

**Analysis of Proposed Consent Order
To Aid Public Comment**

In the Matter of Sanofi-Synthelabo and Aventis, File No. 041 0031

The Federal Trade Commission has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Sanofi-Synthelabo (“Sanofi”) and Aventis. The Consent Agreement contains an Order to Maintain Assets to preserve, among other things, the viability, marketability, and competitiveness of the assets to be divested pending their divestiture. The Consent Agreement also contains a Decision and Order that is designed to remedy the anticompetitive effects of Sanofi’s proposed acquisition of Aventis. Under the terms of the Consent Agreement, the companies will be required to: (1) divest all Arixtra® assets; (2) divest to Pfizer all United States intellectual property and key clinical trials, currently conducted by Aventis, related to Camptosar®; and (3) divest Aventis’ royalty rights to Sepracor’s Estorra®.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the agreement and any comments received and will decide whether it should withdraw from the agreement or make final the agreement’s proposed Consent Order.

Pursuant to a tender offer launched January 26, 2004, Sanofi proposes to acquire Aventis. The offer accepted by Aventis’ Board values Aventis at approximately \$64 billion. The Commission’s Complaint alleges that the proposed acquisition, 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 Federal Trade Commission Act, as amended, 15 U.S.C. § 45, in the markets for: (1) factor Xa inhibitors; (2) cytotoxic drugs that treat colorectal cancer; and (3) prescription drugs that treat insomnia. The proposed Consent Agreement would remedy the alleged violations by replacing the lost competition that would result from the acquisition in each of these markets.

Factor Xa Inhibitors

Factor Xa inhibitors are anticoagulant products that are used in acute settings to treat and prevent venous thromboembolism (“VTE”) and other conditions relating to excessive blood clot formation. Although unfractionated heparin was once the standard of care for the acute prevention and treatment of VTE and related complications, factor Xa inhibitors have become the treatment of choice due in large part to a better side effect profile and ease of use. Annual U.S. sales of factor Xa inhibitors totaled \$1.35 billion in 2003.

The U.S. market for factor Xa inhibitors is highly concentrated. Aventis' market leading Lovenox® currently accounts for over 90 percent of factor Xa inhibitor sales in the United States. Sanofi markets Arixtra®, a more recent market entrant whose competitive significance is likely to expand as it receives Food and Drug Administration ("FDA") approval for new indications. Although other factor Xa inhibitors are available in the United States – including Pfizer's Fragmin® and Pharmion's Innohep® – they have not been successful competitors in the market.

As with most pharmaceutical products, entry into the manufacture and sale of factor Xa inhibitors is difficult, expensive and time consuming. In order to enter the market, a firm must incur substantial sunk costs to research, develop, manufacture and sell factor Xa inhibitors. In addition, the approval for multiple indications is critical to the success of a new factor Xa inhibitor. Gaining FDA approval for each indication takes a significant amount of time because of the need to conduct clinical trials in support of each indication. New or expanded entry sufficient to deter or counteract the anticompetitive effects of the acquisition likely would not occur in a timely manner. New entry is unlikely to occur in the face of a 5 to 10 percent increase in the price of these drugs, and current factor Xa inhibitors also would be unlikely to counteract such a price increase. The only firm that is likely to launch a product in the United States in the foreseeable future is AstraZeneca, which recently filed a New Drug Application with the FDA for its own factor Xa inhibitor, Exanta®. However, Exanta® is a direct thrombin inhibitor rather than a factor Xa inhibitor. Further, AstraZeneca is seeking approval for only one of the indications that factor Xa inhibitors are approved for. Therefore, it is unlikely that entry by Exanta® would have a sufficient, timely effect on competition to resolve the competitive effects of the proposed acquisition.

The proposed acquisition would cause significant anticompetitive harm in the U.S. market for factor Xa inhibitors by eliminating the actual, direct, and substantial competition between Sanofi and Aventis. This loss of competition likely would result in higher prices.

The proposed Consent Order maintains competition in the factor Xa inhibitor market by requiring that: (1) Sanofi divest Arixtra® to GlaxoSmithKline; (2) Sanofi transfer to GlaxoSmithKline the manufacturing facilities used by Sanofi to produce Arixtra® in final finished form; (3) Sanofi contract manufacture the active pharmaceutical ingredient ("API") and certain intermediate step ingredients until such time as GlaxoSmithKline obtains the necessary regulatory approvals and supply sources that will allow it to manufacture the API independently; (4) Sanofi assist GlaxoSmithKline in completing three key clinical trials; (5) Sanofi provide incentives to certain employees to continue in their positions until the divestiture is accomplished; (6) for a period of time after the assets are divested, Sanofi provide GlaxoSmithKline an opportunity to enter into employment contracts with individuals who have experience relating to Arixtra®; and (7) Sanofi take steps to maintain the confidentiality of confidential information related to Arixtra®.

Cytotoxic Drugs for the Treatment of Colorectal Cancer

Colorectal cancer is the second leading cause of cancer-related deaths in the United States for both men and women. Approximately 146,940 new cases of colorectal cancer will be diagnosed in 2004 and 56,730 people will die from the disease. Cytotoxic colorectal cancer drugs have been shown to be more effective than older, generic drug treatments. The U.S. market for cytotoxic colorectal cancer therapies currently generates approximately \$1 billion in annual sales.

The U.S. market for cytotoxic colorectal cancer drugs is highly concentrated. Two major cytotoxic products approved by the FDA for the treatment of colorectal cancer are Sanofi's product, Eloxatin®, and Camptosar®, a product developed by Yakult Honsha ("Yakult") and marketed in the U.S. by Pfizer. Combined, the two products have over 80 percent of the U.S. cytotoxic colorectal cancer drug market. Roche is the only other provider in the market with more than a 1 percent market share.

Entry into the market for cytotoxic colorectal cancer drugs is difficult, time consuming, and costly because of the lengthy development periods, the need for FDA approval, and the substantial sunk costs required to research, develop, manufacture and sell these drugs.

Although Aventis does not directly market a cytotoxic colorectal cancer drug in the United States, there are significant contractual entanglements between Aventis and Pfizer that affect the U.S. market. Pfizer licenses irinotecan (under the brand name Camptosar®) from Yakult for sales in the United States. Aventis licenses irinotecan (under the brand name Campto®) from Yakult for sales in other territories. Under a data transfer agreement, Pfizer and Aventis share the results of key clinical trials. Aventis also possesses a number of U.S. patents relating to Camptosar®. These entanglements allow Aventis to impact the Camptosar® business. The proposed acquisition thus creates an overlap in the U.S. market between Sanofi's Eloxatin® and Aventis' contractual ties to Camptosar®. This overlap affords the combined firm (1) access to competitively sensitive information from its main competitor, Pfizer, and (2) control over key clinical trials that Pfizer relies on for FDA applications that would expand Camptosar® indications in the United States. Therefore, the proposed acquisition would cause significant anticompetitive harm in the U.S. market for cytotoxic colorectal cancer drugs by reducing the actual, substantial competition between Sanofi and Pfizer.

The proposed Consent Agreement eliminates the potential anticompetitive effects of the acquisition in the U.S. cytotoxic colorectal cancer drug market by requiring the parties to: (1) divest to Pfizer key clinical studies for Campto® that are currently conducted by Aventis, together with certain U.S. patents and other assets pertaining to territories where Pfizer currently markets Camptosar®; (2) provide Pfizer with the opportunity to enter into employment contracts

with certain employees involved in the key clinical trials; (3) deliver to Pfizer all confidential business information regarding Camptosar® that Aventis has in its possession; and (4) commit to maintain the assets to be divested in a manner that preserves the integrity, viability, and value of the assets, until the divestitures are accomplished.

Prescription Drugs for the Treatment of Insomnia

More than 50 million people in the United States suffer from insomnia, the perception or complaint of inadequate sleep. The U.S. insomnia treatment market is estimated to have generated approximately \$1.65 billion in 2003 sales and is projected to increase to \$3.36 billion by 2010.

Sanofi dominates the market for prescription drugs that treat insomnia with its well known product, Ambien®. Sanofi's market share in the United States exceeded 85 percent in 2003. Sepracor is developing a product called Estorra®, which is expected to be launched in the beginning of 2005 and is likely to become a significant competitor to Ambien®. Although Aventis does not market a prescription sleep drug in the United States, there are financial and informational entanglements between Aventis and Sepracor relating to the Estorra® product. Therefore, the acquisition creates an overlap between Ambien® and Aventis' royalty rights to Estorra®.

The proposed acquisition would create anticompetitive effects in the market for prescription drugs that treat insomnia by diluting competition between Sanofi and Sepracor. Although several new products are expected to enter the market in the next five years, it is unlikely that the entry of these products, alone or in combination, could counteract the anticompetitive effects of the acquisition. Accordingly, allowing Sanofi to acquire Aventis' rights to Estorra would reduce Sanofi's incentives to compete against Sepracor in the prescription sleep drug market and would be likely to lead to higher prices.

The proposed Consent Agreement remedies the acquisition's anticompetitive effects by requiring the parties to divest their contractual rights to Estorra®. No later than 90 days after the Order becomes final, the parties are required to divest their rights to Estorra® royalties in a manner that receives Commission approval, either to Sepracor or to a third party approved by the Commission.

Interim Monitor

The Commission has appointed Francis J. Civile as Interim Monitor to oversee the asset transfers and to ensure Sanofi's and Aventis' compliance with all of the provisions of the proposed Consent Order. Mr. Civile has over 35 years of experience in the pharmaceutical industry and is well-respected in the industry. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the proposed

Consent Order requires Sanofi and Aventis to file reports with the Commission periodically until the divestitures and transfers are accomplished.

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