

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. )  
 )  
Life Technologies Corporation, Applied )  
Biosystems, LLC, and Ion Torrent )  
Systems, Inc., )  
 )  
Defendants. )

Civil Action No. 1:12-cv-1173

**JURY TRIAL DEMANDED**

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Esoterix Genetic Laboratories, LLC (“EGL”) and The Johns Hopkins University (“JHU”) for their complaint against Defendants Life Technologies Corporation (“Life Technologies”), Applied Biosystems, LLC (“Applied Biosystems”), and Ion Torrent Systems, Inc. (“Ion Torrent”), 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 Life Technologies, Applied Biosystems, and Ion Torrent 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 358 South Main Street, Burlington, North Carolina 27215. EGL is a wholly-owned subsidiary of Laboratory Corporation of America Holdings, which is headquartered in Burlington, North Carolina.

3. Plaintiff The Johns Hopkins University (“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 City, Maryland.

4. On information and belief, Defendant Life Technologies is a corporation incorporated under the laws of the State of Delaware with a principal place of business at 5791 Van Allen Way, Carlsbad, California 92008.

5. On information and belief, Defendant Applied Biosystems is a corporation incorporated under the laws of the State of Delaware with a principal place of business at 5791 Van Allen Way, Carlsbad, California 92008, and is a wholly-owned subsidiary of Life Technologies.

6. On information and belief, Defendant Ion Torrent is a corporation incorporated under the laws of the State of Delaware with a principal place of business at 246 Goose Lane, Suite 100, Guilford, Connecticut 06437, and is a wholly-owned subsidiary of Life Technologies.

### **JURISDICTION AND VENUE**

7. 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).

8. This Court has personal jurisdiction over Defendant Life Technologies because, at a minimum, Life Technologies has purposely availed itself of the privilege of conducting activities within this State and District by registering to do business within the State of North Carolina. Further, Life Technologies regularly conducts business, and has offered for sale and sold infringing products, in this Judicial District, among other places.

9. This Court has personal jurisdiction over Defendant Applied Biosystems because, at a minimum, Applied Biosystems has purposely availed itself of the privilege of conducting

activities within this State and District by registering to do business within the State of North Carolina. Further, Applied Biosystems regularly conducts business, and has offered for sale and sold infringing products, in this Judicial District, among other places.

10. This court has personal jurisdiction over Defendant Ion Torrent because, at a minimum, Ion Torrent regularly conducts business, and has offered for sale and sold infringing products, in this Judicial District, among other places.

11. Venue is proper in this judicial district pursuant to at least 28 U.S.C. §§ 1391(c) and 1400(b).

### **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. A true and correct copy of the ’706 patent is attached to this Complaint as Exhibit 1.

13. The claims of the ’706 patent relate to methods for determining the ratio of a genetic sequence in a sample.

14. 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. A true and correct copy of the ’889 patent is attached to this Complaint as Exhibit 2.

15. The claims of the ’889 patent relate to determining an allelic imbalance in a biological sample.

16. 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. A true and correct copy of the ’015 patent is attached to this Complaint as Exhibit 3.

17. The claims of the ’015 patent also relate to the determination of an allelic imbalance in a biological sample.

18. The ’706, the ’889, and the ’015 patents are members of the same patent family that name Bert Vogelstein and Kenneth W. Kinzler as inventors. These patents are referred to herein as the “Vogelstein patent family” or as the “Patents-in-Suit.”

19. EGL has the right to enforce the ’706, the ’889, and the ’015 patents, including the right to recover past damages, collect ongoing royalties, and pursue any other legal or equitable relief.

### **ACCUSED INFRINGERS**

20. Defendant Life Technologies is a biotechnology company that sells various products, kits, and devices, including sequencing systems, both directly and through its subsidiaries, Applied Biosystems and Ion Torrent (all three collectively referred to as “Life”), that are used in methods for detecting ratios of genetic sequences or detecting allelic imbalances.

21. Life sells sequencing systems under the Applied Biosystems brand, such as the SOLiD system and the 5500 Genetic Analyzer. Life also sells sequencing systems under the Ion Torrent brand, such as the Personal Genome Machine (“PGM”) and the Ion Proton Sequencer (“Ion Proton”).

22. Life also sells an OpenArray system that is designed to provide quantitative information regarding the relative ratios of alleles in a sample designed to detect rare alleles as well as determine low-fold copy number discrimination, mutation detection in cancer in a

heterogeneous sample, and determine the presence of cellular heterogeneity in a biological sample.

23. Life also sells cancer panels that may be used to detect mutations or allelic imbalances in various genes associated with cancer for use on the PGM and Ion Proton. An example of one such cancer panel is the Ion AmpliSeq Cancer Panel which targets mutations in KRAS, BRAF, and EGFR, among other oncogenes or tumor suppressor genes.

24. In addition to the sale of Life's sequencing devices and cancer panels, Life also provides customers with reagents and software that are intended to be used in conjunction with such equipment and products.

25. Life provides instructions to customers on how to use the systems identified above, and related reagents and software. Life instructs customers on how to use the systems identified above to detect ratios of genetic sequences or allelic imbalances in biological samples in a way that infringes the Patents-in-Suit.

26. Life advertises and promotes the use of the SOLiD system, the OpenArray system, the PGM, and the Ion Proton in conjunction with the corresponding reagents and software sold by Life.

27. For example, the PGM has been used by Life customers for detecting ratios of genetic sequences or allelic imbalances in a biological sample. In practice, Life instructs customers to use the PGM and the Ion AmpliSeq Cancer Panel to determine the amount of an allele or particular sequence in a patient sample and determine whether a mutation existed in the patient sample and Life customers follow Life's instructions. These activities by Life customers and others directly infringe the '706 patent, the '889 patent, and the '015 patent (the "Patents-in-Suit") and Life's encouragement of these activities through, among other things, sponsorship of

the research, sale of the systems, and instructions indirectly infringe the Patents-in-Suit.

Furthermore, Life knew and intended that the activities by its customers infringed the Patents-in-Suit.

28. Life has and has had actual knowledge of the Patents-in-Suit during times relevant to this action through at least its research, development, and/or patent application activities. For example, prior to the filing of this lawsuit, Life inquired about a possible license to the Patents-in-Suit. On July 31, 2009, Life contacted EGL's predecessor in interest, Exact Science, and inquired about a license to the Vogelstein patent family. Life indicated that it was specifically interested in the field of DigitalPCR-related applications for oncological studies. Life has continued these discussions with EGL and its predecessor in interest, Genzyme Genetics, until April 2012. Moreover, Life has knowledge of the Patents-in-Suit through the filing of this Complaint.

29. Life had actual knowledge that the Patents-in-Suit claimed methods for the detection of ratios of genetic sequences and/or determination of allelic differences through its knowledge of the Vogelstein patent family and Life's request for a license to the Vogelstein patent family. Life also had actual knowledge that its products, including the OpenArray system, the SOLiD system, the PGM, the Ion Proton, and related reagents, cancer panels, and software ("Life products"), detect ratios of genetic sequences and/or determine allelic differences. The claims of the Patents-in-Suit plainly cover detecting ratios of genetic sequences and determining allelic differences and a reasonable person would know that systems and methods, such as those made, sold, and supported by Life, that detected ratios of genetic sequences and determined allelic differences would infringe the Patents-in-Suit. Life provides instruction manuals and application notes that instruct users on how to use Life products to detect ratios of genetic

sequences and/or determine allelic differences in accordance with the claims of the Patents-in-Suit. Life was aware of the objectively high likelihood that the use of the Life products in the matter instructed would result in an infringement of the Patents-in-Suit. Indeed, Life asked about a license to the Patents-in-Suit indicating that it in fact knew that there was an objectively high likelihood that the use of its products infringed the Patents-in-Suit. Life is a sophisticated and experienced technology and life science company and has experience in patent matters. Life's sale, offer for sale, and use of Life products, and its inducement of its customers to infringe, in view of Life's knowledge of the Patents-in-Suit and this objectively high likelihood, was in reckless disregard of EGL's rights.

30. Life's activities outlined above, and identified further below, directly and indirectly infringe the Patents-in-Suit.

### **COUNT I**

#### **(Direct and Indirect Infringement of United States Patent No. 6,440,706 by Life)**

31. EGL and JHU reallege and incorporates herein by reference the allegations stated in paragraphs 1-30 of this Complaint.

32. Life has infringed and continues to directly infringe the '706 patent in violation of 35 U.S.C. § 271(a). For example, Life uses and has used methods within the United States for the detection of ratios of genetic sequences in a biological sample, for example, through use of the OpenArray system, the SOLiD system, the PGM, the Ion Proton, and related reagents, cancer panels, and software, that infringe the claims of the '706 patent.

33. Life has induced and continues to induce the infringement of the '706 patent in violation of 35 U.S.C. § 271(b). Life does so by knowingly and intentionally making, offering for sale, and selling, for example, the OpenArray system, the SOLiD system, the PGM, Ion

Proton, and related reagents, cancer panels, and software, the use of which by Life's customers directly infringes the '706 patent. Life was aware of and encourages its customers to use Life products in a manner that infringes the '706 patent, and Life intended to cause that infringement. For example, Life provides instruction manuals and application notes for the noted systems, reagents, cancer panels, and software that instruct users on using methods for the detection of ratios of genetic sequences in a biological sample or tissue as claimed in the '706 patent with the intent that users carry out action that infringes the '706 patent. As another example, Life supplies cancer panels for use with the PGM that, when used according to Life's provided instructions, causes Life's customers to carry out methods that infringe the '706 patent. Life has thus induced direct infringement of the '706 patent by others by actively instructing, assisting, and/or encouraging others to practice one or more of the methods claimed in the '706 patent in violation of 35 U.S.C. § 271(b).

34. The infringement by Life of the '706 patent is willful and deliberate as shown by Life's conduct as alleged in at least paragraphs 28 and 29.

35. On information and belief, the infringement of the '706 patent by Life will continue unless and until it is enjoined by this Court.

36. EGL and JHU have been and continue to be damaged by Life's infringement of the '706 patent.

## **COUNT II**

### **(Direct and Indirect Infringement of United States Patent No. 7,824,889 by Life)**

37. EGL and JHU reallege and incorporates herein by reference the allegations stated in paragraphs 1-36 of this Complaint.

38. Life has infringed and continues to directly infringe the '889 patent in violation of 35 U.S.C. § 271(a). For example, Life uses and has used methods within the United States for the detection of allelic imbalances in a biological sample, for example, through use of the OpenArray system, the SOLiD system, the PGM, the Ion Proton, and related reagents, cancer panels, and software, that infringe the claims of the '889 patent.

39. Life has induced and continues to induce the infringement of the '889 patent in violation of 35 U.S.C. § 271(b). Life does so by knowingly and intentionally making, offering for sale, and selling, for example, the OpenArray system, the SOLiD system, the PGM, Ion Proton, reagents, cancer panels, and software, the use of which by Life's customers directly infringes the '889 patent. Life was aware of and encourages its customers to use Life products in a manner that infringes the '889 patent, and Life intended to cause that infringement. For example, Life provides instruction manuals and application notes for the noted systems, reagents, cancer panels, and software that instruct users on using methods for the detection of allelic imbalances in a biological sample or tissue as claimed in the '889 patent with the intent that users carry out action that infringes the '889 patent. As another example, Life supplies cancer panels for use with the PGM that, when used as instructed by Life, causes Life's customers to carry out methods that infringe the '889 patent. Life has thus induced direct infringement of the '889 patent by others by actively instructing, assisting, and/or encouraging others to practice one or more of the methods claimed in the '889 patent in violation of 35 U.S.C. § 271(b).

40. The infringement by Life of the '889 patent is willful and deliberate as shown by Life's conduct as alleged in at least paragraphs 28 and 29.

41. On information and belief, the infringement of the '889 patent by Life will continue unless and until it is enjoined by this Court.

42. EGL and JHU have been and continue to be damaged by Life's infringement of the '889 patent.

### **COUNT III**

#### **(Direct and Indirect Infringement of United States Patent No. 7,915,015 by Life)**

43. EGL and JHU reallege and incorporates herein by reference the allegations stated in paragraphs 1-42 of this Complaint.

44. Life has infringed and continues to directly infringe the '015 patent in violation of 35 U.S.C. § 271(a). For example, Life uses and has used methods within the United States for the detection of allelic imbalances in a biological sample, for example, through use of the OpenArray system, the SOLiD system, the PGM, the Ion Proton, and related reagents, cancer panels, and software, that infringe the claims of the '015 patent.

45. Life has induced and continues to induce the infringement of the '015 patent in violation of 35 U.S.C. § 271(b). Life does so by knowingly and intentionally making, offering for sale, and selling, for example, the OpenArray system, the SOLiD system, the PGM, Ion Proton, reagents, cancer panels, and software, the use of which by Life's customers directly infringes the '015 patent. Life was aware of and encourages its customers to use Life products in a manner that infringes the '015 patent, and Life intended to cause that infringement. For example, Life provides instruction manuals and application notes for the noted systems, reagents, cancer panels, and software that instruct users on using methods for the detection of allelic imbalances in a biological sample or tissue as claimed in the '015 patent with the intent that users carry out action that infringes the '015 patent. As another example, Life supplies cancer panels for use with the PGM that, when used as instructed by Life, causes Life's customers to carry out methods that infringe the '015 patent. Life has thus induced direct infringement of the

'015 patent by others by actively instructing, assisting, and/or encouraging others to practice one or more of the methods claimed in the '015 patent in violation of 35 U.S.C. § 271(b).

46. The infringement by Life of the '015 patent is willful and deliberate as shown by Life's conduct as alleged in at least paragraphs 28 and 29.

47. On information and belief, the infringement of the '015 patent by Life will continue unless and until it is enjoined by this Court.

48. EGL and JHU have been and continue to be damaged by Life's infringement of the '015 patent.

#### **PRAYER FOR RELIEF**

WHEREFORE, EGL and JHU pray that this Court:

- A. Enter a judgment that Life has directly infringed each of the Patents-in-Suit;
- B. Enter a judgment that Life has induced the infringement of each of the Patents-in-Suit;
- C. Grant a permanent injunction restraining and enjoining Life, its officers, directors, agents, servants, employees, successors, assigns, parents, subsidiaries, affiliated or related companies, and attorneys from directly or indirectly infringing the Patents-in-Suit;
- D. Award EGL and JHU damages in an amount sufficient to compensate EGL and JHU for Life's infringement of the Patents-in-Suit, but not less than a reasonable royalty;
- E. Award prejudgment interest to EGL and JHU pursuant to 35 U.S.C. § 284;
- F. Award increased damages, pursuant to 35 U.S.C. § 284, in an amount not less than three times the amount of actual damages awarded to EGL and JHU, by reason of Life's willful infringement of the Patents-in-Suit;

G. Declare this case exceptional under 35 U.S.C. § 285 and award EGL and JHU their reasonable attorneys' fees, expenses and costs incurred in this action; and

H. Grant such other and further relief as this Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

EGL and JHU hereby demand a jury trial on all issues appropriately triable by a jury.

Dated: October 31, 2012

Respectfully submitted,

/s/ Steve Gardner

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