

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

Esoterix Genetic Laboratories, LLC,)	
)	
Plaintiff,)	
)	
vs.)	Civil Action No. 12-cv-411
)	
Life Technologies Corporation, Applied)	
Biosystems, LLC, and Ion Torrent)	JURY TRIAL DEMANDED
Systems, Inc.,)	
)	
Defendants.)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Esoterix Genetic Laboratories, LLC (“EGL”) for its complaint against Defendants Life Technologies Corporation (“Life Technologies”), Applied Biosystems, LLC (“Applied Biosystems”), and Ion Torrent Systems, Inc. (“Ion Torrent”), alleges 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 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. 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.

4. 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.

5. 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

6. 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).

7. 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.

8. 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.

9. 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.

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

THE PATENTS-IN-SUIT

11. EGL is the assignee of United States Patent No. 5,670,325 (hereinafter referred to as “the ’325 patent”), which duly and legally issued on September 23, 1997 and is entitled “Method for the Detection of Clonal Populations of Transformed Cells in a Genomically Heterogeneous Cellular Sample.” A true and correct copy of the ’325 patent is attached to this Complaint as Exhibit 1.

12. The ’325 patent relates generally to methods for detecting certain cells, cancer, lesions, or a change in a biological sample or tissue.

13. EGL is the assignee of United States Patent No. 5,882,856 (hereinafter referred to as “the ’856 patent”), which duly and legally issued on March 16, 1999 and is entitled “Universal Primer Sequence for Multiplex DNA Amplification.” A true and correct copy of the ’856 patent is attached to this Complaint as Exhibit 2.

14. The ’856 patent generally relates to DNA primers and methods for the detection and amplification of DNA sequences and related products.

15. EGL is the assignee of United States Patent No. 6,207,372 (hereinafter referred to as “the ’372 patent”), which duly and legally issued on March 27, 2001 and is entitled “Universal Primer Sequence for Multiplex DNA Amplification.” A true and correct copy of the ’372 patent is attached to this Complaint as Exhibit 3.

16. The '372 patent generally relates to DNA primers and the use of such primers for the detection and amplification of DNA sequences and related products.

ACCUSED INFRINGERS

17. Defendant Life Technologies is a biotechnology company that sells various products, kits, and devices, 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 certain cells, cancer, lesions, or changes in a biological sample or tissue. Further, Life sells various products, kits, and devices that contain DNA primers for use in the detection and amplification of DNA sequences and related products.

18. 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").

19. Life also sells an OpenArray system that is designed to provide quantitative information regarding rare alleles, low-fold copy number discrimination, and mutation detection in cancer in a heterogeneous sample, as well as to conduct analysis of cellular heterogeneity on a biological sample.

20. Life also sells cancer panels that may be used to detect subpopulations of transformed cells or mutations 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.

21. 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.

22. Life provides instructions to customers on how to use the systems identified above, universal primer sequences, and related reagents and software.

23. 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.

24. For example, the PGM has been used by Life customers for detecting certain cells, cancer, lesions or changes in a biological sample or tissue. In practice, Life customers have used the PGM and the Ion AmpliSeq Cancer Panel to determine the amount of an allele or particular sequence in a patient sample and determined whether a mutation existed in the patient sample. The PGM and Ion AmpliSeq Cancer Panel employs emulsion PCR which utilizes DNA primers that allow for multiplex DNA amplification. These activities and others directly infringe the '325 patent, the '856 patent, and the '372 patent (the "Patents-in-Suit"). Life encourages these activities through, among other things, sponsorship of the research, sale of the systems, and instructions, and knew and intended that the activities by its customers infringed the Patents-in-Suit.

25. 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. In addition, and prior to the filing of this lawsuit, Life inquired about a possible license to the '325 patent from Exact Sciences Corporation, from whom EGL obtained the '325 patent. Moreover, Life has knowledge of the Patents-in-Suit through the filing of this Complaint.

26. 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. 5,670,325 by Life)

27. EGL realleges and incorporates herein by reference the allegations stated in paragraphs 1-26 of this Complaint.

28. Life has directly infringed and continues to directly infringe the '325 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 certain cells, cancer, lesions or changes in a biological sample or tissue, for example, through use of the OpenArray system, the SOLiD system, the PGM, the Ion Proton, and related reagents and software, that infringe the claims of the '325 patent.

29. Life has induced and continues to induce the infringement of the '325 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, and software, the use of which by Life's customers directly infringes the '325 patent. Life was aware of and encourages its customers to use Life products in a manner that infringes the '325 patent, and Life intended to cause that infringement. For example, Life provides instruction manuals and application notes for the noted systems, reagents, and software that instruct users on using methods for the detection of certain cells, cancer, lesions, or changes in a biological sample or tissue as claimed in the '325 patent with the intent that users carry out action that infringes the '325 patent. Life has thus induced direct infringement of the '325 patent

by others by actively instructing, assisting, and/or encouraging others to practice one or more of the methods claimed in the '325 patent in violation of 35 U.S.C. § 271(b).

30. Life has contributed to and continues to contribute to the infringement of the '325 patent in violation of 35 U.S.C. § 271(c) by offering for sale, selling, or providing one or more items which constitute a material part of the inventions defined by the claims of the '325 patent, including for example, the OpenArray system, the SOLiD system, the PGM, and the Ion Proton, and including their related reagents and software, knowing that the same were especially made or adapted for use in an infringement of the '325 patent, which components are not staple articles or commodities of commerce suitable for substantial non-infringing use, in violation of 35 U.S.C. § 271(c). For example, Life knowingly and intentionally sells the noted systems, software, reagents, and cancer panels, which are especially made for use in methods for the detection of certain cells, cancer, lesions or changes in a biological sample or tissue, knowing that such systems, software, reagents, and cancer panels will be used in methods that infringe the '325 patent.

31. The infringement by Life of the '325 patent is willful and deliberate.

32. On information and belief, the infringement of the '325 patent by Life will continue unless and until it is enjoined by this Court.

33. EGL has been and continues to be damaged by Life's infringement of the '325 patent.

COUNT II

(Direct and Indirect Infringement of United States Patent No. 5,882,856 by Life)

34. EGL realleges and incorporates herein by reference the allegations stated in paragraphs 1-33 of this Complaint.

35. Life has directly infringed and continues to directly infringe the '856 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and selling DNA primers for the detection and amplification of DNA sequences and related products as claimed in the '856 patent. For example, Life sells such primers that infringe claims of the '856 patent for use in systems, including for example, the SOLiD system, the PGM, and the Ion Proton system.

36. Life has induced and continues to induce the infringement of the '856 patent in violation of 35 U.S.C. § 271(b). Life does so, for example, by knowingly and intentionally making, offering for sale, and selling DNA primers for the detection and amplification of DNA sequences, the use of which by Life's customers directly infringes the '856 patent. Life was aware of the '856 patent and encouraged its customers to use the DNA primers in a manner that infringes the '856 patent and intended to cause that infringement. For example, Life provides instruction manuals and application notes that instruct users how to use the DNA primers in methods for screening to simultaneously detect amplification products of multiple target DNA samples as claimed in the '856 patent with the intent that users carry out the action that infringe the '856 patent. Life has thus induced direct infringement of the '856 patent by others by actively instructing, assisting and/or encouraging others to practice one or more of the methods claimed in the '856 patent in violation of 35 U.S.C. § 271(b).

37. Life has contributed to and continues to contribute to the infringement of the '856 patent in violation of 35 U.S.C. § 271(c) by offering for sale, selling, or providing one or more items which constitute a material part of the inventions defined by the claims of the '856 patent, including for example, DNA primers for use in practicing methods for screening to simultaneously detect amplification products of multiple target DNA sequences using, for example, the SOLiD system, the PGM, and the Ion Proton (including their related reagents and

software), knowing that the same have been especially made or adapted for use in an infringement of the '856 patent, which components are not staple articles or commodities of commerce suitable for substantial non-infringing use, in violation of 35 U.S.C. §271(c). For example, Life knowingly and intentionally sells the noted DNA primers for use in the noted systems, which are especially made for use in methods for screening to simultaneously detect amplification products of multiple target DNA samples, knowing that such DNA primers will be used in methods that infringe the '856 patent.

38. The infringement by Life of the '856 patent is willful and deliberate.

39. On information and belief, Life will continue to infringe the '856 patent unless and until it is enjoined by this Court.

40. EGL has been and continues to be damaged by Life's infringement of the '856 patent.

COUNT III

(Direct and Indirect Infringement of United States Patent No. 6,207,372 by Life)

41. EGL realleges and incorporates herein by reference the allegations stated in paragraphs 1-40 of this Complaint.

42. Life has directly infringed and continues to directly infringe the '372 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and selling DNA primers for the detection and amplification of DNA sequences and related products. For example, Life sells the DNA primers that infringe claims of the '372 patent for use in the noted systems, including the SOLiD system, the PGM, and the Ion Proton system.

43. Life has induced and continues to induce the infringement of the '372 patent in violation of 35 U.S.C. § 271(b). Life does so, for example, by knowingly and intentionally

making, offering for sale, and selling DNA primers for the detection and amplification of DNA sequences and related products, the use of which by Life's customers directly infringes the '372 patent. Life is aware of and encourages its customers to use the DNA primers in a manner that infringes the '372 patent, and Life intended to cause that infringement. For example, Life provides instruction manuals and application notes for the noted systems that details the use of the DNA primers with the intent that the users use the DNA primers. Life has thus induced direct infringement of the '372 patent by others by actively instructing, assisting and/or encouraging others to use the DNA primers claimed in the '372 patent in violation of 35 U.S.C. § 271(b).

44. Life has contributed to and continues to contribute to the infringement of the '372 patent in violation of 35 U.S.C. § 271(c) by offering for sale, selling, or providing one or more items which constitute a material part of the inventions defined by the claims of the '372 patent, including for example, DNA primers for use in practicing methods for screening to simultaneously detect amplification products of multiple target DNA sequences using, for example, the SOLiD system, the PGM, and the Ion Proton, and including their related reagents and software, knowing that the same have been especially made or adapted for use in an infringement of the '372 patent, which components are not staple articles or commodities of commerce suitable for substantial non-infringing use in violation of 35 U.S.C. § 271(c). For example, Life knowingly and intentionally sells the noted DNA primers for use in the noted systems, which are especially made for use in a manner that infringes the '372 patent.

45. The infringement by Life of the '372 patent is willful and deliberate.

46. On information and belief, Life will continue to infringe the '372 patent unless and until it is enjoined by this Court.

47. EGL has been and continues to be damaged by Life's infringement of the '372 patent.

PRAYER FOR RELIEF

WHEREFORE, EGL prays 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. Enter a judgment that Life has contributed to the infringement of each of the Patents-in-Suit;
- D. 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;
- E. Award EGL damages in an amount sufficient to compensate EGL for Life's infringement of the Patents-in-Suit, but not less than a reasonable royalty;
- F. Award prejudgment interest to EGL pursuant to 35 U.S.C. § 284;
- G. 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, by reason of Life's willful infringement of the Patents-in-Suit;
- H. Declare this case exceptional under 35 U.S.C. § 285 and award EGL its reasonable attorneys' fees, expenses and costs incurred in this action; and
- I. Grant such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

EGL hereby demands a jury trial on all issues appropriately triable by a jury.

Respectfully submitted,

Dated: April 26, 2012

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