

**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”) fr

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. §

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 bursal disease (IBD), among other diseases.

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

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 agreeme



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