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24 ELI LILLY AND COMPANY and IMCLONE SYSTEMS LLC

25 UNITED STATES DISTRICT COURT  
26 FOR THE NORTHERN DISTRICT OF CALIFORNIA

27 ELI LILLY AND COMPANY, an Indiana  
28 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.

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:

Filed

FEB 28 2013

RICHARD W. WIEKING  
CLERK, U.S. DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN JOSE

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CV 13 - 0919  
Case No.

YGR

COMPLAINT FOR DECLARATORY  
JUDGMENT OF INVALIDITY,  
UNENFORCEABILITY, AND  
NONINFRINGEMENT

DEMAND FOR JURY TRIAL

ORIGINAL

## NATURE OF THE CASE

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

11 2. ImClone Systems Incorporated (“ImClone”) first received approval for Erbitux in  
12 the United States in 2004 for the treatment of certain types of colorectal cancers. Beginning in  
13 2006, ImClone received approval for Erbitux for the treatment of certain types of head and neck  
14 cancers as well. Lilly has a commercial agreement with Bristol-Myers Squibb Company and E.R.  
15 Squibb & Sons, LLC (collectively “BMS”) relating to Erbitux. Lilly co-develops Erbitux in the  
16 U.S. and Canada with BMS. Lilly is responsible for the manufacture and supply of all  
17 requirements of Erbitux in bulk-form active pharmaceutical ingredient (“API”) for clinical and  
18 commercial use in the U.S. and Canada. BMS purchases all of its requirements of API for  
19 commercial use from Lilly and exclusively sells Erbitux in the U.S. and Canada. Eli Lilly and  
20 Company acquired ImClone in 2008 and ImClone currently operates as a wholly-owned  
21 subsidiary of Eli Lilly and Company.

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

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

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

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

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

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

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

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

#### 11 THE PARTIES

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

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

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

21 13. Defendant City of Hope is a California not-for-profit organization having its  
22 principal place of business in Duarte, California. On information and belief, City of Hope has a  
23 place of business in this District at 55 Hawthorne Street, Suite 450, San Francisco, California,  
24 94105.

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

#### 27 JURISDICTION AND VENUE

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

1 2201-2202), Title 28 of the United States Code, for the purposes of determining an actual and  
2 justiciable controversy between the parties, and the patent laws of the United States, Title 35 of  
3 the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331  
4 and 1338(a).

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

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

15 **INTRADISTRICT ASSIGNMENT**

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

18 **The Cabilly II Patent Interference**

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

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

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

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