

Complaint

IN THE MATTER OF

GENZYME CORPORATION, ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE
COMMISSION ACT

Docket C-4128; File No. 0410083

Complaint, December 20, 2004--Decision, January 31, 2005

This consent order, among other things, requires Respondent Genzyme to divest to Schering AG all of its contractual and decision-making rights regarding Campath® -- a monoclonal antibody immunosuppressant drug that is used to suppress the immune system and reduce the likelihood of rejection of a transplanted organ -- for solid organ transplant, including its portion of the earnings from sales of Campath® in solid organ transplant. An accompanying Order to Hold Separate and Maintain Assets requires Respondent Genzyme to hold separate and maintain the viability of the Campath® solid organ transplant assets until their transfer to Schering, and prohibits the exchange of certain material confidential information between Respondent Genzyme and Schering.

Participants

For the Commission: *Norman A. Armstrong, Jr., Paul R. Frontczak, Stephanie C. Bovee, Tammy L. Imhoff, Sylvia M. Brooks, Eric D. Rohlck, Jennifer Lee, Jordan Coyle, Matthew J. Reilly, Michael R. Moiseyev, Daniel P. Ducore, and Mark Hertzendorf.*

For the Respondents: *Michael L. Weiner and Jill A. Ross, Skadden, Arps, Slate, Meagher & Flom, and David M. Foster, Fulbright & Jaworski L.L.P.*

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

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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.

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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

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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

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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.

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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.

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DECISION AND ORDER

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

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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,

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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

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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; 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;
4. 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

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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.

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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

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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:

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.

- A. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent Genzyme, which

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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.

- B. 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.
- C. 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

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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.
- D. 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.
- E. 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.
- F. 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

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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

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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.

Appendix I

ORDER TO HOLD SEPARATE AND MAINTAIN ASSETS

Appendix II

REVISED DISTRIBUTION AGREEMENT

**[Redacted From Public Record Version But Incorporated By
Reference]**

Order to Hold Separate

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

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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.

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- 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

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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

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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.

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- 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

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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:

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- (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.

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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.

Appendix I

INTERIM MONITOR AGREEMENT

**[Redacted From Public Record Version But Incorporated By
Reference]**

Analysis

Analysis of Agreement Containing Consent Orders to Aid Public Comment

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Genzyme Corporation (“Genzyme”) and ILEX Oncology, Inc. (“Ilex”). The purpose of the proposed Consent Agreement is to remedy the anticompetitive effects resulting from Genzyme’s acquisition of Ilex. Under the terms of the proposed Consent Agreement, Genzyme is required to divest all contractual rights to Ilex’s monoclonal antibody, Campath®, for use in solid organ transplant, to Schering AG (“Schering”).

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

Pursuant to an Agreement and Plan of Merger dated February 26, 2004, Genzyme proposes to acquire one hundred percent (100%) of the issued and outstanding shares of Ilex in a stock-for-stock transaction valued at approximately \$1 billion. The Commission’s complaint alleges that the proposed acquisition, if consummated, would violate 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, by lessening competition in the U.S. market for acute therapy drugs used in solid organ transplant (“SOT”). The proposed Consent Agreement would remedy the alleged violations by replacing the competition that would be lost as a result of the acquisition.

SOT acute therapy drugs are immunosuppressant drugs that are used in solid organ transplants to suppress the transplant recipient’s immune system. SOT acute therapy drugs are

prescribed for induction therapy and to treat acute rejection. Induction therapy refers to the use of an immunosuppressant drug for a short time before, during, and/or after a solid organ transplant procedure in order to suppress the immune system and decrease the likelihood of rejection of the transplanted organ. An acute rejection is a sudden attack on the transplanted organ by the transplant recipient's immune system. If an acute rejection occurs, SOT acute therapy drugs are used to provide a high dose of immunosuppression in order to stop the rejection.

The U.S. market for SOT acute therapy drugs is highly concentrated. Genzyme is the leading supplier in the market for SOT acute therapy drugs with its drug, Thymoglobulin®. Ilex's Campath®, the newest entrant into the market for SOT acute therapy drugs, currently accounts for a relatively small share of the SOT acute therapy drug market, but is quickly gaining market share and is expected to continue growing. Campath® is FDA-approved for the treatment of chronic lymphocytic leukemia, but is used off-label as an SOT acute therapy drug.

In addition to Thymoglobulin® and Campath®, there are four other SOT acute therapy drugs used in the United States. However, due to similar mechanisms of action, Campath® and Thymoglobulin® are especially close competitors. Both drugs accomplish immunosuppression by depleting T-cells, which are a type of white blood cell that attack transplanted organs and can result in rejection. Atgam® from Pfizer and OKT-3® from Ortho Biotech/Johnson & Johnson are also T-cell depleting SOT acute therapy drugs, but are diminished and aged competitors and account for a small share of the SOT acute therapy drug market. Novartis' Simulect® and Roche's Zenepax® operate by a different mechanism of action – one that prevents the body's immune system from responding to and rejecting a foreign antigen by blocking the receptor for Interleukin – and are known as Interleukin-2 receptor inhibitors. Although Simulect® and Zenepax® are significant competitors and properly included in the relevant market, they exert more competitive pressure on each other than on Thymoglobulin® or Campath®.

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Other immunosuppressant drugs used in connection with SOT, such as maintenance therapy drugs, are not substitutes for SOT acute therapy drugs. Maintenance therapy drugs refer to low doses of immunosuppressant drugs that are typically used for the duration of a patient's life to prevent rejection. Maintenance therapy drugs are designed to provide a low dose of immunosuppression over a long period of time. Transplant patients typically start on maintenance therapy drugs a short time after the transplant and continue taking maintenance drugs for the rest of their lives. In contrast, SOT acute therapy drugs are designed to deliver a potent dose of immunosuppression over a short period of time, ranging from one day to two weeks. Using maintenance therapy drugs in higher doses to administer the same level of immunosuppression over a short period of time may be toxic to the patient. Thus, doctors would not likely prescribe maintenance therapy drugs in place of SOT acute therapy drugs. Likewise, SOT acute therapy drugs likely would not be used for maintenance therapy because SOT acute therapy drugs may be too powerful to use on a long-term basis.

As with many pharmaceutical products, entry into the manufacture and sale of SOT acute therapy drugs is difficult, expensive, and time-consuming. Developing a drug for SOT acute therapy and conducting clinical trials necessary to gain FDA approval is expensive and takes a significant amount of time. After developing a drug and receiving FDA approval, a company must then convince doctors to prescribe the drug. In order to convince doctors to prescribe a new SOT acute therapy drug, the new drug would need to be more efficacious, safer, and/or significantly less expensive than currently available SOT acute therapy drugs. Off-label entry by a drug already approved for another indication is also expensive and time-consuming, because a drug company would still need to develop and implement costly clinical trials to demonstrate benefits over other SOT acute therapy drugs. A company may not actively market a drug for off-label use. There are no drugs that are being evaluated currently for off-label use in SOT acute therapy. Additionally, entry is unlikely because the market for SOT acute therapy drugs is

relatively small, lessening the incentive to invest the time and money necessary to develop these drugs. It is therefore unlikely that entry into the market for SOT acute therapy drugs, either by a new drug approved by the FDA, or by off-label entry, will occur in a manner that is timely or sufficient to resolve the anticompetitive effects of the proposed acquisition.

The proposed acquisition would cause significant competitive harm in the U.S. market for SOT acute therapy drugs by eliminating the actual, direct, and substantial competition between Genzyme and Ilex. This loss of competition would likely result in higher prices and decreased development in the market for SOT acute therapy drugs.

The proposed Consent Agreement effectively remedies the acquisition's anticompetitive effects in the market for SOT acute therapy drugs by requiring Genzyme to divest to Schering all of its contractual and decision-making rights regarding Campath® for solid organ transplant, including its portion of the earnings from sales of Campath® in solid organ transplant. Through an existing distribution and development agreement with Ilex, Schering already distributes and markets Campath® in the United States, sharing costs and profits. Thus, Schering is already responsible for distributing and marketing Campath® in the United States, and already participates in development activities for the drug. Therefore, the company is well-positioned to acquire the divested assets, and to compete vigorously in the market for SOT acute therapy drugs. In addition, because Campath® is manufactured by a third-party, there is no need for an interim supply agreement as is required in many pharmaceutical merger settlements.

The parties, with the assistance of a Monitor and the approval of the Commission, will implement a formula to determine the portion of Campath® earnings attributable to solid organ transplant sales. The formula uses drug utilization data maintained by the United Network for Organ Sharing ("UNOS") and its federally-mandated database to determine the portion of Campath® sales that are attributable to SOT. This unique

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database provides a reliable, independent source for information regarding the use of Campath® in SOT, because all hospitals performing SOT operations in the United States are required to submit data to UNOS on many aspects of SOT operations. Hospital compliance is high, due in part to the fact that hospitals not submitting the required data face losing Medicare reimbursement. The proposed Consent Agreement also allows for this formula to be reevaluated based on changes in the market or in the use of Campath®.

The Commission has appointed Trinity Partners, LLC (“Trinity”) as Monitor to oversee the divestiture of the Campath® earnings from solid organ transplant. The Monitor will work with the parties to develop and implement the formula to compute Campath® earnings attributable to use in solid organ transplant. John E. Corcoran, Trinity’s Managing Partner, will oversee the monitoring team. Mr. Corcoran founded Trinity in 1996, and has over twenty years of experience servicing clients in the pharmaceutical, biotechnology, diagnostic, and medical device industries.

Genzyme and Schering will continue to have a relationship regarding uses of Campath® outside solid organ transplant. Virtually all Campath® sales are for oncology use and only a very small portion of sales are attributable to SOT use. The price of Campath®, therefore, is driven by the competitive dynamics in the oncology market. To provide further protection, the proposed Consent Agreement contains firewall provisions to ensure that Genzyme does not receive competitively sensitive information regarding Campath®’s use and development in solid organ transplant. Additional firewalls prohibit Genzyme from participating in pricing decisions should Campath® SOT sales surpass a set percentage of overall Campath® sales.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to

constitute an official interpretation of the proposed Decision and Order or the Agreement to Hold Separate, or to modify their terms in any way.

Statement

**CONCURRING STATEMENT OF COMMISSIONER JON
LEIBOWITZ**

I support the conclusion reached by my fellow Commissioners to approve the consent order regarding Genzyme's acquisition of ILEX. Through this transaction, Genzyme intends to acquire ILEX's key oncology product Campath. However, because a small percentage of Campath sales are used off-label for acute therapy in solid organ transplants ("SOT"), a significant competitive problem arises concerning the overlap between ILEX's SOT use and Genzyme's Thymoglobulin acute therapy SOT product. The relief provides a solution designed to protect consumers against the likely harm otherwise caused by this transaction, while allowing the parties to move forward, even though it creates entanglements that could raise serious concerns under a different set of facts. Thus, I write separately to clarify my support for the relief here, and to express some general observations on merger policy, which I am sure will continue to develop during my tenure here at the Commission.

Merger enforcement is a vital component of the Commission's mission. We are charged under the Clayton Act with ensuring that competition and consumers do not suffer from transactions whose effects may be to "substantially lessen competition." Of course, the Clayton Act provides no inalienable right to merge. It is important, then, for the Commission to rigorously scrutinize each transaction we review in fulfilling our mission. Where a transaction may substantially lessen competition, a high burden should be placed on the parties to show that harm is demonstrably outweighed by efficiencies or that potential relief restores competition. My fellow Commissioners and our attorneys, economists and staff take our responsibility very seriously.

At the same time, where transactions present potential economic benefit – through efficiencies or enhanced research and innovation – we should weigh those benefits relative to the likely harm, and not seek to impose unnecessary obstacles to the parties achieving those benefits. In particular, each merger should be

reviewed carefully on its merits and its own facts, and we should remain flexible in considering remedies that restore competition.

My support of the remedy regarding Genzyme's acquisition of ILEX is consistent with these principles. *Absent the relief*, this transaction would have resulted in significant harm to consumers through increased prices and a possible reduction in research and innovation. And since the original transaction's purported efficiencies (assuming they were cognizable under the Merger Guidelines) were not sufficient to reverse the likely anticompetitive harm, it was incumbent that the parties demonstrate that the relief effectively restores competition.

Here, the remedy likely accomplishes that purpose. It is a creative solution – severing Genzyme from its rights and revenues relating to use of ILEX's Campath product in the SOT market (while allowing Genzyme to maintain its rights and revenues to the product in the oncology market) in a manner that substantially diminishes the likelihood of anticompetitive harm.

As a general matter, creative and flexible remedies should be encouraged where we are confident they will succeed in restoring competition. However, no matter how creative the parties are in devising relief, and no matter how flexible the Commission is willing to be, such an approach will not work in many situations. The specific facts concerning each transaction will drive the analysis.

The unique facts of this case add assurance that the relief will work. For example, virtually all of Campath sales are derived from the competitive oncology market, and only a very small portion of its sales are attributable to SOT use. Thus, the price of Campath is constrained by the oncology market (not the SOT market), substantially diminishing the ability or incentive of Genzyme to attempt a price increase on Campath. Another key fact that allows the remedy to work here is the divestiture to Schering AG of the Campath SOT rights and revenues. Schering AG was already responsible (through a pre-merger relationship with ILEX) for distributing and marketing Campath in the United States, and thus is well-positioned to acquire the ILEX SOT rights and vigorously compete post-merger. These facts, along with

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other particulars of this transaction, allow for this well-tailored order to fit the facts, and remedy the likely competitive harm.

One concern raised by this transaction is that the remedy creates entanglements between the merged firm and Schering AG: Genzyme will continue to receive revenues post-merger from oncology sales for Campath, while Schering will receive revenues for Campath's SOT sales. It is possible that this relationship could lead to collusion (via side payments or some other mechanism) between the companies that make it mutually profitable for them to increase price or reduce research and development to the detriment of consumers.

We should be concerned ordinarily about such entanglements. However, the possibility of collusion *in this case* is not a sufficient concern for us to challenge this transaction. First, the entanglements are minimized because Campath SOT earnings can easily be determined without requiring communication between the parties since a federally-mandated independent database on organ transplants will identify the number of SOT patients using Campath. Second, the order makes use of several of the Commission's key tools to prevent this from happening (*e.g.*, employing a monitor, erecting firewalls, and the threat of civil penalties for violating the proposed order), and a violation of the proposed order through collusion could result in criminal sanctions for violating Section 1 of the Sherman Act. In the past, the Commission has demonstrated its willingness to sue companies for illegal side payments in the pharmaceutical industry (*e.g.*, *In the Matter of Schering-Plough Corp.*), and the Commission, no doubt, will remain vigilant in ensuring that we continue to do so in the future.

For these reasons, I concur in the decision of the Commission, but will remain cautious about considering future consent orders that create entanglements which could foster collusion and potentially harm consumers.

Complaint

IN THE MATTER OF

PETCO ANIMAL SUPPLIES, INC.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-4133; File No. 0323221**Complaint, March 4, 2005--Decision, March 4, 2005*

This consent order, among other things, prohibits the respondent -- in connection with the online advertising, marketing, promotion, offering for sale, or sale of any product or service -- from misrepresenting the extent to which it maintains and protects the security of any personal information collected from or about consumers. The order also requires the respondent to create a written security policy reasonably designed to protect the security, confidentiality, and integrity of personal information collected from or about consumers. In addition, the order requires the respondent, for twenty years, to secure biennial assessments and reports from a qualified, objective, and independent third-party professional certifying that the respondent has a security program in place that operates with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of consumers' personal information has been protected.

Participants

For the Commission: *Alain Sheer, Joel Winston, Jessica L. Rich, and Louis Silversin.*

For the Respondent: *Peter H. Benzian, Latham & Watkins.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Petco Animal Supplies, Inc. ("respondent") has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Petco Animal Supplies, Inc. is a Delaware corporation with its principal office or place of business at 9125 Rehco Road, San Diego, California 92121.