

- C. “Schering” means Schering AG, a corporation organized, existing and doing business under and by virtue of the laws of Germany, with its office and principal place of business located at D-13342 Berlin, Germany. Schering includes, but is not limited to, its United States affiliates Berlex, Inc. and Berlex Laboratories, LLC, with headquarters in Montville, NJ.
- D. “Respondent Genzyme” shall mean Genzyme, and Genzyme and ILEX after the Acquisition.
- E. “Commission” means the Federal Trade Commission.
- F. “Acquirer” means Schering or any other entity that receives the prior approval of the Commission to acquire the Campath SOT Earnings pursuant to Paragraph III. of the Decision and Order.
- G. “Acquisition” means the proposed acquisition by Genzyme of ILEX pursuant to the Merger Agreement dated February 26, 2004, by and among Respondent Genzyme and Respondent ILEX.
- H. “Acquisition Date” means the date the Acquisition is consummated.
- I. “Bone Marrow Transplant” means blood and marrow transplantation including, but not limited to, the transplantation of stem cells, bone marrow, peripheral blood, and cord blood.
- J. “Campath” means ILEX’s trademarked and patented drug Campath 1H, a

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

1. a fully paid, and royalty-free worldwide license with the rights to sublicense all Campath Intellectual Property and Campath Trade Dress to make, distribute, offer for sale, promote, advertise, sell, import, export, or have used, made, distributed, offered for sale, promoted, advertised, sold, imported, or exported Campath SOT anywhere in the world;
 2. access to and copies of Campath Scientific and Regulatory Materials;
 3. FDA rights of reference or use to Campath;
 4. access to and copies of all of ILEX's books, records, and files related to Campath development, including, but not limited to, the following specified documents: the product registrations; pharmacology and toxicology data contained in all BLAs, ABLAs, SBLAs, and MAAs; all data submitted to and all correspondence with the FDA and other governmental agencies; all validation documents and data; all market studies; all sales histories, including, without limitation, clinical data, and sales force call activity, for Campath from January 1, 2001, through the Effective Date, and quality control histories pertaining to Campath owned by, or in the possession or control of, Respondents, or to which Respondents have a right of access, in each case such as is in existence as of the Effective Date;
 5. Campath Manufacturing Technology (if and when Respondents receive such information).
- V. "Campath Trade Dress" means the trade dress of Campath to the extent owned, controlled or licensed by Respondents, including, but not limited to, product packaging associated with the sale of Campath worldwide and the lettering of Campath's trade name or brand name.
- W. "Campath Trademarks" means, to the extent owned, controlled or licensed by Respondents, all proprietary names or designations, trademarks, tradenames, and brand names for Campath, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith.
- X. "Confidential Business Information" means all information owned by, or in the possession or control of Schering that is not in the public domain related to the research, development, manufacture, marketing, commercialization, distribution, importation, exportation, cost, pricing, supply, sales, sales support, after-sale servicing, or use of Campath SOT.
- Y. "Distribution Agreement" means the Distribution and Development Agreement entered into as of August 23, 1999 (as amended on December 19, 2000, and

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

- Z. “Divestiture Agreement” means the Revised Distribution Agreement or any agreement between the Respondents or the Divestiture Trustee and an Acquirer, as well as all amendments, exhibits, attachments, agreements, and schedules thereto, that have been approved by the Commission, related to the divestiture of the Campath SOT Assets.
- AA. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph III. of the Decision and Order.
- BB. “Effective Date” means the date on which Respondent Genzyme divests to Schering or a Divestiture Trustee divests to an Acquirer the Campath SOT Assets completely and as required by Paragraph II. or III. of the Decision and Order.
- CC. “FDA” means the United States Food and Drug Administration or any successor agency with responsibilities comparable to those of the United States Food and Drug Administration.
- DD. “Held Separate Amount” means seven and one-half (7.5) percent of the U.S. sales of Campath from the Acquisition Date until the end of the Hold Separate Period.
- EE. “Hold Separate Period” means the time period during which the Hold Separate Order is in effect, which shall begin as of the date the Acquisition occurs and terminate pursuant to Paragraph VI. of this Hold Separate Order.
- FF. “Monitor” means the person or entity appointed pursuant to this Hold Separate Order.
- GG. “Pacific Rim” means the following countries: Bhutan, Cambodia, Indonesia, Japan, Laos, Malaysia, Maldives, Mongolia, Myanmar (Burma), Nepal, North Korea, Peoples Republic of China, the Philippines, Republic of China (Taiwan), South Korea, Thailand, and Vietnam.
- HH. “Patents” means all patents, patent applications, and statutory invention registrations, in each case existing as of the Effective Date (*except* where this Order specifies a different time), and includes all reissues, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, all rights therein provided by international treaties and conventions, and all rights to obtain and file for patents and registrations thereto in the world, related to Campath as of the Effective Date.
- II. “Revised Distribution Agreement” means the Distribution and Development Agreement by and between Respondents and Schering, as amended by

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

- JJ. “SOT” means solid organ transplant and refers to transplantation procedures related to solid organs including, but not limited to, heart, intestine, kidney, liver, lung, and pancreas. SOT does not include Bone Marrow Transplant.
- KK. “UNOS Data” means data compiled by the United Network for Organ Sharing or its successor or equivalent.

II.

IT IS FURTHER ORDERED that:

- A. During the Hold Separate Period, Respondents shall take such actions as are necessary to maintain the viability, marketability, and competitiveness of the Campath SOT Assets, and shall prevent the destruction, removal, wasting, deterioration, sale, disposition, transfer, or impairment of the Campath SOT Assets, except for ordinary wear and tear.
- B. During the Hold Separate Period, Respondents shall:
 - 1. Allow Schering to retain the Held Separate Amount for the duration of the Hold Separate Period; and
 - 2. not exercise direction or control over, or influence directly or indirectly,

- 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

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

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

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

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

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

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

7. The Commission may require the Monitor to sign an appropriate confidentiality agreement relating to materials and information received from the Commission in connection with performance of the Monitor's duties.
8. Respondents may require the Monitor to sign an appropriate confidentiality agreement prohibiting the disclosure of any Confidential Business Information gained as a result of his/her role as Monitor to anyone other than the Commission.
9. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.

- (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

V.

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

- A. Access, during office hours of that Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of that Respondent relating to compliance with this Hold Separate Order; and
- B. Upon five (5) days' notice to that Respondent and without restraint or interference from that Respondent, to interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

VI.

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

- A. Three (3) business days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. The day after the appropriate percentage of the Held Separate Amount is distributed to Respondents pursuant to Paragraph II.D. of this Hold Separate Order.

By the Commission, Commissioner Harbour recused.

Donald S. Clark
Secretary

SEAL
ISSUED: December 20, 2004

Appendix I

INTERIM MONITOR AGREEMENT

[Redacted From Public Record Version But Incorporated By Reference]