0410083

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

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

ORDER TO HOLD SEPARATE AND MAINTAIN ASSETS

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Genzyme Corporation ("Genzyme") of Respondent ILEX Oncology, Inc. ("ILEX"), hereinafter referred to as "Respondents," who has a distribution contract with Schering AG, through its wholly owned United States subsidiary, Berlex, Inc. ("Schering"), and Respondents having been furnished thereafter with a draft Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and that, if issued by the Commission, would charge Respondent Genzyme and Respondent ILEX with violations 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; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by

Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission, having thereafter considered the matter and having determined that it had reason to believe that Respondent Genzyme and Respondent ILEX have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues this Order to Hold Separate and Maintain Assets ("Hold Separate Order").

1. Respondent Genzyme Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the Commonwealth of Massachusetts, with its office and principal place of business located at 500 Kendall Street, Cambridge, Massachusetts 02142.

2. Respondent ILEX Oncology, Inc. 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.

3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

I.

IT IS ORDERED that, as used in this Hold Separate Order, the following definitions shall apply:

A. "Genzyme" means Genzyme Corporation, its directors, officers, employees, agents, attorneys, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Genzyme Corporation, and the respective directors, officers, employees, agents, attorneys, representatives, predecessors, successors, and assigns of each. After the Acquisition, Genzyme shall include ILEX.

B. "ILEX" means ILEX Oncology, Inc., its directors, officers, employees, agents, attorneys, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by ILEX Oncology, Inc., and the respective directors, officers, employees, agents, attorneys, representatives, predecessors, successors, and assigns of each. After the Acquisition Date, ILEX shall mean the assets and businesses of ILEX that have been acquired by Genzyme.

C. "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-13342 Berlin, Germany. Schering includes, but is not limited to, its United States affiliates Berlex, Inc. and Berlex Laboratories, LLC, with headquarters in Montville, NJ.

D. "Respondent Genzyme" shall mean Genzyme, and Genzyme and ILEX after the Acquisition.

E. "Commission" means the Federal Trade Commission.

F. "Acquirer" means Schering or any other entity that receives the prior approval of the Commission to acquire the Campath SOT Earnings pursuant to Paragraph III. of the Decision and Order.

G. "Acquisition" means the proposed acquisition by Genzyme of ILEX pursuant to the Merger Agreement dated February 26, 2004, by and among Respondent Genzyme and Respondent ILEX.

H. "Acquisition Date" means the date the Acquisition is consummated.

I. "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.

J. "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.

K. "Campath Earnings" means the U.S. sales of Campath less certain costs and expenses as described in the Revised Distribution Agreement, including, among other things, the expenses Schering incurs in marketing and selling Campath.

L. "Campath Intellectual Property" means all of the following related to Campath, to the extent owned, controlled, or licensed by Respondents:

1. Patents;

2. copyrights;

3. Campath Trademarks; and

4. trade secrets, know-how, techniques, data, inventions, practices, methods and other confidential or proprietary technical, business, research,

development and other information, and all rights in any jurisdiction to limit the use or disclosure thereof.

M. "Campath Manufacturing Technology" means all technology, trade secrets, know-how, and proprietary information related to the manufacture, validation, packaging, release testing, stability, and shelf life of Campath including Campath's formulation, in existence and in the possession of Respondents as of the Effective Date, including, but not limited to, manufacturing records, sampling records, standard operating procedures, and batch records related to the manufacturing process, and supplier lists.

N. "Campath Non-SOT" means Campath that is sold for purposes of treating patients for any therapy, procedure, or protocol other than a SOT.

O. "Campath Non-SOT Earnings" means the Campath Earnings minus the Campath SOT Earnings.

P. "Campath Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and clinical trial materials and information in existence and in the possession of Respondent(s) as of the Effective Date, to the extent related to Campath and all rights thereto, in any and all jurisdictions.

Q. "Campath SOT" means Campath that is used in treating patients before, during, or after a SOT.

R. "Campath SOT Assets" includes the following:

1. The Campath SOT License; and

2. The Campath SOT Earnings.

S. "Campath SOT Earnings" means the U.S. sales of Campath for SOT less certain costs and expenses as described in the Revised Distribution Agreement, including, among other things, the expenses Schering incurs in marketing and selling Campath SOT.

T. "Campath SOT Formula" means the formula that will be used as a basis for the Monitor and Schering to account for the U.S. sales of Campath SOT as described in the Revised Distribution Agreement.

U. "Campath SOT License" means all of ILEX's rights, title, and interest in and to all assets related to ILEX's worldwide business related to Campath SOT, to the extent legally transferable, including the research, development, manufacture, distribution, marketing, or sale of Campath SOT, including, without limitation, the following:

1. a fully paid, and royalty-free worldwide license with the rights to sublicense all Campath Intellectual Property and Campath Trade Dress to make, distribute, offer for sale, promote, advertise, sell, import, export, or have used, made, distributed, offered for sale, promoted, advertised, sold, imported, or exported Campath SOT anywhere in the world;

2. access to and copies of Campath Scientific and Regulatory Materials;

3. FDA rights of reference or use to Campath;

4. access to and copies of all of ILEX's books, records, and files related to Campath development, including, but not limited to, the following specified documents: the product registrations; pharmacology and toxicology data contained in all BLAs, ABLAs, SBLAs, and MAAs; all data submitted to and all correspondence with the FDA and other governmental agencies; all validation documents and data; all market studies; all sales histories, including, without limitation, clinical data, and sales force call activity, for Campath from January 1, 2001, through the Effective Date, and quality control histories pertaining to Campath owned by, or in the possession or control of, Respondents, or to which Respondents have a right of access, in each case such as is in existence as of the Effective Date;

5. Campath Manufacturing Technology (if and when Respondents receive such information).

V. "Campath Trade Dress" means the trade dress of Campath to the extent owned, controlled or licensed by Respondents, including, but not limited to, product packaging associated with the sale of Campath worldwide and the lettering of Campath's trade name or brand name.

W. "Campath Trademarks" means, to the extent owned, controlled or licensed by Respondents, all proprietary names or designations, trademarks, tradenames, and brand names for Campath, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith.

X. "Confidential Business Information" means all information owned by, or in the possession or control of Schering that is not in the public domain related to the research, development, manufacture, marketing, commercialization, distribution, importation, exportation, cost, pricing, supply, sales, sales support, after-sale servicing, or use of Campath SOT.

Y. "Distribution Agreement" means the Distribution and Development Agreement entered into as of August 23, 1999 (as amended on December 19, 2000, and

January 29, 2003) by and between ILEX Pharmaceuticals, L.P., as successor to L&I Partners, L.P., and Schering.

Z. "Divestiture Agreement" means the Revised Distribution Agreement or any agreement between the Respondents or the Divestiture Trustee and an Acquirer, as well as all amendments, exhibits, attachments, agreements, and schedules thereto, that have been approved by the Commission, related to the divestiture of the Campath SOT Assets.

AA. "Divestiture Trustee" means the trustee appointed by the Commission pursuant to Paragraph III. of the Decision and Order.

BB. "Effective Date" means the date on which Respondent Genzyme divests to Schering or a Divestiture Trustee divests to an Acquirer the Campath SOT Assets completely and as required by Paragraph II. or III. of the Decision and Order.

CC. "FDA" means the United States Food and Drug Administration or any successor agency with responsibilities comparable to those of the United States Food and Drug Administration.

DD. "Held Separate Amount" means seven and one-half (7.5) percent of the U.S. sales of Campath from the Acquisition Date until the end of the Hold Separate Period.

EE. "Hold Separate Period" means the time period during which the Hold Separate Order is in effect, which shall begin as of the date the Acquisition occurs and terminate pursuant to Paragraph VI. of this Hold Separate Order.

FF. "Monitor" means the person or entity appointed pursuant to this Hold Separate Order.

GG. "Pacific Rim" means the following countries: Bhutan, Cambodia, Indonesia, Japan, Laos, Malaysia, Maldives, Mongolia, Myanmar (Burma), Nepal, North Korea, Peoples Republic of China, the Philippines, Republic of China (Taiwan), South Korea, Thailand, and Vietnam.

HH. "Patents" means all patents, patent applications, and statutory invention registrations, in each case existing as of the Effective Date (*except* where this Order specifies a different time), and includes all reissues, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, all rights therein provided by international treaties and conventions, and all rights to obtain and file for patents and registrations thereto in the world, related to Campath as of the Effective Date.

II. "Revised Distribution Agreement" means the Distribution and Development Agreement by and between Respondents and Schering, as amended by

Amendment No. 3 dated November 23, 2004, and attached as Confidential Appendix II. to the Decision and Order.

JJ. "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.

KK. "UNOS Data" means data compiled by the United Network for Organ Sharing or its successor or equivalent.

II.

IT IS FURTHER ORDERED that:

A. During the Hold Separate Period, Respondents shall take such actions as are necessary to maintain the viability, marketability, and competitiveness of the Campath SOT Assets, and shall prevent the destruction, removal, wasting, deterioration, sale, disposition, transfer, or impairment of the Campath SOT Assets, except for ordinary wear and tear.

B. During the Hold Separate Period, Respondents shall:

1. Allow Schering to retain the Held Separate Amount for the duration of the Hold Separate Period; and

2. not exercise direction or control over, or influence directly or indirectly, the Held Separate Amount, or the Monitor, appointed pursuant to this Hold Separate Order.

C. During the Hold Separate Period, Schering shall continue to retain the designated income Schering receives from sales of Campath as described in the Revised Distribution Agreement.

D. The Held Separate Amount shall continue to remain with Schering until the Monitor has collected the applicable data to input into the Campath SOT Formula whereby the amount of Campath SOT Earnings generated by Campath SOT sales since the Acquisition Date will have been accounted for, and future Campath SOT Earnings can be accounted for and collected by Schering. Within five (5) days after the Monitor, the Commission Staff, and Schering have approved these procedures, Respondent Genzyme shall have the right to receive from Schering, as described in the Revised Distribution Agreement, the appropriate percentage of the Held Separate Amount not attributed to SOT sales.

PROVIDED, HOWEVER, Schering's approval shall not be required to the extent that it is unreasonably withheld or made contingent upon or tied to issues not related to such accounting procedures.

E. The Monitor Agreement, entered into pursuant to Paragraph II.G. of this Hold Separate Order, shall require continued accounting by the Monitor of the Campath SOT Earnings on a periodic basis, including any adjustments in the Campath SOT Formula and data inputs as are necessary. *PROVIDED, HOWEVER*, nothing in this Hold Separate Order shall prohibit Respondents from engaging an independent auditor at their own expense, which auditor shall be subject to appropriate covenants precluding the disclosure of any Confidential Business Information to Respondents, to verify the methods used to calculate the Campath SOT Earnings and that the amount of Campath SOT Earnings gathered by Schering is consistent with those calculations.

F. Each of Respondents' employees having access to Confidential Business Information, whether directly or indirectly, must maintain such information on a confidential basis, and such employees shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any such information to or with any other of Respondent Genzyme's employees involved in Respondent Genzyme's SOT business. Respondents shall cause each of Respondents' employees having access to Confidential Business Information to submit to the Commission a signed statement that the individual will maintain the confidentiality required by the terms and conditions of this Hold Separate Order and of the Decision and Order. These individuals shall not be involved in any way in the management, production, distribution, sale, marketing, or financial operations of Respondent Genzyme's competing SOT products.

G. John Corcoran of Trinity Partners, Waltham, Massachusetts, shall serve as the Monitor, pursuant to the agreement executed by the Monitor and Respondents, approved by Schering, and attached as Confidential Appendix A to this Hold Separate Order ("Monitor Agreement").

1. The Monitor Agreement shall require that, no later than five (5) days after this Hold Separate Order becomes final, Respondents shall transfer to the Monitor all rights, powers, and authorities necessary to permit the Monitor to perform his/her duties and responsibilities, pursuant to this Hold Separate Order and consistent with the purposes of the Decision and Order.

2. The Monitor shall have the responsibility, consistent with the terms of this Hold Separate Order and the Decision and Order, for:

   a. working with Schering to implement the Campath SOT Formula; and

   b. monitoring Respondents' compliance with their obligations pursuant to this Hold Separate Order and the Decision and Order.

3. Subject to all applicable laws and regulations, the Monitor shall have full and complete access to all personnel, books, records, and documents relating to the Campath SOT Earnings and to any other relevant information as the Monitor may reasonably request, including, but not limited to, all documents and records kept by Respondents in the ordinary course of business that relate to the Campath SOT Assets. Respondents shall develop such financial or other information as the Monitor may reasonably request and shall cooperate with the Monitor. Respondents shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with this Hold Separate Order and the Decision and Order or otherwise to perform his/her duties and responsibilities consistent with the terms of this Hold Separate Order.

4. The Monitor shall have the authority to employ, at Respondent Genzyme's cost and expense, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.

   PROVIDED, HOWEVER, that nothing in this Hold Separate Order shall prohibit Respondents and Schering from agreeing that (a) Schering shall pay for or reimburse Respondents for up to one-half of the costs described in this subparagraph II.G.4., and (b) Schering may be liable pursuant to the Distribution Agreement and Revised Distribution Agreement to reimburse Respondents for Schering's share of the costs described in this subparagraph II.G.4. if Schering fails to pay such costs.

5. The Monitor shall serve, without bond or other security, at Respondent Genzyme's cost and expense, on reasonable and customary terms commensurate with the person's experience and responsibilities.

   PROVIDED, HOWEVER, that nothing in this Hold Separate Order shall prohibit Respondents and Schering from agreeing that (a) Schering shall pay for or reimburse Respondents for up to one-half of the costs described in this subparagraph II.G.5., and (b) Schering may be liable pursuant to the Distribution Agreement and Revised Distribution Agreement to reimburse Respondents for Schering's share of the costs described in this subparagraph II.G.5. if Schering fails to pay such costs.

6. Respondent Genzyme shall indemnify the Monitor and hold him or her harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from misfeasance,

gross negligence, willful or wanton acts or omissions, or bad faith by the Monitor, or the respective agents.

7. The Commission may require the Monitor to sign an appropriate confidentiality agreement relating to materials and information received from the Commission in connection with performance of the Monitor's duties.

8. Respondents may require the Monitor to sign an appropriate confidentiality agreement prohibiting the disclosure of any Confidential Business Information gained as a result of his/her role as Monitor to anyone other than the Commission.

9. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.

10. Thirty (30) days after the Hold Separate Order becomes final, and every thirty (30) days thereafter until the Hold Separate Order terminates, the Monitor shall report in writing to the Commission concerning the efforts to accomplish the purposes of this Hold Separate Order.

11. If the Monitor ceases to act or fails to act diligently and consistently with the purposes of this Hold Separate Order, the Commission may appoint a substitute Monitor consistent with the terms of this paragraph, subject to the consent of Respondent Genzyme, which consent shall not be unreasonably withheld. If Respondent Genzyme has not opposed, in writing, including the reasons for opposing, the selection of the substitute Monitor within five (5) days after notice by the staff of the Commission to Respondent Genzyme of the identity of any substitute Monitor, Respondent Genzyme shall be deemed to have consented to the selection of the proposed substitute Monitor. Respondent Genzyme and the substitute Monitor shall execute a monitor agreement, subject to the approval of the Commission, consistent with this paragraph.

12. Respondent Genzyme's employees shall not receive, have access to, or use or continue to use any Confidential Business Information except:

    a. as required by law; and

    b. to the extent that necessary information is provided:

        (1) in the course of consummating the Acquisition;

        (2) in negotiating agreements to divest assets pursuant to the Consent Agreement and engaging in related due diligence;

(3) in complying with this Hold Separate Order, the Consent Agreement, and the Decision and Order in this matter.

(4) in defending legal claims, investigations or enforcement actions threatened or brought against or related to the Campath SOT Assets; or

(5) in obtaining legal advice.

H. The purpose of this Hold Separate Order is to: (1) preserve the Campath SOT Earnings independent of Respondent Genzyme until the divestiture required by the Decision and Order is achieved; (2) assure that no Confidential Business Information is exchanged between Respondent Genzyme and Schering, except in accordance with the provisions of this Hold Separate Order; and (3) prevent interim harm to competition pending the divestiture of the Campath SOT Assets.

III.

IT IS FURTHER ORDERED that, beginning thirty (30) days after the initial report is required to be filed pursuant to the Consent Agreement in this matter, and every sixty (60) days thereafter until Respondents have fully complied with these obligations pursuant to this Hold Separate Order, Respondents shall each submit to the Commission verified written reports setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with Paragraph II. of this Hold Separate Order. Each Respondent shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with this Hold Separate Order, including copies of all written and electronic communications to and from the parties, all internal memoranda, and all reports and recommendations concerning its obligations under this Order.

IV.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least thirty (30) days prior to any proposed (1) dissolution of that Respondent, (2) acquisition, merger or consolidation of that Respondent, or (3) any other change in that Respondent that may affect compliance obligations arising out of this Hold Separate Order, including but not limited to assignment or the creation or dissolution of subsidiaries.

V.

IT IS FURTHER ORDERED that, for the purposes of determining or securing compliance with this Hold Separate Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to either Respondent, Respondents shall permit any duly authorized representatives of the Commission:

A. Access, during office hours of that Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of that Respondent relating to compliance with this Hold Separate Order; and

B. Upon five (5) days' notice to that Respondent and without restraint or interference from that Respondent, to interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

VI.

IT IS FURTHER ORDERED that this Hold Separate Order shall terminate on the earlier of:

A. Three (3) business days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or

B. The day after the appropriate percentage of the Held Separate Amount is distributed to Respondents pursuant to Paragraph II.D. of this Hold Separate Order.

By the Commission, Commissioner Harbour recused.

Donald S. Clark
Secretary

SEAL
ISSUED: December 20, 2004

Appendix I

INTERIM MONITOR AGREEMENT

[Redacted From Public Record Version But Incorporated By Reference]