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 tim

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.