1610077

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Maureen K. Ohlhausen
Terrell McSweeny

In the Matter of	)	
C.H. Boehringer Sohn AG & Co. KG **a corporation.**	)	**Docket No. C-**

business of Sanofi, and Respondent having been furnished thereafter with a copy of a draft of the Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having n2 TJ 0 -1.165 TD [(not)-2(c)-1(ons

G. “Acquirer” means the Companion Animal Products Acquirer or the Cydectin Products Acquirer.

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limitation, potency and microorganism cell protein assays); Master Cells; Master Seeds; hybridomas; antibodies; cell culture media and similar materials; nutrient feed for cells and microorganisms; challenge material; and references that Respondent is using, are suitable for use, has used, or is planning to use in the manufacture, use, Development, or commercialization of a Companion Animal Product or a Companion Animal Pipeline Product.

O. "Business" means the following: (i) the commercialization, distribution, marketing, importation, advertisement, and sale of a Product within the Geographic Territory and (ii) the research, Development, manufacture of such Product throughout the world for the purposes of the commercialization, distribution, marketing, importation, advertisement and sale of such Product within the Geographic Territory.

P. "Clinical Trial(s)" means a controlled study in animals, including the target species with respect to a particular Product, of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other animal study used in research and Development of Divestiture Products.

Q. "Companion Animal Pipeline Products" means all Products (other than Companion Animal Products, Solo-Jec Products or Products containing the antigen produced from the Master Seeds used in the Naramune Products) that are in Development by Respondent as of the Acquisition Date or were in Development (whether or not such Development has been discontinued) by Respondent at any time within the five (5) year period immediately preceding the Acquisition Date for use in the Geographic Territory in the following Fields:

1. the following diseases, pathogens, viruses, and bacterium within canines: Adenoviruses, bordetellosis, borreliosis (Lyme disease), coronavirus, canine distemper virus (CDV), leptospirosis, parvovirus, and parainfluenza virus:
2. the following diseases, pathogens, viruses and bacterium within felines: calicivirus, chlamydia, feline immunodeficiency virus, feline leukemia, panleukopenia, feline viral rhinotracheitis; and
3. rabies.

R. "Companion Animal Products" means the following Products sold by Respondent in the Geographic Territory prior to the Acquisition for use with the following diseases, pathogens, viruses and bacterium:

i) within canines: adenoviruses, bordetellosis, borreliosis (Lyme disease), coronavirus, canine distemper virus (CDV), leptospirosis, parvovirus, and parainfluenza virus;

ii) within felines: calicivirus, chlamydia, feline immunodeficiency virus, feline leukemia, panleukopenia and feline viral rhinotracheitis; and

iii) rabies;

c) that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the virus that causes feline viral rhinotracheitis (FVR),

d) that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the Chlamydia psittaci bacterium,

e) that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the virus that causes feline leukemia virus (FeLV), and

f) that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the feline immunodeficiency virus;

5. LeptoVax Products, meaning all Products (other than Solo-Jec Products) that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the Leptospira bacterium, including without limitation, Leptospira grippotyphosa, Leptospira icterohaemorrhagiae, Leptospira canicola, and Leptospira pomona; and

6. Rabvac Products, meaning all Products that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the rabies virus marketed and sold by Respondent for use in animals prior to the Acquisition.

S. "Companion Animal Products Acquirer" means Elanco or any other Person approved by the Commission to acquire the Companion Animal Products Assets pursuant t3 t3 ts pu3.g3to.001 T

2. Fort Dodge License Agreement by and among Boehringer Ingelheim Vetmedica, Inc., Boehringer Ingelheim Vetmedica GMBH, and Elanco US Inc.;

3. Fort Dodge Services Agreement by and between Boehringer Ingelheim Vetmedica, Inc. and Elanco US Inc.;

4. St. Joseph Transitional Packaging Services Agreement; and

5. St. Joseph Transitional Manufacturing and Supply Agreement by and between Boehringer Ingelheim Vetmedica, Inc. and Elanco US Inc. as it relates to the Naramune Products and the canine parainfluenza antigen to be transferred to Fortiiand 2(n).07-0.

or Companion Animal Pipeline Products) that relates to the Companion Animal Products Business or the Companion Animal Products Facility,

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

AA. "Component(s)" means any active ingredient, Antigen, nucleic acids encoding an Antigen, adjuvant, and/or other component of a Product that is intended to affect the efficacy or safety of an active ingredient of such Product; provided however, that Respondent may retain the right, concurrently with the Acquirer's rights, to use adjuvants and excipients that are used in Divestiture Products and Retained Products.

BB. "Contract Manufacture Products" means the Companion Animal Products for which Respondent provides finish, fill, and/or packaging services pursuant to a Remedial Agreement.

CC. "Contract Manufacture" means the finish, fill, and/or packaging of a Companion Animal Divestiture Product by Respondent on behalf of the Companion Animal Products Acquirer.

DD. "Confidential Business Information" means all information owned by, or in the possession or control of, Respondent that is not in the public domain and that is directly related to the conduct of the Business of a specified Divestiture Product. Confidential Business Information does not include the following:

1. information relating to Respondent's general business strategies or practices that does not discuss with particularity the specified Divestiture Product;
2. information contained in documents, records, or books that is provided to an Acquirer by Respondent that is unrelated to the Divestiture Product;
3. Information prepared in connection with the Acquisition that relates to the antitrust or competition Laws of any Governmental Entity and that is protected from disclosure by attorney work-product, attorney-client, joint defense, or other privilege.

EE. "Cydectin Pipeline Products" means all Products in Development by Respondent prior to the Acquisition Date and all Products (other than the Cydectin Products) that were in Development (whether or not such Development has been discontinued) by Respondent at any time within the five (5) year period immediately preceding the Acquisition Date for use in the Geographic Territory that contain the active pharmaceutical ingredient moxidectin.

FF. "Cydectin Products" means all Products manufactured, marketed, or sold by Respondent within the Geographic Territory prior to the Acquisition for use in bovines or sheep that contain the active pharmaceutical ingredient generically known as moxidectin, together with any salts, esters, metabolites, derivatives, isomers, hydrates, solvates, ethers, quaternary amines, polymorphs and prodrugs thereof.

GG. "Cydectin Products Acquirer" means Bayer or any other Person approved by the Commission to acquire the Cydectin Product Assets pursuant to this Order.

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5. all Product Manufacturing Technology;

6. all Product Marketing Materials;

7. all Website(s) related exclusively to the Divestiture Products divested to the same Acquirer and all content related exclusively to such Divestiture Products displayed on any other Website;

8. a list of all of the Product Code Numbers, and rights, to the extent permitted by Law:

    a) to require Respondent to discontinue the use of those Product Code Numbers other than with respect to returns, rebates, allowances, and adjustments for Divestiture Products sold prior to the Acquisition Date,

    b) to prohibit Respondent from seeking from any customer any type of cross-referencing of those Product Code Numbers with any Retained Products,

    c) to seek to change any cross-referencing by a customer of those Product Code Numbers with any Retained Products (including the right to receive notification from Respondent of any such cross-referencing that is discovered by Respondent),

    d) to seek cross-referencing from a customer of those Product Code Numbers with the relevant Acquirer's Product Code Numbers,

    e) to approve the timing of Respondent's discontinued use of those Product Code Numbers in the sale or marketing of Products other than with respect to returns, rebates, allowances, and adjustments for Companion Animal Products sold prior to the Acquisition Date, and

    f) to approve any notification(s) from Respondent to any customer(s) regarding the use or discontinued use of such Product Code Numbers by Respondent prior to such notification(s) being disseminated to the customer(s);

9. all rights to all Applications or Veterinary Biological Product Authorization(s), as applicable, and the related Master Files, including without limitation, the pharmacology and toxicology data contained in all Application(s) or Veterinary Biological Product Authorization(s);

10. all Product Development Reports and research data and test results;

11. at the Acquirer's option, all Product Assumed Contracts (copies to be provided to the Acquirer on or before the relevant Divestiture Closing Date);

12. all strategic safety programs submitted to the FDA or USDA, as applicable, that are designed to decrease p(s)-1(s)(ev)1(el)3(e)-1(a)1(s)-14s ans2(eu-1(r)upl)3(i)-<</MCID 131(r

required to be maintained by the FDA or USDA, as applicable, to facilitate the investigation of adverse effects;

14. a list identifying each customer and targeted customer (other than High Volume Accounts) and providing the net sales (in either units or dollars) of the Divestiture Product on an annual basis for 2014 and 2015 and on a monthly basis for 2016;

15. a list identifying each High Volume Account and providing the following information regarding the High Volume Account:

    a) the name and business contact information for the employee(s) that is or has been responsible for the purchase of the specified Divestiture Product,

    b) providing the net sales (in either units or dollars) of the Divestiture Product on an annual basis for 2014 and 2015 and on a monthly basis for 2016,

    c) inventory levels (weeks of supply) as of the Companion Animal Closing Date or Cydectin Product Closing Date, as applicable, and

    d) the anticipated reorder date of the Divestiture Product;

16. at the relevant Acquirer's option and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods;

17. copies of all unfilled customer purchase orders for such Divestiture Product as of the Closing Date, to be provided to the relevant Acquirer not later than five (5) days after the Closing Date; and

18. all of the Respondent's books, records, and files directly related to the foregoing or to such Divested Product;

provided, however, that Divestiture Products, Divested Assets, [illegible]

circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that Respondent provides the Acquirer with the above-described information without requiring Respondent completely to divest itself of information that, in content, also relates to the Retained Products.

TT. "Divestiture Pipeline Products" means the Cydectin Pipeline Products and the Companion Animal Pipeline Products.

UU. "Divestiture Product(s)" means the Cydectin Products, the Cydectin Pipeline Products, the Companion Animal Products and the Companion Animal Pipeline Products, individually and collectively.

VV. "Divestiture Product Releasee(s)" means the Acquirer for the assets related to a particular Divestiture Product or any Person controlled by or under common control with such Acquirer, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of such Acquirer, or of such Acquirer-affiliated entities.

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

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DDD. “Master Cell(s)

consumables, list of equipment, solution recipes, process set points, and sampling requirements),

e) Cell Culture Process Development Reports (i.e., summary of experiments performed during development of the cell culturing process),

f) Harvest Process Development Reports (i.e., summary of experiments performed during development of the harvesting process),

g) Purification Process Development Reports (i.e., summary of experiments performed during development of the purification process),

h) Formulation Process Development Reports (i.e., summary of experiments performed during development of the formulation process),

i) Viral Clearance Study In-House and Contract Lab Reports (i.e., summary of viral clearance/inactivation study results and conclusions (i.e., total logs clearance)),

j) Drug and Biological Substance Specification (i.e., the quality assurance approved drug substance specification and biological quality standards for all Components),

k) Drug and Biological Substance Process Raw Materials Documentation (including: list of raw materials used for drug and biological substance manufacturing and verification of origin, including specifications and risk assessment),

l) Batch Records for Agency Manufacturing Standards - Purification (i.e., executed and released batch records, including in-process controls and testing results),

m) Batch Records for Agency Manufacturing Standards - Formulation (i.e., executed and released batch records, including in-process controls and testing results),

n) Drug Substance Stability Reports (including: summary of drug substance stability), and

o)

4. Analytical Methods for Technical Transfer: potency, identity, and safety assay development report detailing the development and qualification of the assay; potency and safety assay transfer protocol, detailing responsibilities, procedures, and criteria for transfer success; and potency assay transfer report summarizing the results of the transfer.

MMM. "Product(s)" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound that is referenced as the composition's pharmaceutically, biologically, or genetically active ingredient.

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

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

1. pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the Divestiture Product from the Respondent;

2. pursuant to which Respondent purchases or had planned to purchase the active pharmaceutical ingredient, Biological Manufacturing and Testing Materials, Components, or other necessary ingredient from any Third Party for use in connection with the manufacture of the Divestiture Product;

3. relating to any Clinical Trials involving the Divestiture Product;

4. with universities or other research institutions for the use of the Divestiture Product in scientific research;

5. relating to the particularized marketing of the Divestiture Product or educational matters relating solely to one or more Divestiture Products;

6. pursuant to which a Third Party manufactures or packages the Divestiture Product on behalf of Respondent;

7. pursuant to which a Third Party provides the Product Manufacturing Technology related to the Divestiture Product to Respondent;

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

9. constituting confidentiality agreements involving the Divestiture Product;

10. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the Divestiture Product;

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

12. pursuant to which any Third Party collaborates with Respondent in the performance of research, Development, marketing, distribution or selling of the Divestiture Product or the Divestiture Product business;

provided, however, that where any such contract or agreement also relates to a Retained Product or other assets not being divested to an Acquirer, Respondent shall provide to the Acquirer all rights under the contract or agreement that are related to Divestiture Products, but concurrently may retain similar rights with respect to the Retained Products or other assets.

PPP. "Product Code Numbers means:

1. for the Cydectin Products, the National Drug Code ("ND

laboratory notebooks relating to the Divestiture 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; all correspondence with the FDA; and all correspondence with the USDA.

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

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

provided, however, "Product Intellectual Property" does not include the corporate names or corporate trade dress of Respondent or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by Respondent or the related logos thereof.

TTT. "Product Improvements" means all of the following that are in existence as of the Divestiture Closing Date for the relevant Divestiture Product:

1. for Companion Animal Products and Companion Animal Pipeline Products, any new, improved or modified composition, formulation or line extension of, or derived from, a Companion Animal Product or Companion Animal Pipeline Product (including, without limitation, the addition, subtraction, substitution and/or modification of one or more Components in an Companion Animal Products or Companion Animal Pipeline Product), including, without limitation, the following:

   a) the combination of one or more such Components with other Components,

   b) the substitution of a Component in a Companion Animal Product or Companion Animal Pipeline Product with a different Component (e.g., without limitation, substitution with an Antigen from the same or a different virus, bacterin, substitution of one strain of virus/bacterium for another, substitution of an Antigen with a nucleic acid encoding an Antigen, substitution of an Antigen by a recombinant Antigen with a nucleic acid encoding an Antigen, and/or substitution of an Antigen by a recombinant Antigen in a viral vector such as baculo-virus vector), and/or

   c) modification of a Component in a Companion Animal Product or Companion Animal Pipeline Product (e.g., without limitation, modifying the Antigen/virus used in a Product by mutation, chimerization, et0 Td tuomie/bactnion A

UUU. “Product Manufacturing Technology” means:

1. all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of a Divestiture Product, including, but not limited to, the following: compositions; product specifications; processes; product designs and plans; trade secrets, ideas and concepts; manufacturing, engineering, and other manuals and drawings; standard operating procedures and flow diagrams; chemical and research records; cell culture processes (including all cell culture processes developed or being developed for use in such manufacture, and results of all experiments used to evaluate such processes); product preparation (including vial thaw and inoculum preparation), synthesis, culture (including fed-batch bioreactor culture), recovery and purification (including chromatography and filtration steps); product formulation (including concentration, buffer exchange, and excipient addition); safety, quality assurance and quality control processes, techniques and specifications; analytical methods for process controls and drug substance release; clinical data; a

WWW. "Product Marketing Employees" means management level employees of Respondent who participate in the marketing, contracting, or promotion of Products in the Geographic Territory or have so participated during the eighteen (18) month period immediately prior to the Acquisition Date. These employees include, without limitation, all management level employees having any responsibilities in the areas of sales management, brand management, sales training, market research, veterinary market and other specialty markets, and exclude administrative assistants.

XXX. "Product Research and Development Employees" means salaried employees of Respondent who directly participate in the research, Development, or regulatory approval process, or clinical studies of Products or so participated during the eighteen (18) month period immediately prior to the Closing Date, unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance.

YYY. "Product Sales Employees" means employees of Respondent who directly participate in detailing, marketing or promotion of Products in the Geographic Territory directly to veterinarians, animal breeders, and/or professional distributors, or have so participated during the twelve (12) month period immediately prior to the Acquisition Date.

ZZZ. "Product Trade Dress" means the current trade dress of the Divestiture Product, including without limitation, Product packaging, and the lettering of the Product trade name or brand name.

AAAA. "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 Divestiture Product(s). The term "Product Trademarks" includes, without limitation, all trademarks specifically identified in the definition of Companion Animal Products and Cydectin Products, and any variations of such trademarks.

BBBB. "Proposed Acquirer" means a Person proposed by Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by Respondent

amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final;

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

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

DDDD. "Retained Product" means any Product of Respondent, including a pipeline Product, that is not a Divestiture Product.

EEEE. "Solo Jec Products" means Products referred to on Schedule 1.01(f) of the Fort Dodge Asset Purchase Agreement by and among Boehringer Ingelheim Vetmedica, Inc. and Elanco US Inc. and Eli Lilly and Company (solely for the purposes of Section 12.16).

FFFF. "Supply Cost" means a cost not to exceed the manufacturer's average direct per unit cost in United States dollars of manufacturing the Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date. "Supply Cost" shall expressly exclude any intracompany business transfer profit; provided, however, that in each instance where: (1) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, "Supply Cost" means the cost as specified in such Remedial Agreement for that Divesti(e) 2(r t)5(h)3t DivnhT1 1 Tf1 Tf1 Tf(" m)3(u)1.1(r)-.13c(pr)hm(

3. preparing and implementing a detailed technological transfer plan that contains, inter alia

II.

F. Respondent shall:

1. submit to the Companion Animal Acquirer, at Respondent's expense, all Confidential Business Information related to the Companion Animal Products, the Companion Animal Pipeline Product, the Companion Animal Facility or the Companion Animal Products Business ("Companion Animal Confidential Information");

2. deliver the Companion Animal Confidential Information to the Companion Animal Products Acquirer in good faith, in a timely manner, i.e., as soon as practicable, avoiding any delays in transmission of the respective information; and in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;

3. pending complete delivery of all Companion Animal Confidential Information, provide the Companion Animal Products Acquirer and the Monitor with access to the Companion Animal Confidential Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files that contain Companion Animal Confidential Information, and facilitating the delivery of the Companion Animal Confidential Information in a manner consistent with this Order;

4. on or before the Companion Animal Products Closing Date, and as a condition of continued employment, require that each employee whose respolsenb-1(aly4 -1.1)2(ho28.2101 T

Products Acquirer with copies of all certifications, notifications, and reminders sent to Respondent's personnel.

G. Respondent shall

Product or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by the Companion Animal Acquirer;

3. not make any counteroffer to any Companion Animal Products Employee who has received a written offer of employment from the Companion Animal Acquirer; and

4. not directly or indirectly, hire,

2. make representations and warranties to the Companion Animal Products Acquirer that each Contract Manufacture Product supplied by the Respondent meets the relevant Agency-approved specifications. Respondent shall agree to indemnify, defend, and hold the Companion Animal Products Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to result from the failure Respondent to meet cGMP in the of a Contract Manufacture Product supplied to the Companion Animal Products Acquirer pursuant to a Remedial Agreement to meet cGMP. This obligation may be made contingent upon the Companion Animal Products Acquirer giving the Respondent prompt written notice of such claim and cooperating fully in the defense of such claim;

provided, however, that in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on Respondent's aggregate liability to the Acquirer for such a breach; for s toh if (1) an aRe(ec)5(i)-0c 01(s i)-1(s)5(s2o di)-2(ve5(su)1.1(i)ity)i-2(j
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7. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Monitor to monitor compliance with the obligations to Contract Manufacture.

The foregoing provisions shall remain in effect with respect to each Contract Manufacturer Product until the date the Companion Animal Products Acquirer is able to finish, fill, and package the Product in commercial quantities, in a manner consistent with Agency and Manufacturing Standards, independently of Respondent.

K. Respondent shall cease having the Naramune Products manufactured at the Companion Animal Products Facility as soon as practicable after the Companion Animal Closing Date, and in no event later than one year after the Companion Animal Closing Date.

L. Until Respondent completes the divestiture of the Companion Animal Products Assets (including fully providing Product Manufacturing Technology to the Companion Animal Acquirer) Respondent shall take all actions necessary to:

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provided, however, that if Respondent has divested the Cydectin Product Assets and granted the Cydectin Product License to Bayer p intin

Confidential Information, and the direct supervisor

provided that, Respondent [illegible] cnt)]t0ccvTJ

of the Cydectin Product(s) and to ensure successful execution of the pre-Acquisition plans for such Cydectin Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent until the Cydectin Product Closing Date, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law).

J. Until Respondent completes the divestiture of the Cydectin Product Assets (including fully providing Product Manufacturing Technology to the Cydectin Acquirer) Respondent shall take all actions necessary to:

1. maintain the full economic viability and marketability of the Business associated with the Cydectin Products;

2. minimize any risk of loss of competitive potential for that Business;

3. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to the Cydectin Products;

4. ensure the assets related to the Cydectin Products are provided to the Cydectin Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the associated Business; and

5. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology.

K. Respondent shall not sell, transfer, encumber, or otherwise impair the Cydectin Product Assets (other than in the manner prescribed in this Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the Business related to the Cydectin Products.

IV.

IT IS FURTHER ORDERED that

A. Respondent shall:

1. not use, direct5 0 Tdw -1-11.0.eFU73dld d3(m)3(pa)-1i(t)-2(s)lcB(e)1s1(y, o)5((m)8(pl)-2(e)-2.1

Divestiture Product to the marketing or sales employees associated with the Business related to those Retained Products

directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into , or the supply, distribution, sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer. The provisions of this Paragraph do not apply to any Patent owned by, acquired by, or licensed to or from the Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date.

C. Upon reasonable written notice and request from an Acquirer to Respondent, Respondent shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, or the supply, distribution, sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired

E.

C. The Monitor's duties and responsibilities shall include the following:

1. The Monitor shall act in a fiduciary capacity for the benefit of the Commission;

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

3. The Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities; and

4. The Monitor shall evaluate the reports submitted to the Commission by any Respondent pursuant to this Order, the Order to Maintain Assets, and the Consent Agreement, and within thirty (30) days from the date the Monitor receives a report, report in writing to the Commission concerning the performance by Respondent of its obligations under the Orders, including without limitation the transfer of Naramune-2 manufacturing from the Companion Animal Products Facility and the completion of the Fill and Packaging Improvements.

D. Respondent shall grant and transfer to the Monitor, and such Monitor shall have, all rights, powers, and authority necessary to carry out the Monitor's duties and responsibilities, 2(y)5(oor 2s(l)-2(, gw)-1(n n44d, gw5 (i)c5i65 (i)c5i65 , gs2(t)-2(o a)-1(n)5(y -2(r)-

Attorney General brings an action pursuant to Section 5(l

however, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.

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

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

E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.

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

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

VII.

IT IS FURTHER ORDERED that

A. It shall not be violation of this Order for Respondent's counsel (including in house counsel under appropriate confidentiality arrangements) to retain documents or other materials provided to an Acquirer, or access original documents provided to an Acquirer to:

1. assure Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or

2. to defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and Businesses associated with those Divestiture Products,

so long as copies of such documents are insufficient or otherwise unavailable, Respondent requires those who view such un-redacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and Respondent uses best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VIII.

IT IS FURTHER ORDERED that:

A. Any Remedial Agreement shall be incorporated by reference into this Order and made a part hereof, and Respondent shall comply with all terms of the Remedial Agreement. A breach by Respondent of any term of a Remedial Agreement shall constitute a violation of this Order.

B. A Remedial Agreement shall not limit or contradict, or be construed to limit or contradict, the terms of this Order and nothing in this Order shall be construed to reduce any rights or benefits of the Acquirer or to reduce any obligations of Respondent under any Remedial Agreement. To the extent that any term of a Remedial Agreement conflicts with a term of this Order such that Respondent cannot fully comply with both, Respondent shall comply with the term of this Order.

C. Respondent shall not modify, replace or extend the terms of a Remedial Agreement without thth of of

thereafter until Respondent has fully complied with Paragraphs II and III, setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order.

Order, which copying services shall be provided by Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and

2. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

XII.

IT IS FURTHER ORDERED that this Order shall terminate on the date ten (10) years after the date this Order is issued.

By the Commission.

Donald S. Clark
Secretary

SEAL

ISSUED:

In re C.H. Boehringer Sohn AG & Co. KG

C-

Appendix A

Monitor Agreement

In re C.H. Boehringer Sohn AG & Co. KG

C-

CONFIDENTIAL Appendix A-1

Exhibit to the Monitor Agreement

[Redacted From the Public Record Version,

But Incorporated By Reference]

In re C.H. Boehringer Sohn AG & Co. KG

C-

CONFIDENTIAL Appendix B

In re C.H. Boehringer Sohn AG & Co. KG

C-

CONFIDENTIAL Appendix C

Cydectin Products Divestiture Agreements

[Redacted From the Public Record Version,

But Incorporated By Reference]