IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

ABBVIE INC.

and

ABBVIE BIOTECHNOLOGY LTD.,

Plaintiffs

v.

MEDIMMUNE LIMITED,

Defendant.

Civil Action No. 2:16-cv-322 AWA/DEM

COMPLAINT

AbbVie Inc. and AbbVie Biotechnology Ltd. (collectively "AbbVie") bring this action against MedImmune Limited ("MedImmune") for a declaratory judgment that the claims of U.S. Patent No. 6,248,516 (the "'516 patent") are invalid. A true and correct copy of the '516 patent is attached as Exhibit A.

NATURE OF ACTION

1. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202.

PARTIES

2. Plaintiff AbbVie Inc. is a corporation organized and existing under the laws of Delaware with corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie Inc. is a global biopharmaceutical company, which discovers and advances innovative therapies for many diseases, including cancer, hepatitis C, multiple sclerosis, rheumatoid arthritis, and ulcerative colitis.

3. Plaintiff AbbVie Biotechnology Ltd. is a corporation organized under the laws of Bermuda with a place of business at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda. AbbVie Inc. owns AbbVie Biotechnology Ltd.

4. Upon information and belief, Defendant MedImmune is a company organized and existing under the laws of the United Kingdom with a principal place of business at Milstein Building, Granta Park, Cambridge, CB21 6GH, United Kingdom.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338, and 2201 *et seq.*

6. Venue lies in this District pursuant to 28 U.S.C. § 1391(b)(3) and 35 U.S.C. § 293.

7. This Court has personal jurisdiction over MedImmune under Federal Rule of Civil Procedure 4(k)(2), because this action arises under federal law and, upon information and belief, MedImmune is not subject to the jurisdiction of the courts of general jurisdiction of any state and the exercise of personal jurisdiction over MedImmune is consistent with the Constitution and the laws of the United States.

8. Alternatively, this Court separately has personal jurisdiction over MedImmune because Medimmune, standing in the shoes of the patentee, having obtained all substantial rights in the '516 patent as set forth in paragraph 16-21 below (including the right to prosecute the application leading to the '516 patent), has purposefully availed itself of this jurisdiction by obtaining a United States Patent before the PTO. Specifically, MedImmune retained Nixon & Vanderhye, PC, at 901 North Glebe Road, 11th Floor, Arlington, VA 22203, to prosecute the patent application before the Patent and Trademark Office ("PTO"), resulting in the '516 patent. *See* Ex. B (Designation of Agent). On information and belief, Nixon & Vanderhye remains counsel of record in filings before the PTO relating to the '516 patent.

9. This Court also has personal jurisdiction over MedImmune under 35 U.S.C. § 293. Section 293 provides that "[e]very patentee not residing in the United States may file in the Patent and Trademark Office a written designation stating the name and address of a person residing within the United States on whom may be served process or notice of proceedings affecting the patent or rights thereunder." MedImmune, standing in the shoes of the patentee, having obtained all substantial rights in the '516 patent as set forth in paragraph 16-21 below (including the right to prosecute the application leading to the '516 patent), designated Nixon & Vanderhye, PC, at 901 North Glebe Road, 11th Floor, Arlington, VA 22203, as its agent to receive process or notice of proceedings affecting the '516 patent or rights thereunder. *See* Ex. B (Designation of Agent).

10. Also, if MedImmune is found not to have designated a person residing within the United States on whom may be served process or notice of proceedings affecting MedImmune's rights with respect to the '516 patent, this Court has personal jurisdiction over MedImmune under 35 U.S.C. § 293, which further provides that in cases involving a "patentee not residing in the United States," the United States District Court for the Eastern District of Virginia "shall have the same jurisdiction to take any action respecting the patent or rights thereunder that it would have if the patentee were personally within the jurisdiction of the court," where "no person" has been designated in the PTO "on whom may be served process or notice of proceedings affecting the patent or rights thereunder."

FACTUAL BACKGROUND

The AbbVie/MedImmune Agreement

11. In the early 1990s, Cambridge Antibody Technology Limited ("CAT") and Knoll AG ("Knoll") began a collaboration to develop therapeutic human antibodies and, in 1995, entered into a Development and License Agreement (the "1995 Agreement").

12. The collaboration led to the antibody adalimumab, the active ingredient of Humira®.

13. Under the 1995 Agreement, Knoll received a license from CAT to certain patents claiming priority to International Patent Application No. PCT/GB91/01344, including the '516 patent and U.S. Patent No. 7,306,907 (the "'907 patent," a true and correct copy of which is attached as Exhibit C), and agreed to pay royalties on sales of certain antibodies resulting from the collaboration, including Humira®.

14. AbbVie is Knoll's successor-in-interest under the 1995 Agreement.

15. On October 29, 2007, CAT changed its name to MedImmune Limited. *See* Ex. D (Certificate of Incorporation on Change of Name). MedImmune therefore is CAT's successor-in-interest under the 1995 Agreement.

MedImmune Has the Exclusive Right to Defend a Validity Challenge to the '516 Patent

16. The Medical Research Council of the United Kingdom ("MRC"), The Scripps Research Institute ("Scripps"), and Stratagene (also known as Agilent Technologies Inc.) co-own the '516 patent. *See* Assignment Recorded October 1, 2001, a true and correct copy of which is attached as Exhibit E.

17. Upon information and belief, MRC, Scripps, and Stratagene have given sole and exclusive control of the defense of validity challenges to the '516 patent to MedImmune.

18. Specifically, in an agreement dated January 7, 1997 (the "MRC Agreement"),[1] MRC granted CAT an exclusive license to, *inter alia*, all patents claiming priority to International

[1] The MRC Agreement was publicly filed as Docket No. 10-5 in *MorphoSys AG v. Cambridge Antibody Technology, Ltd.*, No. 1:01-cv-01384-JR (D.D.C. Aug. 6, 2001), a true and correct copy of which is attached as Exhibit G. The MRC Agreement superseded earlier agreements between MRC and CAT. *Id.* at 1.

Patent Application No. PCT/GB89/01344. *See* Ex. F at p. 5 and §§ 2.1 and 7.2.1. Under the MRC Agreement, if the validity of a patent covered by CAT's license with MRC is challenged, CAT "shall at its own cost defend . . . such proceedings . . . to protect the Patent Rights and interests of MRC and CAT under [the MRC Agreement]." *Id.* at § 5.7.

19. Subsequently, in a settlement agreement dated June 25, 1999 (the "Scripps/Stratagene Settlement Agreement"),[2] MRC granted Scripps and Stratagene "an undivided ownership interest in all patents and patent applications within the MRC Patent Rights," which include, *inter alia*, the '516 patent. *See* Ex. G at §§ 1.06 and 2.01 and exhibit A. However, Stratagene and Scripps agreed that their ownership interests would be "subject to the CAT/MRC Agreement," and that Stratagene and Scripps "shall only have non-exclusive rights under the MRC Patent Rights . . . to make, use, import and dispose of Products" under the license. *Id.* §§ 2.01, 3.03, 3.04.

20. While on October 29, 2007, CAT changed its name to MedImmune as set forth above in paragraph 15, it has maintained the exclusive rights to the '516 patent under the MRC Agreement. *See* Ex. H (6/20/2016 Email from Thomas Fletcher).

21. Therefore, upon information and belief, MedImmune has the sole right and responsibility to defend this litigation on behalf of the '516 patent owners.

The '516 Patent Is Invalid for Obviousness-Type Double Patenting Over the '907 Patent

22. The '516 patent was filed on June 6, 1995, as U.S. Patent Application No. 08/470,031, issued on June 19, 2001, and expires on June 19, 2018. *See* Ex. A.

[2] A redacted copy of the Scripps/Stratagene Settlement Agreement was publicly filed as Docket No. 10-6 in *MorphoSys AG v. Cambridge Antibody Technology, Ltd.*, No. 1:01-cv-01384-JR (D.D.C. Aug. 6, 2001), a true and correct copy of which is attached as Exhibit H.

23. The '907 patent was filed on November 8, 2002, as U.S. Patent Application No. 10/290,252, which was a grandchild continuation of the application that issued as the '516 patent. The '907 patent issued on December 11, 2007, and expired no later than November 2011. *See* Ex. C.

24. The '516 and '907 patents list the same inventors (Gregory Paul Winter, Elizabeth Sally Ward, and Detlef Güssow). *See* Exs. A and C.

25. The '516 and '907 patents are co-owned by MRC, Scripps, and Stratagene. *See* Terminal Disclaimer dated April 22, 2005, a true and correct copy of which is attached as Exhibit I.

26. The '516 and '907 patents are identical in all respects, except for the claims.

27. The claims of the '516 patent are directed to either methods for generating expression libraries or the resulting expression libraries. *See* Ex. A at cols. 34-36.

28. The claims of the '907 patent are directed to methods of making an antibody to a target antigen by generating an expression library. *See* Ex. C at cols. 34-36.

29. Thus, the claims of the '516 and '907 patents are patentably indistinct.

30. Even though the claims of the '516 and '907 patents are patentably indistinct, the '516 patent expires more than six years after the '907 patent.

31. The '516 patent thus provides MedImmune with an unjustified and improper timewise extension of the right to exclude others from practicing the invention claimed in the '907 patent and its obvious variants.

32. The '516 patent, therefore, violates the doctrine against double patenting and is invalid.

AbbVie Is Harmed by MedImmune's Unjustified Extension of Its Period of Patent Exclusivity

33. The U.S. Food and Drug Administration approved Humira® on December 31, 2002.

34. Since January 2003, AbbVie, or its predecessors-in-interest, have been selling Humira® and paying royalties to CAT or its successors-in-interest (as of 2006, Royalty Pharma). *See* October 26, 2006 Royalty Pharma Press Release, a true and correct copy of which is attached as Exhibit J.

35. The 1995 Agreement continues "until the last to expire of the Patents or the expiry of fifteen years from the date of First Commercial Sale of a Product by Knoll or its Affiliates or sublicensees (whichever is the later)."

36. The last to expire of the patents under the 1995 Agreement is the '516 patent. Thus, unless the '516 patent is held invalid, AbbVie will be forced to pay royalties until its June 2018 expiration date (i.e., six months past January 2018).

COUNT I
(Declaratory Judgment of Invalidity of the '516 Patent)

37. AbbVie re-alleges paragraphs 1-36 as if fully set forth herein.

38. There is a real, immediate, substantial, and justiciable controversy between AbbVie, on the one hand, and MedImmune, on the other hand, concerning whether the claims of the '516 patent are invalid for failing to meet the requirements of patentability under the federal patent laws, including for obviousness-type double patenting over the '907 patent.

39. This controversy is amenable to specific relief through a decree of a conclusive character.

40. The claims of the '516 patent are invalid for failing to meet the requirements of patentability under the federal patent laws, including for obviousness-type double patenting over the '907 patent.

41. AbbVie requests a declaratory judgment that each of the claims of the '516 patent is invalid.

PRAYER FOR RELIEF

WHEREFORE, AbbVie respectfully requests the following relief:

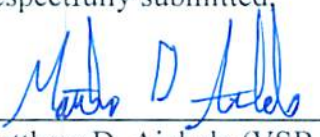
(a) A declaration that all the claims of U.S. Patent No. 6,248,516 are invalid and a final judgment incorporating the same;

(b) A "speedy hearing" on AbbVie's declaratory judgment action as authorized by Federal Rule of Civil Procedure 57; and

(c) Any and all such other relief as the Court determines to be just and proper.

Dated: June 22, 2016

Respectfully submitted,



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