, successors, joint ventures, subsidiaries, divisions, groups and affiliates and assigns of each of the foregoing.

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

FF. "Merial" means Merial Limited, an English private company, and Merial LLC, a limited liability corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address located at 2100 Ronson Road, Iselin, New Jersey 08830, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Merial Limited and/or Merial LLC (including, but not limited to, Ancare Australia (Pty) Limited, Ancare Ireland Limited, Animal Health Care South Africa (Pty) Limited, ASP, Inc., Beijing Merial Vital Laboratory Animal Technology Co. Ltd., IM Merial Holdings, LLC, Laboratorios Merial Peru S.A., Merial (IA) LLP, Merial (Thailand) Ltd., Merial Animal Health Co. Ltd., Merial Animal Health Limited (U.K.), Merial Animal Health Limited, Merial Argentina SA, Merial Asia Pte, Ltd., Merial Australia Pty Ltd., Merial B.V., Merial Belgium, Merial Canada, Inc., Merial Colombia S.A., Merial de Mexico S.A. de C.V., Merial Distribution SAS, Merial Finance LLC, Merial GmbH, Merial Hong Kong Limited, Merial Inc., Merial International Trading (Shanghai) Co., Ltd., Merial Italia SpA, Merial Japan, Limited, Merial Korea Ltd, Merial Laboratories SA, Merial Limited/L.L.C., Merial Mexico S.A. de C.V., Merial Nanjing Animal Health Co. Ltd., Merial New Zealand Limited, Merial Norden A/S, Merial Philippines, Inc., Merial Portuguese - Saude Animal L.A., Merial Production SAS, Merial SA, Merial SAS, Merial Saude Animal LTD, Merial Select, Inc., Merial South Africa (Proprietary) Limited, Merial Taiwan Co., Ltd., Merial Technologies, Inc., Merial Venezuela, C.A., Nomad New Jersey, Inc., Rhone-Merieux Limited, SFPA, Inc.), and the respective directors, officers, employees, agents, representatives, successors, joint ventures, subsidiaries, divisions, groups and affiliates and assigns of each of the foregoing.

GG. "Merial Divestiture Agreements" means the following:

1. Only Clauses 3 and 6 of the Share Purchase Agreement by and among Sanofi-Aventis and Merck SH, Inc., Merck Sharp & Dohme (Holdings) Limited and Merck & Co. Inc., dated July 29, 2009 ("Share Purchase Agreement"); and

PP. "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 existing as of 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, related to any Product of or owned by Respondent(s) as of the Closing Date (*except* where this Order specifies a different time).

QQ. "Person" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, joint venture, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.

RR. "PONV" means the treatment of post-operative nausea and vomiting in humans.

SS. "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 in any stage of Development, including pre-clinical and clinical Development stages and commercialized Products.

TT. "Product Approval(s)" means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage or transport of the Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application.

UU. "Product Assumed Contracts" means all of the following contracts or agreements (copies of each such contract to be provided to the Acquirer on or before the Closing Date and segregated in a manner that clearly identifies the purpose(s) of each such contract):

1. that make specific reference to the Rolapitant Product(s) and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the Rolapitant Product(s) from the Respondent(s), unless such contract applies generally to the Respondent's sales of Products to that Third Party;

2. pursuant to which Respondent(s) purchases the active pharmaceutical ingredient(s) or other necessary ingredient(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) from any Third Party for use

5. relating to the particularized marketing of the Rolapitant Product(s) or educational matters relating solely to the Rolapitant Product(s);

6. pursuant to which a Third Party manufactures or packages the Rolapitant Product(s) on behalf of Respondent(s);

7. pursuant to which a Third Party provides the Product Manufacturing Technology related to the Rolapitant Product(s) to Respondent(s);

8. pursuant to which a Third Party is licensed by Respondent(s) to use the Product Manufacturing Technology;

9. constituting confidentiality agreements involving the Rolapitant Product(s);

10. involving any royalty, licensing, or similar arrangement involving the Rolapitant Product(s);

11. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the Rolapitant Product to Respondent(s) including, but not limited to, consultation arrangements; and/or

12. pursuant to which any Third Party collaborates with Respondent(s) in the performance of research, Development, ma

provided, however, "Product Intellectual Property" does not include the corporate names or corporate trade dress of "Merck" or "

Rolapitant Product(s) that is owned, controlled or licensed by Respondent Schering-Plough prior to the Effective Date, the price for which will be set at a reasonable price, not to exceed the Respondent's depreciated value of such equipment.

CCC. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of a Rolapitant Product(s) in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data, and marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer repurchase information to be provided on the ba

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

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

4. any agreement between Respondent(s) and a Third Party to effect the assignment of assets or rights of Respondent(s) related to a Rolapitant 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;

provided, however, where only particular terms or provisions of an agreement are referenced in this Order, the term "Remedial Agreement" shall only include such terms and/or provisions as are specifically referenced herein.

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

JJJ. "Right of Reference or Use" means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an Application, including the ability to make available the underlying raw data from the investigation for FDA audit.

KKK. "Rolapitant Products" means all Products that contain either of the active pharmaceutical ingredients known as the NK-1 Compounds and any dose form, presentation, or line extension thereof. "Rolapitant Products" includes, without limitation, any combination of "Rolapitant" with any other Product and all other Products in Development prior to the Effective Date by Respondent Schering-Plough that are neurokinin 1 receptor antagonists for CINV and/or PONV.

LLL. "Rolapitant Product Assets" means all of the Respondent Schering-Plough's rights, title and interest in and to all assets related to such Respondent's business throughout the world related to the Rolapitant Products to the extent legally transferable, including these Tradename

1. all Product Intellectual Property;

2. all Freedom to Operate Searches;

3. all Product Approvals;

4. all Product Manufacturing Technology that is tangible and exclusive to the Rolapitant Products;

5. all Produc

14.

1. a perpetual, non-exclusive, fully paid-up, royalty-free, irrevocable, transferable, license(s) with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing and research and Development know-how solely:

   a. to research and Develop the Rolapitant Products for marketing, distribution or sale within the United States of America;

   b. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the Rolapitant Products within the United States of America;

   c. to import or export the Rolapitant Products to or from the United States of America to the extent related to the marketing, distribution or sale of the Rolapitant Products in the United States of America; and

   d. to have the Rolapitant Products made anywhere in the World for distribution or sale within, or import into the United States of America; and

2. a perpetual, exclusive (even as to the Respondents), fully paid-up, royalty-free, irrevocable, transferable, license(s), with rights to sublicense, to all NK-1 Know-how;

   provided, however, that for any Product Licensed Intellectual Property that is the subject of a license from a Third Party to the Respondents, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to the Respondents.

PPP. "Sanofi-Aventis" means Sanofi-Aventis S.A., a French *société anonyme*, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups, and affiliates in each case controlled by Sanofi-Aventis and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

QQQ. "SCH 619734 (Rolapitant)" means the NK-1 Compound designated as neurokinin-1 (NK-1) receptor antagonist SCH 619734 (Rolapitant).

RRR. "Supply Cost" means a cost not to exceed the manufacturer's average direct per unit cost in United States dollars of manufacturing the Rolapitant Product for the twenty-four (24) 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 Contract Manufacture is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Rolapitant Product, "Supply Cost" means the cost as specified in such Remedial Agreement for that Rolapitant Product.

provided, however, "Website" shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by Respondents that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that Respondents can convey its rights, if any, therein; or (2) content unrelated to any of the Rolapitant Product(s).

II.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Effective Date, Respondent Merck shall divest the Merial Ownership Interest, absolutely and in good faith, to Sanofi-Aventis, and shall terminate all of the Respondent Merck's interest in the Merial Joint Venture pursuant to, and in accordance with, the Merial Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order), and each such agreement (or portions of such agreement), if it becomes a Remedial Agreement related to the Merial Ownership Interest and the termination of Respondent Merck's interest in the Merial Joint Venture, is incorporated by reference into this Order and made a part hereof;

provided, however, that:

1. if Respondent Merck has divested the Merial Ownership Interest to Sanofi-Aventis and/or terminated Respondent Merck's interest in the Merial Joint Venture prior to the Order Date, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that the manner in which the divestiture and/or termination was accomplished is not acceptable, the Commission may direct Respondent Merck, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Merial Ownership Interest to Sanofi-Aventis and the termination of Respondent Merck's interest in the Merial Joint Venture (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order; and

2. any determination by the Commission to accept the Consent Agreement, or to approve the divestiture of the Merial Ownership Interest to Sanofi-Aventis and/or the termination of Respondent Merck's interest in the Merial Joint Venture, shall not constitute an approval of any Call Option or any terms or provisions contained therein or any acquisition, merger, sale, or other combination contemplated by any Call Option; *provided further, however*, Respondents may, pursuant to Paragraph II of this Order, seek the prior approval of the Commission for any acquisition, merger, sale, or other combination contemplated by any Call Option.

B. Respondent Merck shall terminate all of Respondent Merck's Operational Interest in Merial pursuant to an agreement with Sanofi-Aventis that fully and completely terminates all of Respondent Merck's Operational Interest in Merial.

C. Respondents shall:

1. submit to Sanofi-Aventis, at Respondents' expense, all Confidential Business Information related to Merial;

2. deliver such Confidential Business Information to Sanofi-Aventis:

a. in good faith;

b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and

c. in a

C. Acquire any assets including, without limitation, licenses to intellectual property, owned or controlled by Sanofi-Aventis used in, or used within six (6) months of such proposed acquisition in, the research, Development, manufacture, distribution, marketing or sale of Animal Health Products; *provided, however*, that the acquisition of goods and realty transferred in the ordinary course of business, as defined in 16 C.F.R. §§ 802.1 and 802.2, that are exempt from the notification requirements of the HSR Act, shall be exempt from the prior approval provision of this Paragraph II.C.;

IV.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Effective Date, Respondents shall divest the Rolapitant Product Assets and grant the Rolapitant Product Licenses, absolutely and in good faith, to OPKO pursuant to, and in accordance with, the Rolapitant Product Divestiture Agreement (which agreements shall not limit or contradict, or be construed to var

C. Respondents shall transfer and deliver, or cause to be transferred and delivered, all Product Manufacturing Technology (including all related intellectual property) related to the Rolapitant Products and shall transfer and deliver, or cause to be transferred and delivered, all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed by Respondent Schering-Plough to the Acquirer in a manner consistent with the Technology Transfer Standards. Respondents shall obtain any consents from Third Parties required to comply with this provision; *provided, howev*

1. submit to the Acquirer, at Respondents' expense, all Confidential Business Information related to the Rolapitant Products;

2. deliver such Confidential Business Information to the Acquirer:

   a. in good faith;

   b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and

   c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;

3. pending complete delivery of all such Confidential Business Information to the Acquirer, provide the Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information 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 Rolapitant Products that contain such Confidential 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 Rolapitant Products other than as necessary to comply with the following:

   a. the requirements of this Order;

   b. Respondents' obligations to the Acquirer of the Rolapitant Products under the terms of any Remedial Agreement related to Rolapitant 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

6. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the research, Development, manufacturing, marketing or sales of the Rolapitant Products to the employees associated with business that either:

   a. relates to those Retained Products that are either neurokinin 1 receptor antagonists, 5-HT3 receptor antagonists; and/or

   b. relates to any Product Developed or in Development for CINV and/or PONV.

F. Respondents shall not enforce any agreement against a Third Party or the Acquirer to the extent that such agreement may limit or otherwise impair the ability of such Acquirer to acquire or use the Product Manufacturing Technology (including all related intellectual property) related to the Rolapitant Products from the Third Party. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology.

G. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to an agreement as described in Paragraph IV.F. that allows the Third Party to provide the relevant Product Manufacturing Technology to the Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to the Acquirer.

H. Respondents shall:

1. for a period of six (6) months (the "Access Period"), the Closing Date or upon the hiring of nineteen (19) Rolapitant Product Core Employees by the Acquirer, whichever occurs earlier, provide the Acquirer with the opportunity to enter into employment contracts with the Rolapitant Product Core Employees. Each of these periods is hereinafter referred to as the "Rolapitant Product Core Employee Access Period(s)";

2. not later than the earlier of the following dates: (1) ten (10) days after notice by staff of the Commission to Respondents to provide the Product Employee Information; or (2) ten (10) days after a written request by the Acquirer, provide such Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Rolapitant Product Core Employees. Failure by Respondents to provide the Product Employee Information for any Rolapitant Product Core Employee within the time [illegible]

generally applicable to similarly situated employees who are not Rolapitant Core Employees;

4. until the Closing Date, provide all Rolapitant Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, and manufacture the Rolapitant Product(s) consistent with past practices and/or as may be nece

Confidential Business Information related to the Rolapitant Products as strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondents (other than as necessary to comply with the requirements of this

nts

d. ensure the assets required to be divested are transferred and delivered to the Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the business associated with the Rolapitant Product; and

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

2. Respondents shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the businesses associated with the Rolapitant Products.

L. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the Acquirer of the Rolapitant Product Assets or the Rolapitant Product Releasee(s) of that Acquirer under the following Patents:

1. any Patent owned or licensed by Respondents as of the day after the Effective Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Effective Date) that claims a method of making, using, or administering or a composition of matter, relating to the NK-1 Compounds or that claims advice relating to the use thereof;

2. any Patents owned or licensed by Respondents at any time after the Effective Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Effective Date) that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the NK-1 Compounds;

if such suit would have the potential to interfere with such Acquirer's freedom to practice the research or Development of the NK-1 Compounds anywhere in the World. Respondents shall also covenant to such Acquirer that as a condition of any assignment, transfer, or license to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue such Acquirer or the related Rolapitant Product Releasee(s) under such Patents, if the suit would have the potential to interfere with that Acquirer's freedom to practice the research or Development of the NK-1 Compounds anywhere in the World.

M. Upon reasonable written notice and request from the Acquirer to Respondent(s), Respondent(s) shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Product Intellectual Property related to the Rolapitant Products, if such litigation would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Rolapitant Products; or (2) the use, import, export, supply, distribution, or sale of the Rolapitant Products within the Geographic Territory.

N. For any patent infringement suit in which Respondent Schering-Plough is alleged to have infringed a Patent of a Third Party prior to the Closing Date or for such suit as such Respondent Schering-Plough has prepared or is preparing as of the Closing Date to defend against such infringement claim(s), and where such a suit would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Rolapitant Products; or (2) the use, import, export, supply, distribution, or sale of the Rolapitant Products, Respondents shall:

1. cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from Respondent(s) in connection with obtaining resolution of any pending patent litigation involving the Rolapitant Products;

2. waive conflicts of interest, if any, to allow either Respondent's outside legal counsel to represent the relevant Acquirer in any ongoing patent litigation involving such Rolapitant Products; and

3. permit the transfer to the relevant Acquirer of all of the litigation files and any related attorney work-product in the possession of either Respondent's outside counsel relating to such Rolapitant Products.

O. Respondents shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Rolapitant Products a decision the result of which would be inconsistent with the terms of this Order and/or the remedial purposes thereof.

P. The purpose of the divestiture of the Rolapitant Product Assets and the transfer and delivery of the related Product Manufacturing Technology and the related obligations imposed on the Respondents by this Order is:

1. to ensure the continuation and/or resumption of the use of such assets in the research, Development, and manufacture of the Rolapitant Products and for the purposes of the business associated with the Rolapitant Products within the Geographic Territory;

2. to provide for the future use of such assets for the distribution, sale and marketing of the Rolapitant Products in the Geographic Territory;

3. to create a viable and effective competitor, that is independent of the Respondents, in the research, Development, manufacture, marketing and sale of the Rolapitant Products for the purposes of the business associated with the Rolapitant Products within the Geographic Territory; and;

4. 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:

A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order and the Remedial Agreements.

B. The Commission shall select the Interim Monitor, subject to the consent of Respondent Merck, which consent shall not be unreasonably withheld. If Respondent Merck 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 Merck of the identity of any proposed Interim Monitor, Respondents 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, Respondents 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 perform the Interim Monitor's duties and responsibilities pursuant to this Order and the Remedial Agreements.

(1) the date the Acquiror (or its Designee(s)

7. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by the 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 Respondents of their obligations under the Order;

   provided, however, beginning one hundred twenty (120) days after Respondents have filed their final report pursuant to Paragraph IX.B., and every one hundred twenty (120) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by the Acquirer toward obtaining FDA approval to commercialize Products containing SCH 619734 (Rolapitant) for CINV and/or PONV and obtaining the ability to manufacture such Products in commercial quantities, in a manner consistent with cGMP, independently of Respondents.

8. Respondents 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.

E. 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 agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.

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

G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.

H. The Interim Monitor appointed pursuant to this Order may be the same Person appointed as a a Divestiture Trustee pursuant to the relevant provisions of this Order

VI .

IT I S FURTHER ORDERED tha

2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated lega

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

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

8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

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

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

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

VII.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, Respondents shall assure that Respondents' counsel (including in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access original documents provided to an Acquirer, except under circumstances [illegible]

and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity or any taxation requirements; or

B. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Merial Ownership Interest, the termination of Respondents' interest in the Merial Joint Venture, the Rolapitant Products, or the Rolapitant Product Assets;

provided, *however*, that Respondents may disclose such information as necessary for the purposes set forth in this Paragraph VII pursuant to an appropriate confidentiality order, agreement or arrangement;

provided further, *however,* that pursuant to this Paragraph VII, Respondents shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if such Acquirer withholds such agreement unreasonably); and (2) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VIII.

IT IS FURTHER ORDERED that:

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

No nP ubi cAp

Mdr

[Rda

Non-Public Appendix
Rolapitant Product Divestiture Agreement
[Redacted From the Public Record Version, But Incorporated By Reference]