

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HUMAN GENOME SCIENCES, INC.,

Plaintiff,

v.

GENENTECH, INC., and CITY OF HOPE,

Defendants.

C.A. No. _____

DEMAND FOR JURY TRIAL

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Human Genome Sciences, Inc. (“HGS”), by and through undersigned counsel, files this Complaint against Genentech, Inc. and City of Hope (collectively, “Defendants”) and alleges as follows:

NATURE OF THE CASE

1. HGS 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 Reexamination Nos. 90/007,542 and 90/007,859, is invalid, unenforceable and not infringed by the manufacture, use, importation, offer to sell or sale of HGS’s Benlysta® (belimumab) antibody.

2. HGS has manufactured and is currently manufacturing Benlysta®, a recombinantly engineered monoclonal antibody which is being developed for the treatment of autoantibody-positive patients with systemic lupus erythematosus (“Lupus”). If approved, Benlysta® would be the first new approved drug for Lupus in more than fifty years.

3. HGS has expended substantial resources researching and developing Benlysta®, including filing a Biologic License Application (“BLA”) with the United States Food and Drug Administration (“FDA”). HGS also has expended substantial resources in preparing to launch and commercialize Benlysta®.

4. In the near future, HGS expects a decision from the FDA regarding the approval of HGS’s BLA for Benlysta®. Upon approval, HGS intends to market Benlysta® in this District.

5. Defendants have asserted that the Cabilly II Patent broadly covers the use of certain well-known, conventional recombinant methods to produce virtually any antibody product in any type of host cell. Defendants also have asserted multiple 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 methods used by HGS to make Benlysta®. See *MedImmune Inc. v. Genentech, Inc.*, Case No. 03-cv-02567 (C.D. Cal.); *Centocor, Inc. v. Genentech, Inc.*, Case No. 08-cv-03573 (C.D. Cal.); *Glaxo Group Ltd. v. Genentech, Inc.*, Case No. 2:10-cv-02764 (C.D. Cal.).

6. In a pending action pertaining to a different antibody, Arzerra™, Defendants specifically averred that Benlysta® infringes Claims 18 and 20 of the Cabilly II Patent and that they “intend shortly” to assert infringement claims against HGS. See *Glaxo Group Ltd. v. Genentech, Inc.*, Case No. 2:10-cv-02764 (C.D. Cal.) (Genentech, Inc. and City of Hope’s Opening Brief on Claim Construction dated Jan. 7, 2011), Dkt. No. 83 at FN4. Given Defendants’ acts and statements and HGS’s intended sale of Benlysta®, a real, immediate and substantial dispute exists between the parties concerning the Cabilly II Patent for which HGS now seeks declaratory relief.

PARTIES

7. Plaintiff HGS is a corporation duly organized and existing under the laws of the State of Delaware, with its principal place of business at 14200 Shady Grove Road, Rockville, Maryland 20850.

8. Defendant Genentech, Inc. (“Genentech”) is a corporation duly organized and existing under the laws of the State of Delaware, with its principal place of business in South San Francisco, California.

9. Defendant City of Hope is a not-for-profit organization duly organized and existing under the laws of the State of California, with its principal place of business in Duarte, California. On information and belief, City of Hope conducts business in the State of Delaware and has developed valuable relationships and generated goodwill through advertising and educational initiatives, including having a Regional Development Office serving Delaware at 1608 Walnut Street #1702, Philadelphia, Pennsylvania 19103. On information and belief, as part of its business efforts, City of Hope routinely invites businesses in Delaware to donate time and raise funds for its research and treatment programs.

10. On information and belief, Genentech and City of Hope are co-assignees of the Cabilly II Patent. On information and belief, City of Hope has an ongoing relationship with Genentech which involves dealings beyond simply receiving royalty income on the Cabilly II Patent, including coordinating patent prosecution and maintenance and the federal litigation of infringement claims (in which City of Hope and Genentech are represented jointly by counsel).

JURISDICTION AND VENUE

11. This action arises under the Declaratory Judgment Act of 1934 (28 U.S.C. § 2201), 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).

12. This Court has personal jurisdiction over Genentech based on its incorporation and business in Delaware. On information and belief, this Court has personal jurisdiction over City of Hope based on its business activities in and directed to Delaware and its established and ongoing relationship with its co-assignee Genentech. Because of the multifaceted relationship between City of Hope and Genentech, including coordinating prosecution and maintenance of the Cabilly II Patent and control over federal litigation, City of Hope has purposefully availed itself of the benefits and protections of Delaware law.

13. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b), because Genentech is incorporated, both Defendants do business in the State of Delaware, and HGS intends to market Benlysta® in this District upon approval by the FDA.

THE CABILLY PATENTS

14. 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 that issued on March 28, 1989, as U.S. Patent No. 4,816,567 (the “Cabilly I Patent”).

15. At the time the Cabilly I Patent issued, the Cabilly Applicants had a continuation application (the “Cabilly II Application”) pending in the United States Patent and Trademark Office (“PTO”). The PTO issued the Cabilly II Patent on December 18, 2001. On its face, the Cabilly II Patent is assigned to Genentech, and, by certificate of correction, is also assigned to City of Hope.

Patent Reexamination

16. In 2005, two separate requests to re-examine the Cabilly II Patent were submitted to the PTO. The PTO mailed two separate orders granting a request for reexamination, on July

7, 2005 and January 23, 2006. *See* Decision Granting *Ex Parte* Reexamination, Reexamination Control No. 90/007,542 (July 7, 2005); Decision Granting *Ex Parte* Reexamination, Reexamination Control No. 90/007,859 (January 23, 2006). The reexamination proceedings were merged on June 6, 2006.

17. On July 19, 2008, the PTO mailed an Advisory Action, maintaining its final rejection of all claims in the Cabilly II Patent as invalid for reasons including obviousness-type double patenting. *Ex Parte* Reexamination Advisory Action, Reexamination Control Nos. 90/007,859 and 90/007,542 (July 19, 2008).

18. In response to the final rejection, Defendants filed an Appeal Brief on December 9, 2008.

19. After an *Ex Parte* Examiner Interview on February 13, 2009, Genentech amended claims 21, 27 and 32 to overcome the obviousness-type double patenting rejection. *See* Supplemental Amendment Under 37 C.F.R. § 1.550(b), Reexamination Control Nos. 90/007,859 and 90/007,542 (February 13, 2009).

20. On February 23, 2009, the PTO issued a Notice of Intent to Issue a Reexamination Certificate to Genentech, confirming claims 1-20 and 33-36 and allowing amended claims 21, 27 and 32. Notice of Intent to Issue *Ex Parte* Reexamination Certificate, Reexamination Control Nos. 90/007,859 and 90/007,542 (February 23, 2009). On May 19, 2009, the *Ex Parte* Reexamination Certificate Issued for U.S. Patent No. 6,331,415 C1 with amended claims 21, 27 and 32.

Defendants' Admissions Regarding State of the Art in April 1983

21. Defendants made a number of admissions in their December 2008 Appeal Brief regarding the state of the art prior to the filing of the Cabilly II Patent application in April 1983. According to Defendants:

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