

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA  
GREENSBORO DIVISION

Esoterix Genetic Laboratories, LLC )  
and The Johns Hopkins University, )

Plaintiffs, )

vs. )

Ambry Genetics Corporation, )

Defendant. )

Civil Action No. 16-cv-1111

**JURY TRIAL DEMANDED**

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Esoterix Genetic Laboratories, LLC (“EGL”) and The Johns Hopkins University (“JHU”) (collectively, “Plaintiffs”) for their complaint against Defendant Ambry Genetics Corporation (“Ambry”) allege as follows:

**NATURE OF ACTION**

1. This is an action under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, for infringement by Ambry of patents owned by JHU and exclusively licensed by EGL.

**THE PARTIES**

2. Plaintiff EGL is a Delaware limited liability company with a principal place of business at 531 South Spring Street, Burlington, North Carolina 27215. EGL is a wholly-owned subsidiary of Laboratory Corporation of America Holdings (also known as LabCorp), which is headquartered in Burlington, North Carolina.

3. Plaintiff JHU is a private not-for-profit corporation organized under the laws of the State of Maryland and has its principal place of business in Baltimore, Maryland.

4. On information and belief, Defendant Ambry is a corporation incorporated under the laws of the State of California with a principal place of business at 15 Argonaut, Aliso Viejo, California, 92656.

### **JURISDICTION AND VENUE**

5. This is a patent infringement action, and this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Defendant Ambry because, at a minimum, Ambry regularly conducts business in this District and has offered for sale and sold infringing services in this District, among other places. Ambry sells, offers for sale, and has sold genetic testing products and services to residents of this District. Ambry has advertised, presented, and marketed to residents in this jurisdiction products and services it sells, offers for sale, and has sold relating to its genetic testing products. Ambry has marketed that it is able to conduct genetic testing on samples received from any state in the United States. Ambry has business relationships and/or has collaborated with medical service providers, businesses, and/or research entities, including Wake Forest School of Medicine in Winston-Salem, NC, in this District. On information and belief, Ambry employs persons to provide education and support concerning its products and services to healthcare providers that are residents in this jurisdiction.

7. Venue is proper in this judicial district pursuant to at least 28 U.S.C. §§ 1391 and 1400 at least because injuries from Ambry's actions are felt in this District, Ambry engages in actions of infringement in this District, Ambry is subject to personal jurisdiction in this District, and Ambry conducts substantial business and has substantial contacts with the State of North Carolina and within this District.

### **BACKGROUND FACTS**

8. Plaintiffs are leaders in the field of genetic testing for hereditary cancer risk-markers. Each of the patents asserted herein relate generally to genetic testing, including for hereditary cancer risk-markers.

9. The two named inventors on United States Patent No. 6,440,706, United States Patent No. 7,824,889, United States Patent No. 7,915,015, and United States Patent No. 8,859,206 (collectively "Patents-in-Suit") are Dr. Bert Vogelstein and Dr. Kenneth W. Kinzler. Both Dr. Vogelstein and Dr. Kinzler are affiliated with The Johns Hopkins Sidney Kimmel Comprehensive Cancer Center. Dr. Vogelstein is a very well-known pioneer in the field of cancer genomics. Among other awards and achievements, Dr. Vogelstein is a prolific author of scientific articles in the genetics field, which include some of the most frequently cited references in the field, and was named as one of the 11 scientists who received The Breakthrough Prize in Life Sciences in its inaugural year. Dr. Kinzler is likewise well known in the genetics field and was recently elected to the National Academy of Medicine, an honor to which Dr. Kinzler was elected by his peers for his accomplishments and contributions to medical sciences, health care, and public health.

10. EGL, as the exclusive licensee of the Patents-in-Suit, provides tests that detect mutations in genes, including mutations which have been associated with an increased risk of developing cancers.

11. Ambry makes, uses, offers for sale, and sells, without authorization, services, products, and/or methods that infringe the Patents-in-Suit.

12. EGL is the exclusive licensee of United States Patent No. 6,440,706 (hereinafter referred to as “the ’706 patent”) which duly and legally issued on August 27, 2002 and is entitled “Digital Amplification.” The ’706 patent is assigned to and owned by JHU. The ’706 patent was reexamined by the United States Patent and Trademark Office (“USPTO”). After reexamination, the USPTO certified the ’706 patent, as amended, as valid on October 24, 2014. A true and correct copy of the ’706 patent, including the reexamination certificate, is attached to this Complaint as Exhibit A.

13. EGL is the exclusive licensee of United States Patent No. 7,824,889 (hereinafter referred to as “the ’889 patent”) which duly and legally issued on November 2, 2010 and is entitled “Digital Amplification.” The ’889 patent is assigned to and owned by JHU. The ’889 patent was reexamined by the USPTO. After reexamination, the USPTO certified the ’889 patent, as amended, as valid on October 31, 2014. A true and correct copy of the ’889 patent, including the reexamination certificate, is attached to this Complaint as Exhibit B.

14. EGL is the exclusive licensee of United States Patent No. 7,915,015 (hereinafter referred to as “the ’015 patent”) which duly and legally issued on March 29, 2011 and is entitled “Digital Amplification.” The ’015 patent is assigned to and owned

by JHU. The '015 patent was reexamined by the USPTO. After reexamination, the USPTO certified the '015 patent, as amended, as valid on October 23, 2014. A true and correct copy of the '015 patent, including the reexamination certificate is attached to this Complaint as Exhibit C.

15. EGL is the exclusive licensee of United States Patent No. 8,859,206 (hereinafter referred to as “the '206 patent”) which duly and legally issued on October 14, 2014 and is entitled “Digital Amplification.” The '206 patent is assigned to and owned by JHU. A true and correct copy of the '206 patent is attached to this Complaint as Exhibit D.

16. Previously, Plaintiffs accused Life Technologies, Inc. (“Life Technologies”) of infringing the '706 patent, the '889 patent, and the '015 patent before this Court in Civil Action No. 1:12-cv-01173. In response to the complaint, Life Technologies sought reexamination of the '706 patent, the '889 patent, and the '015 patent before the USPTO. In each of the patent reexaminations, Life Technologies identified prior art that had not been considered before by the USPTO. After its review and consideration of the prior art, the USPTO issued reexamination certificates for all three patents, finding each patent valid.

17. The USPTO has found the claims of the asserted patents to claim novel and non-obvious methods after reviewing over 100 prior art documents, including scientific articles from peer-reviewed journals. Over 180 U.S. patent publications have cited one or more of the asserted patents.

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