IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

| | |
|---|---|
| HUMAN GENOME SCIENCES, INC.,<br><br>Plaintiff,<br><br>v.<br><br>GENENTECH, INC., and CITY OF HOPE,<br><br>Defendants. | C.A. No._____<br><br>**DEMAND FOR JURY TRIAL** |

## COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Human Genome Sciences, Inc. ("HGS"), by and through its undersigned counsel, hereby 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. 7,923,221, entitled "Methods of Making Antibody Heavy and Light Chains Having Specificity For a Desired Antigen" (hereinafter the "Cabilly III Patent," attached as Exhibit A hereto), 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 that is approved for the treatment of adult patients with active, autoantibody-positive systemic lupus erythematosus ("Lupus") who are receiving standard therapy.

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. On March 9, 2011, the FDA approved Benlysta® to treat patients with active, autoantibody-positive lupus who are receiving standard therapy, including corticosteroids, antimalarials, immunosuppressives, and nonsteroidal anti-inflammatory drugs. The March 9, 2011 FDA News Release headline read as follows:

**FDA approves Benlysta® to treat lupus**
**First new lupus drug approved in 56 years**

*See* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm246489.htm. HGS markets Benlysta® in this District.

5. The Cabilly III Patent was filed as a continuation application on April 13, 1995, claiming priority to an earlier-filed patent application that issued on December 18, 2001, as U.S. Patent No. 6,331,415 (the "Cabilly II Patent"). The Cabilly II Patent in turn claims priority to an earlier-filed application that was granted on March 28, 1989, as U.S. Patent No. 4,816,567 (the "Cabilly I Patent" and, collectively, the "Cabilly Patents"). The Cabilly I Patent expired on March 28, 2006. The Cabilly II patent expires on December 18, 2018. Defendants have filed a terminal disclaimer to disclaim any portion of the term of the Cabilly III Patent beyond the term of the Cabilly II Patent.

6. Upon information and belief, Defendants contend that the Cabilly Patents cover the "fundamental technology" required for the artificial synthesis of antibody molecules, including the use of certain well known, conventional recombinant methods used to produce virtually any antibody product in any type of host cell. Defendants 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, e.g.*, *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.).

7. On January 28, 2011, in a pending action pertaining to a different antibody, Arzerra™ (ofatumumab), Defendants moved for leave to add HGS as a counter-defendant and to assert a patent infringement counterclaim against HGS concerning the Cabilly II Patent. *See Glaxo Group Ltd. v. Genentech, Inc.*, Case No. 2:10-cv-02764 (C.D. Cal.) (Genentech, Inc. and City of Hope's Notice of Motion for Leave to Amend Answer and Counterclaim to Add Counter-Defendants, dated January 28, 2011), Docket No. 85. In its motion to amend, Defendants asserted that HGS "ha[s], or will imminently, infringe and/or induce infringement of the Cabilly II [P]atent" and that "HGS does and will make Benlysta® in Rockville, Maryland, using a method that, on information and belief, infringes the Cabilly II [P]atent." *Id.* In an accompanying filing that same day, Defendants notified the court that the U.S. Patent and Trademark Office ("PTO") had issued a Notice of Allowance for the then "currently pending U.S. Patent Application No. 08/422,187," which has now issued as the Cabilly III Patent. *Id.* (Notice of Notice of Allowance and Fee(s) Due Issued by the United States Patent and Trademark Office, dated January 28, 2011), Docket No. 84.

8. Given Defendants' acts and statements and HGS's manufacture and sale of Benlysta®, a real, immediate, and substantial dispute exists between the parties concerning the Cabilly III Patent, for which HGS now seeks declaratory relief.

## PARTIES

9. 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.

10. 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.

11. 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. Upon 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. Upon 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.

12. Upon information and belief, Genentech and City of Hope are co-assignees of the Cabilly III Patent. Pursuant to an exclusive license agreement between the co-assignees, City of Hope has transferred all substantial rights in the Cabilly Patents to Genentech, in return for royalties from Genentech's sales of antibody products and Genentech's sub-licenses with prominent companies resident or doing business in Delaware.

## JURISDICTION AND VENUE

13. 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 under 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).

14. This Court has personal jurisdiction over Genentech based on its incorporation and business in Delaware. Upon 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 Patents and control over federal litigation, City of Hope has purposefully availed itself of the benefits and protections of Delaware law.

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

## THE CABILLY PATENTS

16. 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 PTO that issued on March 28, 1989, as 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.

17. 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.

18. 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.

19. The Cabilly Patents, all of which relate to recombinant techniques for manufacturing antibody therapeutics, all claim priority to a patent application filed on April 8, 1983, in the early days of monoclonal antibodies. The Cabilly I Patent has expired. The Cabilly II Patent has been through several patent interferences and reexaminations. The Cabilly III

Patent has also been through a patent interference and extended prosecution. The events that occurred in the Cabilly II Patent prosecution history caused the claims of the Cabilly II Patent to have an effective patent life of 29 years. The Cabilly III Patent is subject to a terminal disclaimer and thus the Cabilly III Patent claims will have the same end term as the Cabilly II Patent claims. The following highlights of the Cabilly Patents' prosecution histories are particularly relevant to this action:

***Cabilly II Patent Interference***

20. After the time the Cabilly I patent issued, the Cabilly Applicants had a continuation application (the "Cabilly II Application") pending in the PTO. Claims were copied from U.S. Patent No. 4,816,397 (the "Boss Patent") into the Cabilly II Application in order to provoke the PTO to initiate an interference proceeding, to determine whether the Boss patentees or the Cabilly Applicants were entitled to priority for the inventions claimed in the Boss Patent.

21. On February 28, 1991, the PTO declared a patent interference, Interference No. 102,572, between certain claims pending in the Cabilly II Application and all of the issued claims of the Boss Patent. After seven years of adversarial proceedings in the PTO, in August 1998, the PTO Board found that the Boss patentees were entitled to priority over the Cabilly Applicants. *See Cabilly v. Boss*, 55 U.S.P.Q.2d 1238 (B.P.A.I. Aug. 13, 1998). The PTO concluded that the Cabilly Applicants had failed to establish conception or reduction to practice of the claimed inventions prior to March 25, 1983—the filing date of the Boss Patent. According to the PTO, "there is no evidence that immunoglobulins, multiple chain proteins, had been produced by recombinant DNA techniques from a single host cell prior to March 25, 1983." Moreover, the PTO found that "the evidence indicates that Cabilly et al. ***had but a hope or wish*** to produce active antibodies in bacteria; and, there is no supporting evidence to establish the

development of the means to accomplish that result or evidence of a disclosure to a third party of complete conception." (Emphasis added.)

22. In October 1998, Genentech filed suit against Celltech Therapeutics Ltd. ("Celltech"), the owner of the Boss Patent, pursuant to 35 U.S.C. § 146, to appeal the decision of the PTO awarding priority to the Boss Patent. *Genentech, Inc. v. Celltech Ltd.*, Case no. C98-3926 (N.D. Cal.) ("146 Action"). In March 2001, the parties agreed to settle the action and, on March 6, 2001, filed a document titled "Notice of Settlement and Joint Request for Entry of Settlement Instruments." The precise terms of the settlement agreement are confidential. Upon information and belief, pursuant to the agreement, the parties asked the district court to find that, contrary to the PTO's prior decision, the Cabilly Applicants were entitled to priority over the Boss patentees, and Celltech obtained certain rights relating to the Cabilly II Patent as well as certain reverse payments from Genentech, in exchange for its agreement to stipulate that the Cabilly Applicants were entitled to priority for the inventions claimed in the Boss Patent.

23. On March 16, 2001, the district court in the 146 Action issued a "Judgment" directing the PTO to vacate its determination that the Boss patentees were entitled to priority, to revoke the Boss Patent, and to issue a patent to the Cabilly Applicants claiming the same subject matter as the Boss Patent. The Cabilly II Patent issued on December 18, 2001. It is on its face assigned to Genentech and, by certificate of correction, is also assigned to City of Hope.

24. If the Boss Patent had not been revoked by the PTO, it would have expired in 2006. The Cabilly II Patent does not expire until 2018—more than 35 years after the Cabilly Applicants' original 1983 patent application, and more than 12 years after the expiration of the Boss Patent. The Cabilly III Patent also will expire in 2018. Accordingly, the combined period of patent exclusivity for the Cabilly Patents, which all share the same patent specification, is 29 years.

***Cabilly II Patent Reexaminations***

25. In 2005, two separate requests to reexamine 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.

26. 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).

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

28. 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).

29. 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). Finally, 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.

***Cabilly III Patent Interference***

30. On January 16, 2007, the PTO declared a patent interference, Interference No. 105,531, between U.S. Application No. 08/422,187 (the "Cabilly III Application") and U.S. Application No. 08/450,727 (the "Boss Application"). Defendants asserted that the Cabilly Applicants had "invented" the same subject matter claimed by the Boss Application. While the Cabilly III Application claimed priority benefit to an application filed on April 8, 1983, the Boss Application claimed priority benefit to an application filed earlier, on March 25, 1983. Accordingly, the PTO designated Boss as the senior party in the interference.

31. The subject matter of the interference "count" in dispute was defined as "[a] composition of matter according to either of claim 110 of [the Cabilly Application] or claim 49 of [the Boss Application]."

32. The Cabilly claim 110 in interference read:

> An antibody or antibody fragment capable of specifically binding a desired antigen and comprising (a) an antibody heavy chain or fragment thereof comprising a human constant region sequence and a variable region comprising a non human mammalian variable region sequence and (b) an antibody light chain or fragment thereof comprising a human constant region sequence and a variable region comprising non human mammalian variable region sequences, where the antibody has been made by the method of [Cabilly] claim 104.

The Cabilly claim 104 in interference read:

> A method for making an antibody or antibody fragment capable of specifically binding a desired antigen, wherein the antibody or antibody fragment comprises (a) an antibody heavy chain or fragment thereof comprising a human constant region sequence and a variable region comprising non human mammalian variable region sequences and (b) an antibody light chain or fragment thereof comprising a human constant region sequence and a variable region comprising non human mammalian variable region sequences, the method comprising coexpressing the heavy chain or fragment thereof and the light chain or fragment thereof in a recombinant cell.

Rewritten in independent form, the Cabilly claim 110 in interference read:

> An antibody or antibody fragment capable of specifically binding a desired antigen and comprising (a) an antibody heavy chain or fragment thereof

> comprising a human constant region sequence and a variable region comprising a non human mammalian variable region sequence and (b) an antibody light chain or fragment thereof comprising a human constant region sequence and a variable region comprising non human mammalian variable region sequences, wherein the antibody or antibody fragment has been made by the method comprising coexpressing the heavy chain or fragment thereof and the light chain or fragment thereof in a recombinant cell.

33. On December 8, 2008, the PTO found that the Cabilly Application was entitled to priority over the Boss Application. *See Cabilly v. Boss*, (B.P.A.I., unpublished decision, Dec. 8, 2008). The PTO declined to consider the issue of double patenting by Cabilly, stating that "we believe obviousness-type double patenting is best considered in the first instance by the examiner upon resumption of ex parte prosecution." *Id.* at 25.

34. On appeal, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") affirmed the PTO's ruling regarding priority. *See Boss v. Cabilly*, 355 Fed. Appx. 416 (Fed. Cir. 2009) (Appeal No. 2009-1264).

35. On July 12, 2010, Defendants filed a request to reopen prosecution and concurrently submitted 409 prior art references to the PTO.

36. On December 21, 2010, without any further substantive prosecution, the Examiner issued an Examiner's Amendment, recorded the terminal disclaimer that had been filed over the Cabilly II patent and allowed the pending claims.

37. On April 12, 2011, the Cabilly III patent issued with claims 1-47.

***Defendants' Admissions Regarding The State of the Art Prior to April 1983***

38. Defendants made a number of admissions in their December 2008 Appeal Brief during the Cabilly II Patent reexamination regarding the state of the art prior to April 1983—the earliest patent application filing date from which the Cabilly III Patent claims priority. According to Defendants:

a. "[I]n April 1983, the biological mechanisms that controlled expression of foreign DNA and assembly of proteins were not well understood. This lack of understanding was especially true for eukaryotic genes, which were known to be far more complex than prokaryotic genes. As Dr. Harris, one of Owners' experts in this case, explained in his 1983 review paper, 'it is clear that not all the rules governing the expression of cloned genes have been elaborated and those rules that do exist are still largely empirical.'" (Appeal Brief at 20.)

b. "In early April of 1983, the field of genetic engineering was still developing . . . . A relatively small number of proteins had been made by recombinant DNA technology. Almost all of those were relatively simple monomeric (i.e., one polypeptide chain) proteins." (Appeal Brief Appendix at B551 [Harris Decl.].)

c. "As of April 1983, insulin was the only 'multimeric' protein that had been made using genetic engineering." (Appeal Brief at 21.)

d. "Several experts with actual experience in the field of the invention in April 1983 explained that those references cited by the Examiner that include experimental results show a significant amount of unpredictability in achieving success in simpler experiments than what is required by the '415 patent claims." (Appeal Brief at 28.)

e. "[S]uccessful production of immunoglobulins was highly dependent on the sequence of expression and levels at which the two immunoglobulin genes were expressed." (Appeal Brief at 63.)

f. "[L]evels of expression of each immunoglobulin gene could affect production of the other immunoglobulin polypeptide." (Appeal Brief at 63.)

g. "Such a person would have been familiar with the many complications of producing eukaryotic polypeptides in bacterial host cells known by April 1983." (Appeal Brief at 73.)

h. "I believe a person of ordinary skill in the art, in early April of 1983, would have thought that successful expression of two immunoglobulin proteins in one transformed host cell would have been unpredictable and that assembly of the two proteins into an immunoglobulin tetramer would have been even more unpredictable." (Appeal Brief Appendix at B224 [McKnight Decl.].)

i. "Experimental results would have been important to a person of ordinary skill in the art in April 1983 because many of the biological mechanisms that controlled expression of foreign DNA and assembly of proteins were not well understood at that time." (Appeal Brief Appendix at B376 [Second McKnight Decl.].)

j. "Each of these papers shows that successful transformation and expression of even one foreign immunoglobulin gene in a lymphoid host cell could not be reasonably expected in April 1983. I do not believe these references can be read as suggesting that something even more challenging—expressing two different foreign immunoglobulin genes in one transformed cell—would have been something that could be predictably achieved at that time." (Appeal Brief Appendix at B382 [Second McKnight Decl.].)

k. "I disagree with the suggestion, that by early April 1983, my PNAS paper had made routine or predictable the task of expressing exogenous immunoglobulin light and heavy chain genes in the same cell. In later experiments, I attempted to use the techniques described in the PNAS paper to introduce and express single Ig genes into other lymphoid cell lines. Most of these experiments failed to produce

> stable transfectants. Thus, my experience was that using the same transfection and selection conditions described in the PNAS paper with other cell lines or other Ig genes did not routinely yield stable transformants containing even a single exogenous Ig gene." (Appeal Brief Appendix at B391 [Rice Decl.].)

**HGS'S BENLYSTA® (BELIMUMAB)**

39. Benlysta® (belimumab) is a new, human monoclonal antibody that targets the B-lymphocyte stimulator ("BLyS"), a naturally occurring protein, which is involved in the mediation of immunological responses and autoimmune diseases, including Lupus. HGS first discovered BLyS in 1996 and published a scientific article describing its activity in the journal *Science* in July 1999. Following that discovery, HGS initiated a program to develop human monoclonal antibodies that would specifically recognize and inhibit the biological activity of BLyS.

40. After years of research and development, on June 2, 2010, HGS submitted a BLA to the FDA seeking to market Benlysta® with an indication for the treatment of autoantibody-positive patients with Lupus. On March 9, 2011, the FDA approved Benlysta® to treat adult patients with active, autoantibody-positive Lupus (i.e., systemic lupus erythematosus) who are receiving standard therapy, including corticosteroids, antimalarials, immunosuppressives, and nonsteroidal anti-inflammatory drugs. Benlysta® is the first new lupus drug approved in over fifty years.

41. HGS has expended substantial revenues researching and developing Benlysta®. HGS also has expended substantial revenues preparing to launch and commercialize Benlysta®. HGS is marketing Benlysta® throughout the United States, including in this District.

42. HGS currently manufactures belimumab in Rockville, Maryland, in anticipation of commercial sales throughout the United States as the Benlysta® product. In addition, copies

of the working cell bank used to produce Benlysta® are maintained by HGS in Rockville, Maryland.

**HGS'S DISPUTE WITH DEFENDANTS REGARDING THE CABILLY PATENTS**

43. Through its statements and actions, Defendants have made clear to the biopharmaceutical industry generally and to HGS particularly that it contends the Cabilly Patents preclude others from commercially manufacturing recombinantly-produced monoclonal antibodies without Defendants' permission. In 2002, after the Cabilly II Patent issued, Sean Johnston, then Genentech's Vice President of Intellectual Property and now Genentech's Senior Vice President and General Counsel, stated explicitly:

> "The recently issued 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."

Genentech Awarded Critical Antibody Patent, *Nature Biotechnology*, vol. 20, p. 108 (Feb. 2002) (emphasis added).

44. According to Defendants' statements during the course of one of the Cabilly II Patent litigations, the manufacturing methods claimed therein are "the backbone of recombinant antibody production in the biotech industry." *Centocor, Inc. v. Genentech, Inc.*, Case No. 2:08-cv-03573 (C.D. Cal.) (Opening Brief of Claim Construction, March 24, 2009), Docket No. 78.

45. Defendants have also made public statements about pursuing an aggressive litigation policy to protect its products against competition and to protect against alleged infringement of the Cabilly Patents. For example, in its disclosures for the third quarter ended June 30, 2010, City of Hope documented the extent to which it has "been engaged in various proceedings," including exerting coordinated control with Genentech over prosecution and litigation filings and in appearances before the PTO, and stating explicitly that "Genentech and

City of Hope ***are both actively defending [The Cabilly II] patent***"). (Emphasis added.) Similarly, in its 2009 Form 10-K filing with the Securities and Exchange Commission, Genentech states that:

> "Intellectual property protection of our products is crucial to our business. Loss of effective intellectual property protection could result in lost sales to competing products and loss of royalty payments (for example, royalty income associated with the ***Cabilly patent***) from licensees. We are often involved in disputes over contracts and intellectual property, and we work to resolve these disputes in confidential negotiations or litigation. We expect legal challenges in this area to continue. We plan to continue to build upon and defend our intellectual property position."

(Emphasis added.) Genentech also states that "[w]e have in the past been, are currently, ***and may in the future be involved in material litigation*** and other legal proceedings related to our proprietary rights, ***such as the Cabilly patent litigation and reexamination*** . . . ." (Emphasis added.)

46. In addition to these general statements and conduct directed at others, Defendants have also made statements and engaged in conduct directed specifically at HGS that create a real and immediate dispute between the parties regarding the Cabilly Patents. On January 7, 2011, Defendants averred in a court filing that HGS's process to make Benlysta® infringes the Cabilly II Patent. Specifically, in Defendants' Opening Brief on Claim Construction, a patent infringement action involving GlaxoSmithKline's antibody Arzerra™ and the Cabilly II Patent, Defendants stated that "[t]he process used to make Benlysta® is similar to that for Arzerra, except that it uses two vectors instead of one (and thus will implicate claims 18 and 20)." *See Glaxo Group Ltd. v. Genentech, Inc.*, Case No. 2:10-cv-02764 (C.D. Cal.), Docket No. 83 at n. 4.

47. In light of Genentech's statements that it would enforce the Cabilly Patents to defend its products against competing products generally, as well as Defendants' sworn contention that HGS's Benlysta® product infringes at least two claims of the Cabilly II Patent, HGS had a reasonable apprehension of suit by Defendants regarding the Cabilly II Patent. Accordingly, HGS chose an immediate means to resolve that uncertainty and filed an action against Defendants in this District seeking a declaratory judgment of non-infringement and invalidity of the Cabilly II Patent. *See Human Genome Sciences, Inc. v Genentech, Inc.*, No. 1:11-cv-0082-LPS (D. Del.).

48. After HGS filed its lawsuit in this District, Defendants moved to assert the Cabilly II Patent against HGS in a pending litigation involving GlaxoSmithKline LLC and a different antibody, Arzerra™ (ofatumumab). *See Glaxo Group Ltd. v. Genentech, Inc.*, Case No. 2:10-cv-02764 (C.D. Cal.) (Genentech, Inc. and City of Hope's Notice of Motion for Leave to Amend Answer and Counterclaim to Add Counter-Defendants, dated Jan. 28, 2011), Docket No. 85. In moving for leave to add HGS as a counter-defendant and to assert a patent infringement counterclaim against HGS concerning the Cabilly II Patent, Defendants again asserted that HGS "ha[s], or will imminently, infringe and/or induce infringement of the Cabilly II [P]atent . . .," that "HGS . . . is involved in the same series of infringing transactions and occurrences as is [GlaxoSmithKline LLC]," and that "HGS does and will make Benlysta® in Rockville, Maryland, using a method that, on information and belief, infringes the Cabilly II [P]atent."

49. That same day, Genentech alerted the court that the Cabilly III Patent had been allowed. Genentech filed with the court the PTO Notice of Allowance for the then "currently pending U.S. Patent Application No. 08/422,187," which has now issued as the Cabilly III Patent. *Id.* (Notice of Notice of Allowance and Fee(s) Due Issued by the United States Patent and Trademark Office, dated January 28, 2011), Docket No. 84.

50. On March 10, 2011, the court in California denied Defendants' motion to add HGS as a counter-defendant and to add allegations concerning Benlysta® against GlaxoSmithKline LLC and other counter-defendants. *See Glaxo Group Ltd. v. Genentech, Inc.*, Case No. 2:10-cv-02764 (C.D. Cal.) (Order Granting in Part Defendants and Counter-Plaintiffs' Motion to Amend Answer and Counterclaim and to Add Counter-Defendants, dated Mar. 10, 2011), Docket No. 101.

51. Because Defendants have consistently alleged that the use of well known, conventional recombinant methods to produce monoclonal antibodies in mammalian cell culture is within the scope of claims of the Cabilly Patents, and have asserted the Cabilly II Patent against HGS and a number of other parties who are similarly situated, Defendants' prior statements and conduct establish an actual and substantial dispute between HGS and Defendants regarding the invalidity, unenforceability, and noninfringement of the claims of the Cabilly III Patent. Moreover, based on Defendants' specific assertions that the process and certain starting materials used to produce Benlysta® infringe one or more claims of the Cabilly II Patent, HGS likewise has a reasonable apprehension of suit by Defendants regarding the Cabilly III Patent.

**FIRST CAUSE OF ACTION**
**NON-INFRINGEMENT**

52. HGS incorporates the allegations of paragraphs 1 through 51 as if fully set forth herein.

53. An actual controversy has arisen and now exists between the parties concerning whether HGS's manufacture of Benlysta® (belimumab) infringes any valid and enforceable claim of the Cabilly III Patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

54. HGS therefore seeks a declaratory judgment that making, using, importing, offering to sell, and selling Benlysta® (belimumab) does not and will not infringe any valid and enforceable claim of the Cabilly III Patent.

**SECOND CAUSE OF ACTION**
**INVALIDITY**

55. HGS incorporates the allegations of paragraphs 1 through 54 as if fully set forth herein.

56. The Cabilly III Patent is invalid because it is anticipated and/or obvious under 35 U.S.C. §§ 102 and 103.

57. The Cabilly III Patent is also invalid based on the judicially created doctrine of obviousness-type double patenting and/or under 35 U.S.C. §§ 101 and/or 103.

58. The Cabilly III Patent is additionally invalid under 35 U.S.C. § 112.

59. HGS therefore seeks a declaratory judgment that the Cabilly III Patent is invalid under 35 U.S.C. §§ 101, 102, 103, and 112 and/or under the judicially created doctrine of obviousness-type double patenting.

**THIRD CAUSE OF ACTION**
**PROSECUTION LACHES**

60. HGS incorporates the allegations of paragraphs 1 through 59 as if fully set forth herein.

61. An actual controversy has arisen and now exists between the parties concerning the enforceability of the Cabilly III Patent.

62. The Cabilly III Patent is unenforceable under the doctrine of prosecution laches. The Cabilly II Patent issued after an unreasonable and unexplained delay in the patent interference proceedings between the Cabilly II Application and U.S. Patent No. 4,816,397. Genentech also unreasonably delayed the prosecution of claims 21, 22, 27-30, and 32, which

were filed as part of the Cabilly II Application in 1983 but did not issue until 2001. Because the Cabilly III Patent will expire on the same date as the Cabilly II Patent, it benefits from the unreasonable delay of the prosecution of the Cabilly II Application.

63. HGS therefore seeks a declaratory judgment that the Cabilly III Patent is unenforceable due to prosecution laches.

## DEMAND FOR JURY TRIAL

64. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, HGS demands a trial by jury of all issues so triable.

## PRAYER FOR RELIEF

WHEREFORE, HGS requests that judgment be entered in favor of HGS and against Defendants Genentech and City of Hope:

a) Declaring that the manufacture, use, importation, offer to sell, and sale of HGS's Benlysta® (belimumab) product does not infringe any valid and enforceable claim of the Cabilly III Patent;

b) Declaring that the Cabilly III Patent is invalid and unenforceable;

c) Enjoining Genentech and City of Hope from enforcing the Cabilly III Patent;

d) Awarding costs to HGS in accordance with 35 U.S.C. § 284;

e) Declaring HGS's case to be exceptional and awarding HGS its attorneys' fees and expenses under 35 U.S.C. § 285; and

f) Awarding HGS such other relief as the Court may deem just, equitable, and proper.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

*/s/ Adam W. Poff*

Adam W. Poff (No. 3990)
Monté T. Squire (No. 4764)
The Brandywine Building
100 West Street, 17th Floor
Wilmington, DE 19899-0391
(302) 571-6600
apoff@ycst.com
msquire@ycst.com

*Attorneys for Plaintiff*
*Human Genome Sciences, Inc.*

*Of Counsel:*

Henry B. Gutman
Noah M. Leibowitz
SIMPSON THACHER & BARTLETT LLP
425 Lexington Avenue
New York, New York 10017
Telephone: (212) 455-2000
Facsimile: (212) 455-2502
hgutman@stblaw.com
nleibowitz@stblaw.com

Harrison J. Frahn IV
SIMPSON THACHER & BARTLETT LLP
2550 Hanover Street
Palo Alto, CA 94304
Telephone: (650) 462-9406
Facsimile: (650) 255-5035
hfrahn@stblaw.com

Dated: April 12, 2011