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,	)	**Docket No. C-4128**
	)	**DECISION AND ORDER**
and	)	
ILEX ONCOLOGY, INC.,	)	
a corporation.	)	

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," which has a distribution contract with Schering AG, through its wholly owned United States subsidiary, Berlex, Inc., and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, 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 Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Hold Separate and Maintain Assets ("Hold Separate Order" attached to this Order as Appendix I), and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from an interested person pursuant to section 2.34 of its Rules, 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 the following Decision and Order ("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.

ORDER

I.

IT IS ORDERED that, as used in this 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 this 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 this 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 this 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 is in effect, which shall begin as of the date the Acquisition occurs and terminate pursuant to Paragraph VI of the Hold Separate Order.

FF. "Monitor" means the person or entity appointed pursuant to the Order to Hold Separate and Maintain Assets in this matter.

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 this 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. No later than one (1) day after the Acquisition Date, Respondent Genzyme shall divest the Campath SOT Assets, in good faith, to Schering pursuant to and in accordance with the Revised Distribution Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order) which is incorporated by reference to this Order and made a part hereof. Pursuant to this divestiture, Respondent Genzyme shall, among other things:

1. not exercise any veto rights or otherwise interfere with or impede Schering's exclusive rights to control the development of, and conduct sales and marketing activities of Campath SOT;

2. relinquish its rights to Campath SOT Earnings;

3. divest, at Schering's option, all of Respondent Genzyme's interest in the net sales of Campath for SOT sold outside of the United States and the Pacific Rim (hereinafter "Such Areas"), as described in the Revised Distribution Agreement;

   PROVIDED, HOWEVER, Genzyme shall (a) be reimbursed for all development expenses it has incurred in connection with the development of Campath SOT for Such Areas and shall not be required to incur any additional non-reimbursable expenses for Campath SOT for Such Areas, and (b) not be required to pay for the calculations and accounting to determine the income from Campath SOT in Such Areas.

4. establish the Campath SOT Formula and agree to pay for the UNOS Data, the Monitor, and the collection of inputs and any other things necessary to determine the Campath SOT Earnings in the United States as described in the Revised Distribution Agreement;

   PROVIDED, HOWEVER, that nothing in this 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 of the Monitor and all of the other costs described in this subparagraph II.A.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.A.4. if Schering fails to pay such costs.

5. Respondents shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with the Hold Separate Order and this Order or otherwise to perform his/her duties and responsibilities consistent with the terms of the Hold Separate Order and this Order.

6. not manufacture Campath without:

   a. having obtained the prior written consent of Schering, *PROVIDED, HOWEVER,* that such consent shall not be required to the extent that it has been unreasonably withheld or made contingent upon or tied to issues not related to Campath manufacturing; and

   b. giving the Commission:

      (1) notice, within thirty (30) days, that Respondent Genzyme has given notice, pursuant to section 6.13 of the Distribution Agreement, that it intends to terminate the current contract manufacturing agreement for Campath;

      (2) copies, within thirty (30) days, of any documents Schering provides Respondent Genzyme pursuant to section 6.13 of the Distribution Agreement; and

      (3) sixty (60) days notice prior to the start of such manufacturing.

7. not receive or use any Confidential Business Information.

   PROVIDED, HOWEVER, Respondent Genzyme may receive information and be involved in the decision-making related to Campath Non-SOT including, but not limited to, pricing information, except that which is precluded in this Paragraph II.;

   PROVIDED FURTHER, HOWEVER, if Campath SOT worldwide sales account for twenty-five percent (25%) of Campath sales for all indications worldwide in any calendar quarter, Respondent Genzyme shall: (i) notify the Commission and the Monitor; and (ii) for the duration of the Order, be prohibited from receiving information and exercising any decision-making rights that may affect Campath SOT, including pricing information.

B. 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.

C. 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

D. The Monitor Agreement, entered into pursuant to the Hold Separate Order in this matter, 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 Order or the 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.

E. Prior to the Effective Date, Respondent Genzyme shall secure all consents and waivers from all entities that are necessary for the divestiture of the Campath SOT Assets pursuant to this Order.

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 the Hold Separate Order and of this 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. If, at the time the Commission determines to make this Order final, the Commission notifies Respondent Genzyme that Schering is not an acceptable acquirer of the Campath SOT Assets or that the manner in which the divestiture was accomplished is not acceptable, then, after receipt of such written notification:

1. Respondent Genzyme shall immediately notify Schering of the notice received from the Commission and shall as soon as practicable effect the rescission of the Revised Distribution Agreement;

2. Respondent Genzyme shall have the Monitor hold separate the Held Separate Amount in an interest-bearing escrow account pending the divestiture of the Campath SOT Assets;

3. Respondent Genzyme shall, within six (6) months from the date this Order becomes final, divest the Campath SOT License, at no minimum price, to an acquirer that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission; and

4. Respondent Genzyme shall, within six (6) months from the date this Order becomes final, divest the Campath SOT Earnings, at no minimum price, to an acquirer that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission.

H. Any Divestiture Agreement shall be deemed incorporated into this Order. Any failure by Respondents to comply with any term of the Divestiture Agreement shall constitute a failure to comply with this Order.

I. Pending divestiture of all Campath SOT Assets, Respondents shall take such actions as are necessary to maintain the viability and marketability of the Campath SOT Assets and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Campath SOT Assets.

J. The purpose of the divestiture of the Campath SOT Assets is to ensure the continued independent sales and development of Campath SOT in the same manner in which it was engaged before the Acquisition Date, to ensure the future development, promotion and marketing (as is legal) of Campath SOT by an entity independent of Respondents, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

III.

IT IS FURTHER ORDERED that:

A. If Respondent Genzyme has not fully complied with the obligations to divest the Campath SOT Assets as required by Paragraph II. or IV.D. of this Order, the Commission may appoint a Divestiture Trustee to divest the Campath SOT Assets in a manner that satisfies the requirements of Paragraph II. and IV. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a

Divestiture Trustee in such action to divest the Campath SOT Assets and enter into a Divestiture Agreement. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph III. shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.

B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent Genzyme, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent Genzyme has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent Genzyme of the identity of any proposed Divestiture Trustee, Respondent Genzyme shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent Genzyme shall execute a trust agreement that, subject to the prior approval of the Commission and, in the case of a court-appointed Divestiture Trustee, of the court, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by Paragraph II. of this Order.

D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph III., Respondent Genzyme shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to divest the Campath SOT Assets and enter into a Divestiture Agreement.

2. The Divestiture Trustee shall have one (1) year after the date the Commission, or a court, approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed Divestiture Trustee, by the court; *PROVIDED, HOWEVER*, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be

divested by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent Genzyme shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent Genzyme shall extend the time for divestiture under this Paragraph III. in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent Genzyme's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an acquirer as required by this Order;

PROVIDED, HOWEVER, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondent Genzyme from among those approved by the Commission;

PROVIDED FURTHER, HOWEVER, that Respondent Genzyme shall select such entity within five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent Genzyme, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent Genzyme, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed Divestiture Trustee, by the court, of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondent Genzyme, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent Genzyme shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee'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 losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.

8. The Divestiture Trustee shall act in a fiduciary capacity for the benefit of the Commission.

9. The Divestiture Trustee shall report in writing to Respondent Genzyme and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

10. Respondent Genzyme may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *PROVIDED, HOWEVER*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph III.

F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

G. The Divestiture Trustee appointed pursuant to Paragraph III. of this Order may be the same Person appointed as Monitor pursuant to the relevant provisions of the Hold Separate Order in this matter.

IV.

IT IS FURTHER ORDERED that:

A. Respondent Genzyme shall not terminate the Distribution Agreement, Revised Distribution Agreement, or the Divestiture Agreement, if applicable, or reacquire

the assets divested pursuant to Paragraphs II. or III. of this Order without receiving prior Commission approval.

B. Respondent Genzyme shall give the Commission notice within one day of receiving notice from Schering of Schering's intention to terminate the Distribution Agreement, Revised Distribution Agreement, or the Divestiture Agreement, if applicable.

C. Upon receiving notice of Schering's intention to terminate the Distribution Agreement, Revised Distribution Agreement, or the Divestiture Agreement, if applicable, Respondent Genzyme shall establish, with Commission approval, procedures to hold separate the Campath SOT Assets pending divestiture of the Campath SOT Assets as required by Paragraph IV. D.

D. No later than the last to occur of (i) ninety (90) days after receiving notice of Schering's intention to terminate the Distribution Agreement, Revised Distribution Agreement, or the Divestiture Agreement, if applicable, or (ii) the effective date of any termination by Schering of the Distribution Agreement, Revised Distribution Agreement, or the Divestiture Agreement, if applicable, Respondent Genzyme shall divest the Campath SOT Assets and enter into a new distribution agreement at no minimum price, to an acquirer that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission;

PROVIDED, HOWEVER, if Respondent Genzyme has not divested the Campath SOT Assets pursuant to this Paragraph IV.D., a Divestiture Trustee may be appointed pursuant to Paragraph III. of this Order to divest the Campath SOT Assets.

E. The purpose this Paragraph IV. is to ensure the continued independent sales and development of Campath SOT in the same manner in which it was engaged before the Acquisition Date, to ensure the future development, promotion and marketing (as is legal) of Campath SOT by an entity independent of Respondents, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

V.

IT IS FURTHER ORDERED that:

A. Respondent Genzyme shall, within thirty (30) days after the date this Order becomes final, and every sixty (60) days thereafter until Respondent Genzyme has fully complied with Paragraphs II. and III. of this Order, submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent Genzyme shall submit at the same time a copy of its report concerning compliance with this Order to the Monitor, if any Monitor has been appointed pursuant to the Hold Separate Order in this matter. Respondent Genzyme 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 the relevant Paragraphs of the Order, including a description of all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all parties contacted. Respondent Genzyme shall include in its reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning completing the obligations.

B. Respondents shall, one year from the date this Order becomes final and annually thereafter until the Order terminates, submit a verified written report to the Commission setting forth in detail the manner and form in which each Respondent has complied and is complying with this Order, and shall specifically include, among other things and to the extent known by each Respondent, in such reports:

1. The quantity of Campath and Campath Non-SOT sold in the United States, on a monthly and quarterly basis;

2. The dollar amount of Campath Earnings and Campath Non-SOT Earnings, on a monthly and quarterly basis; and

3. All planning documents, Board presentations, and senior management-level documents relating to Respondent Genzyme's plans for changing the manufacturing location of Campath.

VI.

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

VII.

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

A. access, during office hours of Respondents 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 Respondents related to compliance with this Order; and

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

VIII.

IT IS FURTHER ORDERED that this Order shall expire on January 31, 2015.

By the Commission, Commissioner Harbour recused.

Donald S. Clark
Secretary

SEAL

ISSUED: January 31, 2005

Appendix I

ORDER TO HOLD SEPARATE AND MAINTAIN ASSETS

Appendix II

REVISED DISTRIBUTION AGREEMENT

[Redacted From Public Record Version But Incorporated By Reference]