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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

JSW

CV 10 675

GLAXO GROUP LIMITED and GLAXOSMITHKLINE LLC,

Plaintiffs,

vs.

GENENTECH, INC., and CITY OF HOPE,

Defendants.

Case No.:

COMPLAINT FOR DECLARATORY JUDGMENT OF INVALIDITY, UNENFORCEABILITY, AND NONINFRINGEMENT

Plaintiffs Glaxo Group Limited and GlaxoSmithKline LLC (collectively, "GSK"), for their Complaint against Genentech, Inc. and City of Hope (collectively, "Defendants"), allege as follows:

NATURE OF THE CASE

1. GSK seeks a declaration that U.S. Patent 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 (attached as Exhibit B), is invalid, unenforceable, and not infringed by the manufacture, use, sale, offer to sell, or importation of GSK's ofatumumab (Arzerra™) antibody product.

2. GSK recently began marketing and selling Arzerra™ in the United States for the treatment of patients whose chronic lymphocytic leukemia ("CLL") is refractory to previous

therapies (fludarabine and alemtuzumab). GSK brings this action to lift the cloud created by the imminent threat of Defendants' enforcement of the Cabilly II patent against GSK. Without declaratory relief, the threat of enforcement of the Cabilly II patent poses a substantial risk of injury to GSK as well as the patients, nurses, and doctors now using Arzerra™ for treatment. The continued existence and enforcement of this invalid and unenforceable patent impedes not only the development and sale of Arzerra™, but also the development and sale of other life-saving recombinant antibody products.

3. 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. 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 GSK to make Arzerra™. Defendant Genentech, Inc. has specifically identified GSK's Arzerra™ antibody 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. During GSK's dealings with Genentech, Genentech has repeatedly taken the position that GSK requires a license under the Cabilly II patent to make and sell a variety of different antibody products, including products produced by the same or similar process as Arzerra™. As recently as the Fall of 2008, after GSK acquired rights to Arzerra™, counsel for Genentech inquired what GSK would do about the Cabilly II patent. Given Defendants' past acts and statements and GSK's sale of Arzerra™ in the United States, a real, immediate, and substantial dispute exists between the parties concerning the Cabilly II patent for which GSK now seeks declaratory relief.

THE PARTIES

4. Plaintiff Glaxo Group Limited d/b/a GlaxoSmithKline is an English corporation having a principal place of business at Glaxo Wellcome House, Berkley Avenue, Greenford, Middlesex, UB6 0NN, United Kingdom.

5. Plaintiff GlaxoSmithKline LLC is a Delaware limited liability company having a principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania, 19102.

6. Defendant Genentech, Inc. ("Genentech") is a Delaware corporation having its principal place of business in South San Francisco, California.

7. 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.

8. On information and belief, Genentech and City of Hope are co-assignees of the Cabilly II patent.

JURISDICTION AND VENUE

9. This action arises under the Declaratory Judgment Act of 1934 (28 U.S.C. §§ 2201-2201), 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) (2006).

10. 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.

11. Venue is proper in this District pursuant to 28 U.S.C. § 1391 (2006) 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.

INTRADISTRICT ASSIGNMENT

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

THE CABILLY PATENTS

13. On April 8, 1983, Shmuel Cabilly, Herbert Heyneker, William Holmes, Arthur Riggs, and Ronald Wetzel (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 4,816,567 (the "Cabilly I patent"). The Cabilly Applicants assigned their rights to Genentech and the City of Hope.

Patent Interference

14. At the time the Cabilly I patent issued, the Cabilly Applicants had a continuation application (the "Cabilly II application") pending in the PTO. The Cabilly Applicants copied claims from U.S. Patent 4,816,397 (the "Boss patent") in order to provoke the PTO Board of Patent Appeals and Interferences 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.

15. In February 1991, the PTO Board declared a patent interference between the pending Cabilly II application and the Boss patent on the ground that both the Boss patentees and the Cabilly Applicants claimed the same purported invention. 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. 1998). The PTO Board 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 Board, "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 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). The Final Decision therefore indicated that the Cabilly Applicants were "not entitled to a patent."

16. In October 1998, Genentech filed an action in this District under 35 U.S.C. § 146 against the owner of the Boss patent, Celltech Therapeutics Ltd. ("Celltech"), to appeal the decision of the PTO Board awarding priority to the Boss patent. *Genentech, Inc. v. Celltech Therapeutics Ltd.*, Case No. C98-3926 (N.D. Cal.). In March 2001, the parties to that action filed a notice of settlement and joint request for entry of settlement instruments. As part of their settlement agreement, the parties asked the district court to find that, contrary to the PTO Board's prior decision, Genentech's Cabilly Applicants were entitled to priority. On information and belief, as part of the Genentech-Celltech agreement, Celltech obtained certain rights relating to the Cabilly II

patent as well as certain 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. The precise terms of the settlement agreement are confidential and, despite reasonable inquiry, unknown to GSK.

17. Notably, the Boss patent would have expired by 2006. By obtaining Celltech's stipulation to priority of invention for the claimed subject matter of the Boss patent, GSK is informed and believes that Genentech sought to extend the life of patent protection for the inventions claimed in the Boss patent beyond the expiration date of the Boss patent.

18. Pursuant to the Genentech-Celltech agreement, the district court issued an order directing the PTO to vacate its determination that the Boss applicants 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, and on its face is assigned to Genentech, and, by certificate of correction, is also assigned to City of Hope.

19. If the PTO Board's decision in favor of the Boss patent had not been reversed as a result of the private Genentech-Celltech agreement, the Boss patent would have expired in 2006, and the public would thereafter have been free to use the inventions claimed in the Cabilly II patent. Instead, because Genentech and Celltech agreed to request that the court reverse that result, Defendants received the Cabilly II patent, which will not expire until 2018. Consequently, due to the private Genentech-Celltech agreement, Defendants have ostensibly extended their power to exclude others from making, using, or selling the inventions claimed in the Boss and Cabilly II patent until 2018 – more than 35 years after their original 1983 patent application, and more than 12 years after the expiration of the Boss patent. The combined period of patent exclusivity secured by Defendants for the Cabilly I and Cabilly II patents, which share the same patent specification, is 29 years.

20. In 2008 alone, according to Genentech's 2009 Form 10-K filing, Defendants received $298 million in royalties on the Cabilly II patent. In short, two years after the original expiration date of the Boss patent, Genentech is receiving nearly $300 million in annual royalties on the inventions claimed in the Boss patent.

Patent Reexamination

21. Two separate requests to re-examine the Cabilly II patent were submitted to the PTO in 2005. The PTO originally concluded that the prior art submitted by the requestors raised substantial new questions of patentability with respect to each of the claims of the Cabilly II patent and commenced separate reexamination proceedings 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 separate reexamination proceedings were merged on June 6, 2006.

22. In an Advisory Action on July 19, 2008, the PTO maintained its final rejection of the 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).

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

24. 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) (2007), Reexamination Control Nos. 90/007,859 and 90/007,542 (February 13, 2009).

25. 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 6,331,415 C1 with amended claims 21, 27, and 32. (Exhibit B).

Defendants' Admissions Regarding State of the Art in April 1983

26. In order to overcome the PTO's obviousness-type double patenting rejections during the reexamination, 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, the state of the art prior to the April 1983 filing of the Cabilly patent application was as follows:

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 generic 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.])

GSK'S OFATUMUMAB (ARZERRA™)

27. Ofatumumab (Arzerra™) is a new, human monoclonal antibody which targets the CD20 antigen, a naturally occurring protein present on B-lymphocytes, which is believed to be involved in the mediation of lymphoproliferative and autoimmune diseases.

28. Genmab A/S originally developed ofatumumab. In December 2006, GSK and Genmab A/S entered into an agreement to co-develop ofatumumab for therapeutic use. Under the terms of its agreements with Genmab, GSK has the exclusive right to make, use, import, offer to sell, and sell ofatumumab (Arzerra™) in the United States.

29. Pursuant to a contract with GSK, Lonza Biologics plc currently manufactures Arzerra™ in the United Kingdom for commercial sale by GSK in the United States. In addition, copies of the working cell bank used to produce Arzerra™ are maintained by Lonza Biologics, Inc. in Portsmouth, New Hampshire. On information and belief, Lonza Biologics plc and Lonza Biologics, Inc. (collectively "Lonza") may have received from Genentech certain rights or covenants not to sue relating to the Cabilly II patent pursuant to the 2001 Settlement Agreement between Celltech and Genentech. The scope of those rights, however, is confidential and unknown to GSK, despite reasonable efforts to ascertain what, if any, rights Lonza may have. Therefore, Genentech has affirmed through its conduct and agreement with Lonza that permission is needed from Genentech for Lonza to manufacture recombinant antibody products.

30. On October 26, 2009, GSK received accelerated approval from the U.S. Food and Drug Administration ("FDA") to market Arzerra™ in the United States for the treatment of patients whose chronic lymphocytic leukemia ("CLL") is refractory to previous therapies (fludarabine and alemtuzumab). Following that approval, GSK has begun marketing and selling Arzerra™ in the United States, doctors have begun prescribing Arzerra™, and patients suffering from refractory CLL have begun taking Arzerra™ to treat their CLL.

GSK'S DISPUTE WITH GENENTECH REGARDING CABILLY II PATENT

31. Through its statements and actions, Genentech has made clear to the biopharmaceutical industry generally and to GSK that it contends that the claims of the Cabilly II patent effectively preclude others from commercially manufacturing recombinant monoclonal

antibodies without Genentech's 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 said:

> "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 [90% human sequence], or human) or by host cell type."

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

32. According to Defendants, the manufacturing methods claimed in the Cabilly II patent are "the backbone of recombinant antibody production in the biotech industry." (*Centocor, Inc. v. Genentech, Inc.*, Case No. 2:08-cv-03573-MRP-CT (C.D. Cal.), 3/24/09 Opening Brief of Claim Construction).

33. Genentech has asserted the Cabilly II patent in litigation against other manufacturers of recombinant monoclonal antibodies, including MedImmune, Inc. ("MedImmune") and Centocor Ortho Biotech Inc. ("Centocor"). On information and belief, the recombinant methods used by GSK to produce Arzerra™ are similar to the recombinant methods used by MedImmune and Centocor to produce their monoclonal antibody products, Synagis®, ReoPro®, and Remicade®.

34. On information and belief, Genentech contends that the process and certain starting materials used to produce Arzerra™ infringe one or more claims of the Cabilly II patent.

35. For example, both GSK's Arzerra™ and MedImmune's Synagis® are produced by genetically engineering mammalian host cells to produce the desired antibody in cell culture. Arzerra™ is produced in a recombinant murine (mouse) cell line called NS0 using standard mammalian cell cultivation and purification techniques. On information and belief, Synagis® is also produced in a recombinant murine (mouse) cell line called NS0 using standard mammalian cell cultivation and purification techniques. Arzerra™ is an IgG1κ monoclonal antibody comprised of two heavy chains and two light chains. On information and belief, Synagis® is also an IgG1κ monoclonal antibody comprised of two heavy chains and two light chains. Like Arzerra™, on

information and belief, MedImmune's Synagis™ product is manufactured by Lonza. Since Genentech has previously enforced the Cabilly II patent against another Lonza customer that, on information and belief, uses the same NS0 cell line as Lonza uses for GSK, the same or similar transformation process as Lonza uses for GSK, and the same or similar manufacturing process as Lonza uses for GSK, GSK is informed and believes that Genentech contends that the methods used to produce Arzerra™ infringe one or more claims of the Cabilly II patent.

36. On information and belief, Genentech has also alleged that the corresponding recombinant methods and starting materials used to produce its Rituxan® antibody product fall within the scope of the Cabilly II patent. Like Arzerra™, Genentech's Rituxan® is produced by genetically engineering mammalian host cells to produce the desired antibody in cell culture. Like Arzerra™, Genentech's Rituxan® is an IgG1κ monoclonal antibody comprised of two heavy chains and two light chains. Like Arzerra™, Genentech's Rituxan® is directed against the CD20 antigen. Like Arzerra™, Lonza has manufactured Rituxan® for Genentech. If Genentech contends that the manufacturing process used by Lonza to produce Rituxan® for Genentech fell within the scope of the Cabilly II patent, then GSK is informed and believes that Genentech also contends that the manufacturing process used by Lonza to produce Arzerra™ for GSK also falls within the scope of the Cabilly II patent.

37. Since 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 II patent and have asserted the patent against others who are similarly situated to GSK, Defendants' prior statements and conduct necessarily establish an actual and substantial dispute between GSK and Defendants regarding the invalidity, unenforceability, and noninfringement of claims of the Cabilly II patent. Therefore, GSK has a reasonable apprehension of suit by Genentech regarding the Cabilly II patent.

38. In addition to the statements and conduct directed at others, Defendants, including particularly Genentech, have made statements and engaged in conduct directed at GSK that create a real and immediate dispute between the parties regarding the Cabilly II patent.

39. Genentech has made public statements about pursuing an aggressive litigation policy to protect its products against competition and to protect against alleged infringement of the Cabilly II patent claims in its 2009 Form 10-K filing with the Securities and Exchange Commission. Genentech states:

> "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 licenses. 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: "We 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)

40. In early 2009, Genentech made public statements specifically identifying Arzerra™ as an imminent competitor to Genentech's product Rituxan® in its filings with the Securities and Exchange Commission. In Genentech's 2009 Form 10-K, Genentech states:

> "**Rituxan may face future competition** in both hematology-oncology and RA **from Arzerra™ (ofatumumab)**, an anti-CD20 antibody being co-developed by Genmab A/S and GSK. Genmab and GSK recently presented positive results from their pivotal trial for CLL at the American Society of Hematology meeting. They announced on January 30, 2009 that they filed for approval for Arzerra™ for monotherapy use in refractory CLL." (emphasis added)

41. Taken together, Genentech's statements that it will enforce its intellectual property, specifically the Cabilly II patent, to defend its products against competing products, and its contention that GSK's Arzerra™ will be a competitor with Genentech's Rituxan® in hematology-oncology, establish that a real and immediate dispute exists between parties with adverse legal

interests concerning the Cabilly II patent. GSK therefore has a reasonable apprehension of suit by Genentech regarding the Cabilly II patent.

42. Genentech and GSK also have had repeated discussions and interactions relating to the Cabilly II patent that further establish the existence of a substantial dispute.

a. In 1991, one of GSK's predecessors-in-interest, Wellcome Foundation Ltd., entered into a license agreement with Genentech that included certain license rights relating to what later issued as the Cabilly II patent with respect to antibodies targeting CD4.

b. In 2002, Genentech and GSK entered into an agreement that provided for the parties to attempt to negotiate licenses under the Cabilly II patent for several different recombinant antibodies then in development by GSK. Licensing terms were ultimately never resolved and those antibody products have not yet been commercially sold in the United States.

c. In 2005, there were renewed discussions between Genentech and GSK regarding licensing the Cabilly II patent for a monoclonal antibody called mepolizumab that targeted the antigen IL-5. The parties were unable to reach agreement because Genentech proposed onerous terms that GSK believed were commercially unreasonable for the product, which was ultimately withdrawn from the regulatory approval process.

d. In 2005, a representative of Genentech, Tim Schwartz, asked GSK's counsel, Frank Grassler, to begin a discussion regarding a "Cabilly license for BEXXAR (anti-CD20) now that GSK has acquired the rights to this product." Like Arzerra™, BEXXAR is an antibody that targets the antigen CD20.

e. Mark Lemley, outside counsel for Genentech, and Sherry Knowles, Chief Patent Counsel for GSK are professional colleagues of mutual respect. In September 2008, following GSK's acquisition of rights to Arzerra™, Mr. Lemley told Ms. Knowles that he believed the Cabilly II patent would issue following reexamination and asked what GSK would then do about the Cabilly II patent. On information and belief, Mr.

Lemley believed the Cabilly II patent would be of interest to GSK, and his remarks conveyed that impression to Ms. Knowles.

43. Given Genentech's past positions and statements regarding the scope of the Cabilly II patent and the fact that GSK has begun marketing and selling Arzerra™ in the United States without a direct license from Genentech, the dispute between the parties is real and immediate.

44. The threat of litigation by Genentech to assert the Cabilly II patent against Arzerra™ is underscored by the parties' past legal disputes. Throughout the 1990s and early 2000s, Genentech and GSK's predecessors-in-interest were embroiled in multiple patent infringement actions, including at least one relating to recombinant antibody production.

Prior Action in the Southern District of Florida

45. To protect itself from the disruption of its commercial launch of Arzerra™ and secure a timely adjudication of its dispute with Genentech regarding the Cabilly II patent, on October 8, 2009, GSK filed a claim for declaratory judgment in the Southern District of Florida against Defendants. *See Glaxo Group Ltd. v. Genentech, Inc.*, Case No. 09-61608-CIV-LENARD/TURNOFF (S.D. Fla.). Defendants moved to dismiss the Florida complaint for lack of subject matter jurisdiction or, in the alternative, to transfer the action from the Southern District of Florida to the Central District of California. In their motion to dismiss, Defendants characterized GSK's action as "premature" because, among other things,

a. "At the time that plaintiffs (collectively 'GSK') filed this complaint, GSK had not received FDA approval for or made any commercial sales of Arzerra™ . . . ."

b. "GSK had no communications at all with Genentech or City of Hope regarding the Cabilly II patent in connection with Arzerra™."

Notably, Defendants did not state that they would not assert the Cabilly II patent against GSK's Arzerra™ product.

46. In their motion to transfer venue, Defendants challenged venue in Florida because, among other things, none of the parties were based in Florida. According to Defendants, "the locus of operative facts was in California" and "California is more convenient and less expensive for the parties and witnesses."

47. After filing the Florida complaint (and before filing this suit), GSK offered on two occasions to discuss with Genentech how the parties could resolve or otherwise dispose of the dispute relating to the Cabilly II patent. Genentech, however, failed to respond to GSK's offers to discuss the issue, nor did Genentech ever indicate that a license was unnecessary or that it did not intend to enforce the Cabilly II patent against GSK.

48. Rather than oppose Defendants' motion, GSK filed with the Southern District of Florida a notice of dismissal of its complaint under Federal Rule of Civil Procedure 41(a)(1)(A)(i), dismissing its complaint without prejudice.

49. GSK files the present action, in part, to address Defendants' objections to GSK's prior complaint for declaratory relief. The FDA has now approved Arzerra™ for commercial sale, and GSK has begun selling Arzerra™ in the United States. GSK has attempted to discuss the Cabilly II patent with Genentech in the context of Arzerra™, but Genentech declined to respond. To the extent Defendants objected to venue in Florida based on the convenience of the parties and witnesses, GSK files this suit in the Northern District of California, where Genentech has its headquarters and City of Hope has an established place of business.

50. Based on all of the circumstances, there is now an actual and justiciable controversy between GSK and Defendants with respect to whether the manufacture, importation, offer to sell, sale, or use of ofatumumab (Arzerra™) in the United States infringes any valid and enforceable claim of the Cabilly II patent.

FIRST CAUSE OF ACTION

PATENT INVALIDITY

51. GSK incorporates the allegations of paragraphs 1 through 50 as if fully set forth herein.

52. An actual and substantial controversy has arisen and now exists between the parties concerning the validity of the Cabilly II patent.

53. The Cabilly II patent is invalid because it is anticipated and/or obvious under 35 U.S.C. §§ 102 and 103 (2006).

54. The Cabilly II patent is invalid based on the judicially created doctrine of obviousness-type double patenting and/or under 35 U.S.C. §§ 101 and/or 103 (2006).

55. The Cabilly II patent is invalid under 35 U.S.C. § 112 (2006).

56. Claims 21-32 of the Cabilly II patent are invalid as being broadened in scope during reexamination in violation of 35 U.S.C. § 305 (2006).

57. GSK seeks a declaratory judgment that the Cabilly II patent is invalid under 35 U.S.C. §§ 101, 102, 103, 112, and 305 (2006) and/or under the judicially created doctrine of obviousness-type double patenting.

SECOND CAUSE OF ACTION

NON-INFRINGEMENT

58. GSK incorporates the allegations of paragraphs 1 through 57 as if fully set forth herein.

59. An actual controversy has arisen and now exists between the parties concerning whether GSK's manufacturing process or importation or sale of ofatumumab (Arzerra™) infringes any valid and enforceable claim of the Cabilly II patent.

60. GSK seeks a declaratory judgment that making, using, importing, offering to sell, and selling ofatumumab (Arzerra™) does not and will not infringe any valid and enforceable claim of the Cabilly II patent.

THIRD CAUSE OF ACTION

PROSECUTION LACHES

61. GSK incorporates the allegations of paragraphs 1 through 60 as if fully set forth herein.

62. An actual controversy has arisen and now exists between the parties concerning the enforceability of the Cabilly II patent.

63. The Cabilly II patent is unenforceable under the doctrine of prosecution laches. The Cabilly II patent issued after an unreasonable and unexplained delay in the interference proceedings between the Cabilly II application and the Boss patent. 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.

64. GSK seeks a declaratory judgment that the Cabilly II patent is unenforceable due to prosecution laches.

PRAYER FOR RELIEF

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

1. Declaring the Cabilly II patent invalid;

2. Declaring the Cabilly II patent unenforceable;

3. Declaring that the manufacture, use, sale, offer to sell, or importation of GSK's ofatumumab (Arzerra™) product does not infringe any valid and enforceable claim of the Cabilly II patent;

4. Enjoining Genentech and City of Hope from enforcing the Cabilly II patent;

5. Awarding GSK its costs and attorneys' fees; and

6. Awarding GSK such other relief as the Court deems just and proper.

Date: February 17, 2010

Respectfully submitted,

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