UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

GLAXOSMITHKLINE BIOLOGICALS S.A., Rue de l'Institut 89, Rixensart, Belgium B-1330,

Plaintiff,

v.

NOVARTIS VACCINES AND DIAGNOSTICS SRL, Via Fiorentina 1, I-53100, Siena, Italy, **and NOVARTIS AG,** Lichtstrasse 35, 4056 Basel, Switzerland,

Defendants.

Civil Action No. _____

COMPLAINT UNDER 35 U.S.C. § 146

Plaintiff GlaxoSmithKline Biologicals S.A. ("GSK") for its complaint against Defendants Novartis Vaccines and Diagnostics SRL ("Novartis SRL") and Novartis AG, states as follows:

THE PARTIES

1. GSK is a corporation organized under the laws of Belgium and has a place of business at Rue de l'Institut 89, Rixensart, Belgium B-1330.

2. Upon information and belief, Novartis SRL is a corporation organized under the laws of Italy and has a principal place of business at Via Fiorentina 1, I-53100, Siena, Italy.

3. Upon information and belief, Novartis AG is a corporation organized under the laws of Switzerland and has a principal place of business at Lichtstrasse 35, 4056 Basel, Switzerland.

THE NATURE OF THE ACTION

4. This action relates to Patent Interference No. 105,551 ("the '551 interference"), entitled Jean-Louis Ruelle, Junior Party ("Ruelle") v. Vincenzo Scarlato et al., Senior Party ("Scarlato"). The technology involved is an isolated protein from the B strain of *N. meningitidis* (menB) or a fragment of that protein that would induce an immune response.

5. A patent interference is a proceeding before the United States Patent and Trademark Office, Board of Patent Appeals and Interferences ("Board"). Its purpose is to determine whether two parties claim the same patentable invention, and if so, who under the law is entitled to a U.S. patent on that invention.

6. Pursuant to 35 U.S.C. § 102(g), a party is entitled to a patent unless during an interference a second party establishes that before the first party's invention, the second party made the invention. In determining such priority of invention, the parties' dates of conception and reduction to practice of the invention shall be considered along with the reasonable diligence of the party who was first to conceive and last to reduce to practice from a time prior to conception by the other party.

7. Ruelle's involvement in the '551 interference is based on U.S. Patent No. 6,780,419, issued August 24, 2004, and entitled "BASB029 Polynucleotide(s) and Polypeptides from Neisseria Meningitidis" ("the Ruelle '419 patent," Exh. A), and U.S. Patent Application Serial No. 10/896,778, filed July 22, 2004, and entitled "BASB029 Polynucleotide(s) and Polypeptides from Neisseria Meningitidis" ("the Ruelle '778 application," Exh. B). Both the Ruelle '419 patent and the Ruelle '778 application name Jean-Louis Ruelle as inventor. GSK has the entire right, title, and interest in both the Ruelle '419 patent and the Ruelle '778 application.

8. Scarlato's involvement in the '551 interference is based on U.S. Patent Application Serial No. 11/212,443, filed August 24, 2005, and entitled "Meningococcal Antigens" ("the Scarlato '443 application," Exh. C). The Scarlato '443 application names Vincenzo Scarlato, Vega Masignani, Rino Rappuoli, Mariagrazia Pizza, and Guido Grandi as inventors. Novartis SRL identified itself as Scarlato's real-party-in interest in the '551 interference, having the entire right, title, and interest in the Scarlato '443 application. Upon information and belief, Novartis SRL assigned the entire right, title, and interest in the Scarlato '443 application to Novartis AG on or about September 30, 2008. However, upon information and belief, Scarlato never informed the Board of this apparent change in the real party, which occurred during the pendency of the '551 interference.

9. On July 26, 2010, the Board entered judgment of priority in favor of Scarlato and against Ruelle. Pursuant to 35 U.S.C. § 146, GSK brings this civil action against Novartis SRL and Novartis AG to remedy that incorrect judgment and the underlying decisions adverse to Ruelle in the '551 interference.

JURISDICTION AND VENUE

10. This Court has personal jurisdiction over the Defendants pursuant to 35 U.S.C. § 146.

11. This Court is vested with subject matter jurisdiction pursuant to 35 U.S.C. § 146, and 28 U.S.C. §§ 1331 and 1338(a).

12. Venue is proper in this judicial district under 28 U.S.C. § 1391.

FACTS GIVING RISE TO THE COMPLAINT

13. The '551 interference was first declared on June 11, 2007, and redeclared on October 29, 2007, and June 4, 2009.

14. In declaring the interference, the Board determined that certain claims of the Ruelle '419 patent and the Scarlato '443 application "interfere" because they claim a common invention. The '551 interference was redeclared on October 29, 2007, to add the Ruelle '778 application as also interfering with the Scarlato '443 application. The redeclaration on June 4, 2009, was to accord the parties benefit of the filing dates of various priority applications.

15. The '551 interference was based on a single "count" (Count 1), which defines the invention contested in the interference. Only the first inventor of the count is entitled to a patent covering the count. The Board defined Count 1 as claim 1 of the Ruelle '419 patent or claim 18 of the Scarlato '443 application.

16. Claim 1 of the Ruelle '419 patent recites:

> An isolated polypeptide comprising a member selected from the group consisting of
> (a) the amino acid sequences SEQ ID NO: 2;
> (b) an immunogenic fragment of at least 15 contiguous amino acids of SEQ ID NO: 2;
> wherein the immunogenic fragment, when administered to a subject in a suitable composition which can include an adjuvant, or a suitable carrier coupled to the polypeptide, induces an antibody or T-cell mediated immune response that recognizes the isolated polypeptide SEQ ID NO: 2.

17. Claim 18 of the Scaralato '443 application recites:

> An isolated polypeptide comprising a member selected from the group consisting of
> (a) the amino acid sequence of SEQ ID NO: 4; and
> (b) an immunogenic fragment of at least 15 contiguous amino acids of SEQ ID NO: 4,
> wherein the immunogenic fragment, when administered to a subject in a suitable composition which can include an adjuvant, or a suitable carrier coupled to the polypeptide induces an antibody or T-cell mediated immune response that recognizes a polypeptide of the amino acid sequence as set forth in SEQ ID NO: 4.

18. The Board designated the following claims as corresponding to Count 1: all claims of the Ruelle '419 patent (claims 1-15), all pending claims of the Ruelle '778

application (claims 1-14, as renumbered by the examiner in the Notice of Allowance, Exh. D), and all pending claims of the Scarlato '443 application (claims 18-32 as presented in November 20, 2006 Amendment to the Scarlato '443 application, Exh. E).

19. Ruelle was accorded priority benefit of PCT application PCT/EP99/03255, filed May 17, 1999. In addition, the Board granted Ruelle's preliminary motion (unopposed by Scarlato) to be accorded priority benefit of Great Britain application 98/10276, filed May 13, 1998.

20. Scarlato was accorded priority benefit of U.S. Patent Application Serial No. 10/695,499, filed October 28, 2003, and U.S. Patent Application Serial No. 09/302,626, filed April 30, 1999. In addition, the Board granted Scarlato's preliminary motion (over Ruelle's opposition) to be accorded priority benefit of Great Britain application 98/00760, filed January 14, 1998; Great Britain application 98/19015, filed September 1, 1998; Great Britain application 98/22143, filed October 9, 1998; and PCT application PCT/IB99/00103, filed January 14, 1999.

21. In its initial priority statement, Ruelle alleged October 6, 1997, as its earliest corroborated conception date for Count 1, and January 16, 1998, as its earliest corroborated actual reduction to practice date for Count 1.

22. The Board denied Ruelle's miscellaneous motion seeking authorization to file an amended priority statement alleging December 10, 1997, as its earliest corroborated actual reduction to practice date for Count 1.

23. Each party filed a motion for judgment based on priority.

24. In its priority motion, Scarlato asserted August 13, 1997, as its conception date for Count 1, and January 14, 1998, as its constructive reduction to practice date. Ruelle's

priority motion urged that Ruelle was entitled to a November 17, 1997, conception date for Count 1, and an actual reduction to practice date of at least as early as December 10, 1997, January 16, 1998, or February 13, 1998.

25. In its opposition to Ruelle's priority motion, Scarlato admitted that Ruelle had established a conception of Count 1 as of no later than November 17, 1997, and a reduction to practice on February 13, 1998.

26. In opposing Scarlato's priority motion, Ruelle contended that Scarlato did not establish a conception of the invention of Count 1 on August 13, 1997, and did not provide corroboration of such alleged conception. Ruelle further asserted that Scarlato was not entitled to a constructive reduction to practice date of January 14, 1998.

27. By Decision dated July 26, 2010, the Board incorrectly ruled that Scarlato was both the first to conceive and the first to reduce to practice an invention of Count 1. The Board thereupon entered judgment of priority in favor of Scarlato and against Ruelle.

CLAIMS FOR RELIEF

28. GSK incorporates the preceding paragraphs of this Complaint by reference.

29. GSK seeks relief here under 35 U.S.C. § 146, because it is dissatisfied with the decision of the Board on the interference.

30. This action is filed with respect to each and every judgment or decision adverse to Ruelle in the interference. The particular decisions set forth below are by way of example and without prejudice to Ruelle's right to present evidence of other errors as this matter proceeds. The evidence introduced at the '551 interference, as well as other evidence which may be introduced during this action, will show that the decisions made by the Board were erroneous and that judgment should have been entered in favor of Ruelle.

31. The Board erroneously accorded Scarlato priority benefit of at least Great Britain application 98/00760, filed January 14, 1998; Great Britain application 98/19015, filed September 1, 1998; Great Britain application 98/22143, filed October 9, 1998; and PCT application PCT/IB99/00103, filed January 14, 1999. This contributed to an erroneous outcome of the interference.

32. The Board erroneously found that Scarlato conceived the invention of Count 1 on August 13, 1997. This contributed to an erroneous outcome of the interference.

33. The Board erroneously found that Scarlato presented sufficient corroboration of its alleged conception of the invention of Count 1 on August 13, 1997. This contributed to an erroneous outcome of the interference.

34. The Board erred in not finding that Ruelle had achieved an actual reduction to practice of Count 1 by December 10, 1997. This contributed to an erroneous outcome of the interference.

35. The Board erred in ruling that Ruelle did not have a conception of Count 1 together with diligence before Scarlato's conception of Count 1. This contributed to an erroneous outcome of the interference.

36. Upon information and belief, no appeal has been taken to the United States Court of Appeals for the Federal Circuit.

PRAYER

WHEREFORE, GSK prays that the Court grant:

1. Leave to introduce the record of the '551 interference and to take discovery and introduce additional evidence to supplement the record in this action regarding issues that were before the Board;

2. *De novo* consideration of the '551 interference record, if introduced, and the supplemental evidence adduced by way of additional discovery regarding issues of conception, reduction to practice, and diligence;

3. A reversal of all portions of the Board's decisions or judgment adverse to Ruelle;

4. An entry of judgment for Ruelle and against Scarlato in the '551 interference;

5. A declaration that this action is an exceptional case;

6. An award to GSK of its costs in this action, including its reasonable attorney fees; and

7. An award to GSK of such other and further relief as the Court may deem just and proper.

Dated: September 23, 2010

Respectfully submitted,

NIXON PEABODY LLP

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