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NANCY MAYER WHITTINGTON, CLERK
U.S. DISTRICT COURT

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MEDIMMUNE, INC.,
35 W. Watkins Mill Road
Gaithersburg, Maryland,

Plaintiff,

v.

CELLTECH R&D LTD.,
208 Bath Road
Slough
Berkshire
SL1 3WE
England

Defendant.

Civil Action No.: _____

COMPLAINT

CASE NUMBER 1:04CV00143
JUDGE: Richard W. Roberts
DECK TYPE: General Civil
DATE STAMP: 01/30/2004

COMPLAINT

Plaintiff MedImmune, Inc. ("MedImmune"), by its undersigned attorneys, brings this action against Defendant Celltech R&D Ltd. ("Celltech") for declaratory relief. In support of its Complaint, MedImmune alleges as follows:

NATURE OF THIS ACTION

1. Plaintiff MedImmune seeks a declaration that its Synagis® product does not infringe any valid claim of U.S. Patent 6,632,927 (the "'927 Patent"), one of a series of related patents known as the "Adair Patents."

THE PARTIES

2. Plaintiff MedImmune is a Delaware corporation with its principal place of business in Gaithersburg, Maryland. MedImmune uses biotechnology to develop and produce antibody therapies. MedImmune's Synagis® product helps prevent serious lower respiratory

tract disease caused by respiratory syncytial virus ("RSV"), a highly contagious and infectious disease. RSV infection can be fatal in certain high-risk pediatric patients.

3. Upon information and belief, defendant Celltech is a company incorporated under the laws of England and Wales with its principal place of business in Slough, England.

4. Upon information and belief, defendant Celltech is the same corporate entity as Celltech Chiroscience Limited and Celltech Therapeutics Limited. Upon information and belief, Celltech Therapeutics Limited changed its name to Celltech Chiroscience Limited on May 16, 2000. Upon information and belief, Celltech Chiroscience Limited changed its name to Celltech R&D Limited on April 2, 2001.

5. Upon information and belief, Celltech is the current assignee of the '927 Patent and is the appropriate defendant in any suit relating to the '927 Patent.

JURISDICTION AND VENUE

6. MedImmune seeks declaratory relief pursuant to FED. R. CIV. P. 57 and 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction of the claims asserted hereunder pursuant to 28 U.S.C. §§ 1331, 1332 and 1338(a). There is complete diversity of citizenship between the parties and the amount in controversy exceeds $75,000 exclusive of interest and costs. The subject matter of the controversy is also a federal question because the dispute arises under U.S. patent law.

7. This Court has personal jurisdiction over Celltech based on 35 U.S.C. § 293 because Celltech does not reside in the United States and has not designated with the U.S. Patent and Trademark Office (the "PTO") an agent residing in the United States on whom process and notice may be served.

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), (c) and (d).

BACKGROUND CONCERNING SYNAGIS® AND THE '927 PATENT

9. MedImmune obtained FDA approval to sell Synagis® in the United States on June 18, 1998. Synagis® was the first monoclonal antibody approved by the FDA for the prevention of an infectious disease. Synagis® is referred to as a "monoclonal" antibody (as opposed to a "polyclonal" antibody) because the antibody molecules contained therein are uniform, having been generated by host cells that are genetically identical. This antibody molecule is recombinant (*i.e.*, genetically engineered) and was created by combining the DNA for human and mouse antibody sequences.

10. MedImmune obtained United States Patent No. 5,824,307 (the "'307 Patent"), which claims, among other things, the monoclonal antibody molecule that is the active ingredient in Synagis®. The '307 Patent, entitled "Human-Murine Chimeric Antibodies Against Respiratory Syncytial Virus," was issued on or about October 20, 1998, and lists Leslie Sydnor Johnson as the inventor and MedImmune as the assignee.

11. The '927 Patent also relates to the field of monoclonal antibodies. In general terms, the '927 Patent purports to cover recombinant antibody molecules in which specific combinations of amino acids (or "residues") have been changed to match the residues contained in the corresponding antibody generated by another species (referred to as the "donor").

PRIOR LITIGATION BETWEEN THE PARTIES

12. MedImmune and Celltech have been embroiled in two litigations in England over whether Synagis® would infringe a valid claim of two other Adair Patents.

13. More particularly, Celltech, under its previous name of Celltech Chiroscience Limited, filed a suit against MedImmune in the High Court of Justice, Chancery Division in

London on October 19, 2000 ("English Action I") in order to collect royalties for Synagis® based on United States Patent No. 5,859,205, a U.S. Adair Patent that issued in 1999 (the "U.S. Parent Patent"). The U.S. Parent Patent issued from the same chain of patent applications that led to the '927 Patent.

14. In English Action I, Celltech conceded that Synagis® would not literally infringe the U.S. Parent Patent because it lacked an element required by that patent, namely that the amino acid at position 23 of the heavy chain of the antibody molecule be a "donor residue." Celltech therefore alleged that Synagis® would infringe the U.S. Parent Patent under the doctrine of equivalents.

15. MedImmune obtained dismissal of English Action I on the basis that prosecution history estoppel prevented Celltech from relying upon the doctrine of equivalents to assert that Synagis® would infringe the U.S. Parent Patent. During patent prosecution Celltech had disclaimed coverage of an antibody that lacked a "donor residue" at position 23 and could not, as a matter of law, seek to recapture such coverage through reliance upon the doctrine of equivalents. This dismissal was affirmed on appeal, but Celltech filed a petition requesting permission to file a further appeal to the House of Lords, which is England's highest court. The application for permission was refused by the House of Lords on January 21, 2004. As a result, English Action I has been formally dismissed by the English courts.

16. During the pendency of English Action I, Celltech obtained a new Adair Patent in Europe which resulted in the grant, *inter alia*, of patent number 690 33 857.0-08 in Germany (the "German Patent"). On September 16, 2002, Celltech filed a second action against MedImmune in the High Court of Justice, Chancery Division in London ("English Action II") in which

Celltech seeks to collect royalties based on the allegation that the sale and manufacture of Synagis® in Germany would infringe the German Patent.

17. Much like the U.S. Parent Patent that was the subject of English Action I, the German Patent that is the subject of English Action II requires that the antibody molecule contain a "donor residue" at position 23 of its heavy chain. As it did in English Action I, Celltech has conceded in English Action II that there would be no literal infringement of its German Patent because Synagis® does not have a "donor residue" at position 23 of its heavy chain. Therefore, Celltech is relying upon the German analogue of the doctrine of equivalents in pursuing a claim for royalties based on its German Patent. The trial in English Action II is scheduled to occur in March 2004.

18. On October 14, 2003, the PTO issued the '927 Patent without the express claim language concerning position 23 that had proven fatal to English Action I and that provided the basis for MedImmune's primary defense in English Action II.

19. It appears clear that Celltech sought the claims contained in the '927 Patent for the purpose of claiming royalties against MedImmune based on an allegation that Synagis® would infringe the '927 Patent.

20. In light of the foregoing, MedImmune filed this action in order to obtain a declaration that Synagis® does not infringe any valid claim of the '927 Patent.

FIRST CAUSE OF ACTION FOR A DECLARATORY JUDGMENT OF NON-INFRINGEMENT

21. MedImmune repeats and realleges the allegations of paragraphs 1 through 20.

22. An actual controversy exists as to whether Synagis® infringes the '927 Patent.

23. The history of dealings between MedImmune and Celltech, including two prior actions alleging that Synagis® would infringe patents that are based on the same application that matured into the '927 Patent and Celltech's successful effort during prosecution of the '927 Patent to eliminate express claim language that was troublesome to Celltech in these prior litigations, leaves MedImmune in little doubt that Celltech will claim royalties from MedImmune by alleging that Synagis® would infringe the '927 Patent.

24. Synagis® does not infringe any claim of the '927 Patent, *inter alia*, because it does not contain "donor residues" at positions 6, 24, 48, 49, 71, 73 and 78 of its heavy chain, as required by the claims of the '927 Patent.

25. MedImmune hereby seeks a declaratory judgment that the manufacture, sale, and use of Synagis® do not infringe any claim of the '927 Patent.

SECOND CAUSE OF ACTION FOR A DECLARATORY JUDGMENT OF PATENT INVALIDITY

26. MedImmune repeats and realleges the allegations of paragraphs 1 through 25.

27. An actual controversy now exists as to whether the claims of the '927 Patent are invalid. MedImmune contends that the claims of the '927 Patent are invalid, particularly (but not exclusively) to the extent they are construed broadly enough by Celltech to support an argument that Synagis® infringes them. MedImmune therefore seeks the declaration of this Court that the claims of the '927 Patent are invalid.

28. The courts of England, where Celltech has sued MedImmune twice before, are not competent to declare a U.S. patent invalid. Therefore, MedImmune can obtain a determination that the claims of the '927 Patent are invalid only in the federal courts of the United States. Moreover, if MedImmune waits to be sued in England where the courts cannot declare the '927 Patent invalid, Celltech will be free to advocate a broad construction of the '927 Patent claims

that would render them invalid under U.S. law without the risk of the English court invalidating such claims.

29. MedImmune is aware of at least the following grounds for invalidity of one or more claims of the '927 Patent, although this Court's claim construction and other developments, including information learned through discovery, may provide the basis for additional invalidity and/or unenforceability theories.

30. The claims of the '927 Patent are invalid because they are obvious in light of the prior art under 35 U.S.C. § 103. The invalidating prior art includes, but is not limited to, Riechmann *et al.*, Nature, 332, 323-324 (1988), Queen *et al.*, Proc. Natl. Acad. Sci. USA, 26, 10029-10033 (1989) and U.S. Patents 5,530,101, 5,585,089, 5,693,761, 5,693,762 and 6,180,370.

31. Additionally, the '927 Patent is invalid because it fails to meet one or more of the enablement, written description and definiteness requirements imposed by 35 U.S.C. § 112.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff MedImmune respectfully requests that judgment be entered in favor of MedImmune and against Celltech:

DECLARING that MedImmune does not infringe any claim of the '927 Patent;

DECLARING that the claims of the '927 Patent are invalid; and

PROVIDING MedImmune such other and further relief as the Court may deem just and proper under the circumstances.

Dated: January 30, 2004

Respectfully submitted,

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