

Complaint

IN THE MATTER OF

C.H. BOEHRINGER SOHN AG & CO. KGCONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT*Docket No. C-4601; File No. 161 0077**Complaint, December 28, 2016 – Decision, February 14, 2017*

This consent order addresses the \$13.53 billion acquisition by C.H. Boehringer Sohn AG & Co. KG of certain assets of Sanofi. The complaint alleges that the Acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act in the U.S. markets for two types of animal health products: (1) companion animal vaccines, which include various canine, feline, and rabies vaccines, and (2) cattle and sheep parasiticides. The consent order requires Boehringer Ingelheim to divest its relevant U.S. companion animal vaccine business to Eli Lilly and Company, which participates in the animal health industry through its Elanco Animal Health division and its U.S. Cydectin parasiticide product to Bayer AG.

Participants

For the *Commission*: Michael R. Barnett, Stephanie Bovee, and Yan Gao.

For the *Respondent*: Ryan Foley and William A. Henry, Baker Botts LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent C.H. Boehringer Sohn AG & Co. KG (“Boehringer Ingelheim”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire the Merial Animal Health business (“Merial”) from Sanofi, a corporation subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that

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a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENT

1. Respondent Boehringer Ingelheim is a corporation organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany, with its headquarters address located at Binger Strasse 173, 55216, Ingelheim am Rhein, Germany, and the address of its United States subsidiary, Boehringer Ingelheim Vetmedica, Inc., located at 3902 Gene Field Rd., St. Joseph, Missouri 64506.

2. Respondent Boehringer Ingelheim is engaged in, among other things, the research, development, manufacture, distribution, and sale of human pharmaceutical products, as well as animal health products through its Boehringer Ingelheim Vetmedica, Inc. division.

3. Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is a company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE ACQUIRED COMPANY

4. Sanofi is a corporation organized, existing and doing business under and by virtue of the laws of the French Republic, with its headquarters address located at 54, rue La Boétie, 75008, Paris, France, and the address of its United States subsidiary, Sanofi US, located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

5. Sanofi is engaged in, among other things, the research, development, manufacture, distribution, and sale of human pharmaceutical products, as well as animal health products through its Merial Animal Health division.

6. Sanofi is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is a company

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whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

III. THE PROPOSED ACQUISITION

7. Pursuant to an Exclusivity Agreement dated December 15, 2015, Boehringer Ingelheim proposes to swap its consumer health care business for Sanofi’s Merial animal health business (the “Acquisition”). In the proposed swap, Boehringer Ingelheim obtains Merial, valued at \$13.53 billion, and Sanofi obtains Boehringer Ingelheim’s Consumer Health Care business unit, valued at \$7.98 billion, as well as cash compensation of \$5.54 billion. The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

IV. THE RELEVANT MARKETS

8. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the research, development, manufacture, and sale of:

- a. canine vaccines for the prevention of disease caused by canine distemper virus, canine parvovirus, leptospirosis, canine adenovirus, canine parainfluenza virus, canine coronavirus, borreliosis (“Lyme disease”), and/or *Bordetella bronchiseptica* bacterium;
- b. feline vaccines for the prevention of disease caused by panleukopenia, calicivirus, viral rhinotracheitis, *Chlamydia psittaci* bacterium, and/or feline leukemia;
- c. companion animal vaccines for the prevention of rabies virus;
- d. macrocyclic lactone cattle parasiticides; and
- e. macrocyclic lactone sheep parasiticides.

9. For the purposes of this Complaint, the United States is the relevant geographic area in which to assess the competitive effects of the Acquisition in the relevant lines of commerce.

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V. THE STRUCTURE OF THE MARKETS

10. The markets for canine vaccines in the United States are highly concentrated. Boehringer Ingelheim, Merial, Zoetis, Inc. (“Zoetis”), and Merck & Co. (“Merck”) are the only four companies offering or likely to offer canine vaccines for the prevention of canine distemper virus, canine parvovirus, leptospirosis, canine adenovirus, canine parainfluenza virus, canine coronavirus, Lyme disease, and/or *Bordetella bronchiseptica* bacterium in the United States. In 2015, Boehringer Ingelheim, Merial, Zoetis, and Merck had shares representing approximately 30%, 11%, 35%, and 24%, respectively, of all canine vaccines sold in the United States and comparable shares in each relevant market, except *Bordetella bronchiseptica* bacterium, where Merial is the next likely entrant. The proposed transaction would reduce the number of current or likely competitors in each market from four to three.

11. The markets for feline vaccines in the United States are highly concentrated. Boehringer Ingelheim, Merial, Zoetis, and Merck are the only four companies offering feline vaccines for the prevention of panleukopenia, calicivirus, viral rhinotracheitis, *Chlamydia psittaci* bacterium, and/or feline leukemia in the United States. In 2015, these four companies represented approximately 28%, 33%, 16%, and 23%, respectively, of all feline vaccines sold in the United States and comparable shares in each relevant market. The proposed transaction would combine the two leading feline vaccine suppliers, reducing the number of competitors in each market from four to three.

12. The market for rabies vaccines in the United States is highly concentrated. Boehringer Ingelheim, Merial, Zoetis, and Merck are the only four significant suppliers of rabies vaccines in the United States, with market shares of 10%, 65%, 13%, and 12%, respectively.

13. The market for macrocyclic lactone cattle parasiticide in the United States is highly concentrated. Boehringer Ingelheim, Merial, and Zoetis are the three primary participants in the macrocyclic lactone cattle parasiticide market. Merial offers three brands: Ivomec, Eprinex, and LongRange that collectively accounted for 45% of the macrocyclic lactone cattle parasiticide

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market in 2015. Boehringer Ingelheim's Cydectin, a parasiticide that is functionally identical to Ivomec and Eprinex for beef cattle, accounted for 22% of the macrocyclic lactone cattle parasiticide market in 2015. Zoetis offers Dectomax, a macrocyclic lactone similar to Merial's and Boehringer Ingelheim's products, which accounted for 17% of macrocyclic lactone cattle parasiticide sales in 2015. Eprinex and Cydectin are the only two macrocyclic lactone cattle parasiticides with a "zero-day milk withhold" required for dairy cattle. The Acquisition would consolidate the most significant competitors in the macrocyclic lactone cattle parasiticide market, would produce a single firm controlling more than 65% of the relevant market, and would consolidate the only two suppliers of "zero-day milk withhold" macrocyclic lactone cattle parasiticides.

14. The parties are the two primary suppliers of macrocyclic lactone sheep parasiticides. Boehringer Ingelheim offers Cydectin Oral Drench, and Merial offers Ivomec Oral Drench. In 2015, Cydectin Oral Drench and Ivomec Oral Drench approximated 57% and 22%, respectively, of total sales in the United States. Following the acquisition, the merged firm would control more than 78% of this market.

VI. ENTRY CONDITIONS

15. Entry into the relevant markets described in Paragraph 8 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. *De novo* entry would require significant investment to, among other things, develop products, obtain regulatory approvals, and effectively establish recognized brands. Entry would be unlikely because the required investment would be difficult to justify given the sales opportunities in the affected markets. Entry would also not be timely because drug development times and FDA or USDA approval requirements are lengthy. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition.

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VII. EFFECTS OF THE ACQUISITION

16. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, by, among other things:

- a. eliminating actual or future, direct, and substantial competition between Boehringer Ingelheim and Merial in the relevant markets;
- b. increasing the likelihood that the merged entity will unilaterally exercise market power in the relevant markets;
- c. increasing the likelihood of coordinated interaction between or among suppliers in the relevant markets;
- d. increasing the likelihood that consumers would be forced to pay higher prices or accept reduced service.

VIII. VIOLATIONS CHARGED

17. The Exclusivity Agreement described in Paragraph 7 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

18. The Acquisition described in Paragraph 7, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-eighth day of December, 2016, issues its Complaint against said Respondents.

By the Commission.

Order to Maintain Assets

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent C.H. Boehringer Sohn AG & Co. KG of the animal health 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 thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of the Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

1. Respondent C.H. Boehringer Sohn AG & Co. KG is a corporation organized, existing, and doing business under and by virtue of the laws of Germany with its headquarters address at Binger Strasse 173, Ingelheim am Rhein, Germany, 55216 and the address of its United States subsidiary, Boehringer Ingelheim Vetmedica, Inc., located at 3902 Gene Field Rd., St. Joseph, Missouri 64506.

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2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, and the proceeding is in the public interest.

ORDER TO MAINTAIN ASSETS**I.**

IT IS ORDERED that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. “Boehringer” means C.H. Boehringer Sohn AG & Co. KG, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Boehringer, including but not limited to Boehringer Ingelheim Vetmedica, Inc. (“BIVI”) and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Boehringer shall include Merial.
- B. “BIVI” means Boehringer Ingelheim Vetmedica, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Boehringer Ingelheim Vetmedica, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Commission” means the Federal Trade Commission.
- D. “Decision and Order” means the:
 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and

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2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission in this matter.
- E. “Decision and Order” means the Decision and Order incorporated into and made a part of the Agreement Containing Consent Orders.
- F. “Monitor” means any monitor appointed pursuant to Paragraph V of this Order to Maintain Assets or Paragraph V of the Decision and Order.
- G. “Orders” means the Decision and Order and this Order to Maintain Assets.

II.**IT IS FURTHER ORDERED** that:

- A. Until Respondent completes the divestiture of the Companion Animal Product Assets (including fully providing Product Manufacturing Technology to the Companion Animal Acquirer) Respondent shall take all actions necessary to:
1. maintain the full economic viability and marketability of the Business associated with the Companion Animal 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 Companion Animal Products;
 4. ensure the assets related to the Companion Animal Products are provided to the Companion Animal Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the associated Business; and

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5. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology.
- B. Respondent shall not sell, transfer, encumber, or otherwise impair the Companion Animal 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 Businesses related to the Companion Animal Products, and shall continue in the same manner all current and planned capital expenditure plans and products.
- C. Respondent shall:
1. on or before the Companion Animal Product Closing Date, and as a condition of continued employment, require that each employee whose responsibilities (in whole or part) includes sales or marketing and who has or may have had access to Companion Animal Confidential Information, and the direct supervisor(s) of each such employee, sign a confidentiality agreement pursuant to which the employee is required to maintain the confidentiality of the Companion Animal Confidential Information and not disclose it to other employees, executives, or other personnel of Respondent (other than as necessary to comply with the requirements of this Order). Respondent shall maintain complete records of signed confidentiality agreements at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming that all confidentiality agreements have been signed; and
 2. not later than thirty (30) days after the Companion Animal Closing Date, provide written notification of the restrictions on the use and disclosure of Companion Animal Confidential Information to all of its employees who may be in possession of or

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have access to Companion Animal Confidential Information. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Companion Animal Closing Date. Respondent shall provide a copy of the notification to the Companion Animal Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondent shall provide the Companion Animal Product Acquirer with copies of all certifications, notifications, and reminders sent to Respondent's personnel.

- D. Until the Companion Animal Closing Date, Respondent shall provide all Companion Animal Product Employees with reasonable financial incentives to continue in their positions and to research, Develop, market, sell, and manufacture the Companion Animal Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Companion Animal Product(s) and to ensure successful execution of the pre-Acquisition plans for such Companion Animal Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent until the Companion Animal Product Closing Date, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law).

III.[Cydectin]**IT IS FURTHER ORDERED** that:

- A. Until Respondent completes the divestiture of the Cydectin Product Assets (including fully providing Product Manufacturing Technology to the Cydectin

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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.
- B. 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.
- C. Respondent shall:
1. on or before the Cydectin Product Closing Date, and as a condition of continued employment, require that each employee whose responsibilities (in whole or part) includes sales or marketing and who has or may have had access to Cydectin Confidential Information, and the direct supervisor(s) of each such employee, sign a confidentiality agreement pursuant to which the employee is required to maintain the

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confidentiality of the Cydectin Confidential Information and not disclose it to other employees, executives, or other personnel of Respondent (other than as necessary to comply with the requirements of this Order). Respondent shall maintain complete records of signed confidentiality agreements at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming that all confidentiality agreements have been signed; and

2. not later than thirty (30) days after the Cydectin Closing Date, provide written notification of the restrictions on the use and disclosure of Cydectin Confidential Information to all of its employees who may be in possession of or have access to Cydectin Confidential Information. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Cydectin Closing Date. Respondent shall provide a copy of the notification to the Cydectin Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondent shall provide the Cydectin Product Acquirer with copies of all certifications, notifications, and reminders sent to Respondent's personnel.

- D. Until the Cydectin Closing Date, Respondent shall provide all Cydectin Products Employees with reasonable financial incentives to continue in their positions and to research, Develop, market, sell, and manufacture the Cydectin Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Cydectin Product(s) and to ensure successful execution

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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).

IV.**IT IS FURTHER ORDERED** that**A.** Respondent shall:

1. not use, directly or indirectly, any Confidential Business Information solely related to the Divestiture Product Assets or the Business of the Divestiture Products, other than as necessary to comply with the requirements of this Order, Respondent's obligations to each respective Acquirer under the terms of any related Remedial Agreement, or applicable Law;
2. not disclose or convey any Confidential Business Information solely related to the Divestiture Product Assets or the Business of the Divestiture Products, directly or indirectly, to any Person except (i) the Acquirer of the relevant Divestiture Product, (ii) other Persons specifically authorized by the Acquirer to receive such information, (iii) the Commission, or (iv) the Monitor (if any has been appointed);
3. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of a Divestiture Product to the marketing or sales employees associated with the Business related to those Retained Products in the Geographic Territory that are the Therapeutic Equivalent of the Divestiture Product; and

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4. take all reasonable steps to ensure the Companion Animal Products Acquirer:
 - a. does not use, directly or indirectly, any Confidential Business Information related to the Naramune Products other than as necessary to comply with the Fort Dodge Transitional Manufacturing and Supply Agreement by and between Boehringer Ingelheim Vetmedica, Inc. and Elanco US Inc., or any applicable Law;
 - b. does not disclose or convey any Confidential Business Information related the Naramune Products directly or indirectly, to any Person except (i) the Respondent, other Persons specifically authorized by Respondent to receive such information, (iii) the Commission, or (iv) the Monitor (if any has been appointed); or
 - c. does not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Naramune Products the marketing or sales employees associated with the Companion Animal Products Business.
- B. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Companion Animal Products Business and the Cydectin Products Business within the Geographic Territory through its full transfer and delivery of the Divestiture Product Assets to the respective Acquirers, to maintain the confidentiality of the Confidential Business Information related to the Divestiture Products, and to minimize any risk of loss of competitive potential for the Companion Animal Products Business and the Cydectin Products Business within the Geographic Territory.

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V.**IT IS FURTHER ORDERED** that:

- A. The Commission may appoint a monitor or monitors (“Monitor”) to assure that Respondent expeditiously complies with all obligations and performs all responsibilities required by this Order to Maintain Assets, the Decision and Order and the Remedial Agreements. The Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions to which the Monitor and Respondent agree and that the Commission approves.
- B. The Commission appoints Dr. Stephen J. Bell as a Monitor and approves the agreement between Dr. Bell and Respondent, attached as an Appendix to the Decision and Order.
- 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 to Maintain Assets 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 to Maintain Assets 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

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4. The Monitor shall evaluate the reports submitted to the Commission by Respondent pursuant to this Order to Maintain Assets, the Decision and Order, 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 Fort Dodge 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, including, but not limited to, the following:
1. Respondent 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 the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor;
 2. Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent's compliance with this Order to Maintain Assets, the Decision and Order and the Remedial Agreements;
 3. Subject to any demonstrated legally recognized privilege, the Respondent shall provide the Monitor with full and complete access to Respondent's personnel, books, documents,

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records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondent's compliance with their obligations under the Orders, including, but not limited to, its obligations related to the Divestiture Assets; and

4. Respondent shall deliver to the Monitor a copy of each report submitted to the Commission pursuant to this Order to Maintain Assets, the Decision and Order or the Consent Agreement.
- E. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement; however, such agreement shall not limit the ability of the Monitor to provide information to the Commission without the consent of Respondent.
- F. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Respondent's materials and information received in connection with the performance of the Monitor's duties,
- provided, however,* that such agreement shall not restrict the Monitor from providing any information to the Commission or require the Monitor to report to the Respondent the substance of communications to or from the Commission or the Acquirer.
- G. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- H. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the

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Commission may appoint a substitute Monitor. The Commission shall select the substitute Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent have not opposed, in writing, including the reasons for opposing, the selection of any proposed substitute Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed substitute Monitor, Respondent shall be deemed to have consented to the selection of the proposed substitute Monitor.

- I. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.
- J. The Monitor shall serve until the later of: a) the completion of the transfer of the Divestiture Products, including the transfer and delivery of the related Product Manufacturing Technology; b) the date the Companion Animal Acquirer is able, independently of the Respondent, to manufacture the Contract Manufacture Products in final finished form, in commercial quantities and in a manner consistent with cGMP; or c) four (4) years.

VI.**IT IS FURTHER ORDERED** that:

- A. Respondent shall submit to the Commission and to the Monitor verified written reports within thirty (30) days after the date this Order to Maintain Assets is issued and every sixty (60) days thereafter until Respondent have 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 to Maintain Assets and the Decision and Order. Respondent shall include in its reports, among other things that are required from time to time, a full

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description of the efforts being made to comply with the relevant paragraphs of the Orders, including:

1. a detailed description of all substantive contacts, negotiations, or recommendations related to: (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by Respondent to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
2. a detailed description of the timing for the completion of such obligations,

provided, however, that, after the Decision and Order becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondent pursuant to Paragraph IX of the Decision and Order.

VII.

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

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

VIII.

IT IS FURTHER ORDERED that for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to Respondent, it shall, without restraint

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or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of Respondent and in the presence of counsel, to all facilities and access to inspect and copy all non-privileged business records and documentary material, including without limitation electronically stored information as defined in Rule 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1), (2), books, ledgers, accounts, correspondence, memoranda and all other records and documents (in whatever form such records and documents are kept) in the possession or under the control of the Respondent related to compliance with this 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 Respondents; and
- B. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

IX.

IT IS FURTHER ORDERED that this Order shall terminate the earlier of:

- A. three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. §2.34, or
- B. the day after transfer of all Divestiture Product Assets to their respective Acquirers,

provided, however, that if the Commission, pursuant to Paragraph II.A or Paragraph III.A. of the Decision and Order, requires the Respondent to rescind any or all of the divestitures contemplated by any Divestiture Agreement, then, upon rescission, the requirements of this Order to Maintain Assets shall again be in effect with respect to the relevant Divestiture Product Assets until the day after Respondent's (or a Divestiture Trustee's) completion

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of the divestiture(s) of the relevant Divestiture Product Assets, as described in and required by the Decision and Order.

By the Commission.

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent C.H. Boehringer Sohn AG & Co. KG of the animal health 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 thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of the Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent

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Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent C.H. Boehringer Sohn AG & Co. KG is a corporation organized, existing, and doing business under and by virtue of the laws of Germany with its headquarters address at Binger Strasse 173, Ingelheim am Rhein, Germany, 55216 and the address of its United States subsidiary, Boehringer Ingelheim Vetmedica, Inc., located at 3902 Gene Field Rd., St. Joseph, Missouri 64506.
2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, and the proceeding is in the public interest.

ORDER**I.**

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

- A. “Boehringer” means C.H. Boehringer Sohn AG & Co. KG, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Boehringer, including but not limited to Boehringer Ingelheim Vetmedica, Inc. (“BIVI”), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Boehringer shall include Merial.
- B. “Sanofi” means Sanofi, a corporation organized, existing and doing business under and by virtue of the laws of France and its principal executive offices are located at 54, Rue La Boetie, 75008 Paris, France. Sanofi includes its wholly-owned subsidiaries Merial,

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S.A.S. and Merial Inc. and all other assets and shares comprising its animal health business.

- C. “Merial” means all assets and shares comprising Sanofi’s animal health business, including without limitation Merial, S.A.S. and Merial, Inc.
- D. “Bayer” means Bayer AG, a corporation organized, existing and doing business under and by virtue of the laws of Germany, with its principal executive offices located at Kaiser Wilhelm-Allee, 51368 Leverkusen, Germany, and its successors, assigns, subsidiaries and divisions, including Bayer Healthcare US Funding LLC, a Delaware Limited Liability Company and Bayer HealthCareLLC, a Delaware Limited Liability Company.
- E. “Elanco” means Eli Lilly and Company, a corporation organized, existing and doing business under and by virtue of the laws of the state of Indiana, with its principal executive offices located at Lilly Corporate Center, Indianapolis, Indiana, 46285, and its successors, assigns, subsidiaries and divisions, including Elanco US Inc., a corporation organized, existing and doing business under and by virtue of the laws of the state of Delaware, with its principal executive offices located at 2500 Innovation Way, Greenfield, IN 46140.
- F. “Commission” means the Federal Trade Commission.
- G. “Acquirer” means the Companion Animal Products Acquirer or the Cydectin Products Acquirer.
- H. “Acquisition” means the transaction contemplated by the agreements executed by Boehringer and Sanofi on June 2, 2016, through which Boehringer will acquire the assets and shares comprising Sanofi’s animal health business and in exchange, Sanofi will acquire the assets and shares comprising Boehringer’s consumer healthcare business (excluding the consumer

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healthcare business in China) and receive a cash payment of approximately \$5.1 billion.

- I. “Acquisition Date” means the date Respondent Boehringer and Sanofi close on the Acquisition.
- J. “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 Business of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”), and the United States Department of Agriculture (“USDA”).
- K. “Agency Manufacturing Standards” means:
 - 1. for any Product regulated by the FDA, current Good Manufacturing Practice, *i.e.*, cGMP, as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and all rules and regulations promulgated by the FDA thereunder; or
 - 2. for any Product regulated by the USDA, current manufacturing regulations contained in Title 9 of the Code of Federal Regulations pertaining to veterinary biologics and all rules and regulations promulgated by the USDA thereunder.
- L. “Antigen” means any substance that when introduced to the body stimulates an immunological response. The term “Antigen” includes, without limitation, live or killed viruses, attenuated viruses, parts of viruses, toxins, bacteria, and foreign blood cells.
- M. “Application(s)” means all of the following, as defined in the United States Federal Food, Drug and Cosmetic Act, as amended: “Investigational New Animal Drug Application” (“INADA”), “New Animal Drug Application” (“NADA”), “Abbreviated New Animal Drug Application” (“ANADA”), or “Conditional New Animal Drug Application” (“CNADA”) for a Product

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filed or to be filed with the FDA, or its foreign Agency equivalent, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Respondent and the FDA or other Agency related thereto. The term “Application” and all of the foregoing terms or abbreviations include the foreign equivalents of the above-referenced filings and activities with the foreign counterpart(s) of the FDA.

- N. “Biological Manufacturing and Testing Materials” means reagents, microorganisms antibodies, sera, proteins, clinical and tissue samples, and raw materials used to perform the applicable potency, immunogenicity and/or antigen compatibility testing (including without limitation, the reference vaccine); assays (including, without 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

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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:
1. within canines: adenoviruses, bordetellosis, borreliosis (Lyme disease), coronavirus, canine distemper virus (CDV), leptospirosis, parvovirus, and parainfluenza virus;
 2. within felines: calicivirus, chlamydia, feline immunodeficiency virus, feline leukemia, panleukopenia and feline viral rhinotracheitis; and

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3. rabies;

including without limitation, all dosages, strengths, formulations, routes of administration, and presentations of the Products, all Product Improvements related to the Products, and all medical and/or veterinary devices that are proprietary to Respondent and used for the administration or application of the Products:

1. Bronchi-Shield Products, meaning all Products, other than Naramune Products, that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the *Bordetella bronchiseptica* bacterium;
2. Calicivax Products, meaning all Products that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the calicivirus;
3. Duramune® Products, and ULTRA-Duramune Products, meaning all Products (other than Solo-Jec Products),
 - a. that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the canine distemper virus,
 - b. that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the canine parvovirus,
 - c. 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*;

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- d. that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the canine adenovirus Type 2 virus,
 - e. that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the canine adenovirus Type 1 virus,
 - f. that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the parainfluenza virus,
 - g. that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the canine coronavirus, and
 - h. that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the bacteria that causes borreliosis (Lyme disease), including without limitation, *Borrelia burgdorferi*, *Borrelia afzelii*, and *Borrelia gattinii*;
4. Fel-O-Guard Products, Fel-O-Vax Products, and ULTRA Fel-O-Vax® Products, meaning all Products (other than Solo-Jec Products)
- a. that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the virus that causes panleukopenia,
 - b. that contain one or more Antigens derived from, or to stimulate immunity to, one or more strains of the calicivirus,
 - 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),

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- 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 to this Order.
- T. “Companion Animal Products Assets” means the Divestiture Product Assets for all Companion Animal Products and Companion Animal Pipeline Products.
- U. “Companion Animal Products Business” means the Companion Animal Products Business of Respondent related to the Companion Animal Products and the Companion Animal Pipeline Products to the extent that such Business is owned, controlled, or managed by Respondent and the assets related to such Business to

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the extent such assets are owned by, controlled by, managed by, or licensed to, Respondent.

- V. “Companion Animal Products Closing Date” means the date on which the Respondent (or Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Companion Animal Products Assets to the Companion Animal Products Acquirer.
- W. “Companion Animal Products Divestiture Agreements” means the following agreements between Respondent and Elanco to accomplish the requirements of the Order (attached hereto as Confidential Appendix B), and all amendments, exhibits, attachments, agreements, and schedules thereto:
1. 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);
 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 Fort Dodge.

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- X. “Companion Animal Products Employees” means (i) Product Marketing Employees, Product Research and Development Employees, and Product Sales Employees who directly participated in the Companion Animal Products Business (irrespective of the portion of working time involved) and (ii) employees of Respondent whose principal place of work is the Companion Animal Products Facility, or was the Companion Animal Products Facility at any time within the twelve (12) month period immediately prior to the Acquisition Date other than employees who did not, in whole or part, participate in the Companion Animal Products Business.
- Y. “Companion Animal Products Facility” means all assets comprising the facilities of Respondent located at 800 Fifth Street NW, Fort Dodge, Iowa, including assets to be transferred into the facilities pursuant to the Companion Animal Products Divestiture Agreements. These assets include, without limitation, all of the following: real estate; buildings; warehouses; storage tanks; structures; manufacturing equipment; other equipment; machinery; tools; spare parts; personal property; furniture; fixtures; supplies associated with each particular facility; and other tangible property, owned, leased, or operated on or behalf of Respondent.
- Z. “Companion Animal Products License” means a perpetual, non-exclusive, fully paid-up and royalty-free license with rights to sublicense, in the Geographic Territory, the following as of the Companion Animal Products Closing Date:
1. All Patents owned, licensed or controlled by Respondent related to a Companion Animal Product or a Companion Animal Pipeline Product that Respondent can demonstrate are also related to a Retained Product that is being marketed or sold as of the Acquisition Date;

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2. trade secrets, know how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to a Companion Animal Product or a Companion Animal Pipeline Product that Respondent can demonstrate are also related to a Retained Product that is being developed, marketed or sold as of the Acquisition Date; and
3. Product Manufacturing Technology that is general manufacturing know-how (i.e. manufacturing know-how not exclusively related to Companion Animal Products 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

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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

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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.
- HH. “Cydectin Product Assets” means the Divestiture Product Assets for all Cydectin Products and Cydectin Pipeline Products.
- II. “Cydectin Product Business” means the Business of Respondent related to the Cydectin Products and the Cydectin Pipeline Products to the extent that such Business is owned, controlled, or managed by Respondent and the assets related to such Business to the extent such assets are owned by, controlled by, managed by, or licensed to, Respondent.
- JJ. “Cydectin Products Closing Date” means the date on which the Respondent (or Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Cydectin Product Assets to an Acquirer.
- KK. “Cydectin Products Divestiture Agreements” means the following agreements between Respondent and Bayer to accomplish the requirements of the Order (attached hereto as Confidential Appendix B), and all amendments, exhibits, attachments, agreements, and schedules thereto:
1. Amended and Restated Cydectin Asset Purchase Agreement by and between Boehringer Ingelheim Vetmedica, Inc. and Bayer Healthcare US Funding LLC dated as of December 5, 2016;
 2. Cydectin License Agreement by and among Boehringer Ingelheim Vetmedica, Inc., Boehringer

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Ingelheim Vetmedica GMBH, and Bayer HealthCare LLC; and

3. Cydectin Services Agreement by and between Boehringer Ingelheim Vetmedica, Inc. and Bayer HealthCare LLC.

LL. “Cydectin Products Employees” means Product Research and Development Employees who directly participated in the Cydectin Products Business (irrespective of the portion of working time involved).

MM. “Cydectin Product License” means a perpetual, non-exclusive, fully paid-up and royalty-free license with rights to sublicense the following as of the Cydectin Closing Date:

1. All Patents owned, licensed or controlled by Respondent related to a Cydectin Product or a Cydectin Pipeline Product that Respondent can demonstrate are also related to a Retained Product that is being marketed and sold as of the Acquisition Date;
2. trade secrets, know how, techniques, data, inventions, practices, methods, and other confidential or proprietary information related to the Cydectin Products Business, and all rights in the Geographic Territory to limit the use or disclosure thereof, that Respondent can demonstrate are also related to a Retained Product that is being marketed and sold as of the Acquisition Date; and
3. Product Manufacturing Technology that is general manufacturing know-how (i.e. manufacturing know-how not exclusively related to Cydectin Products Business) and relates to the Cydectin Products Business,

provided that for any Licensed Intellectual Property that is the subject of a license from a Third Party to the

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Respondent, the scope of the rights granted hereunder shall only be required to be equal to the rights granted by the Third Party to the Respondent.

- NN. “Designee” means any Person other than Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- OO. “Development” means all preclinical and clinical drug and biological research and development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.
- PP. “Direct Cost” means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of Respondent’s employees’ labor shall not exceed the average hourly wage rate for such employee;

provided, however, in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, “Direct Cost” means such cost as is provided in such Remedial Agreement for that Divestiture Product.

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- QQ. “Divestiture Agreements” means the Cydectin Divestiture Agreements and Companion Animal Divestiture Agreements.
- RR. “Divestiture Closing Date” means, as applicable, the Companion Animal Products Closing Date or the Cydectin Products Closing Date.
- SS. “Divestiture Product Assets” means Respondent’s rights, title and interest in all Respondent’s assets related to the Business of a Divestiture Product, to the extent legally transferable, including without limitation the following:
1. rights to all Applications;
 2. all Product Intellectual Property;
 3. all Product Improvements;
 4. all Product Approvals;
 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

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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);

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12. all strategic safety programs submitted to the FDA or USDA, as applicable, that are designed to decrease product risk by using one or more interventions or tools beyond the package insert;
13. all pharmaco and vaccino vigilance data and records, post-marketing surveillance program to collect patient data, laboratory data and identification information 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

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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 Product Assets shall not include (1) information relating to the Respondent's general business strategies or practices relating to marketing or sales of Products that does not discuss with particularity a Divested Product, (2) administrative, financial, and accounting records; (3) assets licensed to the Acquirer pursuant to the Companion Animal Products License and the Cydectin Product License (Respondent shall, however, be required to transfer the information and assets as provided for in by the Companion Animal Products License), and (4) any other asset specifically identified in a Remedial Agreement as being retained by Respondent.

provided, further, Respondent shall only be required to provide copies of documents and materials for which (1) the information to be divested cannot be separated from the information to be retained in a manner that preserves its meaning and usefulness; or (2) Respondent has a legal obligation to retain the original documents or materials. If Respondent provides such copies to an Acquirer, Respondent shall also provide such Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that Respondent provides the Acquirer with the above-described information without requiring Respondent

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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.
- XX. “Domain Name” means the domain name(s), universal resource locators (“URL”), 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.
- YY. “Field” means the prevention, treatment, diagnosis, or control of a particular disease within a particular family, genus, and/or species of non-human animals.
- ZZ. “Geographic Territory” shall mean the United States of America, including all its territories and possessions.
- AAA. “Government Entity” means any Federal, state, local or non-U.S. government, or any court, legislature,

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government agency, or government commission, or any judicial or regulatory authority of any government.

- BBB. “High Volume Account(s)” means any retailer, wholesaler or distributor whose annual and/or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States of America from the Respondent was, or is projected to be among the top twenty (20) highest of such purchase amounts by the Respondent’s U.S. customers on any of the following dates: (1) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (2) the end of the last quarter that immediately preceded the Acquisition Date; (3) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or (4) the end of the last quarter following the Acquisition and/or the Closing Date.
- CCC. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- DDD. “Master Cell(s)” means the master cell, working cell, and production cell existing as of the Companion Animal Closing Date required or used in the production of a Product.
- EEE. “Master Files” means submissions made to the FDA in order to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more veterinary drugs, and includes both master files maintained by the FDA Center for Drug Evaluation and Research (generally referred to as drug master files) and those maintained by the FDA Center for Veterinary Medicine (generally referred to as veterinary master files).
- FFF. “Master Seed(s)” means the master seed, working seed and production seed existing as of the Companion

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Animal Closing Date required or used in the production of a Product.

- GGG. “Monitor” means any monitor appointed pursuant to Paragraph V of this Order or Paragraph V of the Order to Maintain Assets.
- HHH. “Naramune Products” means Products marketed by Respondent in the Geographic Territory at the time of the Acquisition under the trade name Naramune (or private label analogs).
- III. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- JJJ. “Patent(s)” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case existing as of the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any Product of or owned or licensed by Respondent as of the Closing Date (*except* where this Order specifies a different time).
- KKK. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- LLL. “Process and Analytical Documents” means the following documents, whether in paper, electronic or other format, related to the processes and Product Manufacturing Technology used by Respondent to manufacture, or have manufactured, the Divestiture

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Products and the applicable analytical methods used by Respondent:

1. Master Cell and Master Seed bank documentation, which includes but is not limited to, the following:
 - a. Master Cell Line and Master Seed Generation Technical Report (including: description of the host cell history, cell line generation procedures, vector construction, selection/cloning, if any, and stability data,
 - b. Preliminary Master Cell and Master Seed Bank Preparation Technical Report (including: description of banking procedures including storage conditions, vial thaw results, and in-house and contract lab test reports (sterility, mycoplasma, and any other contaminants)),
 - c. Master Cell and Master Seed Stability Technical Report (including: description of methodology, evaluation of cell growth and Master Seed titers (at increasing cell age), and any results of genetic mutation studies),
 - d. Master Cell and Master Seed Banking Process Description (including: list of raw materials and suppliers, list of consumables, list of equipment, media and solution recipes, culture working volumes and conditions, criteria for transfer, seed ratios and process set points),
 - e. Master Cell and Master Seed Bank Specification (including: quality assurance approved Master Cell and Master Seed bank specification),
 - f. Master Cell and Master Seed Bank Raw Materials Documentation (including: list of raw materials, source and lot numbers used for Master Cell and Master Seed banking and verification of origin),

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- g. Master Cell and Master Seed Bank Batch Record (including: executed and released batch records for Master Cell and Master Seed bank preparation and methodology and certificate of analysis), and
 - h. Master Cell and Master Seed Bank Test Reports (including: copy of test reports for safety and quality assurance testing of Master Cell and Master Seed bank by in-house and contract lab);
2. Drug and Biological Substance Process Information Documentation, which includes the following:
- a. Cell Culture Process Description for Specified Engineering Run (including: list of raw materials and suppliers, list of consumables, list of equipment, media and solution recipes, culture working volumes, criteria for transfer, seed ratios, process set points, sampling requirements, criteria for feeding, and feed schedule),
 - b. Harvest Process Description for Specified Engineering Run (including: list of raw materials and suppliers, list of consumables, list of equipment, solution recipes, process set points, sampling requirements, and criteria for initiating harvest),
 - c. Purification Process Description for Specified Engineering Run (including: list of raw materials and suppliers, list of consumables, list of equipment, solution recipes, process set points, analytic and quality assurance data obtained at the beginning, during and ending of the Run, and sampling requirements),
 - d. Drug Substance Formulation Process Description for Specified Engineering Run

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(including: list of raw materials and suppliers, list of 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

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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. Test Results for Agency Manufacturing Standards (including: antibody concentration, endotoxin, sterility, mycoplasma, in vitro viral, and bioburden);
3. Process for Technical Transfer Documentation including: technical transfer plan detailing responsibilities, deliverables and targeted time line; transfer protocols, detailing responsibilities, procedures, sampling plan and criteria for transfer success for each of the following: cell culture process, harvest process, purification process, formulation process; transfer reports summarizing the results of the following transfers: cell culture process, harvest process, purification process, formulation process; and
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.

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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;

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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.

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PPP. “Product Code Numbers means:

1. for the Cydectin Products, the National Drug Code (“NDC”) numbers, including both the labeler code assigned by the FDA and the additional numbers assigned by an Application holder as a product code for a specific Product; or
2. for the Companion Animal Products, any labeler code assigned by the USDA and any additional number assigned by the holder of the Product Approvals related to the Product that appear on the packaging or labeling of a specific Product.

QQQ. “Product Copyrights” means rights to all original works of authorship of any kind directly related to a Divestiture Product 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 animal owners and/or breeders, 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 Divestiture Product or of any materials used in the research, Development, manufacture, marketing or sale of the Divestiture Product, including all copyrights in raw data relating to Clinical Trials of the Divestiture Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, the Divestiture Product 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

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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 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.

RRR. “Product Development Reports” means:

1. Pharmacokinetic study reports related to the specified Divestiture Product;
2. Bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product;
3. Bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product;
4. all correspondence to the Respondent from the FDA or USDA, as applicable to the specified Product, and from the Respondent to the FDA or USDA, as applicable to the specified Product, relating to the Application(s) or Veterinary Biological Product Authorization(s) submitted by, on behalf of, or acquired by, the Respondent related to the Divestiture Product;
5. annual and periodic reports related to the above-described Application(s) or Veterinary Biological

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Product Authorization(s), including any safety update reports;

6. FDA or USDA, as applicable to the specified Product, approved Product labeling related to the Divestiture Product;
7. currently used product package inserts (including historical change of controls summaries) related to the specified Divestiture Product(s);
8. FDA or USDA, as applicable to the specified Product, approved circulars for animal owners and/or breeders and information related to the Divestiture Product;
9. adverse event/serious adverse event summaries related to the Divestiture Product;
10. summary of Product complaints from physicians or veterinarians related to the Divestiture Product;
11. summary of Product complaints from customers related to the Divestiture Product; and
12. Product recall reports including those filed with the FDA or USDA, as applicable to the specified Product, related to the Divestiture Product.

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

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

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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

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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, etc.); and
2. for Cydectin Products and Cydectin Pipeline Products, any new, improved or modified composition (*e.g.*, without limitation, structural modifications to the active pharmaceutical ingredients, and/or different salt forms, hydrates or polymorphs of such active pharmaceutical ingredients), combination, formulation or line extension of, or derived from, a Cydectin Product or Cydectin Pipeline Product (including, without limitation, the addition, subtraction, substitution and/or modification of one or more Components in a Cydectin Product or Cydectin Pipeline Product).

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-

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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; annual product reviews; regulatory communications; control history; current and historical information associated with the FDA Application(s) conformance, Veterinary Biologic Product Authorization(s), and cGMP compliance, as applicable; Agency Manufacturing Standards compliance; labeling and all other information related to the manufacturing process; and supplier lists;

2. all Biological Manufacturing and Testing Materials related to the Divestiture Products;
3. all ingredients, materials, or components used in the manufacture of the Divestiture Product including the active pharmaceutical ingredient, excipients and packaging materials;
4. all Process and Analytical Documents; and
5. 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 Divestiture Product(s).

VVV. "Product Marketing Materials" means all marketing or promotional materials to the extent used specifically in the marketing or sale of a Divestiture Product in the Geographic Territory as of the relevant Divestiture 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

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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, advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, Product labels, and packaging, television masters and other similar materials related to the Divestiture Product(s).

- 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.

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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 pursuant to this Order.

CCCC. “Remedial Agreement(s)” means the following:

1. any agreement between Respondent and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final;
2. any agreement between Respondent and a Third Party to affect the assignment of assets or rights of

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Respondent related to a Divestiture Product to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final;

3. any agreement between Respondent 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

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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 Divestiture Product.

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

1. designating employees knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer and/or its Designee, and the Monitor, for the purpose of effecting such delivery;
2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product(s) that are acceptable to the Acquirer;
3. 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

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4. providing, in a timely manner, assistance and advice to enable the Acquirer or its Designee to:
 - a. manufacture the specified Divestiture Product(s) in the quality and quantities achieved by the Respondent, or the manufacturer and/or developer of such Divestiture Product;
 - b. obtain any Product Approvals necessary for the Acquirer or its Designee, to manufacture, distribute, market, and sell the specified Divestiture Product(s) in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product(s); and
 - c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product(s).

HHHH. “Third Party(ies)” means any non-governmental Person other than the following: Respondent, Sanofi, the Cydectin Acquirer and the Companion Animal Acquirer.

III. “Veterinary Biological Product Authorization(s)” means all of the following, as defined in Title 9 of the Code of Federal Regulations: a U.S. Veterinary Biological Product License or Permit, and a U.S. Veterinary Biological Establishment License, for a Product filed or to be filed with the USDA, or its foreign Agency equivalent, and all supplements, amendments, and revisions thereto, all outlines of production, protocols, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Respondent and the USDA or other Agency related thereto. The term “Veterinary Biological Product Authorization(s)” and all of the foregoing terms or abbreviations include the foreign equivalents of the above-referenced filings and activities with the foreign counterpart(s) of the USDA.

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

II.**IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) days after the Acquisition Date, Respondent shall divest the Companion Animal Products Assets and grant the Companion Animal Products License, absolutely and in good faith, to Elanco pursuant to, and in accordance with, the Companion Animal Divestiture Agreements,

provided, however, that if Respondent has divested the Companion Animal Products Assets and granted the Companion Animal Products License to Elanco prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that Elanco is not an acceptable purchaser of the Companion Animal Products Assets or licensee of the Companion Animal Products License, then Respondent shall immediately rescind the transaction with Elanco, in whole or in part, as directed by the Commission, and shall divest the Companion Animal Products Assets and grant the Companion Animal Products License (as applicable) within one hundred eighty (180) days after this Order becomes final, absolutely and in good faith, at no minimum price, to an Acquirer or Acquirers that receive(s) the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

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provided further that if Respondent has divested the Companion Animal Products Assets and granted the Companion Animal Products License to Elanco prior to this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that the manner in which the divestiture or license grant was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Companion Animal Products Assets or grant of the Companion Animal Products License, as applicable, to Elanco (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Prior to the Companion Animal Products Closing Date, Respondent shall:
1. provide the Companion Animal Products Acquirer with the opportunity to review all Product Contracts related to the Companion Animal Products and the Companion Animal Pipeline Products for the purpose of determining whether to assume such contracts or agreements, and
 2. secure all consents and waivers from all Third Parties that are necessary to permit Respondent to divest the Companion Animal Products Assets and grant the Companion Animal Products Licenses to the Companion Animal Products Acquirer and permit the Acquirer to continue the Companion Animal Products Business,

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

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- C. Within five (5) days after the Companion Animal Products Closing Date, Respondent shall provide to the Companion Animal Products Acquirer,
1. Copies of all unfilled customer purchase orders for the Companion Animal Products as of the Companion Animal Closing Date; and
 2. The information identified in Paragraphs I.SS(8), (14) and (15) regarding each Companion Animal Product and Companion Animal Pipeline Product.
- D. Respondent shall provide, or cause to be provided, to the Companion Animal Products Acquirer all Product Manufacturing Technology related to the Companion Animal Products in a manner consistent with the Technology Transfer Standards and pursuant to an agreement approved by the Commission as a Remedial Agreement. The duration of such Remedial Agreement shall be no less than two (2) years, except as to any service for which a longer time period is identified in a Remedial Agreement. Further, at the request of the Acquirer, the term of any service offered under the agreement shall be extended for up to two (2) additional six (6) month periods if the monitor, in consultation with Commission staff, determines that such extensions are reasonably necessary to fulfill the requirements of this Paragraph.
- E. Respondent shall:
1. not enforce any agreement that limits or otherwise impairs the ability of the Companion Animal Acquirer to use or to acquire the Companion Animal Products Assets or the Companion Animal Products License (including but not limited to, all Product Manufacturing Technology, and Confidential Business Information related to the Companion Animal Products) in the Companion Animal Products Business, or to operate the Companion Animal Products Facility; and

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2. no later than ten (10) days after the Companion Animal Closing Date, grant to each Third Party subject to an agreement that limits or otherwise impairs the ability of the Companion Animal Acquirer to use or to acquire, pursuant to and in accordance with this Order, the Companion Animal Products Assets or Companion Animal Products License (including but not limited to Product Manufacturing Technology and related intellectual property and Companion Animal Confidential Business Information) or operate the Companion Animal Products Facility, a release that allows the Third Party to provide the relevant information to the Companion Animal Acquirer. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to the Acquirer and the Monitor (if one has been appointed).

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

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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 responsibilities (in whole or part) include sales or marketing and who has or may have had access to Companion Animal Confidential Information, and the direct supervisor(s) of each such employee, sign a confidentiality agreement pursuant to which the employee is required to maintain the confidentiality of the Companion Animal Confidential Information and not disclose it to other employees, executives, or other personnel of the Respondent (other than as necessary to comply with the requirements of this Order). Respondent shall maintain complete records of signed confidentiality agreements at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming that all confidentiality agreements have been signed; and
5. not later than thirty (30) days after the Companion Animal Closing Date, provide written notification of the restrictions on the use and disclosure of Companion Animal Confidential Information to all of its employees who may be in possession of or have access to Companion Animal Confidential Information. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Companion Animal Closing Date. Respondent shall provide a copy of the notification to the Companion Animal Acquirer. Respondent shall maintain complete records of all such notifications

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at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondent shall provide the Companion Animal Products Acquirer with copies of all certifications, notifications, and reminders sent to Respondent's personnel.

- G. Respondent shall deliver to the Companion Animal Products Acquirer the following information regarding each Companion Animal Products Employee no later than ten (10) days after such information is requested by either the Acquirer or staff of the Commission:
1. direct contact information for the employee, including telephone number;
 2. the date of hire and effective service date;
 3. job title or position held;
 4. a specific description of the employee's responsibilities related to the Companion Animal Products; provided, however, in lieu of this description, the Respondent may provide the employee's most recent performance appraisal;
 5. the base salary or current wages;
 6. the most recent bonus paid, aggregate annual compensation for the Respondent's last fiscal year, and current target or guaranteed bonus, if any;
 7. employment status (i.e., active or on leave or disability; full-time or part-time);
 8. all other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and

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9. at the Acquirer's option, a copy of all applicable employee benefit plans and summary plan descriptions (if any),

provided that, Respondent may condition providing this information for an employee whose principal place of work is not the Companion Animal Products Facility on the Acquirer's written confirmation that it will treat the information as confidential, use the information solely in connection with hiring or considering whether to hire the employees and restrict access to the information to only those employees or representatives who need such access in connection with the specified and permitted uses of the information.

- H. For a period ending twelve (12) months after the Companion Animal Closing Date, Respondent shall:
 1. provide the Companion Animal Acquirer with the opportunity to enter into employment contracts with the Companion Animal Products Employees. This period is hereinafter referred to as the "Companion Animal Products Employee Access Period;"
 2. not interfere with the hiring or employing by the Companion Animal Acquirer of the Companion Animal Products Employees, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with the Acquirer, including without limitation, any non-compete or nondisclosure provision of employment with respect to a Companion Animal 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

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written offer of employment from the Companion Animal Acquirer; and

4. not directly or indirectly, hire, solicit or otherwise attempt to induce any employee of the Acquirer to terminate his or her employment relationship with the Acquirer;

provided, however, Respondent may hire any former employee of Respondent whose employment has been terminated by the Acquirer or who independently applies for employment with Respondent, as long as such employee was not solicited in violation of the terms of the Order, and

provided further, that Respondent may advertise for employees in newspapers, trade publications, or other media not targeted specifically at employees of the Acquirer; and may hire an employee of the Acquirer who contacts Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from Respondent;

Failure by Respondent to provide any information requested in Paragraph II.G above within the time provided therein shall extend the time period in this Paragraph II.H in an amount equal to the delay.

- I. Until the Companion Animal Closing Date, Respondent shall provide all Companion Animal Products Employees with reasonable financial incentives to continue in their positions and to research, Develop, market, sell, and manufacture the Companion Animal Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Companion Animal Product(s) and to ensure successful execution of the pre-Acquisition plans for such Companion Animal Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent until the Companion Animal Products Closing Date,

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including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law).

J. Respondent shall:

1. upon reasonable written notice and request from the Companion Animal Acquirer to Respondent, Contract Manufacture and deliver, or cause to be manufactured and delivered, in a timely manner and under reasonable terms and conditions, a supply of any requested Contract Manufacture Product at the Supply Cost, for a period of time sufficient to allow the Acquirer to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished drug product independently of Respondent;
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 of Respondent to meet cGMP in the Contract Manufacture of a Product supplied to the Companion Animal Products Acquirer pursuant to a Remedial Agreement. 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

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limits on Respondent's aggregate liability to the Acquirer for such a breach;

3. give priority to supplying a Contract Manufacture Product to the Companion Animal Products Acquirer over manufacturing and supplying Products for Respondent's own use or sale;
4. make representations and warranties to the Companion Animal Products Acquirer that Respondent shall hold harmless and indemnify the Companion Animal Products Acquirer for any liabilities or loss of profits resulting from the failure of the Contract Manufacture Products to be delivered in a timely manner as required by the Remedial Agreement(s) unless Respondent can demonstrate that the failure was beyond the control of Respondent and in no part the result of negligence or willful misconduct by Respondent,

provided, however, that where (i) an agreement to divest the Companion Animal Products Assets or Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, the agreement may contain limits on the Respondent's aggregate liability for such a failure;

5. during the term of any agreement to Contract Manufacture, upon written request of the Companion Animal Products Acquirer or the Monitor, make available to the Companion Animal Products Acquirer and the Monitor all records generated or created after the Closing Date that relate to the manufacture of the Contract Manufacture Products;
6. during the term of any agreement to Contract Manufacture, take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Products; and

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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:
 1. maintain the full economic viability and marketability of the Business associated with the Companion Animal 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 Companion Animal Products;
 4. ensure the assets related to the Companion Animal Products are provided to the Companion Animal Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the associated Business; and

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5. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology.
- M. Respondent shall not sell, transfer, encumber, or otherwise impair the Companion Animal Products 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 Businesses related to the Companion Animal Products, and shall continue in the same manner all current and planned capital expenditure plans and products.

III.**IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) days after the Acquisition Date, Respondent shall divest the Cydectin Product Assets and grant the Cydectin Product License, absolutely and in good faith, to Bayer pursuant to, and in accordance with, the Cydectin Divestiture Agreements,

provided, however, that if Respondent has divested the Cydectin Product Assets and granted the Cydectin Product License to Bayer prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that Bayer is not an acceptable purchaser of the Cydectin Product Assets or licensee of the Cydectin Product License, then Respondent shall immediately rescind the transaction with Bayer, in whole or in part, as directed by the Commission, and shall divest the Cydectin Product Assets and grant the Cydectin Product License (as applicable) within one hundred eighty (180) days after this Order becomes final, absolutely and in good faith, at no minimum price, to an Acquirer or Acquirers that receive(s) the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

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provided further that if Respondent has divested the Cydectin Product Assets and granted the Cydectin Product License to Bayer prior to this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that the manner in which the divestiture or license grant was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Cydectin Product Assets or grant of the Cydectin Product License, as applicable, to Bayer (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

B. Prior to the Cydectin Product Closing Date, Respondent shall:

1. provide the Cydectin Product Acquirer with the opportunity to review all Product Contracts related to the Cydectin Products and the Cydectin Pipeline Products for the purpose of determining whether to assume such contracts or agreements: and
2. secure all consents and waivers from all Third Parties that are necessary to permit Respondent to divest the Cydectin Product Assets and grant the Cydectin Product Licenses to the Cydectin Products Acquirer and permit the Acquirer to continue the Cydectin Products Business,

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

C. Within five (5) days after the Cydectin Products Closing Date, Respondent shall provide to the Cydectin Products Acquirer,

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1. copies of all unfilled customer purchase orders for the Cydectin Products as of the Cydectin Closing Date; and
 2. the customer information identified in Paragraphs I.SS(8), (14) and (15) regarding each Cydectin Product and Cydectin Pipeline Product.
- D. Respondent shall provide, or cause to be provided, to the Cydectin Product Acquirer all Product Manufacturing Technology related to the Cydectin Products in a manner consistent with the Technology Transfer Standards and pursuant to an agreement approved by the Commission as a Remedial Agreement. The duration of such Remedial Agreement shall be no less than one (1) year and, at the request of the Acquirer, shall be extended for up to one (1) additional six (6) month period if the monitor, in consultation with Commission staff, determines that such extensions are reasonably necessary to fulfill the requirements of this Paragraph.
- E. Respondent shall:
1. not enforce any agreement that limits or otherwise impairs the ability of the Cydectin Acquirer to use or to acquire the Cydectin Products Assets or the Cydectin Products License (including but not limited to, all Product Manufacturing Technology, and Confidential Business Information related to the Cydectin Products) in the Cydectin Products Business, and
 2. no later than ten (10) days after the Cydectin Closing Date, grant to each Third Party subject to an agreement that limits or otherwise impairs the ability of the Cydectin Acquirer to use or to acquire, in accordance with and pursuant to this Order, the Cydectin Product Assets or Cydectin Product License (including without limitation Product Manufacturing Technology and related intellectual property and Cydectin Confidential

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Business Information), a release that allows the Third Party to provide the relevant information to the Cydectin Acquirer. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to the Acquirer and the Monitor.

F. Respondent shall:

1. submit to the Cydectin Acquirer, at Respondent's expense, all Confidential Business Information related to the Cydectin Products and the Cydectin Pipeline Products and the Cydectin Products Business ("Cydectin Confidential Information");
2. deliver the Cydectin Confidential Information to the Cydectin Product 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 the Cydectin Confidential Information to the Cydectin Product Acquirer, provide the Acquirer and the Monitor with access to the Cydectin 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 Cydectin Confidential Information, and facilitating the delivery of the Cydectin Confidential Information in a manner consistent with this Order;
4. on or before the Cydectin Product Closing Date, and as a condition of continued employment, require that each employee whose responsibilities (in whole or part) include sales or marketing and who has or may have had access to Cydectin Confidential Information, and the direct supervisor(s) of each such employee, sign a

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confidentiality agreement pursuant to which the employee is required to maintain the confidentiality of the Cydectin Confidential Information and not disclose it to other employees, executives, or other personnel of the Respondent (other than as necessary to comply with the requirements of this Order). Respondent shall maintain complete records of signed confidentiality agreement at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming that all confidentiality agreements have been signed; and

5. not later than thirty (30) days after the Cydectin Closing Date, provide written notification of the restrictions on the use and disclosure of Cydectin Confidential Information to all of its employees who may be in possession of or have access to Cydectin Confidential Information. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Cydectin Closing Date. Respondent shall provide a copy of the notification to the Cydectin Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondent shall provide the Cydectin Product Acquirer with copies of all certifications, notifications, and reminders sent to Respondent's personnel.
- G. Respondent shall deliver to the Cydectin Products Acquirer the following information regarding each Cydectin Products Employee no later than ten (10) days after such information is requested by either the Acquirer or staff of the Commission:

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1. direct contact information for the employee, including telephone number;
2. the date of hire and effective service date;
3. job title or position held;
4. a specific description of the employee's responsibilities related to the Cydectin Products; provided, however, in lieu of this description, the Respondent may provide the employee's most recent performance appraisal;
5. the base salary or current wages;
6. the most recent bonus paid, aggregate annual compensation for the Respondent's last fiscal year, and current target or guaranteed bonus, if any;
7. employment status (i.e., active or on leave or disability; full-time or part-time);
8. all other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
9. at the Acquirer's option, a copy of all applicable employee benefit plans and summary plan descriptions (if any),

provided that, Respondent may condition providing this information on the Acquirer's written confirmation that it will treat the information as confidential, use the information solely in connection with hiring or considering whether to hire the employees and restrict access to the information to only those employees or representatives who need such access in connection with the specified and permitted uses of the information.

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- H. For a period ending twelve (12) months after the Cydectin Closing Date, Respondent shall:
1. provide the Cydectin Acquirer with the opportunity to enter into employment contracts with the Cydectin Product Employees. This period is hereinafter referred to as the “Cydectin Product Employee Access Period;”
 2. not interfere with the hiring or employing by the Cydectin Acquirer of the Cydectin Product Employees, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with the Acquirer, including without limitation, any non-compete or nondisclosure provision of employment with respect to a Cydectin Product or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by the Cydectin Acquirer;
 3. not make any counteroffer to any Cydectin Product Employee who has received a written offer of employment from the Cydectin Acquirer; and
 4. not directly or indirectly, hire, solicit or otherwise attempt to induce any employee of the Acquirer to terminate his or her employment relationship with the Acquirer;

provided, however, Respondent may hire any former employee of Respondent whose employment has been terminated by the Acquirer or who independently applies for employment with Respondent, as long as such employee was not solicited in violation of the terms of the Order, and

provided further, that Respondent may advertise for employees in newspapers, trade publications, or other media not targeted specifically at employees of the Acquirer; and may hire an employee of the Acquirer who contacts Respondent on his or her own initiative

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without any direct or indirect solicitation or encouragement from Respondent;

Failure by Respondent to provide any information requested in Paragraph III.G above within the time provided therein shall extend the time period in this Paragraph III.H in an amount equal to the delay.

- I. Until the Cydectin Closing Date, provide all Cydectin Products Employees with reasonable financial incentives to continue in their positions and to research, Develop, market, sell, and manufacture the Cydectin Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness 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;

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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, directly or indirectly, any Confidential Business Information solely related to the Divestiture Product Assets or the Business of the Divestiture Products, other than as necessary to comply with the requirements of this Order, Respondent's obligations to each respective Acquirer under the terms of any related Remedial Agreement, or applicable Law;
 2. not disclose or convey any Confidential Business Information solely related to the Divestiture Product Assets or the Business of the Divestiture Products, directly or indirectly, to any Person except (i) the Acquirer of the relevant Divestiture Product, (ii) other Persons specifically authorized by the Acquirer to receive such information, (iii) the Commission, or (iv) the Monitor (if any has been appointed);

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3. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of a Divestiture Product to the marketing or sales employees associated with the Business related to those Retained Products in the Geographic Territory that are the Therapeutic Equivalent of the Divestiture Product; and
 4. take all reasonable steps to ensure the Acquirer:
 - a. does not use, directly or indirectly, any Confidential Business Information related to the Naramune Products other than as necessary to comply with the Fort Dodge Transitional Manufacturing and Supply Agreement by and between Boehringer Ingelheim Vetmedica, Inc. and Elanco US Inc., or any applicable Law
 - b. does not disclose or convey any Confidential Business Information related the Naramune Products directly or indirectly, to any Person except (i) the Respondent, other Persons specifically authorized by Respondent to receive such information, (iii) the Commission, or (iv) the Monitor (if any has been appointed); and
 - c. does not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Naramune Products the marketing or sales employees associated with the Companion Animal Products Business.
- B. Respondent shall not join, file, prosecute, or maintain any suit, in law or equity, against an Acquirer, any Person controlled by or under common control with an Acquirer, the Manufacturing Designee of an Acquirer, or any Person that has an agreement with an Acquirer

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to commercialize, distribute, market or import a Divestiture Product:

1. under any Patent owned by or licensed to the Respondent as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof; or
2. under any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to the Respondent at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

if such suit would have the potential 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 Respondent shall also covenant to that Acquirer that as a condition of any assignment or license from the Respondent 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 that Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential 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

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(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 by that Acquirer.
- D. For any patent infringement suit filed prior to the relevant Divestiture Closing Date in which Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that Respondent has prepared or is preparing to defend against as of such Divestiture Closing Date, and where such a suit would have the potential directly to limit or interfere with the relevant 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

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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, Respondent shall:

1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from the Respondent in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;
2. waive conflicts of interest, if any, to allow the Respondent's outside legal counsel to represent that Acquirer in any ongoing patent litigation related to that Divestiture Product; and
3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work product in the possession of the Respondent's outside counsel related to that Divestiture Product.

E. The purpose of the divestiture of the Divestiture Product Assets and the related obligations imposed on the Respondent by this Order is:

1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the Geographic Territory;
2. to create a viable and effective competitor that is independent of the Respondent in the Business of each Divestiture Product within the Geographic Territory; and
3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

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F. Respondent shall not, in the Geographic Territory:

1. use the Product Trademarks related to the Divestiture Products or any mark confusingly similar to such Product Trademarks, as a trademark, trade name, or service mark, except to manufacture Retained Products for export from the Geographic Territory;
2. attempt to register such Product Trademarks;
3. attempt to register any mark confusingly similar to such Product Trademarks;
4. challenge or interfere with the relevant Acquirer's use and registration of such Product Trademarks; or
5. challenge or interfere with the relevant Acquirer's efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties;

provided, however, that this paragraph shall not preclude Respondent from continuing to use all trademarks, trade names, or service marks that have been in use in commerce on a Retained Product at any time prior to the Acquisition Date.

V.

IT IS FURTHER ORDERED that:

- A. The Commission may appoint a monitor or monitors ("Monitor") to assure that Respondent expeditiously complies with all obligations and performs all responsibilities required by this Order, the Order to Maintain Assets and the Remedial Agreements. The Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions to which the Monitor

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and Respondent agree and that the Commission approves.

- B. The Commission appoints Dr. Stephen J. Bell as a Monitor and approves the agreement between Dr. Bell and Respondent, attached as Public Appendix A and Non-Public Appendix A-1 to this Order.
- 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.

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- 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, including, but not limited to, the following:
1. Respondent 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 the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor;
 2. Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent's compliance with this Order, the Order to Maintain Assets and the Remedial Agreements;
 3. Subject to any demonstrated legally recognized privilege, the Respondent shall provide the Monitor with full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets; and
 4. Respondent shall deliver to the Monitor a copy of each report submitted to the Commission pursuant to this Order, the Order to Maintain Assets or the Consent Agreement.

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- E. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement; however such agreement shall not limit the ability of the Monitor to provide information to the Commission without the consent of Respondent.
- F. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Respondent's materials and information received in connection with the performance of the Monitor's duties,

provided, however, that such agreement shall not restrict the Monitor from providing any information to the Commission or require the Monitor to report to the Respondent the substance of communications to or from the Commission or the Acquirer.
- G. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- H. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor. The Commission shall select the substitute Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed substitute Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed substitute Monitor, Respondent shall be deemed to have consented to the selection of the proposed substitute Monitor.

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- I. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.
- J. The Monitor shall serve until the later of: a) the completion of the transfer of the Divestiture Products, including the transfer and delivery of the related Product Manufacturing Technology; b) the date the Companion Animal Acquirer is able, independently of the Respondent, to manufacture the Contract Manufacture Products in final finished form, in commercial quantities and in a manner consistent with cGMP; or c) four (4) years.

VI.**IT IS FURTHER ORDERED** that:

- A. If Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to Section 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.

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- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
 - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed.
 - 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be

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achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondent from among those approved by the Commission; *provided further, however*, that Respondent shall select such Person within five (5)

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days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission 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 Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

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

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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

Decision and Order

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 the prior approval of the Commission, except as otherwise provided under Rule §2.41(f), 16 C.F.R. §2.41(f).
- D. Respondent shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of Respondent's obligation to the Acquirer pursuant to this Order.
- E. Respondent 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 Divestiture Products, a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.

Decision and Order

IX.**IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Respondent shall submit to the Commission and to the Monitor verified written reports within thirty (30) days after the date this Order is issued and every sixty (60) days 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. Respondent shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including:
 - 1. a detailed description of all substantive contacts, negotiations, or recommendations related to: (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondent to the relevant Acquirer, and (iii) any agreement to Contract Manufacture; and
 - 2. a detailed description of the timing for the completion of such obligations.
- C. One (1) year after the Order is issued, and annually for the next nine (9) years on the anniversary of the date this Order is issued, and at other times as the Commission may require, Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

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X.

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

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

XI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to Respondent, it shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of Respondent and in the presence of counsel, to all facilities and access to inspect and copy all non-privileged business records and documentary material, including without limitation electronically stored information as defined in Rule 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1), (2), books, ledgers, accounts, correspondence, memoranda and all other records and documents (in whatever form such records and documents are kept) in the possession or under the control of the Respondent related to compliance with this 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
- B. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

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XII.

IT IS FURTHER ORDERED that this Order shall terminate on February 14, 2027.

By the Commission.

**In re C.H. Boehringer Sohn AG & Co. KG
Docket No. C-4601**

Appendix A**Monitor Agreement**

**In re C.H. Boehringer Sohn AG & Co. KG
Docket No. C-4601**

CONFIDENTIAL Appendix A-1**Exhibit to the Monitor Agreement**

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

Analysis to Aid Public Comment

**In re C.H. Boehringer Sohn AG & Co. KG
Docket No. C-4601**

CONFIDENTIAL Appendix B

Companion Animal Divestiture Agreements

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

**In re C.H. Boehringer Sohn AG & Co. KG
Docket No. C-4601**

CONFIDENTIAL Appendix C

Cylectin Products Divestiture Agreements

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

INTRODUCTION

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from C.H. Boehringer Sohn AG & Co. KG (“Boehringer Ingelheim”), which is designed to remedy the anticompetitive effects of Boehringer Ingelheim’s acquisition of the Merial Animal Health business (“Merial”) from Sanofi. Under the terms of the proposed Decision and Order (“Order”)

Analysis to Aid Public Comment

contained in the Consent Agreement, Boehringer Ingelheim is required to divest its relevant U.S. companion animal vaccine business to Eli Lilly and Company, which participates in the animal health industry through its Elanco Animal Health (“Elanco”) division. Boehringer Ingelheim is also required to divest its U.S. Cydectin parasiticide product to Bayer AG (“Bayer”).

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, in order to make a final decision as to whether it should withdraw from the proposed Consent Agreement, modify it, or make it final.

THE TRANSACTION

Pursuant to an Exclusivity Agreement dated December 15, 2015, Boehringer Ingelheim proposes to swap its consumer health care business for Sanofi’s Merial animal health business (the “Proposed Acquisition”). In the proposed swap, Boehringer Ingelheim obtains Merial, valued at \$13.53 billion, and Sanofi obtains Boehringer Ingelheim’s Consumer Health Care business unit, valued at \$7.98 billion, as well as cash compensation of \$5.54 billion. The Commission alleges in its Complaint that the Proposed Acquisition, if consummated, would violate 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, in the U.S. markets for two types of animal health products: (1) companion animal vaccines—which include various canine, feline, and rabies vaccines—and (2) cattle and sheep parasiticides. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the Proposed Acquisition.

THE PARTIES

Headquartered in Germany, Boehringer Ingelheim is one of the world’s leading pharmaceutical companies. It manufactures, researches, develops and markets an array of human and animal

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health products. The company's animal health division, Boehringer Ingelheim Vetmedica, Inc., is the sixth-largest animal health supplier in the world.

Sanofi is a multinational pharmaceutical company headquartered in Gentilly, France. The company develops and markets a diverse portfolio of products, including pharmaceuticals, human vaccines, and, through its subsidiary Merial, animal health products. Merial is the fourth-largest animal health supplier in the world.

THE RELEVANT PRODUCTS AND STRUCTURE OF THE MARKETS

Companion Animal Vaccines

There are three classes of companion animal vaccines in which to analyze the effects of the Proposed Acquisition: canine vaccines, feline vaccines, and rabies vaccines. A vaccine is a version of an antigen that triggers an immune response to the antigen but not the disease, causing the animal to develop an immunity that prevents the disease. Only vaccines containing an antigen of a specific virus can provide the desired immunity response to that virus and the corresponding disease. No substitute product immunizes against a disease. Nor is treatment following infection a substitute for the vaccinations at issue. For these reasons, each vaccine containing an antigen to immunize against a particular disease constitutes a relevant market in which to analyze the effects of the acquisition.

Canine vaccines prevent specific illnesses in dogs. The Proposed Acquisition raises competitive concerns in the markets for seven canine vaccines: canine distemper virus, canine parvovirus, leptospirosis, canine adenovirus, canine parainfluenza virus, canine coronavirus, and borreliosis ("Lyme disease"). In addition, the proposed transaction raises future competition concerns in the canine vaccine market for *Bordetella bronchiseptica* bacterium, in which Boehringer Ingelheim currently competes and Merial is the most likely entrant in the near future. The canine vaccine markets are highly concentrated. Boehringer Ingelheim, Merial, Zoetis, Inc. ("Zoetis"), and Merck & Co. ("Merck") are the only four suppliers offering or likely to

Analysis to Aid Public Comment

offer canine vaccines in the United States. In 2015, Boehringer Ingelheim, Merial, Zoetis and Merck had market shares of approximately 30%, 11%, 35%, and 24%, respectively, of all revenues from canine vaccines sold in the United States and comparable shares in each relevant market, except *Bordetella bronchiseptica* bacterium, where Merial is the next likely entrant. The Proposed Acquisition would reduce the number of current or likely competitors in each market from four to three.

Feline vaccines prevent diseases common to cats. The transaction raises competitive concerns in the feline vaccine markets for five diseases: panleukopenia, calicivirus, viral rhinotracheitis, *Chlamydia psittaci* bacterium, and feline leukemia. The feline vaccine industry in the United States is highly concentrated with the same four market participants—Boehringer Ingelheim, Merial, Zoetis, and Merck—as the canine vaccine industry. In 2015, these four companies had market shares of approximately 28%, 33%, 16%, and 23%, respectively, of all revenues from feline vaccines sold in the United States and comparable shares in each relevant market. The proposed transaction would combine the two leading feline vaccine suppliers, reducing the number of competitors in each market from four to three.

The rabies virus, transmitted through bites from infected animals, triggers a fatal neurological condition culminating in paralysis, respiratory failure, and eventual death. Because this fatal disease is transmittable to humans, most U.S. states have mandatory rabies vaccination requirements. Regular vaccination for all animals is the only means of protection, and there are no substitutes for rabies vaccines. All rabies vaccines are approved for use in both dogs and cats, although some are approved for use in additional species as well. The market for the sale of rabies vaccines in the United States is highly concentrated. Boehringer Ingelheim, Merial, Zoetis, and Merck are the only four significant suppliers of rabies vaccines in the United States, with market shares of 10%, 65%, 13%, and 12% of revenues, respectively.

Cattle and Sheep Parasiticides

Parasiticides prevent and control outbreaks of parasites such as worms, flies, lice, and ticks.

Analysis to Aid Public Comment

Cattle Parasiticides

Parasiticides are a key part of cattle health care regimens. If left unchecked, parasites reduce milk production in dairy cattle and prevent weight gain in beef cattle. There are two primary types of cattle parasiticides: macrocyclic lactones, which prevent both internal and external parasites, and benzimidazoles, which prevent only internal parasites. Because macrocyclic lactones reach a much broader spectrum of parasites, other parasiticides, including benzimidazoles, are not viable substitutes.

Boehringer Ingelheim, Merial, and Zoetis are the three primary participants in the macrocyclic lactone cattle parasiticide market, and the Proposed Acquisition would combine the two most significant competitors. Merial, the market leader, offers three brands: Ivomec, Eprinex, and LongRange. After Merial, Boehringer Ingelheim is the next largest supplier of macrocyclic lactone cattle parasiticides. Boehringer Ingelheim's sole product is Cydectin, a parasiticide that is functionally identical to Ivomec and Eprinex for beef cattle. Zoetis also offers a macrocyclic lactone product, Dectomax, that is similar to the products of Merial and Boehringer Ingelheim. Merial, Boehringer Ingelheim and Zoetis accounted for 45%, 22%, and 17% of revenues, respectively, of U.S. sales in 2015. Beyond these three companies, multiple manufacturers produce generic versions of Merial's Ivomec. Although these generic products are significantly cheaper than the branded products, they have limited competitive significance. Many customers prefer the branded products because the branded product manufacturers offer valuable technical support, field support, and education. In addition, many customers also perceive the generic products to be inferior and unreliable, preferring to pay a higher price for the guaranteed success of branded products.

Merial and Boehringer Ingelheim are the only two macrocyclic lactone cattle parasiticide suppliers that offer "zero-day milk withhold" products—Cydectin and Eprinex, respectively. The Proposed Acquisition would eliminate the competition between them, effectively leaving dairy cattle customers with a sole supplier.

Analysis to Aid Public Comment

Sheep Parasiticides

Sheep parasiticides are critical for optimizing wool and meat production. Sheep parasiticides utilize the same compounds as cattle parasiticides, but use a different route of administration. Because a sheep's wool and skin prevent the absorption of topical products and the thickness of a sheep's wool makes injections difficult, customers view oral administration as the only viable option for sheep parasiticides. Both macrocyclic lactones and benzimidazoles can be used as sheep parasiticides, but benzimidazoles are not economic substitutes for macrocyclic lactones in most cases because they do not treat external parasites and are less efficacious.

Merial and Boehringer Ingelheim are the two primary suppliers of macrocyclic lactone sheep parasiticides. Boehringer Ingelheim offers Cydectin Oral Drench and Merial offers Ivomec Oral Drench. Following the Proposed Acquisition, the merged firm would control more than 78% of this market. The other macrocyclic lactone sheep parasiticides are generic versions of the Merial product, which are of limited competitive significance.

Relevant Geographic Market

The United States is the relevant geographic market in which to assess the competitive effects of the Proposed Acquisition. The USDA must approve companion animal vaccines before they are sold in the United States. Cattle and sheep parasiticides must be approved by the FDA before being sold in the United States. Thus, products sold outside the United States, but not approved for sale in the United States, are not alternatives for U.S. consumers.

ENTRY

Entry into the U.S. markets for companion animal vaccines and cattle and sheep parasiticides would not be timely, likely or sufficient in magnitude, character and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. Three major obstacles stand in the way of a prospective entrant into the relevant markets: lengthy development periods, FDA and USDA approval requirements, and difficulty of establishing a brand name

Analysis to Aid Public Comment

and reputation and convincing veterinarians to prescribe new products.

EFFECTS OF THE ACQUISITION

The Proposed Acquisition would cause significant competitive harm to consumers in the relevant U.S. markets for companion animal vaccines and cattle and sheep parasiticides by eliminating actual or future, direct, and substantial competition between Boehringer Ingelheim and Merial. The transaction would increase the likelihood that Boehringer Ingelheim will be able to unilaterally exercise market power, increase the likelihood of coordinated interaction between or among suppliers, and increase the likelihood that consumers will pay higher prices.

THE CONSENT AGREEMENT

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects by requiring Boehringer Ingelheim to divest its relevant companion animal vaccine business and certain of its cattle and sheep parasiticides assets to Elanco and Bayer, respectively.

Under the proposed Order, Boehringer Ingelheim will divest its relevant U.S. rights and interests in its companion animal vaccine business to Elanco no later than ten days after the consummation of the Proposed Acquisition or on the date on which the proposed Order becomes final, whichever is earlier. Similarly, the proposed Order requires Boehringer Ingelheim to divest all of its respective U.S. rights and interests in its parasiticide product, Cydectin, to Bayer. These divestitures include all regulatory approvals, brand names, marketing materials, confidential business information, customer information, and other assets associated with marketing and selling both products. To ensure the divestitures are successful, the proposed Order requires Boehringer Ingelheim to secure all third-party consents and waivers required to permit both buyers to conduct business with the divested assets. Additionally, Elanco and Bayer also will have the right to interview and offer employment to employees associated with the divested businesses.

Analysis to Aid Public Comment

Elanco is an experienced supplier in the global animal health industry and has the resources and expertise to replicate Boehringer Ingelheim's role in the companion animal vaccine markets. In 2015, Elanco generated approximately \$1 billion in revenue. Elanco currently offers a limited portfolio of companion animal pharmaceutical products such as parasiticides, pain relievers, and dermatological products. Elanco, however, is not a meaningful participant in any of the companion animal vaccines subject to divestiture, and its proposed acquisition of those assets will complement and expand its existing companion animal portfolio. Elanco is well positioned to replicate immediately Boehringer Ingelheim's competitive position in all companion animal vaccine markets.

Bayer is similarly well qualified to replicate Boehringer Ingelheim's competitive position in the United States with respect to the Cydectin product line. Bayer is currently the fifth-largest animal health company both worldwide and in the United States. Bayer had 2015 worldwide sales of \$1.6 billion, of which \$595 million derived from its animal health business. Bayer does not currently offer a parasiticide that controls external and internal parasites to cattle and sheep farmers. However, Bayer offers a variety of other products to cattle and sheep farmers, such as ear tags and external parasite control products.

The Commission has agreed to appoint a Monitor to ensure that Boehringer Ingelheim complies with all of its obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to Elanco and Bayer.

The Commission's goal in evaluating possible purchasers of divested rights and assets is to maintain the competitive environment that existed prior to the Proposed Acquisition. If the Commission determines that either buyer is not an acceptable acquirer, or that the manner of the divestiture is not acceptable, the proposed Order requires the parties to unwind the sale and then divest the products to another Commission-approved acquirer within six months of the date that the proposed Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products.

Analysis to Aid Public Comment

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

Complaint

IN THE MATTER OF

**ABBOTT LABORATORIES
AND
ST. JUDE MEDICAL, INC.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT

*Docket No. C-4600; File No. 161 0126
Complaint, December 7, 2016 – Decision, February 14, 2017*

This consent order addresses the \$25 billion acquisition by Abbott Laboratories of certain assets of St. Jude Medical, Inc. The complaint alleges that the Acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening competition in the U.S. markets for vascular closure devices, steerable sheaths, and lesion-assessing ablation catheters. The consent order requires the parties are required to divest St. Jude’s vascular closure device business and Abbott’s steerable sheath business to Terumo Corporation.

Participants

For the *Commission*: Jordan S. Andrew and Sarah E. Wohl.

For the *Respondents*: George S. Cary and Tara Tavernia, Cleary Gottlieb Steen & Hamilton LLP; Bob Nichols and Joshua H. Soven, Gibson, Dunn & Crutcher LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Abbott Laboratories (“Abbott”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Respondent St. Jude Medical, Inc. (“St. Jude”), a corporation subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the