

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,)	Docket No. C-4268
a corporation,)	
and)	
)	
MERCK & CO., INC.,)	
a corporation.)	
)	
)	

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Schering-Plough Corporation (“Schering-Plough”) of Respondent Merck & Co., Inc. (“Merck”) and subsequent merger of Respondents, and Respondents 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 Respondents 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

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondents 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 Respondents 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 Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and 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 Schering-Plough 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 located at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.
2. Respondent Merck 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 One Merck Drive, P.O. Box 100, WS3A-65, Whitehouse Station, New Jersey 08889-0100.
3. The Commission has jurisdiction of the subject matter of this proceeding and of Respondents, 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. “Schering-Plough” means Schering-Plough Corporation, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Schering-Plough (including, but not limited to, Intervet Holdings B.V., Blue, Inc., and Purple, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Merck” means Merck & Co., Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Merck, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, “Merck” shall mean the Person that includes Merck and Schering-Plough.
- C. “Respondent(s)” means Schering-Plough and Merck, individually and collectively.
- D. “Commission” means the Federal Trade Commission.
- E. “Acquirer(s)” means the following:
 1. a Person specified by name in this Order to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise

convey pursuant to this Order and 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; or

2. a Person approved by the Commission to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- F. "Acquisition" means the acquisition and subsequent merger contemplated by the Agreement and Plan of Merger by and among Merck & Co., Inc., Schering-Plough Corporation, Blue, Inc. and Purple, Inc., dated as of March 8, 2009 ("Acquisition Agreement").
- G. "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").
- H. "Animal Health Products" means all pharmaceutical, biological and medicinal products, including, without limitation, in-feed products, vaccines, parasiticides, all other products intended to enhance the health or performance of any and all species of animals (including livestock, aquatic animals and companion animals, but excluding humans) and all products developed using genetic techniques (including selective breeding) to improve poultry (including chickens, turkeys, ducks, geese, guinea fowl, pheasants, partridges and quail), whether for meat production, egg production or any other purpose.
- I. "Application(s)" means:
1. for the Rolapitant Products, 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, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Respondent(s) and the FDA related thereto. The term "Application" also includes an Investigational New Drug Application ("IND") for a Product 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, drafts and data necessary for the preparation thereof, and all correspondence between Respondent(s) and the FDA related thereto;
 2. for Animal Health Products,
 - a. means all of the following, as defined in the United States Federal Food, Drug and Cosmetic Act, as amended: "Investigational New Animal Drug Application" ("INADA"), "New Animal Drug Application" ("NADA"), "Abbreviated New

Animal Drug Application” (“ANADA”), or “Conditional New Animal Drug Application” (“CNADA”) for a Product filed or to be filed with the FDA, or its foreign Agency equivalent, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Respondents and the FDA or other Agency related thereto; and

- b. all of the following, as defined in Title 9 of the Code of Federal Regulations: a U.S. Veterinary Biological Product License or Permit, and a U.S. Veterinary Biological Establishment License, for a Product filed or to be filed with the USDA, or its foreign Agency equivalent, and all supplements, amendments, and revisions thereto, all outlines of production, protocols, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Respondents and the USDA or other Agency related thereto.

The term “Application” and all of the foregoing terms or abbreviations include the foreign equivalents of the above-referenced filings and activities with the foreign counterpart(s) of the FDA and/or the USDA, as applicable.

J. “Call Option” means:

- 1. the Call Option Agreement among Merck & Co., Inc., Schering-Plough Corporation and Sanofi-Aventis dated July 29, 2009 (“Call Option Agreement”); and
- 2. any other agreement or arrangement that provides Sanofi-Aventis with any right or option to acquire an Ownership Interest in ISPAH or the business of researching, developing, manufacturing, marketing or selling Animal Health Products operated by Respondents.

K. “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.

L. “CINV” means the treatment of chemotherapy-induced nausea and vomiting in humans.

M. “Clinical Requirements” means all quantities of SCH 619734 (Rolapitant) as are required by the Acquirer of the Rolapitant Product Assets for the conduct of preclinical, clinical studies, and/or Clinical Trials 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.

N. “Clinical Trial(s)” means

- 1. for the Rolapitant Products, a controlled study in humans of the safety or efficacy of an NK-1 Compound, and includes, without limitation, any Phase I clinical trial, Phase II

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;

provided, however, that the restrictions contained in this Order regarding the Respondents’ use, conveyance, provision, or disclosure of “Confidential Business Information” shall not apply to the following:

- a. 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 information by Respondent(s);
- b. information related to the Rolapitant Products that was researched, Developed, manufactured, marketed, or sold by Respondent Schering-Plough that Respondent Merck can demonstrate it obtained without the assistance of Respondent Schering-Plough prior to the Acquisition;
- c. information that is required by Law to be publicly disclosed;

- 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);
 - f. all intellectual property licensed to the Acquirer on a non-exclusive basis; and
 - g. 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.
- Q. "Contract Manufacture" means the manufacture of SCH 619734 (Rolapitant) to be supplied by a Respondent to an Acquirer or the Acquirer's Designee.
- R. "Designee" means any Person other than a Respondent that has been designated by an Acquirer to manufacture a Rolapitant Product for that Acquirer.
- S. "Development" means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. "Develop" means to engage in Development.
- T. "Direct Cost" means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. "Direct Cost" to the Acquirer for its use of any of Respondents' employees' labor shall not exceed the average hourly wage rate for such employee;
- provided, however*, in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Rolapitant Product, "Direct Cost" means such cost as is provided in such Remedial Agreement for that Rolapitant Product.
- U. "Rolapitant Product Releasee(s)" means the Acquirer for the Rolapitant Product Assets or any Person controlled by or under common control with such Acquirer, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of such Acquirer, or of such Acquirer-affiliated entities.

- 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”), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration. “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- X. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- Y. “Effective Date” means the earliest of the following dates:
1. the date the Respondents close on the Acquisition pursuant to the Agreement and Plan of Merger;
 2. the date the merger contemplated by the Acquisition Agreement becomes effective by filing the certificate of merger with the Department of the Treasury of the State of New Jersey;
 3. the date on which Respondent Schering-Plough acquires, directly or indirectly, fifty (50)% or more of the voting securities of Respondent Merck; or
 4. the date on which Respondent Merck acquires, directly or indirectly, fifty (50)% or more of the voting securities of Respondent Schering-Plough.
- Z. “Freedom to Operate Searches” means all studies, analyses, reports and legal opinions that were prepared for the purposes of identifying, evaluating or analyzing potential patent barriers to the commercialization of the NK-1 Compounds and related technologies.
- AA. “Geographic Territory” shall mean the United States of America (including all of the territories within its jurisdiction or control) unless otherwise specified.
- BB. “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.
- CC. “Interim Monitor” means any monitor appointed pursuant to Paragraph V of this Order.
- DD. “ISPAH” or “Intervet Schering-Plough Animal Health” means any of Respondent Schering-Plough’s business of discovering, developing, manufacturing, marketing, or selling Animal Health Products including without limitation, the following Persons: Intervet Australia Pty Ltd; Intervet Belgium N.V.; Intervet Canada Ltd.; Intervet Deutschland GmbH; Intervet do Brasil Veterinaria Ltda.; Intervet GesmbH; Intervet Hellas A.E.; Intervet Inc.; Intervet India

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 Anomim 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 Noreen A/S, Merial Philippines, Inc., Merial Portugese - Sade Animal L.A., Merial Production SAS, Merial SA, Merial SAS, Merial Sade 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

2. The Termination Agreement in connection with the Master Merial Venture Agreement, among Merck & Co., Inc., Merck SH Inc. and Merck Sharp & Dohme (Holdings) Limited and Sanofi-Aventis, and Sanofi 4 and Merial Limited, as such Termination Agreement was submitted to the Commission prior to the Commission's issuance of any Decision and Order in this matter ("Termination Agreement");

provided, however, the Merial Divestiture Agreements exclude any Call Option and the terms or provisions of any agreement, including without limitation, any provision or term that requires Respondents to enter into or abide by the terms of any Call Option in the Share Purchase Agreement and/or the Termination Agreement.

- HH. "Merial Joint Venture" means the joint venture established by the Master Merial Joint Venture Agreement by and among, Rhône-Poulenc S.A., Institute Mérieux S.A., Rhône-Mérieux S.A., Merck & Co., Inc., Merck SH Inc., and Merial Limited, dated as of May 23, 1997.
- II. "Merial Ownership Interest" means all of Respondents' Ownership Interest in Merial.
- JJ. "NK-1 Compound(s)" means the neurokinin-1 (NK-1) receptor antagonists SCH 619734 (Rolapitant) and SCH 900978, any product containing either of these compounds, individually and collectively.
- KK. "NK-1 Know How" means all the know how that is exclusively used for the Rolapitant Products, including any and all specifications, processes, designs, plans, trade secrets, ideas, concepts, inventions, manufacturing, engineering and other manuals and drawings, standard operating procedures, formulae, flow diagrams, toxicological, biological, physical, analytical, safety, stability, supply, selection, constitution, or use of any raw material, quality assurance, quality control and clinical data, technical information, research records, which shall include Product Manufacturing Technology that is intangible and exclusive to the Rolapitant Products. The term "NK-1 Know How" excludes any information that is covered by the claim of any patent issued prior to the Closing Date.
- LL. "OPKO" means OPKO Health, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address located at 4400 Biscayne Blvd, Miami, Florida 33137.
- MM. "Operational Interest" means the right to lease, manage or control the operations of a Person, directly or indirectly.
- NN. "Order Date" means the date on which this Decision and Order becomes final.
- OO. "Ownership Interest" means any and all rights, present or contingent, to hold any voting or nonvoting stock, share capital, equity or other interests, or beneficial ownership in a Person.

- 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 in connection with the manufacture of the Rolapitant Product(s);
 3. relating to any Clinical Trials involving the Rolapitant Product(s);
 4. with universities or other research institutions for the use of the Rolapitant Product(s) in scientific research;

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, marketing, distribution or selling of the Rolapitant Product(s) or the Rolapitant Product(s) business;

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

- VV. “Product Copyrights” means rights to all original works of authorship of any kind directly related to the Rolapitant Product(s) 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 the Rolapitant Product(s) or of any materials used in the research, Development, manufacture, marketing or sale of the Rolapitant Product(s), including all copyrights in raw data relating to Clinical Trials of the Rolapitant Product(s), 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; all copyrights in customer information, promotional and marketing materials, the Rolapitant Product(s) sales forecasting models, medical education materials, sales training materials, and advertising and display materials;

all records relating to employees who accept employment with the Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to the Rolapitant Product(s) or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA.

WW. “Product Development Reports” means:

1. Pharmacokinetic study reports related to the Rolapitant Product(s);
2. Bioavailability study reports (including reference listed drug information) related to the Rolapitant Product(s);
3. Bioequivalence study reports (including reference listed drug information) related to the Rolapitant Product(s);
4. all correspondence to the Respondent(s) from the FDA and from the Respondent(s) to the FDA relating to the Application(s) submitted by, on behalf of, or acquired by, the Respondent(s) related to the Rolapitant Product;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to the Rolapitant Product(s);
7. currently used product package inserts (including historical change of controls summaries) related to the Rolapitant Product(s);
8. FDA approved patient circulars and information related to the Rolapitant Product(s);
9. adverse event/serious adverse event summaries related to the Rolapitant Product(s);
10. summary of Product complaints from physicians related to the Rolapitant Product(s);
11. summary of Product complaints from customers related to the Rolapitant Product(s);
and
12. Product recall reports filed with the FDA related to the Rolapitant Product(s).

XX. “Product Employee Information” means the following, for each Rolapitant Product Core Employee, as and to the extent permitted by Law:

1. a complete and accurate list containing the name of each relevant employee (including former employees who were employed by Respondent(s) within ninety (90) days of the execution date of any Remedial Agreement related to the divestiture of the Rolapitant Product Assets);
2. with respect to each such employee, the following information:
 - a. the date of hire and effective service date;
 - b. job title or position held;
 - c. a specific description of the employee’s responsibilities related to the relevant Rolapitant Product; *provided, however*, in lieu of this description, Respondent(s) may provide the employee’s most recent performance appraisal;
 - d. the base salary or current wages;
 - e. the most recent bonus paid, aggregate annual compensation for the relevant Respondent’s last fiscal year and current target or guaranteed bonus, if any;
 - f. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and
 - g. any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
3. at the Acquirer’s option or the Proposed Acquirer’s option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.

YY. “Product Intellectual Property” means all of the following related to a Rolapitant Product (other than Product Licensed Intellectual Property):

1. Patents, which shall include the NK-1 Patents as defined in the Rolapitant Product Divestiture Agreement;
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 and copyrights and registrations thereof;

provided, however, “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Merck” or “Schering-Plough”, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by Respondents or the related logos thereof.

ZZ. “Product Licensed Intellectual Property” means the following intellectual property owned, controlled, or licensed by Respondent Schering-Plough existing prior to the Effective Date:

1. Patents that are related to a Rolapitant Product that Respondent(s) can demonstrate have been used, prior to the Effective Date, for a Retained Product(s); and
2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related but not exclusive to a Rolapitant Product and that Respondent(s) can demonstrate have been used, prior to the Effective Date, for a Retained Product(s), and shall include tangible and intangible Product Manufacturing Technology not exclusive to the Rolapitant Products.

AAA. “Product Manufacturing Employees” means all salaried employees of Respondents who have directly participated in the planning, design, implementation or operational management of the Product Manufacturing Technology of the Rolapitant Product(s) (irrespective of the portion of working time involved unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the two (2) year period immediately prior to the Closing Date.

BBB. “Product Manufacturing Technology” means:

1. all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of the Rolapitant Product(s) that is owned, controlled or licensed by Respondent Schering-Plough prior to the Effective Date, including, but not limited to, the following: all product specifications, processes, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;
2. all active pharmaceutical ingredients related to the Rolapitant Product(s) that is owned, controlled or licensed by Respondent Schering-Plough prior to the Effective Date; and
3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer’s option, all such equipment used to manufacture the

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), 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 net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the Rolapitant Product(s).
- DDD. "Product Research and Development Employees" means all salaried employees of Respondents who have directly participated in the research, Development, or regulatory approval process, or clinical studies of the Rolapitant Product(s) (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the two-year (2) year period immediately prior to the Closing Date.
- EEE. "Product Trade Dress" means the current trade dress of the Rolapitant Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.
- FFF. "Product Trademark(s)" means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for the Rolapitant Product(s).
- GGG. "Proposed Acquirer" means a Person proposed by Respondents (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by Respondents pursuant to this Order.
- HHH. "Remedial Agreement(s)" means the following:
1. any agreement between Respondent(s) and an Acquirer that is specifically referenced and attached to 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 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 the research, Development, manufacture, distribution, marketing, and sale of the Rolapitant Products, including, without limitation, the following:

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 Product Marketing Materials;
6. all Website(s);
7. all rights to all of Respondents' Applications;
8. Right of Reference or Use to the Drug Master Files related to the above-described Applications including, but not limited to, the pharmacology and toxicology data contained in all Application(s);
9. all Product Development Reports;
10. at the Acquirer's option, all Product Assumed Contracts related to the Rolapitant Products (copies to be provided to the Acquirer on or before the Closing Date);
11. all strategic safety programs submitted to the FDA related to the Rolapitant Products that are designed to decrease product risk by using one or more interventions or tools beyond the package insert;
12. all patient registries related to the Rolapitant Products, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the Rolapitant Product(s);
13. at the Acquirer's option and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory (*except* such inventory that is subject to retention requirements imposed on the Respondent by applicable Law) in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to the Rolapitant Products; *provided, however* that, at the Acquirer's option, Respondents shall be entitled to retain physical possession of up to twenty (20) percent of the inventory of SCH 619734 (Rolapitant) on hand as of the Closing Date to be held by Respondents solely for the purposes of assisting the Acquirer; *provided further, however*, that the Acquirer shall be entitled to legal title to all inventory of SCH 619734 (Rolapitant) including such inventory as is retained in the physical possession the Respondents; and

14. all of the relevant Respondent's books, records, and files directly related to the foregoing or to such Rolapitant Product(s);

provided, however, that "Rolapitant Product Assets" shall not include: (1) documents relating to either Respondent's general business strategies or practices relating to research, Development, manufacture, marketing or sales of pharmaceutical Products, where such documents do not discuss with particularity the Rolapitant Products; (2) shall not include administrative, financial, and accounting records; (3) quality control records that are determined by the Interim Monitor or the Acquirer not to be material to the manufacture of the Rolapitant Products; (4) any real estate and the buildings and other permanent structures located on such real estate; and (5) assets licensed to the Acquirer pursuant to the Rolapitant Product Licenses.

provided further, however, that in cases in which documents or other materials included in the relevant assets to be divested contain information: (1) that relates both to the Rolapitant Products and to other Products or businesses of the Respondent Schering-Plough and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Rolapitant Product(s); or (2) for which the Respondent(s) has a legal obligation to retain the original copies, the Respondent(s) shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer, the Respondent(s) shall provide such Acquirer 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(s) provides the Acquirer with the above-described information without requiring Respondent(s) completely to divest itself of information that, in content, also relates to Retained Product(s).

- MMM. "Rolapitant Product Core Employee(s)" means the Product Research and Development Employees and the Product Manufacturing Employees identified as "Key Rolapitant Employees" in the Rolapitant Product Divestiture Agreement and any additional employees with responsibilities related to SCH 619734 (Rolapitant) as identified by the Interim Monitor (if one has been appointed) as are necessary for the purposes of complying with this Order. Respondent Schering-Plough represents that the Key Rolapitant Employees are all Product Research and Development Employees and Product Manufacturing Employees who were members of the Rolapitant Project Team since January 11, 2008, and who were employed by Respondent Schering-Plough within the ninety (90) prior to the Closing Date.
- NNN. "Rolapitant Product Divestiture Agreement" means The Asset Purchase Agreement by and between Schering Corporation and OPKO Health, Inc. dated October 12, 2009 and all amendments, exhibits, attachments, agreements, and schedules thereto.
- OOO. "Rolapitant Product Licenses" means all of the following related to the Rolapitant Products:

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.

SSS. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*,

- a. designating employees knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to the Rolapitant Product who will be responsible for communicating directly with the Acquirer and/or its Designee, and the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;
- b. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the Rolapitant Product(s) that are acceptable to the Acquirer;
- c. preparing and implementing 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 such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Designee; and
- d. providing, in a timely manner, assistance and advice to enable the Acquirer or its Designee to:
 - (1) manufacture the Rolapitant Product(s) in the quality and quantities achieved by the Respondent(s), or the manufacturer and/or developer of such Rolapitant Product;
 - (2) conduct Clinical Trials for such Rolapitant Product(s);
 - (3) finalize all clinical and study reports, brochures and other documents related to SCH 619734 (Rolapitant);
 - (4) receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the Rolapitant Product(s); and
 - (5) use the Rolapitant Product Assets and the Rolapitant Product Licenses to complete the Clinical Trials.

TTT. “Third Party(ies)” means any non-governmental Person other than the following: Respondents, or the Acquirer for the affected assets, rights and Rolapitant Product(s).

UUU. “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 Respondents;

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 III 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 manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all such Confidential Business Information to Sanofi-Aventis, provide Sanofi-Aventis 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 Merial 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 Merial, including without limitation, the research, Development, manufacturing, marketing, or sale of Animal Health Products researched, Developed, manufactured, marketed or sold by Merial, other than as necessary to comply with the following (and which in each case (a-c) described below, Respondents may also retain copies of such Confidential Business Information):
 - a. the requirements of this Order;
 - b. Respondents' obligations to Sanofi-Aventis and/or Merial under the terms of any Remedial Agreement; or
 - c. applicable Law;

provided, however, that Respondents shall not be required to submit Confidential Business Information under this Paragraph that has been prepared by or for Respondent Merck in connection with its Merial Ownership Interest that Merial was not entitled to receive prior to the divestiture of the Merial Ownership Interest and that is protected by the attorney work product, attorney-client, or other privilege (*except* privileged

Confidential Business Information that is subject to common interest between Merck and Merial).

5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except Sanofi-Aventis or other Persons specifically authorized by Sanofi-Aventis 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 Products researched, Developed, manufactured, marketed or sold by Merial to the Respondents' employees associated with business related to Animal Health Products.
- D. The purpose of the divestiture of the Merial Ownership Interest, the termination of all of Respondent Merck's Operational Interest in the Merial Joint Venture and the related obligations imposed on the Respondents by this Order is:
1. to ensure the continued use of such assets associated with Merial in the research, Development, and manufacture of Animal Health Products;
 2. to provide for the future use of such assets for the distribution, sale and marketing of the Animal Health Products;
 3. to create a viable and effective competitor, that is independent of the Respondents in the research, Development, manufacture, marketing and sale of the Animal Health Products; 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.

III.

IT IS FURTHER ORDERED that, for a period commencing on the Order Date and continuing for ten (10) years, Respondents shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, without the prior approval of the Commission:

- A. Acquire any voting or non-voting stock, share capital, equity, notes convertible into any voting or non-voting stock, Ownership Interest or other interest in Merial;
- B. Acquire any assets including, without limitation, licenses to intellectual property, owned or controlled by Merial; *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 III.B.;

- 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 III.C.;
- D. Consummate any merger or other combination with Merial;
- E. Consummate any merger or other combination with Sanofi-Aventis that relates to Animal Health Products;
- F. Sell to Merial or to Sanofi-Aventis any voting or non-voting stock, share capital, equity, notes convertible into any voting or non-voting stock, Ownership Interest or other interest in ISPAH including, without limitation, pursuant to any Call Option;
- G. Sell or grant to Merial or to Sanofi-Aventis, any assets including, without limitation, licenses to intellectual property, owned or controlled by Respondents 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 including, without limitation, pursuant to any Call Option; *provided, however*, that the sale 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 considered acquisitions exempt from the notification requirements of the HSR Act, shall be exempt from the prior approval provision of this Paragraph III.G.;
- H. Enter into and make operational or consummate any agreement with Sanofi-Aventis or Merial that would restrict or impair Respondents' ability to operate Respondents' business related to Animal Health Products in a manner that is competitive and fully independent of Sanofi-Aventis;
- I. Enter into and make operational or consummate any agreement with Sanofi-Aventis or Merial that would restrict or impair Sanofi-Aventis's or Merial's ability to operate either Sanofi-Aventis's or Merial's businesses related to Animal Health Products in a manner that is competitive and fully independent of Respondents;
- J. Enter into and make operational or consummate any agreement or other arrangement with Merial or Sanofi-Aventis to convey an Operational Interest in ISPAH or in any other assets including, without limitation, licenses to intellectual property, or businesses of the Respondents related to the Animal Health Products; or
- K. Enter into and make operational or consummate any agreement or other arrangement with Merial or Sanofi-Aventis to obtain an Operational Interest in Merial or in any assets including, without limitation, licenses to intellectual property, or businesses of Sanofi-Aventis related to the Animal Health Products.

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 vary or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of OPKO or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Rolapitant Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that: if Respondents have divested the Rolapitant Product Assets and granted the Rolapitant Product Licenses to OPKO prior to the Order Date, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that OPKO is not an acceptable purchaser of the Rolapitant Product Assets, then Respondents shall immediately rescind the transaction with OPKO, in whole or in part, as directed by the Commission, and shall divest the Rolapitant Product Assets and grant the Rolapitant Product Licenses within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer or Acquirers that receive(s) the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that if Respondents have divested the Rolapitant Product Assets and granted the Rolapitant Product Licenses to OPKO prior to 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 was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Rolapitant Product Assets or the granting of the Rolapitant Product Licenses to OPKO (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the Rolapitant Product Assets and grant the Rolapitant Product Licenses to the Acquirer, and/or to permit the Acquirer to continue the research, Development, manufacture, sale, marketing or distribution of the Rolapitant Products;

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

- 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, however*, that any services provided by Respondents pursuant to this Paragraph IV.C. are not required to extend longer than one (1) year after the Closing Date or until Respondents have fully transferred to the Acquirer the Rolapitant Product Assets and the Rolapitant Product Licenses, whichever is later; except that Respondents shall continue for one additional year to make personnel available, in a reasonable time and manner, to respond to inquiries from Acquirer related to the Rolapitant Product Assets and Rolapitant Product Licenses.
- D. Upon the request of the Acquirer, Respondents shall Contract Manufacture and deliver to the Acquirer a supply of SCH 619734 (Rolapitant) at a price not to exceed Respondents' Supply Cost, in the following manner:
1. in such a time so as to avoid any potential disruption or delay in the preclinical or clinical activities, including, without limitation, any clinical studies and/or Clinical Trials, related to SCH 619734 (Rolapitant);
 2. for a period of time sufficient to enable the Acquirer (or the Designee of the Acquirer) to manufacture SCH 619734 (Rolapitant) independently of Respondents in quantities and of the quality necessary to meet the Acquirer's Clinical Requirements; and,
 3. upon request of the Acquirer or Interim Monitor (if any has been appointed), Respondents shall make available to the Acquirer and the Interim Monitor (if any has been appointed) all records that relate to the manufacture of SCH 619734 (Rolapitant) that are generated or created after the Effective Date;

The foregoing provisions shall remain in effect with respect to SCH 619734 (Rolapitant) until the earliest of (1) the date the Acquirer (or the Designee(s) of the Acquirer) is able to manufacture SCH 619734 (Rolapitant), in a manner consistent with cGMP, independently of Respondents, and in sufficient quantities to meet the Acquirer's Clinical Requirements for SCH 619734 (Rolapitant); (2) the date the Acquirer notifies the Commission and the Respondents of its intention to abandon its efforts to Develop SCH 619734 (Rolapitant); (3) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer of the Rolapitant Products has abandoned its efforts to Develop SCH 619734 (Rolapitant), or (4) four (4) years from the Closing Date.

- E. Respondents shall:

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 from 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 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 provided herein shall extend the Rolapitant Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay;
 3. during the Rolapitant Product Core Employee Access Period(s), not interfere with the hiring or employing by the Acquirer of the Rolapitant Product Core Employees, and remove any impediments within the control of Respondent(s) that may deter these employees from accepting employment with the Acquirer, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Rolapitant Product or other contracts with Respondent(s) that would affect the ability or incentive of those individuals to be employed by the Acquirer. In addition, Respondents shall not make any counteroffer to such a Rolapitant Product Core Employee who has received a written offer of employment from the Acquirer;

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph IV.H.3. shall not prohibit Respondents from continuing to employ any Rolapitant Product Core Employee under the terms of such employee’s employment with Respondent(s) in effect prior to the date of the written offer of employment from the Acquirer to such employee or such other terms

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 necessary to preserve the marketability, viability and competitiveness of the Rolapitant Product(s) and to ensure successful execution of the pre-Acquisition plans for such Rolapitant Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Closing Date(s) for the divestiture of the Rolapitant Product Assets has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

provided, however, that, subject to those conditions of continued employment prescribed in this Order, this Order does not require nor shall be construed to require Respondents to terminate the employment of any employee or to prevent Respondents from continuing to employ the Rolapitant Product Core Employees in connection with the Acquisition; and

5. for a period of one (1) year from the Closing Date, not:
 - a. directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer with any amount of responsibility related to a Rolapitant Product (“Rolapitant Product Employee”) to terminate his or her employment relationship with the Acquirer; or
 - b. hire any Rolapitant Product Employee;

provided, however, Respondents may hire any former Rolapitant Product Employee whose employment has been terminated by the Acquirer or who independently applies for employment with Respondents, as long as such employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided further, however, that a violation of this provision will not occur by any of the following actions: (1) Respondent(s) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Rolapitant Product Employees; or (2) Respondent(s) hire a Rolapitant Product Employee who contacts Respondents on his or her own initiative without any direct or indirect solicitation or encouragement from Respondents.

- I. Respondents shall require, as a condition of continued employment post-divestiture of the Rolapitant Product Assets, that each Rolapitant Product Core Employee retained by Respondents, the direct supervisor(s) of any such employee, and any other employee retained by Respondents and designated by the Interim Monitor (if applicable) sign a confidentiality agreement pursuant to which such employee shall be required to maintain all

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 Order).

- J. Not later than thirty (30) days after the Effective Date, Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to the Rolapitant Products by Respondent's personnel to all of Respondents' employees who:
1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of any of the Rolapitant Products;
 2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that are either:
 - a. neurokinin 1 receptor antagonists, 5-HT3 receptor antagonists; and/or
 - b. or any Product Developed or in Development for CINV and/or PONV; and/or
 3. may have Confidential Business Information related to the Rolapitant Products.

Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondents shall provide a copy of such notification to the Acquirer.

Respondents shall maintain complete records of all such agreements at Respondent's registered office within the United States and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondents shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

- K. Until Respondents complete the divestiture required by Paragraphs IV.A. and fully transfer and deliver, or cause to be transferred and delivered, the related Product Manufacturing Technology, to the Acquirer,
1. Respondents shall take such actions as are necessary to:
 - a. maintain the full economic viability and marketability of the businesses associated with the Rolapitant Products;
 - b. minimize any risk of loss of competitive potential for such business;
 - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to the Rolapitant Products except for ordinary wear and tear;

- 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 a device 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 permit the Interim Monitor to monitor Respondents’ 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, Respondents 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 Respondents’ 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:
 - a. the date of completion by Respondents of the divestiture of all the Rolapitant Product Assets and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order, including, without limitation, the provisions of Paragraph IV.C. above; and
 - b. until the earliest of:

- (1) the date the Acquirer (or its Designee(s)) is able to manufacture SCH 619734 (Rolapitant), in a manner consistent with cGMP, independently of Respondents;
- (2) the date the Acquirer notifies the Commission and the Respondents of its intention to abandon its efforts to commercialize Products containing SCH 619734 (Rolapitant) for CINV and/or PONV; or
- (3) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to commercialize Products containing SCH 619734 (Rolapitant) for CINV and/or PONV;

provided, however, that, the Interim Monitor's service shall not exceed five (5) years from the Order Date;

provided, further, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Order.

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' 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 Order, including, but not limited to, its obligations related to the Rolapitant Product Assets. Respondents 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 Respondents' compliance with the Order.
5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents, 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 Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
6. Respondents 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.

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 Divestiture Trustee pursuant to the relevant provisions of this Order.

VI.

IT IS FURTHER ORDERED that:

- A. If Respondents have not fully complied with the obligations to divest the Ownership Interest in Merial and/or the Rolapitant Product Assets, as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*l*), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey the Merial Ownership Interest and/or the Rolapitant Product Assets and the Rolapitant Product Licenses. 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 Respondents to comply with this Order.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent Merck, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent Merck 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 Merck of the identity of any proposed Divestiture Trustee, Respondents 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, Respondents 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 this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee’s powers, duties, authority, and responsibilities:
 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.

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 legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents 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 efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission; *provided further, however*, that Respondents shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
 7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as 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 where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

- A. To assure Respondents' compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals,

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.
- B. Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondents shall include in each Remedial Agreement a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of Respondents' obligations to the Acquirer pursuant to this Order.
- D. Respondents shall also include in each Remedial Agreement related to the Rolapitant Products a representation from the Acquirer that such Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, the Rolapitant Products and to have any such manufacture to be independent of Respondents, all as soon as reasonably practicable.
- E. Respondents shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission.

IX.

IT IS FURTHER ORDERED that:

- A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondents have fully complied with the following: Paragraphs II.A , II.B., IV.A., IV.B., IV.C., IV.D., IV.E, IV.G., and IV.K. Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order. Respondents shall submit at the same time a copy of their report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including a full description of all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all Persons contacted, including copies of all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning completing the obligations.
- C. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which they have complied and are complying with the Order.

X.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of a Respondent;
- B. any proposed acquisition, merger or consolidation of a Respondent; or
- C. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

XI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, such Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of such Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of such Respondent related to compliance with this Order, which copying services shall be provided by such Respondent at the request of the authorized representative(s) of the Commission and at the expense of such Respondent; and
- B. to interview officers, directors, or employees of such Respondent, who may have counsel present, regarding such matters.

XII.

IT IS FURTHER ORDERED that this Order shall terminate on October 29, 2019.

By the Commission, Commissioner Harbour and Commissioner Kovacic recused.

Donald S. Clark
Secretary

SEAL
ISSUED: October 29, 2009

Non-Public Appendix
Merial Divestiture Agreements
[Redacted From the Public Record Version, But Incorporated By Reference]

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