

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ATHENA DIAGNOSTICS, INC.,)
THE UNIVERSITY OF CHICAGO and)
CORRELAGEN DIAGNOSTICS, INC.,)
)
Plaintiffs,) Civil No. 4:09-cv-40200-FDS
)
v.)
)
AMBRY GENETICS CORPORATION,)
)
Defendant.)

AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs allege for their amended complaint in this action as follows:

Parties, Jurisdiction and Venue

1. Athena Diagnostics, Inc. (“Athena”) is a corporation duly organized and existing under the laws of the State of Delaware with a place of business at Four Biotech Park, 377 Plantation Street, Worcester, Massachusetts.
2. The University of Chicago (“Chicago”) is a not-for profit corporation duly organized and existing under the laws of the State of Illinois with a place of business at 5801 South Ellis Avenue, Chicago, Illinois.
3. Correlagen Diagnostics, Inc. (“Correlagen”), formerly known as Correlagen, Inc., is a corporation duly organized and existing under the laws of the Commonwealth of Massachusetts with a place of business at 307 Waverly Oaks Road, Waltham, Massachusetts.
4. Ambry Genetics Corporation (“Ambry”) is, on information and belief, a corporation duly organized and existing under the laws of the State of California with a place of business at 100 Columbia, Suite #200, Aliso Viejo, California.

5. This is an action for patent infringement under 35 U.S.C. § 1 *et seq.*, for which this Court has jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

6. Venue in this District is proper under 28 U.S.C. §§ 1391 and 1400.

Facts Giving Rise to Claims Against Ambry

7. Athena is one of the leading companies in the field of genetic diagnostic testing, and has developed and offers genetic diagnostic tests for numerous diseases and conditions.

8. On June 24, 2003, Athena entered into a Development and License Agreement with Correlagen Diagnostics, Inc., then known as Correlagen, Inc. (as amended, the “Athena Development Agreement”) under which, among other things, Correlagen agreed to develop or find tests for endocrine and metabolism molecular disease prognosis and diagnosis (“EMMD tests”), to acquire patent and other intellectual property rights in and to such tests, and to develop the EMMD tests for Athena. Also under the Athena Development Agreement:

- a. Athena agreed to pay Correlagen for the development of, and the acquisition of patent and other intellectual property rights in, such EMMD tests;
- b. Correlagen granted Athena, among other things, an exclusive license in all the patent and other intellectual property rights that Correlagen acquires in such EMMD tests that relate to or otherwise concern physician-authorized or physician-ordered diagnostic or prognostic testing in any healthcare venue in the United States, with the exception of such testing that is paid for by pharmaceutical companies in the context of their sponsored clinical trials or when such testing is lawfully ordered without the authorization of a physician by consumers, insurance companies, or employers; and

c. Correlagen granted to Athena the right to sue third parties for infringement of Athena's exclusive patent rights in the EMMD tests, including the right to join Correlagen as a party-plaintiff if legally required to do so.

9. Correlagen found technology at, among other research and academic institutions, Chicago that could provide the basis for EMMD tests for the detection and diagnosis of certain forms of diabetes.

10. U.S. Patent No. 5,541,060 (the "'060 Patent"), entitled "Detection of Glucokinase-Linked Early-Onset Non-Insulin-Dependent Diabetes Mellitus," duly issued to ARCH Development Corporation ("ARCH") on July 30, 1996.

11. Chicago had arranged for the incorporation of ARCH as an Illinois not-for-profit corporation affiliated with Chicago for the purpose, among others, of holding title to patents covering university-based research by scientists and engineers at Chicago. ARCH and Chicago entered in an Agreement on July 1, 2001 (the "ARCH-Chicago Agreement"), pursuant to which, among other things, ARCH granted to Chicago, among other rights, the exclusive rights to license such patents owned by ARCH and to act as ARCH's agent in all dealings respecting ARCH's inventions and patents, and the right to cause ARCH to assign to Chicago all such inventions and patents. On September 15, 2009, in accordance with the ARCH-Chicago Agreement, ARCH assigned to Chicago all of ARCH's right, title and interest in and to the '060 Patent, including all rights to enforce the '060 Patent and to sue third parties for past, current and future infringement of the '060 Patent.

12. Chicago entered into a License Agreement with Correlagen as of March 15, 2004, granting Correlagen exclusive rights to make, use, sell, offer to sell, and import the inventions claimed in the '060 Patent in the field of in vitro diagnostics products and services, including the right to grant sublicenses.

13. Correlagen entered into a Sublicense with Athena as of September 13, 2004, granting Athena exclusive rights under the '060 Patent of such rights that Correlagen acquired under its exclusive license with Chicago that relate to or otherwise concern physician-authorized or physician-ordered diagnostic or prognostic testing in any healthcare venue in the United States, with the exception of such testing that is paid for by pharmaceutical companies in the context of their sponsored clinical trials or when such testing is lawfully ordered without the authorization of a physician by consumers, insurance companies, or employers.

14. Using the inventions claimed in the '060 Patent, Correlagen developed for Athena "GCK" EMMD tests for the diagnosis of a certain form of MODY known as MODY 2 and for the diagnosis of neonatal diabetes mellitus, by detection of a mutation in a glucokinase ("GCK") gene. Athena has been offering and performing, and is continuing to offer and perform such GCK EMMD tests for the diagnosis of MODY 2 and neonatal diabetes mellitus under the exclusive '060 Patent rights that Correlagen has acquired from Chicago and has sublicensed to Athena.

COUNT I

15. Plaintiffs repeat, reallege and incorporate herein by reference each of the allegations in paragraphs 1 through 14 of this amended complaint.

16. Ambry has performed, and is continuing to perform GCK EMMD tests for the diagnosis of MODY 2 and neonatal diabetes mellitus in the United States, and Ambry has thereby infringed, and is continuing to infringe, the '060 Patent, directly and/or by active inducement and/or by contributory infringement, including infringement in this District.

17. Ambry's infringement of the '060 Patent is and has been willful.

18. Ambry's infringement of the '060 Patent has caused and will continue to cause Plaintiffs substantial damages and irreparable harm for which there is no adequate remedy at law.

WHEREFORE, Plaintiffs respectfully request that this Court:

- A. Enter judgment on Count I:
 - (i) determining that Ambry has infringed U.S. Patent No. 5,541,060;
 - (ii) enjoining Ambry and its affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns, and those acting for or on its behalf or acting in concert or participation with it, from further infringement of U.S. Patent No. 5,541,060;
 - (iii) awarding damages to Plaintiffs for Ambry's infringement of U.S. Patent No. 5,541,060 in such amount as may be proved, and trebled damages pursuant to 35 U.S.C. § 284 for willful infringement;
 - (iv) awarding Plaintiffs their costs, and pre-judgment and post-judgment interest pursuant to 35 U.S.C. § 284 and other applicable law; and
 - (v) awarding Plaintiffs reasonable attorneys' fees pursuant to 35 U.S.C. § 285.
- B. Grant Plaintiffs such other and further relief as may be just and proper.

Demand for Jury Trial

Plaintiffs demand a trial by jury on all issues so triable.

ATHENA DIAGNOSTICS, INC. and
THE UNIVERSITY OF CHICAGO

By their attorneys,

/s/ David J. Brody
David J. Brody (BBO No. 058200)
david.brody@hbsr.com
Deirdre E. Sanders (BBO No. 630404)
deirdre.sanders@hbsr.com
Christine M. Wise (BBO No. 657324)
christine.wise@hbsr.com
Hamilton, Brook, Smith & Reynolds, P.C.
530 Virginia Road
P.O. Box 9133
Concord, Massachusetts 01742-9133
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Dated: March 15, 2010

CORRELAGEN DIAGNOSTICS, INC.

By its attorneys,

/s/Terry Klein
HENSHON PARKER LLP
Terry Klein, BBO# 652052
160 Federal Street, 10th Floor
Boston, Massachusetts 02110
Telephone: (617) 367-1800
Facsimile: (617) 507-6454
(tklein@henshon.com)

Of counsel:

Steven D. Moore (*Pro hac vice motion to be filed*)
smoore@kilpatrickstockton.com
Matias Ferrario (*Pro hac vice motion to be filed*)
mferrario@kilpatrickstockton.com
KILPATRICK STOCKTON LLP
1001 West Fourth Street
Winston-Salem, NC 27101
Telephone: (336) 607-7300
Facsimile: (336) 607-7500

CERTIFICATE OF SERVICE

I, David J. Brody hereby certify that this document filed through the ECF System will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on March 15, 2010.

/s/ David J. Brody
David J. Brody