

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

In the Matter of Schering-Plough Corporation and Merck & Co., Inc., File No. 091-0075

I. Introduction

The Federal Trade Commission (“Commission”) has accepted for public comment an Agreement Containing Consent Order (“Consent Agreement”) from Schering-Plough Corporation (“Schering-Plough”) and Merck & Co., Inc. (“Merck”), and has issued a Complaint and the Decision and Order (“Order”) contained in the Consent Agreement. The Order seeks to remedy the anticompetitive effects that would otherwise result from the proposed merger of Schering-Plough and Merck in a number of U.S. markets. Under the terms of the Order, Merck is required to divest all of its interest in Merial Limited, an animal health joint venture with Sanofi-Aventis S.A. (“Sanofi-Aventis”), and Schering-Plough is required to divest assets related to rolapitant, a neurokinin 1 (“NK1”) receptor antagonist for chemotherapy-induced nausea and vomiting (“CINV”) and post-operative nausea and vomiting (“PONV”) in humans.

Pursuant to an Agreement and Plan of Merger dated March 8, 2009, Schering-Plough proposes to acquire Merck and rename the surviving entity Merck (the “Acquisition”), in a transaction valued at approximately \$41.1 billion. The Commission’s Complaint alleges 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, by lessening competition in the market for the manufacture and sale of NK1 receptor antagonists for CINV and PONV in humans and the manufacture and sale of numerous animal health products in the United States, including live poultry vaccines, killed poultry vaccines and cattle gonadotropins. The Consent Agreement would remedy the alleged violations by replacing the competition that would be lost in these and other markets as a result of the proposed Acquisition.

II. The Parties

Merck is a global pharmaceutical firm that researches, develops, manufactures and markets a variety of human and animal health products. In 2008, Merck had worldwide revenues of \$23.9 billion, of which 56 percent were derived from U.S. sales. In 1997, Merck and Rhône-Poulenc S.A. (now Sanofi-Aventis S.A.) combined their respective animal health businesses to form Merial Limited, a stand-alone equally-owned animal health company. Merial markets a comprehensive line of animal health pharmaceuticals and vaccines for a variety of species, including companion and production animals. The joint venture generated global revenues of approximately \$2.6 billion in 2008.

Schering-Plough is a global pharmaceutical firm that researches, develops, manufactures and markets human prescription and over-the-counter medications, as well as animal health products. In 2008, the company reported worldwide revenues of approximately \$18.5 billion, of which only \$5.6 billion were derived from sales of products in the United States. The company’s human pharmaceutical business, which includes oncology and women’s health drugs,

ranks sixteenth in sales in North America. In April 2007, Schering-Plough acquired the Intervet animal health business. The combined Schering-Plough/Intervet animal health portfolio consists of more than a thousand pharmaceuticals and vaccines for a variety of companion and production animals. Schering-Plough's animal health business generates worldwide annual revenues of approximately \$3 billion.

III. Animal Health Products

Merck and Schering-Plough are two of the leading animal health suppliers in the United States, and the proposed Acquisition raises significant competitive concerns in numerous U.S. animal health markets where Merck, through Merial Limited, and Schering-Plough compete directly. Both companies have extensive animal health portfolios that include pharmaceutical and vaccine products for a variety of companion and production animals.

The Commission initially focused its animal health investigation on certain overlap markets in poultry and cattle that raised significant competitive concerns. In the United States, for example, Merial and Schering-Plough are the two largest producers of poultry vaccines, and together they account for approximately 75 percent of U.S. sales of poultry vaccines. Poultry vaccines are used extensively by poultry producers to prevent a variety of diseases that can either kill poultry or impede their growth or development.

For example, poultry producers routinely vaccinate their flocks for Marek's disease, Newcastle disease and infectious bronchitis, the most common diseases affecting poultry in the United States. Marek's disease is caused by a herpes virus that affects the central nervous system and can cause lesions on internal organs and feather follicles. When an outbreak occurs, Marek's disease can be deadly, and it is often necessary to condemn the entire flock. Newcastle disease is a highly contagious virus characterized by gastro-intestinal, respiratory and nervous signs. Because it is easily transmitted and can cause significant damage to poultry operations, vaccines against Newcastle are widely administered by poultry producers. A third poultry disease that is commonly vaccinated against is infectious bronchitis, which targets not only the respiratory tract but also the uro-genital tract. Because infection can result in drops in egg production, it is a particularly significant problem for layers and breeders.

In addition to these commonly used vaccines, there are a number of other vaccines that are used in poultry operations to a lesser degree that would be affected by the proposed transaction. These include vaccines for infectious bursal disease, reovirus, infectious laryngotracheitis, coccidiosis, fowl pox, avian encephalomyelitis, and infectious tenosynovitis. Even though they are not used as universally as the core vaccines, these more minor vaccines play an important role in many poultry operations, as an outbreak of the disease can have equally disastrous economic consequences for poultry producers. Because of the unique characteristics of live and killed versions of poultry vaccines, they are not considered substitutes for each other.

The anticompetitive implications of eliminating one of the two leading suppliers of poultry vaccines in the United States are significant. Poultry producers have benefitted from

direct competition between Merial and Schering-Plough, which has resulted in, among other things, steeper discounts and lower prices for customers. The remaining three market participants are smaller than either Merial or Schering-Plough, and do not have the capacity that either of these firms currently enjoys. As a result, these other firms would not be able to replace the competition that the proposed Acquisition would eliminate. In addition, because of research, development and regulatory barriers, entry sufficient to deter or counteract the competitive effects of the proposed transaction is unlikely to occur within two years.

The proposed transaction is also likely to result in anticompetitive harm in the market for cattle gonadotropins. These products are used to treat follicular cysts in cattle and to synchronize the reproductive cycles of cattle undergoing artificial insemination. Although there are other reproductive products on the market, these other products are used in combination with, and not as substitutes for, cattle gonadotropins in order to achieve reproductive synchronization. The combination of Merial and Schering-Plough would result in a duopoly in the market for cattle gonadotropins leaving only Wyeth to compete with the combined firm. Thus, the proposed merger would eliminate a significant competitor in the U.S. market for cattle gonadotropins, and absent a remedy, customers would likely pay higher prices for these drugs.

The Commission's Complaint specifically identifies those markets that the Commission concluded would be adversely impacted by the transaction. The transaction likely affects competition in numerous other existing and future animal health product markets, but the Commission did not reach a conclusion with respect to these markets as the comprehensive settlement addressed any potential competitive concerns in these areas.

IV. NK1 Receptor Antagonists

The proposed Acquisition raises competitive concerns in the market for NK1 receptor antagonists for CINV and PONV. CINV is a common side effect of chemotherapy that can last up to six or seven days after treatment. The most widely prescribed class of drugs used to treat CINV is the 5-HT3 receptor antagonist class. For some patients, particularly those who receive highly emetogenic chemotherapy regimens, treatment with 5-HT3 receptor antagonists alone may not fully relieve CINV. For these patients, NK1 receptor antagonists in combination with 5-HT3 receptor antagonists appear to provide effective relief. Likewise, NK1 receptor antagonists in combination with 5-HT3 receptor antagonists can also benefit patients with PONV.

Merck introduced the first NK1 receptor antagonist, Emend® (aprepitant), in 2003, and remains the only firm in the United States with an approved drug in the class. A very limited number of other firms, including Schering-Plough with its rolapitant, have NK1 receptor antagonists in development for CINV and PONV. At the time the proposed Acquisition was announced, Schering-Plough was in the process of out-licensing rolapitant to a third party. The proposed Acquisition, however, would likely diminish the combined firm's incentive to license the product, as rolapitant's launch could have a significant impact on the revenues for Merck's first-to-market product. The proposed Acquisition could therefore delay or eliminate a future

entrant into the U.S. market for NK1 receptor antagonists for CINV and PONV and any benefits associated with that additional competition.

V. Terms of the Order

The Order issued by the Commission effectively remedies the proposed Acquisition's likely anticompetitive effects in the human and animal health markets at issue. The Order requires Merck to divest all of its interest in Merial Limited to its joint venture partner, Sanofi-Aventis, and requires Schering-Plough to divest all of the assets relating to its NK1 receptor antagonist for CINV and PONV, rolapitant, to Opko Health, Inc. ("Opko"), within ten (10) days after the proposed Acquisition is consummated. In mid-September, Merck completed the sale of its interest in Merial to Sanofi-Aventis and terminated the Merial joint venture in response to the competitive concerns raised by the proposed Acquisition as required by the Order.

The Commission is satisfied that the divestiture of Merck's interest in Merial to Sanofi-Aventis remedies any and all competitive concerns raised by the combination of the parties' animal health businesses. Because Merck has no animal health operations outside of Merial, the divestiture of Merck's interest in Merial and termination of the Merial joint venture effectively eliminates all of the animal health overlaps created by the proposed Acquisition. The Commission is also satisfied that Sanofi-Aventis is a well-qualified acquirer of Merck's interest in Merial. Sanofi-Aventis already owned 50 percent of Merial, as Merck's joint venture partner, and Merial has been operating as a stand-alone business for quite some time. Merial's operations, therefore, would continue without interruption despite the change in ownership.

The Order contains several provisions designed to preserve the remedial benefits of the animal health divestiture to Sanofi-Aventis, most important of which is the "prior approval" provision. At the time the parties entered into an agreement to divest Merck's shares in Merial to Sanofi-Aventis, they also entered into a call option agreement ("Call Option") granting Sanofi-Aventis the right to combine the animal health businesses of Merial and Schering-Plough after the Acquisition is consummated and to recreate the 50/50 joint venture between Merck and Sanofi-Aventis. The effect of the Call Option, if exercised, would be to reverse the animal health remedy required by the Order. Consistent with Commission policy, the Order contains a prior approval provision to address the credible risk (here, the high likelihood) that the combined Merck/Schering-Plough and Sanofi-Aventis would combine their animal health businesses after the divestiture. The call option was entered into with the expectation that it is likely to be exercised, and the firms have publicly identified the advantages of such a combination. As a result, Merck is prohibited from acquiring any of Merial's animal health assets, or in any way combining the animal health businesses of Merck and Sanofi-Aventis without the prior approval of the Commission.

On the human health side, the Commission is satisfied that divestiture of the assets relating to Schering-Plough's NK1 receptor antagonist for CINV and PONV would remedy the competitive concerns raised by the proposed transaction in that market. The Commission is satisfied that Opko is a well-qualified acquirer of the rolapitant assets. Opko, headquartered in

Florida, is a publicly traded healthcare company involved in the discovery, development and commercialization of pharmaceutical and biological products. Opko has the financial resources and experience to develop and launch rolapitant, and to serve as an effective competitor in the market for NK1 receptor antagonists for CINV and PONV in the United States. If the Commission determines that Opko is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures is not acceptable, the parties must unwind the sale and divest the assets to another Commission-approved acquirer within six months of the date the Order becomes final. If Merck fails to divest within the six months, the Commission may appoint a trustee to divest the relevant assets.

The Order includes certain provisions to ensure that the divestiture to Opko is successful. For example, the parties are required to provide transitional services, some of which may extend for up to 24 months, to enable Opko to complete clinical testing and obtain regulatory approval to market the product in the United States. The Order also allows the Commission to appoint an Interim Monitor to ensure that the parties fulfill all of their obligations related to the divestiture of the assets.

In order to ensure, among other things, that the Commission remains informed about the status of the rolapitant assets pending divestiture and about the efforts being made to accomplish the divestiture, as well as the divestiture of Merck's interest in Merial and termination of the joint venture, the Order requires the parties to file periodic reports with the Commission until the divestiture is accomplished.

VI. Effective Date of the Order and Opportunity for Public Comment

The Commission issued the Complaint and the Order, and served them upon respondents at the same time it accepted the Consent Agreement for public comment. As a result of this action, the Order has already become effective. The Commission adopted procedures in August 1999 to allow for immediate implementation of an Order prior to a public comment period. The Commission announced that it "contemplates doing so only in exceptional cases where, for example, it believes that the allegedly unlawful conduct to be prohibited threatens substantial and imminent public harm." 64 Fed. Reg. 46267 (1999).

This case is an appropriate one in which to issue a final order before receiving public comment because of the risk that Sanofi-Aventis will exercise the Call Option shortly after the proposed Acquisition is consummated, which would reverse the animal health remedy of the Consent Agreement. Making the Order final immediately ensures that the safeguards embodied in the Order are implemented before the Call Option can be exercised and subjects the respondents to civil penalties for failing to comply with the Order.

The Consent Agreement and Order have also been placed on the public record for 30 days to solicit comments from interested persons. Comments received during this period will

become part of the public record. After 30 days, the Commission will again review the Order and the comments received, and may determine that the Order should be modified.¹

The Commission anticipates that the Order, as issued, will resolve the competitive problems alleged in the Complaint. The purpose of this analysis is to facilitate public comment on the Order and to aid the Commission in determining whether to modify the Order in any respect. This analysis is not intended to constitute an official interpretation of the Consent Agreement or the Order or to modify their terms in any way.

¹ If the respondents do not agree to such modifications, the Commission may (1) initiate a proceeding to reopen and modify the Order in accordance with Rule 3.72(b), 16 CFR § 3.72(b), or (2) commence a new administrative proceeding by issuing an administrative complaint in accordance with Rule 3.11, 16 CFR § 3.11. See 16 CFR § 2.34(e)(2).