ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of Genzyme Corporation and ILEX Oncology, Inc.
File No. 041 0083, Docket No. C-

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 Interluekin – 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®.

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 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.