

UNITED STATES OF AMERICA  
BEFORE FEDERAL TRADE COMMISSION

<p><b>In the Matter of</b></p> <p style="text-align: center;"><b>SANOFI-SYNTHÉLABO,</b> <b>a <i>société anonyme</i>;</b></p> <p><b>and</b></p> <p style="text-align: center;"><b>AVENTIS,</b> <b>a <i>société anonyme</i>.</b></p>	<p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p>	<p><b>Docket No. C-4112</b></p>
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**COMPLAINT**

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Sanofi-Synthélabo (“Sanofi”), a corporation subject to the jurisdiction of the Commission, has offered to acquire the common shares of Aventis (“Aventis”), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act (“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 public interest, hereby issues its Complaint, stating its charges as follows:

**I. DEFINITIONS**

1. “Arixtra” means all products that contain the active pharmaceutical ingredient Fondaparinux and any dose form, presentation or line extension thereof. “Arixtra” includes, without limitation, any combination of Fondaparinux with any other product.
2. “Camptosar” means all product(s) that contain the active pharmaceutical ingredient Irinotecan and any dose form, presentation or line extension thereof. “Camptosar” includes, without limitation, any combination of Irinotecan with any other product.

3. “Colorectal Cancer” means cancer of the colon or rectum.
4. “Commission” means the Federal Trade Commission.
5. “Cytotoxic Drugs” means drugs that work by targeting and damaging cells that grow at a rapid rate.
6. “Eloxatin” means all products that contain the active pharmaceutical ingredient oxalplatin and/or that are marketed or sold under the Product Trademark Eloxatin or Eloxatine. “Eloxatin” includes all such products whether marketed within or outside the United States.
7. “Estorra” means any product that contains (+) zopiclone as an active pharmaceutical ingredient. “Estorra” includes any product that contains (+) zopiclone and one or more other active ingredients.
8. “Factor Xa Inhibitors” are anticoagulants used to treat and prevent venous thromboembolism and related conditions, including deep vein thrombosis and pulmonary embolism.
9. “FDA” means the United States Food and Drug Administration.
10. “GlaxoSmithKline” means GlaxoSmithKline plc, a corporation organized, existing and doing business under and by virtue of the laws of the United Kingdom, with its offices and principal place of business located at 980 Great West Road, Brentford, Middlesex XO TW8 9GS, United Kingdom.
11. “Insomnia” means the perception or complaint of inadequate sleep.
12. “Pfizer” means Pfizer Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 235 East 42<sup>nd</sup> Street, New York, New York 10017.
13. “Respondents” means Sanofi and Aventis individually and collectively.
14. “Sepracor” means Sepracor Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 84 Waterford Drive, Marlborough, Massachusetts 01752.

15. “Yakult” means Yakult Honsha Co. Limited, a corporation organized, existing and doing business under and by virtue of the laws of Japan, having its principal place of business at No. 1-19, Higashi-Shinbashi 1-chome, Minato-ku, Tokyo, Japan.

## **II. RESPONDENTS**

16. Respondent Sanofi is a corporation organized, existing and doing business under and by virtue of the laws of the French Republic, with its office and principal place of business located at 174, avenue de France, 75013 Paris, France. Sanofi’s principal subsidiary in the United States is located at 90 Park Avenue, New York, New York 10016. Sanofi, among other things, is engaged in the research, development, manufacture and sale of human pharmaceutical products.
17. Respondent Aventis is a corporation organized, existing and doing business under and by virtue of the laws of the French Republic, with its office and principal place of business located at 16, avenue de l’Europe, 67300 Schiltigheim, France. Aventis’ principal subsidiary in the United States is Aventis Pharmaceuticals Inc., located at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807-2854. Aventis, among other things, is engaged in the research, development, manufacture and sale of human pharmaceutical products.
18. Respondents are, and at all times relevant herein have been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and are corporations whose business is in or affects commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

## **III. THE PROPOSED ACQUISITION**

19. On January 26, 2004, Sanofi made an unsolicited tender offer of stock and cash for the voting securities of Aventis. On April 25, 2004, Aventis accepted an improved offer from Sanofi (“Acquisition”). The Acquisition is valued at approximately \$64 billion.

#### **IV. THE RELEVANT MARKETS**

20. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are:
  - a. the research, development, manufacture and sale of factor Xa inhibitors;
  - b. the research, development, manufacture and sale of cytotoxic drugs for the treatment of colorectal cancer; and
  - c. the research, development, manufacture and sale of prescription drugs for the treatment of insomnia.
21. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant lines of commerce.

#### **V. THE STRUCTURE OF THE MARKETS**

22. Aventis dominates the market for the research, development, manufacture and sale of factor Xa inhibitors with its Lovenox product that has a 92 percent share. Sanofi recently entered the market with its product Arixtra. Sanofi and Aventis are two of only three companies that are well-positioned to compete successfully in the market for factor Xa inhibitors for the next two years.
23. Sanofi and Pfizer dominate the market for the research, development, manufacture and sale of cytotoxic drugs for the treatment of colorectal cancer. Sanofi sells Eloxatin and Pfizer sells the main competitor to Eloxatin, Camptosar, under a licensing agreement from Yakult. Pfizer relies on Aventis for the results of key clinical trials conducted by Aventis, the data from which Pfizer relies on in applying for FDA approval. Pfizer also relies on intellectual property rights from Aventis and a data transfer agreement with Aventis. Through the existing relationship between Aventis and Pfizer, the Acquisition would give Respondent Sanofi access to competitively sensitive information concerning Camptosar pricing, forecasts and marketing strategy. Furthermore, post-acquisition, Sanofi would control its main competitor's key clinical trials and important intellectual property.

24. Sanofi dominates the market for the research, development, manufacture and sale of prescription drugs for the treatment of insomnia with its Ambien product that has an 87 percent share. Sepracor plans to enter this market within the next nine months with its product Estorra, which is licensed to Sepracor from Aventis. Under the licence agreement, Aventis is entitled to royalty payments based on Estorra sales. After the acquisition, Sanofi would control the leading product in this market and have a financial stake in what is likely to be its main competitor.

## **VI. ENTRY CONDITIONS**

25. Entry into any of the relevant lines of commerce described in Paragraphs 20(a) through 20(c) would not be timely, likely or sufficient in its magnitude, character and scope to deter or counteract the anticompetitive effects of the Acquisition. Developing and obtaining FDA approval takes at least two years for even the simplest product and significantly longer for more complex products. Additionally, patents and other intellectual property create significant barriers to entry into these markets.

## **VII. EFFECTS OF THE ACQUISITION**

26. 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, in the following ways, among others:
- a. by eliminating actual, direct, and substantial competition between Sanofi and Aventis, and lessening competition, in the market for the research, development, manufacture and sale of factor Xa inhibitors, thereby increasing the ability of the merged entity to unilaterally raise prices of factor Xa inhibitors;
  - b. by affording Respondent Sanofi access to competitively sensitive information concerning Camptosar pricing, forecasts and marketing strategy, and control over its main competitor's key clinical trials and important intellectual property, thus diluting competition between Sanofi and Pfizer in the market for the research, development, manufacture and sale of cytotoxic drugs for the treatment of colorectal cancer, thereby (a) increasing the likelihood of unilateral anticompetitive effects and coordinated interaction, and (b) increasing the likelihood that customers would be forced to pay higher prices for cytotoxic drugs for the treatment of colorectal cancer; and

- c. by giving Respondent Sanofi a financial stake in its imminent main competitor, Sepracor, thus diluting competition in the market for the research, development, manufacture and sale of prescription drugs for the treatment of insomnia and increasing the likelihood that purchasers would be forced to pay higher prices for prescription drugs for the treatment of insomnia.

### **VIII. VIOLATIONS CHARGED**

27. The tender offer and the Acquisition Agreement described in Paragraph 19 constitute violations of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.
28. The Acquisition described in Paragraph 19, 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 July, 2004, issues its Complaint against said Respondents.

By the Commission, Commissioner Harbour recused.

Donald S. Clark  
Secretary

SEAL: