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Jos LaRose for / pour
REGISTRAR / REGISTRAIRE

OTTAWA, ONT

001

PUBLIC VERSION

CT – 2009-015

COMPETITION TRIBUNAL

IN THE MATTER of the *Competition Act*, R.S.C. 1985, c. C-34, and the *Competition Tribunal Rules*, SOR/94-290;

AND IN THE MATTER of the proposed amalgamation of Merck & Co., Inc. and Schering-Plough Corporation;

AND IN THE MATTER of the filing and registration of a consent agreement pursuant to section 105 of the *Competition Act*.

BETWEEN:

THE COMMISSIONER OF COMPETITION

Applicant

– and –

SCHERING-PLOUGH CORPORATION and MERCK & CO., INC.

Respondents

**CONSENT AGREEMENT IN RELATION TO THE AMALGAMATION OF
SCHERING-PLOUGH CORPORATION AND MERCK & CO., INC.**

WHEREAS pursuant to a Merger Agreement, dated March 8, 2009, Merck & Co., Inc. (“**Merck**”) and Schering-Plough Corporation (“**Schering-Plough**”) will combine in a stock and cash transaction (the “**Transaction**”);

AND WHEREAS the Transaction will be structured as a reverse merger pursuant to which Schering-Plough will acquire Merck, but will operate under the name “Merck” (the “**Merged Entity**”);

AND WHEREAS this Consent Agreement (the “**Agreement**”) shall apply to the Merged Entity following the implementation of the Transaction;

AND WHEREAS the Commissioner of Competition (the “**Commissioner**”) has determined that the Transaction is likely to result in a substantial lessening or prevention of competition in Canada for the supply of NK-1 Receptor Antagonists for the treatment of CINV or PONV in humans, and that the divestiture of the Rolapitant Product Assets (as defined herein) is necessary to ensure that such substantial lessening or prevention of competition will not result from the completion of the Transaction;

AND WHEREAS the Respondents do not admit that the Transaction is likely to result in a substantial lessening or prevention of competition in Canada for the supply of NK-1 Receptor Antagonists for the treatment of CINV or PONV in humans, or that, if the Transaction were to result in such substantial lessening or prevention of competition, the divestiture of the Rolapitant Product Assets would be necessary to ensure that such substantial lessening or prevention of competition would not result from the completion of the Transaction, but will not contest the Commissioner’s conclusions for the purposes of the enforcement of any provision of this Agreement or in any subsequent proceeding, including any proceeding under section 106 of the Act, in relation to this Agreement;

AND WHEREAS the Commissioner has determined that the Transaction is likely to result in a substantial lessening or prevention of competition in certain animal health markets in Canada;

AND WHEREAS, in order to address the Commissioner’s concerns that the Transaction is likely to result in a substantial lessening or prevention of competition in certain animal health markets in Canada, Merck divested its 50 percent interest in Merial Limited (“**Merial**”) to Sanofi-Aventis on September 17, 2009, pursuant to a Share Purchase Agreement, dated July 29, 2009, and a Termination Agreement in connection with the Master Merial Venture Agreement;

AND WHEREAS Merck, Schering-Plough, and Sanofi-Aventis have entered into a Call Option Agreement, dated July 29, 2009;

AND WHEREAS the Commissioner has determined that the exercise by Sanofi-Aventis of the call right set out in the Call Option Agreement is likely to result in a substantial lessening or prevention of competition in certain animal health markets in Canada;

AND WHEREAS the Respondents do not admit that the exercise by Sanofi-Aventis of the call right set out in the Call Option Agreement is likely to result in a substantial lessening or prevention of competition in certain animal health markets in Canada;

AND WHEREAS the Respondents will not contest, for the purposes of the enforcement of any provision of the Agreement or in any subsequent proceeding, including any proceeding under section 106 of the Act, in relation to this Agreement, the Commissioner's conclusion that the call right set out in the Call Option Agreement is likely to result in a substantial lessening or prevention of competition in certain animal health markets in Canada;

AND WHEREAS the Respondents consensually attorn to the jurisdiction of the Competition Tribunal for purposes of this Agreement and any proceeding initiated by the Commissioner relating to this Agreement;

AND WHEREAS the Commissioner and the Respondents agree to the immediate registration of this Agreement with the Competition Tribunal by the Commissioner;

NOW THEREFORE Schering-Plough, Merck, and the Commissioner agree as follows:

I. DEFINITIONS

[1] For the purposes of this Agreement, unless something in the subject matter or context is inconsistent therewith, the following capitalized terms have the following meanings:

- (a) **“Act”** means the *Competition Act*, R.S.C., 1985, c. C-34, as amended;
- (b) **“Acquirer(s)”** means the following:
 - (i) a Person specified by name in this Agreement to acquire particular assets or rights that the Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Agreement and that has been approved by the Commissioner; or
 - (ii) a Person approved by the Commissioner to acquire particular assets or rights that the Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Agreement;
- (c) **“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 (the **“Acquisition Agreement”**);
- (d) **“Affiliate”** means an affiliated corporation, partnership or sole proprietorship within the meaning of subsection 2(2) of the Act;
- (e) **“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, Health Canada and the United States Food and Drug Administration (“FDA”);

- (f) “**Agreement**” means this Consent Agreement entered into between Merck, Schering-Plough and the Commissioner pursuant to section 105 of the Act, including the schedules hereto;
- (g) “**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;
- (h) “**Application(s)**” means
 - (i) in respect of Canada, all of the following, as required by Health Canada or the Canadian *Food and Drugs Act*, R.S.C. 1985, c. F-27, as amended, and all rules and regulations promulgated thereunder: “Investigational New Drug Submission” (“INDS”), “New Drug Submission” (“NDS”), “Abbreviated New Drug Submission” (“ANDS”), “Supplemental New Drug Submission” (“SNDS”), “Supplemental Abbreviated New Drug Submission” (“SANDS”), “Clinical Trial Application”, “Clinical Trial Application Amendment”, “DIN Application”, or “Experimental Study Certificate” for a Product filed or to be filed with Health Canada, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between the Respondents and Health Canada related thereto; and
 - (i) in respect of the United States, 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 the 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 the Respondent(s) and the FDA 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 Health Canada and the FDA, as applicable;

- (i) **“Call Option”** means:
 - (i) the Call Option Agreement among Merck & Co., Inc., Schering-Plough Corporation and Sanofi-Aventis dated July 29, 2009 (**“Call Option Agreement”**); and
 - (ii) any other agreement or arrangement that provides Sanofi-Aventis with any right or option to acquire an Ownership Interest in Intervet Schering-Plough Animal Health or the business of researching, developing, manufacturing, marketing or selling Animal Health Products operated by the Respondents;
- (j) **“cGMP”** means:
 - (i) for any Product regulated by Health Canada, current Good Manufacturing Practice, as set forth in the Canadian *Food and Drugs Act*, R.S.C. 1985, c. F-27, as amended, and all rules and regulations promulgated thereunder; and
 - (ii) for any Product regulated by the FDA, 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;
- (k) **“CINV”** means the treatment of chemotherapy-induced nausea and vomiting in humans;
- (l) **“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 Geographic Territory for the use of Products containing SCH 619734 (Rolapitant) for CINV and/or PONV;
- (m) **“Clinical Trial(s)”** means 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 Geographic Territory for the use of Products containing SCH 619734 (Rolapitant) for CINV and/or PONV;
- (n) **“Closing Date”** means the date on which the Respondent(s) (or a Divestiture Trustee) Divests the Rolapitant Product Assets to an Acquirer pursuant to this Agreement;

- (o) “**Commissioner**” means the Commissioner of Competition appointed pursuant to section 7 of the Act or any Person designated by the Commissioner to act on her behalf;
- (p) “**Confidential Business Information**” means 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), provided, however, that the restrictions contained in this Agreement regarding the Respondents’ use, conveyance, provision, or disclosure of “Confidential Business Information” shall not apply to the following:
 - (i) information that subsequently falls within the public domain through no violation of this Agreement or breach of confidentiality or non-disclosure agreement with respect to such information by the Respondent(s);
 - (ii) information related to the Rolapitant Products that was researched, Developed, manufactured, marketed, or sold by the Respondent Schering-Plough that Respondent Merck can demonstrate it obtained without the assistance of Respondent Schering-Plough prior to the Acquisition;
 - (iii) information that is required by Law to be publicly disclosed;
 - (iv) 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;
 - (v) information specifically excluded from the Rolapitant Product Assets (other than the NK-1 Know How exclusively licensed to the Acquirer);
 - (vi) all intellectual property licensed to the Acquirer on a non-exclusive basis; and
 - (vii) 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 Canadian 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 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 labour, 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 the Respondents’ employees’ labour 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 Agreement; 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) “**Divestiture**” means, the sale, transfer, assignment, licensing or other disposal of identified assets, such that the Respondents will have no direct or indirect interest in such assets except as permitted herein or upon the consent of the Commissioner; “**Divest**” means to implement the Divestiture;
- (v) “**Divestiture Trustee**” means a Person appointed by the Commissioner pursuant to the relevant provisions of this Agreement and any employees, agents or other Persons acting for or on behalf of the Divestiture Trustee;
- (w) “**Divestiture Trustee Sale Period**” means the one (1) year period following the expiration of the Initial Sale Period, within which the Divestiture Trustee alone is empowered to sell the Rolapitant Product Assets, or such longer period as the Commissioner, in her sole discretion, considers appropriate in the circumstances;
- (x) “**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;
- (y) “**Drug Master Files**” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product, and all submissions to Health Canada referred to as drug master files in respect of a Product;
- (z) “**Effective Date**” means the earliest of the following dates:
 - (i) the date the Respondents consummate the Acquisition pursuant to the Acquisition Agreement;

- (ii) 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;
 - (iii) the date on which Respondent Schering-Plough acquires, directly or indirectly, fifty (50)% or more of the voting securities of Respondent Merck; or
 - (iv) the date on which Respondent Merck acquires, directly or indirectly, fifty (50)% or more of the voting securities of Respondent Schering-Plough;
- (aa) **“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;
 - (bb) **“Geographic Territory”** shall mean each of (1) Canada and (2) the United States of America;
 - (cc) **“Government Entity”** means any Canadian Federal, provincial, or municipal government, or any U.S. 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;
 - (dd) **“Initial Sale Period”** means ten (10) days from the Effective Date, subject to extension in the sole discretion of the Commissioner;
 - (ee) **“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 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 Venzolana SA; Laboratorios Intervet S.A.; 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;
 - (ff) **“Law”** means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law;

- (gg) “**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;
- (hh) “**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, SFP, Inc.) and the respective directors, officers, employees, agents, representatives, successors, joint ventures, subsidiaries, divisions, groups and Affiliates and assigns of each of the foregoing;
- (ii) “**Monitor**” means a Person appointed pursuant to Part V of this Agreement and any employees, agents or other Persons acting for or on behalf of the Monitor;
- (jj) “**NK-1 Compound(s)**” means the neurokinin-1 (NK-1) receptor antagonists SCH 619734 (Rolapitant) and SCH 900978, and 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, and 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, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and Affiliates, and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each;
- (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 the U.S. Federal Trade Commission’s Decision and Order in respect of the Acquisition 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 Agreement 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 the Respondent(s) as of the Closing Date (except where this Agreement 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 Geographic Territory, 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):
- (i) 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;
 - (ii) pursuant to which the 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);
 - (iii) relating to any Clinical Trials involving the Rolapitant Product(s);
 - (iv) with universities or other research institutions for the use of the Rolapitant Product(s) in scientific research;
 - (v) relating to the particularized marketing of the Rolapitant Product(s) or educational matters relating solely to the Rolapitant Product(s);
 - (vi) pursuant to which a Third Party manufactures or packages the Rolapitant Product(s) on behalf of the Respondent(s);
 - (vii) pursuant to which a Third Party provides the Product Manufacturing Technology related to the Rolapitant Product(s) to the Respondent(s);
 - (viii) pursuant to which a Third Party is licensed by the Respondent(s) to use the Product Manufacturing Technology;
 - (ix) constituting confidentiality agreements involving the Rolapitant Product(s);
 - (x) involving any royalty, licensing, or similar arrangement involving the Rolapitant Product(s);
 - (xi) pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the

Rolapitant Product to the Respondent(s) including, but not limited to, consultation arrangements; and/or

- (xii) pursuant to which any Third Party collaborates with the 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), the 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 and Health Canada;
- (ww) **“Product Development Reports”** means:
 - (i) Pharmacokinetic study reports related to the Rolapitant Product(s);

- (ii) Bioavailability study reports (including reference listed drug information) related to the Rolapitant Product(s);
 - (iii) Bioequivalence study reports (including reference listed drug information) related to the Rolapitant Product(s);
 - (iv) all correspondence to the Respondent(s) from the FDA and Health Canada and from the Respondent(s) to the FDA and Health Canada relating to the Application(s) submitted by, on behalf of, or acquired by, the Respondent(s) related to the Rolapitant Product;
 - (v) annual and periodic reports related to the above-described Application(s), including any safety update reports;
 - (vi) FDA and Health Canada approved Product labeling related to the Rolapitant Product(s);
 - (vii) currently used product package inserts (including historical change of controls summaries) related to the Rolapitant Product(s);
 - (viii) FDA and Health Canada approved patient circulars and information related to the Rolapitant Product(s);
 - (ix) adverse event/serious adverse event summaries related to the Rolapitant Product(s);
 - (x) summary of Product complaints from physicians related to the Rolapitant Product(s);
 - (xi) summary of Product complaints from customers related to the Rolapitant Product(s); and
 - (xii) Product recall reports filed with the FDA and Health Canada 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:
- (i) a complete and accurate list containing the name of each relevant employee (including former employees who were employed by the Respondent(s) within ninety (90) days of the execution date of any Remedial Agreement related to the Divestiture of the Rolapitant Product Assets);
 - (ii) 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, the 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
- (iii) 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):
- (i) Patents, which shall include the NK-1 Patents as defined in the Rolapitant Product Divestiture Agreement;
 - (ii) Product Copyrights;
 - (iii) 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
 - (iv) 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 the 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:

- (i) Patents that are related to a Rolapitant Product that the Respondent(s) can demonstrate have been used, prior to the Effective Date, for a Retained Product(s); and
 - (ii) 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 the 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 the 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:
- (i) 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 and Health Canada Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;
 - (ii) 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
 - (iii) 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 the 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 the Respondents (or a Divestiture Trustee) to the Commissioner and submitted for the approval of the Commissioner as the acquirer for particular assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by the Respondents pursuant to this Agreement;
- (hhh) “**Remedial Agreement(s)**” means the following:
- (i) any agreement between the Respondent(s) and an Acquirer that is specifically referenced and attached to this Agreement, 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 Commissioner;

- (ii) any agreement between the Respondent(s) and a Third Party to effect the assignment of assets or rights of the Respondent(s) related to a Rolapitant Product to the benefit of an Acquirer that is specifically referenced and attached to this Agreement, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commissioner;
- (iii) any agreement between the Respondent(s) and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commissioner to accomplish the requirements of this Agreement, 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 Commissioner; and/or
- (iv) any agreement between the Respondent(s) and a Third Party to effect the assignment of assets or rights of the Respondent(s) related to a Rolapitant Product to the benefit of an Acquirer that has been approved by the Commissioner, including all amendments, exhibits, attachments, agreements, and schedules thereto;

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

- (iii) “**Respondent(s)**” means Schering-Plough and Merck, individually and collectively;
- (jjj) “**Retained Product**” means any Product(s) other than a Rolapitant Product;
- (kkk) “**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 or Health Canada audit;
- (lll) “**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;
- (mmm) “**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:

- (i) all Product Intellectual Property;
- (ii) all Freedom to Operate Searches;
- (iii) all Product Approvals;
- (iv) all Product Manufacturing Technology that is tangible and exclusive to the Rolapitant Products;
- (v) all Product Marketing Materials;
- (vi) all Website(s);
- (vii) all rights to all of the Respondents' Applications;
- (viii) 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);
- (ix) all Product Development Reports;
- (x) 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);
- (xi) all strategic safety programs submitted to each of the FDA and Health Canada related to the Rolapitant Products that are designed to decrease product risk by using one or more interventions or tools beyond the package insert;
- (xii) 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 or Health Canada to facilitate the investigation of adverse effects related to the Rolapitant Product(s);
- (xiii) at the Acquirer's option and to the extent approved by the Commissioner 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, the 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 the 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

- (xiv) 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 the 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) administrative, financial, and accounting records; (3) quality control records that are determined by the 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;

- (nnn) **"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 Monitor (if one has been appointed) as are necessary for the purposes of complying with this Agreement. 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 ninety (90) days prior to the Closing Date;
- (ooo) **"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;
- (ppp) **"Rolapitant Product Licenses"** means all of the following related to the Rolapitant Products:

- (i) 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 Geographic Territory;
 - B. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the Rolapitant Products within the Geographic Territory;
 - C. to import or export the Rolapitant Products to or from the Geographic Territory to the extent related to the marketing, distribution or sale of the Rolapitant Products in the Geographic Territory; and
 - D. to have the Rolapitant Products made anywhere in the World for distribution or sale within, or import into the Geographic Territory; and
- (ii) 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;

- (qqq) “**Rolapitant Product Releasee(s)**” means the Acquirer for the Rolapitant Product Assets or any Affiliate of such Acquirer, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of such Acquirer, or such Affiliate of the Acquirer;
- (rrr) “**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;
- (sss) “**SCH 619734 (Rolapitant)**” means the NK-1 Compound designated as neurokinin-1 (NK-1) receptor antagonist SCH 619734 (Rolapitant);
- (ttt) “**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 and the respective directors, officers, employees, agents, representatives, successors, and assigns of each;

- (uuu) “**Supply Cost**” means a cost not to exceed the manufacturer’s average direct per unit cost 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 Agreement, 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;
- (vvv) “**Technology Transfer Standards**” means requirements and standards sufficient to ensure that the information and assets required to be delivered pursuant to this Agreement 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*:
- (i) 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 Monitor (if one has been appointed), for the purpose of effecting such delivery;
 - (ii) 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;
 - (iii) 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
 - (iv) providing, in a timely manner, assistance and advice to enable the Acquirer or its Designee to:
 - A. 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;
 - B. conduct Clinical Trials for such Rolapitant Product(s);
 - C. finalize all clinical and study reports, brochures and other documents related to SCH 619734 (Rolapitant);

- D. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the Rolapitant Product(s); and
- E. use the Rolapitant Product Assets and the Rolapitant Product Licenses to complete the Clinical Trials;

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

(xxx) **“Tribunal”** means the Competition Tribunal established by the *Competition Tribunal Act*, R.S.C. 1985, c.19 (2nd Supp.), as amended;

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

All other terms defined in this Agreement have the meanings established elsewhere in this Agreement.

II. APPLICATION

[2] The provisions of this Agreement shall apply to:

- (a) Merck;
- (b) Schering-Plough;
- (c) all other Persons acting in concert or participating with one or more of those listed in (a) or (b), with respect to the matters referred to in this Agreement, who shall have received actual notice of this Agreement;
- (d) the Commissioner;
- (e) the Monitor;
- (f) the Divestiture Trustee; and
- (g) each Acquirer and the Acquirer’s heirs, successors, legal representatives and assigns.

III. FUTURE ACQUISITIONS AND AGREEMENTS

- [3] The Respondents shall not, for a period of ten (10) years from the date of this Agreement, directly or indirectly, without the prior approval of the Commissioner:
- (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, except for goods and realty transferred in the ordinary course of business;
 - (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, except for goods and realty transferred in the ordinary course of business;
 - (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 the 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, except for the sale of goods and realty transferred in the ordinary course of business;
 - (h) enter into and make operational or consummate any agreement with Sanofi-Aventis or Merial that would restrict or impair the Respondents' ability to operate the 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 the 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;

- (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; or
- (l) reacquire the Rolapitant Product Assets.

[4] Notwithstanding anything to the contrary in section 3, Respondent Merck shall not be prohibited from entering into a contribution agreement substantially in the form of Exhibit A to the Call Option Agreement (the “**Contribution Agreement**”) provided that the consummation of any transaction contemplated by such Contribution Agreement shall be conditional upon the prior written approval of the Commissioner.

IV. DIVESTITURE OF THE ROLAPITANT PRODUCT ASSETS

[5] Subject to sections 6 and 7 below, during the Initial Sale Period, the 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, and each such agreement, if it becomes a Remedial Agreement related to the Rolapitant Product Assets is incorporated by reference into this Agreement and made a part hereof.

[6] If the Commissioner notifies the Respondents by the Order Date that OPKO is not an acceptable purchaser of the Rolapitant Product Assets, then the Respondents shall immediately rescind the transaction with OPKO, in whole or in part, as directed by the Commissioner, and shall Divest the Rolapitant Product Assets and grant the Rolapitant Product Licenses within one hundred eighty (180) days from the Order Date (the “**Alternate Sale Period**”), absolutely and in good faith, at no minimum price, and on the following terms:

- (a) The Divestiture shall take place:
 - (i) By sale, assignment, transfer or other disposition necessary to ensure that, by the completion of the Divestiture, the Respondents will have no direct or indirect interest in the Rolapitant Product Assets, except as permitted herein, or upon the consent of the Commissioner;
 - (ii) To an Acquirer approved by the Commissioner;
 - (iii) To an Acquirer at arm’s length from the Respondents and who can satisfy the Commissioner that they:
 - A. are committed to carrying on the business of the Rolapitant Product Assets in Canada;

- B. have the managerial, operational and financial capability to compete effectively; and
 - C. will enter into an agreement prior to the expiry of the Alternate Sale Period and complete the Divestiture of the Rolapitant Product Assets prior to the expiry of the Alternate Sale Period;
- (iv) by way of a commercially reasonable public tender, bidding or other procedure instituted in a manner to allow a fair opportunity for one or more bona fide potential Acquirers to obtain notice of the prospective Divestiture and to make an offer to acquire the Rolapitant Product Assets pursuant to this Agreement; and
 - (v) on usual commercial terms for transactions of the size and nature of those contemplated in this Agreement, including reasonable and ordinary commercial representations and warranties.

The determination of whether the above conditions are satisfied is at the sole discretion of the Commissioner. In exercising her discretion to approve a Divestiture of the Rolapitant Product Assets to an Acquirer, the Commissioner may take into account, *inter alia*, the likely impact of the Divestiture on competition. The decision of the Commissioner as to whether to approve the Divestiture shall be in writing.

- (b) Any Person making a bona fide inquiry of the Respondents shall be notified that the Divestiture is being made pursuant to this Agreement and shall be provided with a copy of this Agreement, with the exception of the provisions hereof which are confidential.
- (c) Subject to section 6(d) below, any prospective Acquirer with a bona fide interest in purchasing any of the Rolapitant Product Assets shall:
 - (i) be furnished with all pertinent information regarding the Rolapitant Product Assets within fourteen (14) days of a request therefor;
 - (ii) be permitted to make reasonable inspection of the Rolapitant Product Assets and of all financial, operational or other non-privileged documents and information, including Confidential Business Information, which may be relevant to the Divestiture, except for any documents which, at the time of the request for inspection of such documents the Commissioner has agreed need not be disclosed; and
 - (iii) be given such full and complete access as is reasonable in the circumstances to the management personnel relating to the Rolapitant Product Assets.

If a Monitor is concerned as to the bona fides of any Person making an inquiry, the Monitor shall advise the Commissioner of such concern and the final determination of bona fides shall be made by the Commissioner alone.

- (d) Access by a potential Acquirer to the information identified in section 6(c) above shall be conditional on the execution of a standard confidentiality agreement in a form determined by the Commissioner containing, among other things, nonsolicitation terms relating to personnel and suppliers.
- [7] If the Respondents have divested the Rolapitant Product Assets and granted the Rolapitant Product Licenses to OPKO prior to the Order Date, and if the Commissioner notifies the Respondents by the Order Date that the manner in which the Divestiture was accomplished is not acceptable, the Respondents, or a Divestiture Trustee appointed by the Commissioner, shall 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 Commissioner may determine are necessary to satisfy the requirements of this Agreement.
- [8] Prior to the Closing Date, the Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit the 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, the Respondents may satisfy this requirement by certifying that the Acquirer has executed all such agreements directly with each of the relevant Third Parties.
- [9] The 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. The Respondents shall obtain any consents from Third Parties required to comply with this provision, provided, however, that any services provided by the Respondents pursuant to this section are not required to extend longer than one (1) year after the Closing Date or until the Respondents have fully transferred to the Acquirer the Rolapitant Product Assets and the Rolapitant Product Licenses, whichever is later; except that the 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.
- [10] Upon the request of the Acquirer, the Respondents shall Contract Manufacture and deliver to the Acquirer a supply of SCH 619734 (Rolapitant) at a price not to exceed the Respondents' Supply Cost, in the following manner:

- (a) 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);
- (b) for a period of time sufficient to enable the Acquirer (or the Designee of the Acquirer) to manufacture SCH 619734 (Rolapitant) independently of the Respondents in quantities and of the quality necessary to meet the Acquirer's Clinical Requirements; and,
- (c) upon request of the Acquirer or Monitor (if any has been appointed), the Respondents shall make available to the Acquirer and the 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 the Respondents, and in sufficient quantities to meet the Acquirer's Clinical Requirements for SCH 619734 (Rolapitant); (2) the date the Acquirer notifies the Commissioner and the Respondents of its intention to abandon its efforts to Develop SCH 619734 (Rolapitant); (3) the date of written notification from the Commissioner that the Monitor, in consultation with the Commissioner, 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.

[11] The Respondents shall:

- (a) submit to the Acquirer, at the Respondents' expense, all Confidential Business Information related to the Rolapitant Products;
- (b) deliver such Confidential Business Information to the Acquirer:
 - (i) in good faith;
 - (ii) in a timely manner, i.e., as soon as practicable, avoiding any delays in transmission of the respective information; and
 - (iii) in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
- (c) pending complete delivery of all such Confidential Business Information to the Acquirer, provide the Acquirer and the 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 Agreement;

- (d) 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:
 - (i) the requirements of this Agreement;
 - (ii) the Respondents' obligations to the Acquirer of the Rolapitant Products under the terms of any Remedial Agreement related to Rolapitant Products; or
 - (iii) applicable Law;
 - (e) 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
 - (f) 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 any business that either:
 - (i) relates to those Retained Products that are either neurokinin 1 receptor antagonists, 5-HT3 receptor antagonists; and/or
 - (ii) relates to any Product Developed or in Development for CINV and/or PONV.
- [12] The 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.
- [13] Not later than ten (10) days after the Closing Date, the Respondents shall grant a release to each Third Party that is subject to an agreement as described in section 12 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, the Respondents shall provide a copy of the release to the Acquirer.
- [14] The Respondents shall:
- (a) 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)**”;

- (b) not later than the earlier of the following dates: (1) ten (10) days after notice by the Commissioner to the 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 the 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;
- (c) 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 the 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 the Respondent(s) that would affect the ability or incentive of those individuals to be employed by the Acquirer. In addition, the 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 Agreement, this subsection 14(c) shall not prohibit the Respondents from continuing to employ any Rolapitant Product Core Employee under the terms of such employee's employment with the 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;
- (d) 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 the 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 Agreement, this Agreement does not require nor shall be construed to require the Respondents to terminate the employment of any employee or to prevent the Respondents from continuing to employ the Rolapitant Product Core Employees in connection with the Acquisition; and
- (e) for a period of one (1) year from the Closing Date, not:

- (i) 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
- (ii) hire any Rolapitant Product Employee, provided, however, the Respondents may hire any former Rolapitant Product Employee whose employment has been terminated by the Acquirer or who independently applies for employment with the Respondents, as long as such employee was not solicited in violation of the nonsolicitation requirements contained herein and provided further, however, that a violation of this provision will not occur by any of the following actions: (1) the Respondent(s) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Rolapitant Product Employees; or (2) the Respondent(s) hire a Rolapitant Product Employee who contacts the Respondents on his or her own initiative without any direct or indirect solicitation or encouragement from the Respondents.

[15] The Respondents shall require, as a condition of continued employment post-Divestiture of the Rolapitant Product Assets, that each Rolapitant Product Core Employee retained by the Respondents, the direct supervisor(s) of any such employee, and any other employee retained by the Respondents and designated by the 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 the Respondents (other than as necessary to comply with the requirements of this Agreement).

[16] Not later than thirty (30) days after the Effective Date, the 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 the Respondents’ employees who:

- (a) are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of any of the Rolapitant Products;
- (b) are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that are either:
 - (i) neurokinin 1 receptor antagonists, 5-HT₃ receptor antagonists; and/or
 - (ii) any Product Developed or in Development for CINV and/or PONV; and/or
- (c) may have Confidential Business Information related to the Rolapitant Products.

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

[17] Until the Respondents complete the Divestiture of the Rolapitant Product Assets and fully transfer and deliver, or cause to be transferred and delivered, the related Product Manufacturing Technology, to the Acquirer,

- (a) the Respondents shall take such actions as are necessary to:
 - (i) maintain the full economic viability and marketability of the businesses associated with the Rolapitant Products;
 - (ii) minimize any risk of loss of competitive potential for such business;
 - (iii) prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to the Rolapitant Products except for ordinary wear and tear;
 - (iv) 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
 - (v) ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and
- (b) the Respondents shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in this Agreement) nor take any action that lessens the full economic viability, marketability, or competitiveness of the businesses associated with the Rolapitant Products.

[18] The 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:

- (a) any Patent owned or licensed by the 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;
- (b) any Patents owned or licensed by the 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. The 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.

- [19] Upon reasonable written notice and request from the Acquirer to the Respondent(s), the Respondent(s) shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of the 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.
- [20] 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, the Respondents shall:
- (a) cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from the Respondent(s) in connection with obtaining resolution of any pending patent litigation involving the Rolapitant Products;
 - (b) 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
 - (c) permit the transfer to the relevant Acquirer of all of the litigation files and any related attorney work-product in the possession of either the Respondent's outside counsel relating to such Rolapitant Products.
- [21] The 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 Agreement and/or the remedial purposes thereof.

V. MONITOR

- [22] The Commissioner may appoint a Monitor responsible for monitoring the compliance of the Respondents with the obligations set out in this Agreement in respect of the Rolapitant Product(s) and the Rolapitant Product Assets. The selection of the Monitor by the Commissioner shall be 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 the Monitor within ten (10) days after notice by the Commissioner to Respondent Merck of the identity of the Monitor, Respondent Merck shall be deemed to have consented to the selection of the proposed Monitor. Within ten (10) days of the appointment of such Monitor, the Respondents and the Monitor shall execute an agreement, subject to the approval of the Commissioner, reflecting the terms and conditions of this Agreement and that confers on the Monitor all of the rights and powers necessary to permit the Monitor to monitor the Respondents' compliance with the obligations set out in this Agreement in respect of the Rolapitant Product(s) and the Rolapitant Product Assets. If the Respondents and the Monitor fail to agree on terms within seven (7) days from the date of appointment of the Monitor, the Commissioner shall establish the terms of the Monitor's service.
- [23] The Respondents shall be responsible for all reasonable fees and expenses properly charged or incurred by the Monitor in the course of carrying out the Monitor's duties under this Agreement, and those of any substitute Monitor appointed pursuant to this Agreement.
- [24] If a Monitor ceases to act or fails to act diligently or otherwise in accordance with this Agreement, the Commissioner shall appoint a substitute Monitor in accordance with the terms of this Part V, subject to the consent of Respondent Merck, which shall not be unreasonably withheld. If Respondent Merck has not opposed the selection of the substitute Monitor in writing, including the reasons for the opposition, within ten (10) days after notice by the Commissioner to Respondent Merck of the identity of the substitute Monitor, Respondent Merck shall be deemed to have consented to the selection of the substitute Monitor. Respondent Merck and the substitute Monitor shall execute an agreement, subject to the approval of the Commissioner, reflecting the terms and conditions of this Agreement. In the event that Respondent Merck objects to the Commissioner's appointment of a substitute Monitor, Respondent Merck may apply to the Tribunal for appropriate relief on five (5) days notice to the Commissioner. The notice must set out the grounds for the objection. The provisions of this Agreement shall apply, mutatis mutandis, to any substitute Monitor appointed pursuant to this Part V.
- [25] The Monitor shall have, subject to any valid claim to a legally recognized privilege, full and complete access to all personnel, books, records, documents and facilities related to the Rolapitant Product Assets or to any other relevant information, including Confidential Business Information, as the Monitor may reasonably request. The Respondents shall cooperate with any reasonable request of the Monitor. The Respondents shall not take any action to interfere with or impede the Monitor's compliance with, or ability to oversee the Respondents' performance of, this Agreement.

- [26] The Monitor shall serve, without bond or security, at the expense of the Respondents, on such reasonable and customary terms as are agreed with the approval of the Commissioner. The Monitor shall have the authority to engage, at the cost and expense of the Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities under this Agreement. The Monitor shall account for all expenses incurred, including fees for services, and such account shall be subject to the approval of the Commissioner only.
- [27] The Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities or expenses arising out of, or in connection with, the performance of their duties under this Agreement. This includes all reasonable fees of counsel and other expenses incurred in connection with the preparation or defence of any claim, whether or not such claim results in any liability, except to the extent that such liabilities, losses, damages, claims or expenses result from malfeasance, gross negligence or bad faith by the Monitor.
- [28] The Respondents shall report to the Monitor in accordance with the requirements of this Agreement. The Monitor shall evaluate the reports submitted to the Monitor by the Respondents and any reports submitted by the Acquirer with respect to the performance of Respondent's obligations under this Agreement or the Remedial Agreement(s). Within thirty (30) days from the date the Monitor receive these reports, or at the request of the Commissioner, the Monitor shall report in writing to the Commissioner concerning performance by the Respondents of their obligations under this Agreement.
- [29] The Respondents shall not exert or attempt to exert any influence, direction or control over the Monitor.
- [30] This Agreement shall not be construed as providing the Monitor with ownership, management, possession, charge or control of the Rolapitant Product Assets.
- [31] The Monitor shall execute confidentiality agreements in a form satisfactory to the Commissioner, pursuant to which the Monitor will undertake not to disclose any Confidential Business Information acquired in the performance of the Monitor's duties to any Person, except as permitted by this Agreement.
- [32] If a Monitor believes that either of the Respondents is in breach of any of the terms of this Agreement, the Monitor shall immediately notify the Commissioner and the Respondents of the breach, setting out particulars of such breach.
- [33] The Monitor shall serve until:
- (a) the date of completion by the 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 Agreement, including, without limitation, the provisions of section 5 above; and
 - (b) until the earliest of:

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

provided, however, that the Monitor's service shall not exceed five (5) years from the date of this Agreement, subject to extension in the sole discretion of the Commissioner.

VI. DIVESTITURE TRUSTEE

[34] If the Respondents have not fully complied with the obligation to Divest the Rolapitant Product Assets, as required by this Agreement, the Commissioner may appoint a Divestiture Trustee to Divest the Rolapitant Product Assets. The Divestiture Trustee will be a Person with experience and expertise in acquisitions and Divestitures. The selection of the Divestiture Trustee by the Commissioner shall be 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 any proposed Divestiture Trustee within ten (10) days after notice by the Commissioner to Respondent Merck of the identity of any proposed Divestiture Trustee, Respondent Merck shall be deemed to have consented to the selection of the proposed Divestiture Trustee. Immediately following the appointment of the Divestiture Trustee, and prior to the expiry of the Initial Sale Period, the Respondents shall provide the Divestiture Trustee with complete access to all information relevant to the Rolapitant Product Assets, including Confidential Business Information, to facilitate the Divestiture of the Rolapitant Product Assets by the Divestiture Trustee.

[35] The Respondents consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

- (a) Subject to oversight and approval by the Commissioner only, the Divestiture Trustee shall have the exclusive authority to control the process for the Divestiture of the Rolapitant Product Assets and, subject to this Agreement, to accomplish such Divestiture by whatever procedure the Divestiture Trustee believes in its sole discretion is suitable for completing such Divestiture within the Divestiture Trustee Sale Period, or such longer period as directed by the Commissioner.
- (b) The Respondents will not be included in the process for the Divestiture of the Rolapitant Product Assets, including negotiations, nor will the Respondents have contact with prospective Acquirers except with the prior approval of the

Commissioner; however, the Divestiture Trustee may consult with the Respondents in the presence of a representative of the Commissioner when the Divestiture Trustee considers such consultation to be appropriate and the Commissioner consents.

- (c) Notwithstanding any term of this Agreement, the Divestiture Trustee's obligations and powers under this Agreement shall not expire until the Divestiture of the Rolapitant Product Assets is completed.
- (d) The Divestiture Trustee shall execute a confidentiality agreement in a form determined by the Commissioner and shall refrain from communicating any Confidential Business Information to anyone except to the extent reasonably required to effect the Divestiture of the Rolapitant Product Assets.
- (e) The Commissioner may extend the Divestiture Trustee Sale Period as the Commissioner considers necessary, in her sole discretion, to effect the Divestiture of the Rolapitant Product Assets.
- (f) The Divestiture Trustee shall have, subject to any valid claim to a legally recognized privilege, full and complete access to the personnel, books, records and facilities related to the Rolapitant Product Assets and to any other information, including Confidential Business Information, deemed relevant by the Divestiture Trustee to effect the Divestiture of the Rolapitant Product Assets. The Respondents shall take no action to interfere with or impede the Divestiture Trustee's efforts to complete the Divestiture of the Rolapitant Product Assets.
- (g) The Respondents shall fully and promptly respond to all requests from the Divestiture Trustee and shall provide all information the Divestiture Trustee may request. The Respondents shall identify an individual who shall have primary responsibility for responding to such requests from the Divestiture Trustee on behalf of the Respondents.
- (h) The Divestiture Trustee shall use commercially reasonable efforts to negotiate favourable terms and conditions for the Divestiture of the Rolapitant Product Assets at that time, but, if necessary, shall sell the Rolapitant Product Assets at no minimum price. The Divestiture Trustee's opinion of what constitutes favourable terms and conditions is subject to the Commissioner's approval only.
- (i) The Divestiture Trustee shall have the sole authority to determine, and the Respondents shall provide, all reasonable and ordinary commercial covenants, representations, warranties and indemnities for the purpose of completing the Divestiture of the Rolapitant Product Assets.
- (j) The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of the Respondents, and on such reasonable and customary terms and conditions as the Commissioner may set.

- (k) The Respondents shall pay all reasonable invoices submitted by the Divestiture Trustee on a monthly basis. Any outstanding monies owed to the Divestiture Trustee by the Respondents shall be paid out of the proceeds of the Divestiture of the Rolapitant Product Assets.
- (l) The Divestiture Trustee shall have the authority to employ, at the expense of the 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 Commissioner of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondents, and the Divestiture Trustee's power shall be terminated.
- (m) The 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 or defence of any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from malfeasance, gross negligence or bad faith by the Divestiture Trustee.
- (n) If the Divestiture Trustee ceases to act or fails to act diligently or otherwise in accordance with this Agreement or any agreement between the Commissioner and the Divestiture Trustee, the Commissioner may appoint a substitute Divestiture Trustee in the same manner as provided in this part VI for the initial Divestiture Trustee.
- (o) The Divestiture Trustee shall have no obligation or authority to operate or maintain the Rolapitant Product Assets.
- (p) The Divestiture Trustee shall report in writing to the Commissioner and the Respondents every sixty (60) days, and upon the Commissioner's request within three (3) days, concerning the Divestiture Trustee's efforts to complete the Divestiture of the Rolapitant Product Assets. Such reports shall contain reasonable detail on the steps being taken by the Divestiture Trustee to complete the Divestiture of the Rolapitant Product Assets, including but not limited to: the identity of potential Acquirers; the status of negotiations with such potential Acquirers; and any additional information requested by the Commissioner.
- (q) The Divestiture Trustee shall notify the Commissioner of any proposed Divestiture of the Rolapitant Product Assets. Such notice shall include: the identity of the Proposed Acquirer(s); the details of the proposed Divestiture of the Rolapitant Product Assets; information concerning whether, in the view of the

Divestiture Trustee, the Proposed Acquirer(s) would likely satisfy the terms of this Agreement; and any additional information requested by the Commissioner.

- (r) The Divestiture Trustee shall only Divest the Rolapitant Product Assets to an Acquirer or Acquirers as approved in writing by the Commissioner.
- (s) If the Commissioner notifies the Divestiture Trustee that she has approved a proposed Divestiture of the Rolapitant Product Assets, the Divestiture Trustee shall forthwith notify the Respondents, in writing, of such proposed Divestiture of the Rolapitant Product Assets. Such notice shall include the identity of the Proposed Acquirer and the details of the proposed Divestiture of the Rolapitant Product Assets. Notwithstanding the foregoing, if the Divestiture Trustee receives bona fide offers from more than one Proposed Acquirer, and if the Commissioner determines to approve more than one such Proposed Acquirer, the Divestiture Trustee shall Divest the Rolapitant Product Assets to the Proposed Acquirer selected by the Respondents from among those approved by the Commissioner; provided further, however, that the Respondents shall select such Proposed Acquirer within five (5) days after receiving notification of the Commissioner's approval.
- (t) The Respondents may not object to or challenge the performance of the Divestiture Trustee's duties under this Agreement or Divestiture of the Rolapitant Product Assets by the Divestiture Trustee on any grounds other than the Divestiture Trustee's malfeasance, gross negligence or bad faith in executing its obligations hereunder. If the Respondents object to the terms and conditions of a Divestiture of the Rolapitant Product Assets that has been proposed by the Divestiture Trustee on the grounds of malfeasance, gross negligence or bad faith by the Divestiture Trustee, the Respondents or the Commissioner may apply to the Tribunal for directions, but in no event shall any such dispute serve to suspend the Divestiture Trustee Sale Period.

VII. FAILURE OF DIVESTITURE TRUSTEE SALE

[36] If the Divestiture Trustee has not effected the Divestiture of the Rolapitant Product Assets at the end of the Divestiture Trustee Sale Period (including any extensions), or if the Commissioner is of the opinion that the Divestiture of the Rolapitant Product Assets will not likely be completed prior to the end of the Divestiture Trustee Sale Period, the Commissioner may apply to the Tribunal for such order as is necessary to effect the Divestiture of the Rolapitant Product Assets.

[37] The Respondents agree that the Tribunal has jurisdiction to grant such relief as is required to give effect to this Agreement and complete the Divestiture of the Rolapitant Product Assets.

VIII. CONFIDENTIAL BUSINESS INFORMATION

[38] In addition to any other requirements and prohibitions relating to Confidential Business Information in this Agreement, the Respondents shall ensure that the 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 ensure the Respondents' compliance with any Remedial Agreement, this Agreement, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commissioner), 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 of the Rolapitant Product Assets;

provided, however, that the Respondents may disclose such information as necessary for the purposes set forth in this section pursuant to an appropriate confidentiality order, agreement or arrangement and provided further, however, that pursuant to this section the 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.

IX. REMEDIAL AGREEMENTS

- [39] Any Remedial Agreement shall be deemed incorporated into this Agreement.
- [40] Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Agreement.
- [41] Respondents shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commissioner.

X. COMPLIANCE

- [42] Within five (5) days of the Acquisition, the Respondents shall submit to the Commissioner a letter certifying the date on which the Acquisition occurred.
- [43] Within thirty (30) days after the Order Date and every sixty (60) days thereafter until the Respondents have fully complied with the following sections: 5, 8, 9, 10, 11, 13, and 17, the Respondents shall submit to the Commissioner 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 Agreement. The Respondents shall submit at the same time a copy of their report concerning compliance with this Agreement to the Monitor, if any Monitor has been appointed. The 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 Agreement, 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.

- [44] Each year, on the anniversary of the date of this Agreement, for so long as this Agreement remains in force, and at other times as the Commissioner may require, the Respondents shall file a verified written report with the Commissioner setting forth in detail the manner and form in which they have complied and are complying with this Agreement.
- [45] The Respondents shall notify the Commissioner 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 dissolution, acquisition, merger, consolidation, or change might affect compliance obligations arising out of this Agreement.
- [46] For purposes of determining or securing compliance with this Agreement, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to any Respondent, such Respondent shall, without restraint or interference, permit any duly authorized representative of the Commissioner:
- (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 Agreement, which copying services shall be provided by such Respondent at the request of the authorized representative(s) of the Commissioner 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.

XI. NOTIFICATION

- [47] Notices, reports and other communications required or permitted pursuant to any of the terms of this Agreement shall be in writing and shall be considered to be given if dispatched by personal delivery, registered mail or facsimile transmission to the parties as follows:
- (a) If to the Commissioner:

Competition Bureau
Place du Portage, 21st Floor
50 Victoria Street, Phase I
Gatineau, Quebec K1A 0C9
Attention: Commissioner of Competition
Fax: (819) 953-5013

With a copy to:

Executive Director and Senior General Counsel
Competition Bureau Legal Services
Justice Canada
Place du Portage, Phase I
50 Victoria Street
Gatineau, Quebec K1A 0C9

(b) If to the Respondents:

Merck & Co., Inc.
One Merck Drive
P.O. Box 100, WS3A-65
Whitehouse Station, New Jersey 08889-0100
Attention: Office of Secretary
Fax: (908) 735-1246

Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey 07033
Attention: Thomas Sabatino
Fax: (908) 298-7555

With a copy to:

Blake, Cassels & Graydon LLP
199 Bay Street
Suite 2800, Commerce Court West
Toronto, Ontario M5L 1A9
Attention: Calvin S. Goldman, Rob Kwinter and Navin Joneja
Fax: (416) 863-2653

or to such other street address, individual or electronic communication number or address as may be designated by notice given by any party to the other parties. Any demand, notice or other communication given by personal delivery will be conclusively deemed to have been given on the day of actual delivery and, if given by registered mail, on the fifth day following the deposit thereof in the mail and, if given by electronic communication, on the day of transmittal thereof if given during the normal business hours of the recipient and on the day during which such normal business hours next occur if not given during such hours on any day. If the party giving any

demand, notice or other communication knows or ought reasonably to know of any difficulties with the postal system that might affect the delivery of mail, any such demand, notice or other communication may not be mailed but must be given by personal delivery or by electronic communication.

XII. DURATION

[48] The Respondents shall be bound by the terms of this Agreement:

- (a) in respect of the obligations set forth in Part III of this Agreement, for a period of ten (10) years from the date of this Agreement; and
- (b) in respect of the obligations set forth hereunder relating to the Rolapitant Products and the Rolapitant Product Assets (specifically excluding the obligation set out in section 3(l)), until the Divestiture of the Rolapitant Product Assets is effected in accordance with this Agreement or further order of the Tribunal, and the related Product Manufacturing Technology has been fully transferred and delivered, or caused to be transferred and delivered, to the applicable Acquirer(s).

XIII. GENERAL

[49] The Respondents agree to the immediate registration of this Agreement with the Tribunal.

[50] Nothing in this Agreement (including the recitals hereto) precludes Merck, Schering-Plough, or the Merged Entity from bringing a future application under section 106 of the Act (or a successor or equivalent provision under the Act) to vary or rescind this Agreement on the grounds that the circumstances that led to the making of this Agreement have changed and the other requirements of section 106(1) of the Act are satisfied. The Respondents agree that they shall not, in any such application, contest the Commissioner's present conclusions that: (i) the Acquisition is likely to prevent or lessen competition substantially for the supply of NK-1 Receptor Antagonists for the prevention and treatment of CINV and PONV in humans, and that the divestiture of the Rolapitant Product Assets is necessary to ensure that such substantial lessening or prevention of competition will not result from the completion of the Acquisition; (ii) the Acquisition is likely to result in a substantial lessening or prevention of competition in certain animal health markets; and (iii) the exercise of the call right set out in the Call Option Agreement is likely to result in a substantial lessening or prevention of competition in certain animal health markets in Canada.

[51] This Agreement constitutes the entire agreement between the Commissioner and the Respondents and supersedes all prior agreements with respect to the subject matter hereof.

[52] This Agreement shall be governed by and interpreted in accordance with the laws of Ontario and the laws of Canada applicable therein.

- [53] Computation of time periods contemplated by this Agreement shall be in accordance with the *Interpretation Act*, R.S.C. 1985, c. I-21. For the purpose of this Agreement, the definition of “holiday” in the Interpretation Act shall be deemed to include Saturday.
- [54] Nothing in this Agreement abrogates the notification obligations set out in Part IX of the Act.
- [55] In the event of a dispute regarding the interpretation or application of this Agreement, any of the Commissioner, Merck, Schering-Plough, or the Merged Entity may apply to the Tribunal for an order interpreting any of the provisions of this Agreement. In the event of any conflict or inconsistency between the English language version of this Agreement and the French language version of this Agreement, such conflict or inconsistency shall be resolved in favour of the English language version of this Agreement.

[INTENTIONALLY LEFT BLANK]

[56] This Agreement may be executed in two or more counterparts, each of which shall be an original instrument, but all of which shall constitute one and the same Agreement.

The undersigned hereby agree to the registration of this Agreement.

DATED this 29th day of October, 2009.

[Original Signed by “Melanie L. Aitken”]

Melanie L. Aitken
Commissioner of Competition

MERCK & CO., INC.

By: [Original Signed by “Bruce N. Kuhlik”]
Name: Bruce N. Kuhlik,
Title: Executive Vice President and General Counsel

SCHERING-PLOUGH CORPORATION

By: [Original Signed by “Winston K.C. Lam”]
Name: Winston K.C. Lam
Title: Group Vice President & Associate General Counsel

**CONFIDENTIAL SCHEDULE “A”
ROLAPITANT PRODUCT DIVESTITURE AGREEMENT**

[CONFIDENTIAL]