

**ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS
TO AID PUBLIC COMMENT**
In the Matter of C.H. Boehringer Sohn AG & Co. KG
File No. 161-0077

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”) 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 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 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.

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.

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 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.

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.

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.