**UNITED STATES OF AMERICA 0410083**
**BEFORE FEDERAL TRADE COMMISSION**

**COMMISSIONERS:** **Deborah Platt Majoras, Chairman**
**Orson Swindle**
**Thomas B. Leary**
**Pamela Jones Harbour**
**Jon Leibowitz**

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| **In the Matter of** | ) | |
| **GENZYME CORPORATION,** **a corporation;** | ) | |
| **and** | ) | **Docket No. C-4128** |
| **ILEX ONCOLOGY, INC.,** **a corporation.** | ) | |

## 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 Genzyme Corporation ("Genzyme"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Respondent ILEX Oncology, Inc. ("Ilex"), 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. "Acute rejection" means a sudden injury to the transplanted organ that, if not treated, can cause loss of the organ.

2. "Bone Marrow Transplant" means blood and marrow transplantation including, but not limited to, the transplantation of stem cells, bone marrow, peripheral blood, and cord blood.

3. "Campath" means Ilex's trademarked and patented drug Campath 1H, a humanized monoclonal antibody directed against CD-52 and any product containing such antibody as an active ingredient and any dose form or prescription thereof.

4. "Commission" means the Federal Trade Commission.

5. "FDA" means the United States Food and Drug Administration.

6. "Induction therapy" means the use of an acute therapy drug before, during, and/or immediately after a SOT procedure to suppress the immune system and decrease the likelihood of rejection of the transplanted organ.

7. "Off-label" means the use of a drug for a purpose other than the indication or indications for which the drug has received marketing approval from the FDA.

8. "Respondents" means Genzyme and Ilex individually and collectively.

9. "Schering" means Schering AG, a corporation organized, existing, and doing business under and by virtue of the laws of Germany, with its office and principal place of business located at D-13345 Berlin, Germany. Schering includes, but is not limited to, its United States affiliates Berlex, Inc., and Berlex Laboratories, LLC, with headquarters in Montville, NJ.

10. "SOT" means solid organ transplant and refers to transplantation procedures related to solid organs including, but not limited to, heart, intestine, kidney, liver, lung, and pancreas. SOT does not include Bone Marrow Transplant.

11. "SOT acute therapy" means the use of an immunosuppressant drug in solid organ transplant either as an induction therapy or as an acute rejection treatment.

12. "T-cell depleting drugs" means a class of drugs that work by killing, or depleting, T-lymphocytes, a type of white blood cell that attacks foreign cells, such as a transplanted organ.

13. "Thymoglobulin" means Genzyme's trademarked and patented drug Thymoglobulin, a humanized polyclonal antibody directed against antigens expressed on human T-lymphocytes and any dose form, prescription, or line extension thereof.

## II. RESPONDENTS

14. Respondent Genzyme is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Massachusetts, with its office and principal place of business located at 500 Kendall Street, Cambridge, Massachusetts 02142. Genzyme, among other things, is engaged in the research, development, marketing, and sale of human pharmaceutical products, including SOT acute therapy drugs.

15. Respondent Ilex is 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 4545 Horizon Hill Blvd., San Antonio, Texas 78229. Ilex, among other things, is engaged in the research, development, marketing, and sale of human pharmaceutical products, including SOT acute therapy drugs.

16. 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

17. On February 26, 2004, Genzyme and Ilex entered into a stock-for-stock merger agreement (the "Purchase Agreement") whereby Genzyme agreed to acquire Ilex in a transaction valued at approximately $1 billion (the "Acquisition").

## IV. THE RELEVANT MARKET

18. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the Acquisition is the research, development, manufacture, and sale of SOT acute therapy drugs.

19. 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 line of commerce.

## V. THE STRUCTURE OF THE MARKET

20. The market for SOT acute therapy drugs is highly concentrated as measured by the Herfindahl-Hirschman Index ("HHI"). Genzyme, with its T-cell depleting drug Thymoglobulin, is the leading supplier in the market for the research, development, marketing, and sale of SOT acute therapy drugs in the United States, capturing approximately 45% of that market. Ilex is also a significant supplier in the market for SOT acute therapy drugs, with its T-cell depleting drug, Campath. Approved by the FDA for the treatment of Chronic Lymphocytic Leukemia ("CLL"), Campath is used off-label as a SOT acute therapy drug, and currently has an approximately 8% share of that market. Market participants anticipate that Campath's share of the SOT acute therapy drug market will increase significantly in the near future. Ilex has a distribution and development agreement for Campath with Schering. As part of this agreement, Schering is solely responsible for the marketing and distribution of Campath in the United States.

## VI. ENTRY CONDITIONS

21. Entry into the relevant line of commerce described in Paragraph 18 would not be timely, likely, or sufficient in its magnitude, character and scope to deter or counteract the anti-competitive effects of the Acquisition. Developing a drug, obtaining FDA approval, and convincing doctors to prescribe the drug, takes significantly longer than two years.

## VII. EFFECTS OF THE ACQUISITION

22. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant market 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. eliminating actual, direct and substantial competition between Genzyme and Ilex in the market for the research, development, marketing and sale of SOT acute therapy drugs;

b. increasing the ability of the merged entity to unilaterally raise prices of SOT acute therapy drugs; and

c. reducing innovation in the relevant market.

## VIII. VIOLATIONS CHARGED

23. The Purchase Agreement described in Paragraph 17 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

24. The Acquisition described in Paragraph 17, 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 twentieth day of December, 2004, issues its Complaint against said Respondents.

By the Commission, Commissioner Harbour recused.

Donald S. Clark
Secretary

SEAL: