UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ABBOTT LABORATORIES, ABBOTT BIORESEARCH CENTER, INC., and ABBOTT BIOTECHNOLOGY LTD., Plaintiffs, v. BAYER HEALTHCARE LLC, Defendant.	Civil Action No. 09-40002-FDS
BAYER HEALTHCARE LLC, Plaintiff, v. ABBOTT LABORATORIES, ABBOTT BIORESEARCH CENTER, INC., and ABBOTT BIOTECHNOLOGY LTD., Defendants.	Civil Action No. 09-40061-FDS

ABBOTT LABORATORIES, ABBOTT BIORESEARCH CENTER, INC., AND ABBOTT BIOTECHNOLOGY, LTD.'S
FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT

PUBLIC REDACTED VERSION

INTRODUCTION

1. On December 24, 2008, Defendant Bayer HealthCare LLC ("Bayer") filed a Complaint against Plaintiffs Abbott Laboratories ("Abbott Labs"), Abbott Bioresearch Center, Inc. ("ABC"), and Abbott Biotechnology, Ltd. ("ABL") (collectively, "Abbott") in the United States District Court for the Eastern District of Texas, Tyler Division (the "Texas Lawsuit"). A true and correct copy of the Complaint in the Texas Lawsuit is attached hereto as Exhibit 1.

2. In the Texas Lawsuit, Bayer alleges that Abbott's activities with respect to the pharmaceutical product HUMIRA® infringe one or more claims of United States Patent No. 5,654,407 (the "'407 patent"). A true and correct copy of the '407 patent is attached to Exhibit 1 as Exhibit A thereto.

3. Abbott files this First Amended Complaint seeking a declaratory judgment that the '407 patent is not infringed by Abbott, is invalid, and is unenforceable under the equitable doctrines of laches, estoppel, waiver, and/or inequitable conduct.

THE PARTIES

4. Plaintiff Abbott Labs is a corporation organized under the laws of the State of Illinois, with a place of business located at 100 Abbott Park Road, Abbott Park, Illinois 60064.

5. Plaintiff ABC, a wholly owned subsidiary of Abbott Labs, is a corporation organized under the laws of the State of Delaware, with a place of business located at 100 Research Drive, Worcester, Massachusetts 01605.

6. Plaintiff ABL, a wholly owned subsidiary of Abbott Labs, is a corporation organized under the laws of Bermuda, with a place of business located at Carr #2 Km. 59.2, Segundo Piso, Barceloneta, Puerto Rico 00617.

7. Defendant Bayer is a limited liability company organized under the laws of the State of Delaware, with a place of business at 555 White Plains Road, Tarrytown, New York 10591.

JURISDICTION AND VENUE

8. This is a declaratory judgment action seeking a declaration of noninfringement, invalidity, and unenforceability of the claims of the ’407 patent. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. In light of Bayer’s assertion of the ’407 patent against Abbott in the Texas Lawsuit, an actual case or controversy exists between the parties.

9. Venue is proper in this district pursuant to 28 U.S.C. § 1391.

10. At all times relevant hereto, ABC has engaged in research, development, and/or manufacturing activities relating to HUMIRA® at its Worcester facility. Furthermore, this Court has personal jurisdiction over Bayer because Bayer has continuous and systematic contacts with this forum, including the marketing and sale of animal health products, non-prescription medicines, blood glucose monitoring systems, and prescription medicines.

COUNT 1

(Noninfringement of the ’407 Patent)

11. Abbott repeats and realleges the allegations of paragraphs 1-10 as if fully set forth herein.

12. Abbott does not infringe any valid and enforceable claim of the ’407 patent.

13. To resolve the legal and factual questions raised by Abbott and to afford relief from the uncertainty and controversy that Bayer’s accusations have precipitated, Abbott is entitled to a declaratory judgment that Abbott does not infringe any valid and enforceable claim of the ’407 patent.

COUNT 2

(Invalidity of the ’407 Patent)

14. Abbott repeats and realleges the allegations of paragraphs 1-10 as if fully set forth herein.

15. One or more claims of the ’407 patent are invalid under 35 U.S.C. §§ 101 *et seq.*

16. To resolve the legal and factual questions raised by Abbott and to afford relief from the uncertainty and controversy that Bayer's accusations have precipitated, Abbott is entitled to a declaratory judgment that one or more of the claims of the '407 patent are invalid.

COUNT 3

(Unenforceability of the '407 Patent by Reason of Laches/Estoppel/Waiver)

17. Abbott repeats and realleges the allegations of paragraphs 1-10 as if fully set forth herein.

18. The '407 patent was issued in August 1997. HUMlRA® has been on the market in the United States since at least as early as 2003.

19. One or more claims of the '407 patent are unenforceable under the equitable doctrines of laches, estoppel, and/or waiver.

20. To resolve the legal and factual questions raised by Abbott and to afford relief from the uncertainty and controversy that Bayer's accusations have precipitated, Abbott is entitled to a declaratory judgment that one or more of the claims of the '407 patent are unenforceable.

COUNT 4

(Unenforceability of the '407 Patent by Reason of Inequitable Conduct)

21. Abbott repeats and realleges the allegations of paragraphs 1-10 as if fully set forth herein.

22. One of the central characteristics underlying the patentability of Bayer's claims is the supposed ability of the B5 antibody to inhibit secretion of TNFα. This property is highlighted in the '407 patent specification and explicitly claimed in asserted claim 8. The patent's support for this property rests on the experiments reported in Table 10 of the '407 patent, which purport to show inhibition of TNFα secretion by B5. However, while the '407 patent was being prosecuted, the inventors conducted numerous additional experiments whose results contradict those shown in the patent — and thus undermine Bayer's claims that B5 possesses this property. Contrary to their duties of candor, neither the inventors nor the

prosecuting attorney notified the Examiner in the United States Patent and Trademark Office ("PTO") of these highly material results. This constituted inequitable conduct in the procurement of the '407 patent. The detailed basis for these allegations is set forth in the following paragraphs.

I. Each Inventor Possessed, and Each Expressly Acknowledged, a Duty of Candor and Good Faith in Dealing with the PTO

23. Under 37 C.F.R. § 1.56, each inventor, attorney, and other individual substantially associated with the filing and/or prosecution of a patent application has, during the pendency of the application, a duty of candor and good faith in dealing with the United States Patent and Trademark Office (the "PTO"). Each individual's duty under 37 C.F.R. § 1.56 includes a duty to disclose to the PTO all information known to that individual to be material to the patentability of the pending claims.

24. The '407 patent's inventors — Petra Boyle, Gayle D. Wetzel, and Kenneth J. Lembach — executed multiple inventor oaths in connection with the patent applications that led to the '407 patent. By signing these oaths on or about March 5, 1993, October 28, 1993, and July 22, 1994, Ms. Boyle, Dr. Wetzel, and Dr. Lembach each declared under penalty of perjury that "all statements" made in the corresponding patent applications either "are true" or "are believed to be true." In addition, by signing these oaths, Ms. Boyle, Dr. Wetzel, and Dr. Lembach each expressly acknowledged that "willful false statements may jeopardize the validity of the application or any patent issued thereon." Each also acknowledged "the duty to disclose information which is material to the examination of this application namely, information where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent."

25. As more fully set forth and explained in paragraphs 26-58 below, one or more of the inventors and/or other individuals associated with the filing and/or prosecution of the '407 patent breached their duty of candor to the PTO by failing to disclose material information to the PTO and, on information and belief, by doing so with intent to deceive or mislead the PTO into

granting the ’407 patent. These omissions render the ’407 patent unenforceable under the doctrine of inequitable conduct.

II. The ’407 Patent Reported That B5 Inhibits the Secretion of TNFα and That the Ability to Inhibit Secretion Renders B5 Patentable

26. The ’407 patent contains multiple statements that the B5 antibody — the only antibody characterized and described in detail the ’407 patent — inhibits the secretion of TNFα. On information and belief, the inventors viewed B5’s ability to inhibit the secretion of TNFα as essential to the purported novelty and utility of B5 and therefore as material to the patentability of the claims set forth in the ’407 patent.

27. As one example, asserted claim 8 of the ’407 patent is specifically directed to a composition comprising human monoclonal antibodies “wherein the antibodies inhibit secretion of tumor necrosis factor alpha.” ’407 patent, col. 24, ll. 1-2. The specification’s only description of any antibody that allegedly inhibits secretion of TNFα is of the experiments reported in Table 10 for the B5 antibody.

28. As a second example, claim 12 of the ’407 patent is specifically directed to an antibody preparation “having the further characteristic of inhibiting LPS induced TNF alpha secretion by human monocyte-like cells.” ’407 patent, col. 24, ll. 17-18. Like claim 8, the only support in the specification for claim 12 is the discussion of the experiments reported in Table 10.

29. As a third example, Table 10 of the ’407 patent and the associated discussion from column 17, line 36, through column 18, line 37, describe the results of two experiments conducted by Ms. Boyle in or around July and August 1992. These experiments show, among other things, that the presence of B5 at a concentration of 40 micrograms per milliliter for four hours inhibited at least 90% of the secretion of TNFα induced by lipopolysaccharide (“LPS”) from E.coli in THP-1 cells, a cell line commonly used in immunoassays. By comparison, the same concentration of control antibodies 6F11 and 7T1, as well as the absence of all antibodies, inhibited less than 5% of the secretion of TNFα. As the ’407 patent summarizes, “Table 10

shows that the coculture of the THP-1 cells with B5 mAb inhibits LPS induced TNFα secretion. These data suggest that B5 mAb interaction with csTNFα can inhibit LPS induced TNF secretion." '407 patent, col. 18, ll. 33-37.

30. As a fourth example, the section of the '407 patent entitled "Summary of Invention" states that "[t]he specificity, the autoantibody nature, the binding to cell surface TNFα *and the ability to inhibit TNFα secretion* make a novel mAb." '407 patent, col. 2, ll. 46-48 (emphasis added).

31. As a fifth example, the section of the '407 patent entitled "Usefulness of the Invention" suggests that the invention may be used "to inhibit TNF production. Since we have shown that binding of the antibody can inhibit TNF secretion by some cells, this avenue of therapy may be beneficial." '407 patent, col. 19, ll. 23-26.

32. Outside of prosecution, Bayer's actions and statements have confirmed that it viewed the ability of the B5 antibody to bind to inhibit secretion of TNFα as a critical aspect of its invention. Abbott instituted opposition proceedings in the European Patent Office against the European counterpart to the '407 patent. In response to Abbott's argument in those proceedings that, among other things, the claims for a pharmaceutical formulation lacked a sufficient disclosure, Bayer argued that "[t]he antibody has to be of pharmaceutical value, which is shown e.g. for the non-neutralising human monoclonal antibody B5. *B5 inhibits the LPS-induced TNF alpha secretion (table 10, page 16)*." April 10, 2003, Letter to the EPO, ¶10.2 (emphasis added). It again emphasized B5's utility as a pharmaceutical rested in its ability to "prevent[] the secretion of TNF-alpha which in turn reduces the amount of soluble TNF-alpha available in the blood to bind to its receptor and thus reduce activation of the TNF-alpha receptor." October 1, 2009 Letter to the EPO, ¶ 4.4. Similarly, in its claim construction briefing to this Court, Bayer emphasized B5's purported ability to inhibit TNFα secretion. *See, e.g.*, Bayer's Opening Claim Construction Brief at 14 n.6.

III. Inventor Petra Boyle Knew of the Results of Numerous Experiments Showing that B5 Did Not Inhibit the Secretion of TNFα

33. Between approximately March 6 (just one day after the '407 patent's earliest claimed priority date) and November 16, 1993, Ms. Boyle conducted a series of experiments showing that, contrary to the results reported to the PTO in the applications for what would later become the '407 patent, B5 did not inhibit the secretion of LPS-induced TNFα relative to controls.

34. On or about March 6, 1993, Ms. Boyle completed an experiment in which she incubated THP-1 cells with LPS and 40 micrograms per milliliter of B5 for four hours. This experiment showed that B5 resulted in no inhibition of TNFα secretion relative to the same assay performed with the same concentration of control antibody 6F11.

35. Ms. Boyle obtained these results only one day after she signed the inventor oath on March 5, 1993, in connection with the original patent application leading to the '407 patent.

36. On or about March 24, 1993, Ms. Boyle completed an experiment in which she incubated spleen-derived immune cells with LPS and 40 micrograms per milliliter of B5 for four hours. This experiment showed that B5 resulted in no inhibition of TNFα secretion relative to the same assay performed with the same concentration of control antibody 6F11. Ms. Boyle recorded her conclusions in her notebook: "No inhibition of LPS induced TNF secretion by B5."

37. On or about May 6, 1993, Ms. Boyle completed an experiment in which she incubated THP-1 cells with LPS and 40 micrograms per milliliter of B5 for four hours on plates that had been coated with A6, a mouse antibody that neutralizes human TNFα. This experiment showed that B5 resulted in no inhibition of TNFα secretion relative to the same assay performed with the same concentration of control antibody 6F11.

38. On or about May 17, 1993, Ms. Boyle completed an experiment in which she treated THP-1 cells for 16 hours with interferon-gamma, a cytokine known to activate THP-1 cells, and then incubated the THP-1 cells with LPS and 40 micrograms per milliliter of B5 for four hours on plates that had been coated with A6 or A10G10, mouse antibodies that neutralize

human TNFα. This experiment showed that B5 resulted in no inhibition of TNFα secretion relative to the same assay performed with the same concentration of control antibody 6F11.

39. On or about June 3, 1993, Ms. Boyle completed an experiment in which she incubated THP-1 cells with 3, 10, 30, or 100 micrograms per milliliter of B5 for one hour and then added LPS to the mixture and incubated for another four hours. Some of the samples tested were pretreated with an immunomodulating compound called PMA. This experiment showed that, whether or not the sample was pretreated with PMA, B5 resulted in no inhibition of TNFα secretion relative to the same assay performed with the same concentration of control antibody 6F11.

40. On or about July 30, 1993, Ms. Boyle completed an experiment in which she incubated THP-1 cells with LPS and 40 micrograms per milliliter of B5 for three hours. This experiment showed that B5 resulted in no inhibition of TNFα secretion relative to the same assay performed with the same concentration of control antibody 6F11.

41. On or about November 16, 1993, Ms. Boyle completed an experiment in which she incubated THP-1 cells with LPS and 25, 50, or 100 micrograms per milliliter of B5 for four hours. The experiment showed that concentrations of 50 or 100 micrograms per milliliter of B5 resulted in no inhibition of TNFα secretion relative to the same assay performed with the same concentrations of control antibody 6F11. This experiment contradicts the assertion in the specification of the ’407 patent that “supernatant cytotoxicity was concentration dependent.” ’407 Patent, col. 17, ll. 50-51.

42. In addition, in conducting Experiment 1 reported in Table 10 of the ’407 patent, Ms. Boyle ran an unreported experimental control in which she incubated THP-1 cells with LPS and a buffered solution containing no antibodies for four hours. This buffered solution inhibited 22% of the LPS-induced secretion of TNFα — a rate of inhibition significantly greater than the rates of inhibition reported in Table 10 for the control antibodies or the absence of all antibodies.

43. Similarly, in conducting Experiment 2 reported in Table 10 of the ’407 patent, Ms. Boyle ran an unreported experimental control in which she incubated THP-1 cells with LPS

and a buffered solution containing no antibodies for four hours. This buffered solution inhibited 41% of the LPS-induced secretion of TNFα — a rate of inhibition significantly greater than the rates of inhibition reported in Table 10 for the control antibodies or the absence of all antibodies.

44. On October 28, 1993 — after having performed all but one of the experiments referred to above — Ms. Boyle signed a second inventor's oath in connection with the continuation-in-part application that led to the '407 patent in which she declared under penalty of perjury that, among other things, (a) she "ha[s] reviewed and understand[s] the content of the . . . specification" attached to the patent application, (b) she "acknowledge[s] the duty to disclose information which is material to the examination of th[e] application," (c) she "acknowledge[s] the duty to disclose material information . . . which occurred between the filing date of the prior application [March 5, 1993] and the . . . filing date of this application," (d) "all statements made" in the patent application either "are true" or "are believed to be true," and (e) the statements made in the patent application were made "with the knowledge that willful false statements . . . may jeopardize the validity of the application or any patent issuing thereon."

45. Each of the experimental results described above in paragraphs 34-41 supports the conclusion, contrary to the claims made in the '407 patent, that B5 in fact does not inhibit the secretion of TNFα. Similarly, the results described in paragraphs 42-43 cast doubt on the amount of inhibition in the experiments reported in the patent.

IV. Inventor Gayle D. Wetzel Also Knew of the Results of These Experiments

46. At the time of the experiments described in paragraphs 34-43, inventor Gayle D. Wetzel was Ms. Boyle's immediate supervisor. During this time period, Ms. Boyle performed her experiments at the direction and suggestion of Dr. Wetzel, and it was Ms. Boyle's regular practice to report to Dr. Wetzel the results of the experiments that she conducted. Dr. Wetzel therefore knew that Ms. Boyle had performed experiments showing, contrary to the claims made in the '407 patent, that B5 did not inhibit the secretion of TNFα.

47. On October 28, 1993 — after Ms. Boyle had performed all but one of the experiments referred to above — Dr. Wetzel signed an inventor's oath in which he declared

under penalty of perjury that, among other things, (a) he "ha[s] reviewed and understand[s] the content of the . . . specification" attached to the patent application, (b) he "acknowledge[s] the duty to disclose information which is material to the examination of th[e] application," (c) he "acknowledge[s] the duty to disclose material information . . . which occurred between the filing date of the prior application [March 5, 1993] and the . . . filing date of this application," (d) "all statements made" in the patent application either "are true" or "are believed to be true," and (e) the statements made in the patent application were made "with the knowledge that willful false statements . . . may jeopardize the validity of the application or any patent issuing thereon."

48. Dr. Wetzel was the primary contact among the three inventors for the attorney prosecuting the '407 patent, James Giblin, during the pendency of the prosecution of the patent.

V. The Experiments Were Withheld From the PTO With Intent to Deceive, Rendering the '407 Patent Unenforceable

49. The experimental results described in paragraphs 34-43, above, are highly material to patentability because, among other reasons, they directly contradict experimental results reported in the '407 patent, they undermine and are inconsistent with the principal argument for patentability asserted by the inventors, and they strongly suggest that the inventors never conceived of or reduced to practice any embodiment falling within the scope of claims 8 and 12.

50. Despite the high degree of materiality none of these experimental results were disclosed to the PTO.

51. All three inventors were aware of their duty to disclose material information to the patent office during the pendency of the prosecution, and so indicated by signing oaths three times affirming under penalty of perjury their knowledge of that duty.

52. [redacted]

[redacted]

53. [redacted] Ms. Boyle performed no fewer than seven experiments between March and November 1993 suggesting that the B5 antibody did not inhibit the secretion of TNFα. [redacted]

54. [redacted]

55. [redacted]

56. On information and belief, Ms. Boyle and Dr. Wetzel acted with intent to deceive. For example, the inventors' knowledge of the experiments, their failure to disclose the results to the PTO despite knowledge of their duty to do so, [redacted] and the highly material nature of these experiments together demonstrate an intent to deceive the PTO. Indeed, as Ms. Boyle acknowledged in her laboratory notebook write-up of

one of the withheld experiments, there was "[n]o inhibition of LPS induced TNF secretion by B5."

57. The '407 patent therefore is unenforceable by reason of inequitable conduct by one or more of the inventors and/or other individuals associated with the filing and/or prosecution of the '407 patent.

58. To resolve the legal and factual questions raised by Abbott and to afford relief from the uncertainty and controversy that Bayer's accusations have precipitated, Abbott is entitled to a declaratory judgment that one or more of the claims of the '407 patent are unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Abbott requests entry of judgment in its favor and against Bayer as follows:

A. Declaring that Abbott does not infringe any of the claims of the '407 patent;

B. Declaring that all of the claims of the '407 patent are invalid;

C. Declaring that all of the claims of the '407 patent are unenforceable because of laches, estoppel, and/or waiver;

D. Declaring that all of the claims of the '407 patent are unenforceable because of inequitable conduct;

E. Finding that this is an exceptional case under 35 U.S.C. § 285 and awarding Abbott the costs and expenses of this litigation, including reasonable attorneys' fees and disbursements; and

F. Awarding Abbott other such relief as is just and proper.

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DEMAND FOR JURY TRIAL

Abbott demands a trial by jury on all issues so triable.

Dated: July 14, 2010

Respectfully submitted,

ABBOTT LABORATORIES, ABBOTT BIORESEARCH CENTER, INC., and ABBOTT BIOTECHNOLOGY LTD.,

By their attorneys,

/s/ Heather Takahashi

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified in the Notice of Electronic Filing and paper or electronic copies will be delivered to those indicated as non-registered participants on July 14, 2010.

/s/ Shawna Clement
Shawna Clement