

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

ATHENA DIAGNOSTICS, INC., )  
THE UNIVERSITY OF CHICAGO and )  
CORRELAGEN DIAGNOSTICS, INC., )  
 )  
Plaintiffs, ) Civil No. 4:09-cv-40201-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. 6,187,533 (the "'533 Patent"), entitled "Mutations in the Diabetes Susceptibility Genes Hepatocyte Nuclear Factor (HNF) 1 Alpha ( $\alpha$ ), HNF1 $\beta$  and HNF4 $\alpha$ ," duly issued to ARCH Development Corporation ("ARCH") on February 13, 2001.

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 '533 Patent, including all rights to enforce the '533 Patent and to sue third parties for past, current and future infringement of the '533 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 '533 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 '533 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 '533 Patent, Correlagen developed for Athena "HNF4 $\alpha$ ", "HNF1 $\alpha$ /TCF1" and "HNF1 $\beta$ /TCF2" EMMD tests for the diagnosis of certain forms of MODY known as MODY 1, MODY 3 and MODY 5 by detection of mutations in the HNF4 $\alpha$ , HNF1 $\alpha$ /TCF1 and HNF1 $\beta$ /TCF2 genes, respectively. Athena has been offering and performing, and is continuing to offer and perform the HNF4 $\alpha$ , HNF1 $\alpha$ /TCF1 and HNF1 $\beta$ /TCF2 EMMD tests for the diagnosis of MODY 1, MODY 3 and MODY 5 (previously known as MODY 4) under the exclusive '533 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 the HNF4 $\alpha$ , HNF1 $\alpha$ /TCF1 and HNF1 $\beta$ /TCF2 EMMD tests for the diagnosis of MODY 1, MODY 3 and MODY 5 in the United States, and Ambry has thereby infringed, and is continuing to infringe, the '533 Patent, directly and/or by active inducement and/or by contributory infringement, including infringement in this District.

17. Ambry's infringement of the '533 Patent is and has been willful.

18. Ambry's infringement of the '533 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. 6,187,533;
  - (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. 6,187,533;
  - (iii) awarding damages to Plaintiffs for Ambry's infringement of U.S. Patent No. 6,187,533 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,

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Dated: March 15, 2010

CORRELAGEN DIAGNOSTICS, INC.

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**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