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ELI LILLY AND COMPANY and IMCLONE SYSTEMS LLC

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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

ELI LILLY AND COMPANY, an Indiana corporation, and IMCLONE SYSTEMS LLC, a Delaware limited liability company,

Plaintiffs,

v.

GENENTECH, INC., a Delaware corporation, and CITY OF HOPE, a California not-for-profit company,

Defendants.

Case No. CV13- 0919 YGR

COMPLAINT FOR DECLARATORY JUDGMENT OF INVALIDITY, UNENFORCEABILITY, AND NONINFRINGEMENT

DEMAND FOR JURY TRIAL

Plaintiffs Eli Lilly and Company and ImClone Systems LLC (collectively, "Lilly"), for their Complaint against Genentech, Inc. ("Genentech") and City of Hope (collectively, "Defendants"), allege as follows:

NATURE OF THE CASE

1. Lilly seeks a declaration that U.S. Patent No. 6,331,415 titled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein" (the "Cabilly II patent" attached as Exhibit A), including the *Ex Parte* Reexamination Certificate issued pursuant to merged Reexamination Nos. 90/007,542 and 90/007,859 (attached as Exhibit B), and U.S. Patent No. 7,923,221 titled "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen" (the "Cabilly III patent" attached as Exhibit C) are invalid, unenforceable, and not infringed by the manufacture, use, sale, offer to sell, or importation of Lilly's Erbitux® (cetuximab) product. (The Cabilly II patent and Cabilly III patent are collectively referred to as the "Cabilly Patents").

2. ImClone Systems Incorporated ("ImClone") first received approval for Erbitux in the United States in 2004 for the treatment of certain types of colorectal cancers. Beginning in 2006, ImClone received approval for Erbitux for the treatment of certain types of head and neck cancers as well. Lilly has a commercial agreement with Bristol-Myers Squibb Company and E.R. Squibb & Sons, LLC (collectively "BMS") relating to Erbitux. Lilly co-develops Erbitux in the U.S. and Canada with BMS. Lilly is responsible for the manufacture and supply of all requirements of Erbitux in bulk-form active pharmaceutical ingredient ("API") for clinical and commercial use in the U.S. and Canada. BMS purchases all of its requirements of API for commercial use from Lilly and exclusively sells Erbitux in the U.S. and Canada. Eli Lilly and Company acquired ImClone in 2008 and ImClone currently operates as a wholly-owned subsidiary of Eli Lilly and Company.

3. Lilly brings this action to lift the cloud created by the imminent threat of Defendants' enforcement of the Cabilly Patents against Lilly. Without declaratory relief, the threat of enforcement of the Cabilly Patents poses a substantial risk of injury to Lilly as well as the patients, nurses, and physicians now using Erbitux for treatment. The continued existence and enforcement of these invalid and unenforceable patents impedes not only the development and sale of Erbitux, but also the development and sale of other life-saving recombinant antibody products.

4. Defendants have asserted that the Cabilly II patent broadly covers the use of certain well-known, conventional recombinant methods to produce any antibody product in any type of host cell. For example, according to Sean Johnson, Genentech's then Vice President of Intellectual Property, "[t]he recently issued [Cabilly II] patent *broadly* covers the co-expression of immunoglobulin heavy and light chain genes in a single host. We do not believe the claims are limited by the type of antibody… or by [the] host cell type." *See* Debra Robertson, "Genentech awarded critical antibody patent," *Nature Biotechnology* 20, 108 (2002) (attached as Exhibit D). Defendants have filed infringement claims under the Cabilly II patent against companies who have made and sold antibody products that were produced using recombinant methods similar to the recombinant methods used by Lilly to make Erbitux.

5. In public statements, Defendant Genentech has specifically identified the Erbitux product as a potential competitor to one of Genentech's own products, and has stated that it expects to be involved in future litigation relating to the enforcement of the Cabilly II patent. *See* Genentech, Inc. (2009), 10-K Annual Report 2008, Retrieved from SEC EDGAR at 13, 25, 39.

6. In response to the Defendants' position that ImClone required a license under the Cabilly Patents to make and sell two antibody products, including a product produced by a similar process as Erbitux, ImClone entered into an agreement with Genentech on January 25, 2005 under which it received, *inter alia*, a non-exclusive license to the Cabilly Patents to make, have made, use, sell and have sold, offer for sale, import and export substances which, but for the license, may infringe one or more claims of the Cabilly Patents (the "Genentech Agreement"). As a result of Eli Lilly and Company's acquisition of ImClone in 2008, Eli Lilly and Company became a licensee to the Cabilly Patents and remains a licensee to date.

7. Lilly has paid, and Genentech has accepted, royalties on sales of Erbitux under the Genentech Agreement.

8. Based on the allegations detailed below, Lilly contends that it has no obligation to pay royalties on the sales of Erbitux, or on any other therapeutic, on any of the Cabilly Patents due to the Cabilly Patents being invalid, unenforceable, and, in any event, not infringed by Lilly.

9. Defendants' past acts and public statements show that Defendants believe

therapeutics like Erbitux fall within the scope of the Cabilly Patents, that Defendants believe they are entitled to royalties on the Cabilly Patents, and that Defendants intend to pursue an aggressive litigation policy to protect against alleged infringement of the Cabilly Patents. *See* ¶¶ 106-118 *infra*. Indeed, prior to Lilly's acquisition of ImClone, ImClone temporarily ceased payments of royalties for the license to the Cabilly Patents under the Genentech Agreement and Genentech threatened to pursue litigation against ImClone for this temporary failure to pay royalties. As such, a real, immediate, and substantial dispute exists between the parties concerning the Cabilly Patents for which Lilly now seeks declaratory relief, specifically, whether the manufacture, importation, offer to sell, sale, or use of Erbitux in the United States infringes any valid and enforceable claim of the Cabilly Patents.

THE PARTIES

10. Plaintiff Eli Lilly and Company is an Indiana corporation having its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Eli Lilly and Company is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

11. Plaintiff ImClone Systems LLC is a Delaware limited liability company having its principal place of business at 440 Route 22 East, Bridgewater, New Jersey 08807. ImClone Systems LLC is a wholly owned subsidiary of Eli Lilly and Company.

12. Defendant Genentech is a Delaware corporation having its principal place of business at 1 DNA Way, South San Francisco, California 94080-4990.

13. Defendant City of Hope is a California not-for-profit organization having its principal place of business in Duarte, California. On information and belief, City of Hope has a place of business in this District at 55 Hawthorne Street, Suite 450, San Francisco, California, 94105.

14. On information and belief, Genentech and City of Hope are co-assignees of the Cabilly Patents.

JURISDICTION AND VENUE

15. This action arises under the Declaratory Judgment Act of 1934 (28 U.S.C. §§

2201-2202), Title 28 of the United States Code, for the purposes of determining an actual and justiciable controversy between the parties, and the patent laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

16. This Court has personal jurisdiction over Genentech based on its principal place of business in California and also based on Genentech consenting to jurisdiction of this Court in the Genentech Agreement. This Court has personal jurisdiction over City of Hope based on its organization under the laws of the State of California and because its principal place of operation is in California.

17. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 (b), (c), and (d) because both Defendants reside in this District and a substantial part of the events or omissions giving rise to the claims occurred in this District. In addition, pursuant to the Genentech Agreement, Genentech stipulated and agreed that any disputes arising out of or related to the Genentech Agreement must be brought in this District.

INTRADISTRICT ASSIGNMENT

18. A substantial part of the events or omissions giving rise to the claims occurred in the San Francisco Division.

The Cabilly II Patent Interference

19. On March 25, 1983, Michael Boss, John Kenton, John Emtage, and Clive Wood (the "Celltech applicants") filed their initial application for a patent in the United Kingdom (the "British Patent Application"), presumptively entitling the patent to priority on that date.

20. On March 28, 1989, the U.S. Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,816,397 (the "Boss patent"), which arose from the March 25, 1983 British Patent Application, with Celltech Ltd. ("Celltech") listed as assignee.

21. On April 8, 1983, Shmuel Cabilly, Herbert Heyneker, William Holmes, Arthur Riggs, and Ronald Wetzel (the "Cabilly applicants") filed a patent application in the PTO ("the Cabilly I application") that issued on March 28, 1989, as U.S. Patent 4,816,567 (the "Cabilly I patent"). Messrs. Heyneker, Holmes, and Wetzel were affiliated with Genentech, and Messrs.

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