

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENETICS INSTITUTE, LLC,)
a Delaware limited liability company,)
)
Plaintiff,)
)
v.)
)
NOVARTIS VACCINES AND)
DIAGNOSTICS, INC., a Delaware corporation,))
)
Defendant.)

C. A. No. _____

**COMPLAINT FOR THE ADJUDICATION OF
PLAINTIFF’S PRIORITY OF INVENTION OVER
DEFENDANT’S INTERFERING PATENTS UNDER 35 U.S.C. § 291**

Plaintiff Genetics Institute, LLC (“GI”) files this Complaint against Novartis Vaccines and Diagnostics, Inc. (“Novartis”) seeking an adjudication of priority of invention under 35 U.S.C. § 291 of U.S. Patent No. 4,868,112 (“the ‘112 patent”), assigned to GI, over U.S. Patent Nos. 6,060,447 (“the ‘447 patent”) and 6,228,620 (“the ‘620 patent”), which on information and belief, are assigned to Novartis.

PARTIES

1. Plaintiff GI is a Delaware limited liability company located at 87 CambridgePark Drive, Cambridge, MA 02140. Plaintiff GI owns certain real and intellectual property assets, including the ‘112 patent, and conducts no other business in any jurisdiction in the United States.

2. On information and belief, Defendant Novartis is a Delaware corporation with a principal place of business at 350 Massachusetts Avenue, Cambridge MA 02139. Novartis’s registered agent for service of process in Delaware is the Corporation Trust Company, whose address is 1209 Orange Street, Wilmington, DE 19801.

JURISDICTION AND VENUE

3. This is an action for the adjudication of priority of invention arising under 35 U.S.C. § 291. This Court has subject matter jurisdiction over this action under 35 U.S.C. § 291, 28 U.S.C. §§ 1331 and 1338(a).
4. This Court has personal jurisdiction over Novartis. Novartis is a Delaware corporation and, on information and belief, is purposely engaged in substantial business activities within this judicial district sufficient to subject it to the general jurisdiction of this Court.
5. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c).

THE TEXAS ACTION

6. On February 15, 2008, Novartis filed suit in the United States District Court for the Eastern District of Texas against Wyeth and Wyeth Pharmaceuticals, Inc., asserting that the sale of REFACTO[®], Wyeth's recombinant B-domain deleted Factor VIII:C product for the treatment of hemophilia A, infringes the '447 and '620 patents.

7. GI is a subsidiary of Wyeth, but is not a party to the Texas action.

THE INTERFERING PATENTS

A. GI's '112 Patent

8. By no later than January 22, 1985, Dr. John Toole, an employee of Genetics Institute, Inc., the predecessor of Plaintiff GI, had conceived and actually reduced to practice truncated human Factor VIII:C proteins lacking a portion of the B domain of the full-length Factor VIII:C protein, and related recombinant DNA, vectors, host cells, and methods.

9. On April 12, 1985, Genetics Institute, Inc. filed, on Dr. Toole's behalf, U.S. App. No. 06/725,350 ("the '350 application"), which describes and claims truncated human

Factor VIII:C proteins lacking a portion of the B domain of the full-length Factor VIII:C protein, and related recombinant DNA, vectors, host cells, and methods.

10. On April 11, 1986, Genetics Institute, Inc. filed, on Dr. Toole's behalf, U.S. App. No.07/010,085 ("the '085 application") as a continuation-in-part of the '350 application. The '085 application also describes and claims truncated human Factor VIII:C proteins lacking a portion of the B domain of the full-length Factor VIII:C protein, and related recombinant DNA, vectors, host cells, and methods.

11. The United States Patent and Trademark Office ("the USPTO") allowed the '085 application, and issued it as the '112 patent, entitled "Novel Procoagulant Proteins," on September 19, 1989. A true and correct copy of the '112 patent is attached as Exhibit A.

12. GI is the successor to Genetics Institute, Inc. and owns all right, title and interest in the '112 patent.

13. After the issuance of the '112 patent, the USPTO declared an interference between the claims of the '112 patent, then assigned to Genetics Institute, Inc., and the claims of U.S. App. No. 06/907,297, assigned to Genentech, Inc. ("the interference").

14. The USPTO accorded Genetics Institute, Inc. the benefit of the April 12, 1985 filing date of the '350 application, determined that Dr. Toole was the first and only inventor of the subject matter of the interference, and awarded priority of invention to the '112 patent.

15. The USPTO granted a patent term extension under 35 U.S.C. § 156 for the '112 patent until February 28, 2010, based on the time necessary to conduct clinical trials and obtain FDA approval of REFACTO®. A true and correct copy of the Certificate of patent term extension for the '112 patent is attached as Exhibit B.

B. Novartis's '447 and '620 Patents

16. On information and belief, Novartis is the assignee of all right, title and interest in the '447 and '620 patents. Copies of the '447 and '620 patents are attached as Exhibits C and D, respectively.

17. The '447 patent, entitled "Protein Complexes Having Factor VIII:C Activity and Production Thereof," was issued by the USPTO on May 9, 2000.

18. The '447 patent, through a series of divisional, continuing, and continuation-in-part applications, purports to have an earliest effective filing date of January 27, 1986.

19. The '620 patent, entitled "Protein Complexes Having Factor VIII:C Activity and Production Thereof," was issued by the USPTO on May 8, 2001.

20. The '620 patent, through a series of divisional, continuation, and continuation-in-part applications, purports to have an earliest effective filing date of January 27, 1986.

21. On information and belief, by alleging that REFACTO® infringes the '447 and '620 patents, Novartis asserts that the claims of the '447 and '620 patents encompass truncated human Factor VIII:C proteins lacking a portion of the B domain of the full-length Factor VIII:C protein, and related recombinant DNA, vectors, host cells, and methods.

CLAIM FOR RELIEF

ADJUDICATION OF PRIORITY OF INVENTION OF THE '112 PATENT OVER DEFENDANT'S INTERFERING PATENTS

22. On information and belief, pursuant to Novartis's allegations concerning the '447 and '620 patents, one or more claims of GI's '112 patent and one or more interfering

claims of Novartis’s ‘447 and ‘620 patents encompass the same or substantially the same subject matter.

23. Consequently, an interference-in-fact exists between one or more claims of the ‘112 patent and one or more claims of the ‘447 and ‘620 patents.

24. GI’s ‘112 patent has an earlier effective filing date than the purported effective filing date for Novartis’s ‘447 and ‘620 patents. In patent interferences for the determination of priority by the USPTO, the party with the earlier filing date is the Senior Party and is presumed to be the first to invent. 37 C.F.R. § 41.207(a)(1) (“Parties are presumed to have invented the interfering subject matter in the order of the dates of their accorded benefit for each count.”); 37 C.F.R. § 41.201 (“‘Senior party’ means the party entitled to the presumption under § 41.207(a)(1) that it is the prior inventor.”) Accordingly, GI is the Senior Party and Novartis is the Junior Party in determining priority of invention.

25. The ‘112 patent has priority of invention over the ‘447 and ‘620 patents.

26. Because the ‘112 patent has priority of invention over the ‘447 and ‘620 patents, all the interfering claims of the ‘447 and ‘620 patents are invalid.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

- A. That the ‘112 patent has priority of invention over the ‘447 and ‘620 patents.
- B. That, because the ‘112 patent has priority of invention over the claims of the ‘447 and ‘620 patents, the interfering claims of the ‘447 and ‘620 patents are invalid.
- C. Such other and further relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



Jack B. Blumentfeld (#1014)
Karen Jacobs Loudon (#2881)

1201 North Market Street

P.O. Box 1347

Wilmington, DE 19899

(302) 658-9200

jblumentfeld@mmat.com

klouden@mmat.com

Attorney for Plaintiff

Of Counsel:

Barbara C. McCurdy

Steven P. O'Connor

FINNEGAN, HENDERSON, FARABOW,

GARRETT & DUNNER, LLP

901 New York Avenue, N.W.

Washington, D.C. 20001-4413

(202) 408-4000

Willem G. Schuurman

VINSON & ELKINS L.L.P.

The Terrace 7

2801 Via Fortuna, Suite 100

Austin, TX 78746-7568

(512) 542-8400

May 16, 2008