E-filing

ORIGINAL

MAYER BROWN LLP
MICHAEL A. MOLANO (SBN171057)
mmolano@mayerbrown.com
Two Palo Alto Square, Suite 300
3000 El Camino Real
Palo Alto, CA 94306-2112
Telephone: (650) 331-2000
Facsimile: (650) 331-2060

LISA FERRI (to be admitted *pro hac vice*)
lferri@mayerbrown.com
RICHARD MCCORMICK (to be admitted *pro hac vice*)
rmccormick@mayerbrown.com
1675 Broadway
New York, NY 10016-5820
Telephone: (212) 506-2500
Facsimile: (212) 262-1910

Attorneys for Plaintiff
BRISTOL-MYERS SQUIBB COMPANY

FILED
MAY - 3 2013
RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND

Fee Paid
155
14

ADR

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

C

BRISTOL-MYERS SQUIBB COMPANY,

Plaintiff,

v.

GENENTECH, INC. and CITY OF HOPE,

Defendants.

CASE NO. C13-2045 NC

COMPLAINT FOR DECLARATORY JUDGMENT

DEMAND FOR JURY TRIAL

Plaintiff Bristol-Myers Squibb Company ("Bristol-Myers Squibb") for its Complaint against Genentech, Inc. ("Genentech") and City of Hope (collectively, "Defendants"), alleges as follows:

NATURE OF THE CASE

1. In this action, Bristol-Myers Squibb seek a declaration that U.S. Patent No. 6,331,415 entitled "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 Reexamination Nos. 90/007,542 and 90/007,859

(attached as Exhibit B), and U.S. Patent No. 7,923,221, entitled "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen" (the "Cabilly III Patent," attached as Exhibit C) are invalid and not infringed by the manufacture, use, sale, offer to sell, or importation of: (1) Erbitux® (cetuximab), an antibody product that Bristol-Myers Squibb sells in the United States pursuant to a commercial agreement with ImClone Systems LLC ("ImClone"), a wholly owned subsidiary of Eli Lilly and Company ("Lilly"); and (2) Plaintiff's Yervoy® (ipilimumab) antibody product, which it manufactures and sells in the United States. (The Cabilly II patent and Cabilly III patent are collectively referred to as the "Cabilly Patents.")

2. Bristol-Myers Squibb brings this action to lift the cloud created by the imminent threat of Defendants' enforcement of the Cabilly Patents against Plaintiff. Without declaratory relief, the threat of enforcement of the Cabilly Patents poses a substantial risk to Plaintiff as well as to patients, nurses and doctors now using Erbitux and Yervoy. The continued existence and enforcement of these patents impedes not only the development and sale of Erbitux and Yervoy, but also the development and sale of other life-saving recombinant antibody products.

3. Defendants have asserted that the Cabilly Patents broadly cover 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 Johnston, then Genentech's 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 cell … We do not believe that the claims are limited by type of antibody (murine, humanized, or human) or by host cell type." *See* Debra Robertson, "Genentech Awarded Critical Antibody Patent," *Nature Biotechnology*, vol. 20, p. 108 (Feb. 2002) (attached as Exhibit D).

4. Defendants have filed multiple infringement claims under the Cabilly Patents against companies who have made and sold antibody products that, on information and belief, were produced using recombinant methods similar to the methods used to make Erbitux and Yervoy.

5. In public statements, Genentech has specifically identified Erbitux as a potential competitor to one of Genentech's own antibody products, Avastin. *See* Genentech, Inc., 2008

10-K Annual Report (2-20-2009), retrieved from SEC EDGAR, at 13. On information and belief, Genentech's pipeline antibody product MPDL3280A is presently in clinical trials to test its safety and effectiveness for the treatment of melanoma, non-small-cell lung carcinoma and renal cell carcinoma. These indications overlap with those for Plaintiff's Yervoy product, which is approved by the FDA for melanoma.

6. Genentech has stated that it expects to be involved in future litigations relating to the enforcement of the Cabilly II patent. *See* Genentech, Inc., 2008 10-K Annual Report (2-20-2009), retrieved from SEC EDGAR, at 25, 39. The term of both of the Cabilly Patents expires in December 2018.

7. Given Defendants' past acts and statements, as set forth in further detail below, the manufacture and sale of Erbitux and Yervoy in the United States creates a real, immediate and substantial dispute between the parties concerning the Cabilly Patents, for which Bristol-Myers Squibb now seeks declaratory relief.

PARTIES

8. Bristol-Myers Squibb is a company organized and existing under the laws of the State of Delaware, having its principal place of business at 345 Park Avenue, New York, New York 10154. Bristol-Myers Squibb maintains a research and development facility in Redwood City, California, that houses biologics drug discovery activities focused on antibody therapeutics. Bristol-Myers Squibb employs over 150 scientists at its Redwood City facility.

9. On information and belief, Defendant Genentech, Inc. is a corporation duly organized and existing under the laws of the State of Delaware, having its principal place of business at 1 DNA Way, South San Francisco, California 94080-4990.

10. On information and belief, Defendant City of Hope is a California not-for-profit organization duly organized and existing under the laws of the State of California, 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.

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

JURISDICTION AND VENUE

12. 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).

13. This Court has personal jurisdiction over Genentech based on its principal place of business in California. 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.

14. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because both Defendants reside in this District and because a substantial part of the events or omissions giving rise to the claims occurred in this District.

INTRADISTRICT ASSIGNMENT

15. Pursuant to Civil L.R. 3-2(c), this intellectual property action shall be assigned on a district-wide basis.

RELATED CASE

16. This action concerns substantially the same parties, property, transactions and/or events as another action filed and presently pending in this District (Oakland Division), *Eli Lilly and Company and ImClone Systems LLC v. Genentech, Inc. and City of Hope*, Case No. CV13-0919 (YGR). There will therefore be an unduly burdensome duplication of labor and expense or conflicting results if the cases are conducted before different Judges in this District.

THE CABILLY PATENTS

17. On April 8, 1983, Shmuel Cabilly, Herbert Heyneker, William Holmes, Arthur Riggs, and Ronald Wetzel (collectively, the "Cabilly Applicants") filed a patent application in the United States Patent and Trademark Office ("PTO") that issued on March 28, 1989, as U.S.

Patent No. 4,816,567 (the "Cabilly I Patent"). On its face, the Cabilly I Patent is assigned to Genentech and, by certificate of correction, is also assigned to City of Hope. The Cabilly I patent expired on March 28, 2006.

18. At the time the Cabilly I Patent issued, the Cabilly Applicants had a continuation application pending in the PTO, which issued on December 18, 2001, as the Cabilly II Patent. On its face, the Cabilly II Patent is assigned to Genentech and, by certificate of correction, is also assigned to City of Hope.

19. At the time the Cabilly II Patent issued, the Cabilly Applicants had a continuation application pending in the PTO, which issued on April 12, 2011, as the Cabilly III Patent. The Cabilly III Patent is assigned to Genentech and City of Hope.

20. The Cabilly II Patent and Cabilly III Patent relate to recombinant techniques for manufacturing antibody therapeutics. Both patents claim priority to the Cabilly I Patent application, filed on April 8, 1983, in the early days of monoclonal antibodies.

21. The Cabilly II Patent was the subject of a nine-year patent interference and two reexaminations. The Cabilly III Patent has also been through a patent interference.

22. The nine-year Cabilly II Patent interference caused the claims of the Cabilly II Patent to have an effective patent life of 35 years after the date the Cabilly I Patent application was filed, with an expiration date on December 18, 2018. The Cabilly III Patent is subject to a terminal disclaimer, and thus the Cabilly III Patent claims will have the same expiration date as the Cabilly II Patent claims.

BRISTOL-MYERS SQUIBB'S AND LILLY'S ERBITUX® (CETUXIMAB) PRODUCT

23. Erbitux® (cetuximab) is a recombinant, mouse/human chimeric monoclonal antibody that binds to the extracellular domain of human epidermal growth factor receptor ("EGFR"). Erbitux was first approved by the FDA in 2004 for the treatment of colorectal cancer and, in 2006, for the treatment of head and neck cancer.

24. Erbitux was initially developed by ImClone. Lilly, through its wholly owned subsidiary ImClone, has a commercial agreement with Bristol-Myers Squibb relating to Erbitux.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.