UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ESOTERIX GENETIC LABORATORIES LLC, Plaintiff, -against- QIAGEN N.V., QIAGEN GMBH, QIAGEN NORTH AMERICAN HOLDINGS, INC., QIAGEN INC., and QIAGEN MANCHESTER, LTD., Defendants.	CASE NO. 14-cv-13228 **AMENDED COMPLAINT**

Plaintiff Esoterix Genetic Laboratories, LLC ("Plaintiff" or "EGL"), by its undersigned counsel, as and for its Complaint against Qiagen N.V., Qiagen GmbH, Qiagen North American Holdings, Inc., Qiagen Inc., and Qiagen Manchester, Ltd. (collectively "Defendants" or "Qiagen"), alleges as follows.

NATURE OF THE ACTION

1. Plaintiff brings this action against Qiagen for damages arising out of Qiagen's patent infringement, violation of the Massachusetts Unfair and Deceptive Trade Practices Act, breach of contract, and breach of the covenant of good faith and fair dealing based on Qiagen's sale of certain products prior to FDA approval and beyond the scope of a November 26, 2008 License Agreement to which both Qiagen N.V. and EGL are successors in interest (the "License Agreement").

THE PARTIES

2. Plaintiff EGL is a wholly-owned subsidiary of Laboratory Corporation of America Holdings ("LabCorp"), a corporation organized under the laws of the State of Delaware

with its principal place of business located at 358 South Main Street, Burlington, North Carolina. EGL is licensed to do business in the Commonwealth of Massachusetts and has its primary office there.

3. Upon information and belief, defendant Qiagen N.V. is a company organized under the laws of The Netherlands.

4. Upon information and belief, defendant Qiagen GmbH is a German company.

5. Upon information and belief, defendant Qiagen GmbH is a wholly owned subsidiary of Qiagen N.V.

6. Upon information and belief, defendant Qiagen North American Holdings, Inc. is a corporation organized under the laws of California with its principal place of business in Germantown, Maryland.

7. Upon information and belief, defendant Qiagen North American Holdings, Inc. is licensed to do business in the Commonwealth of Massachusetts.

8. Upon information and belief, defendant Qiagen North American Holdings, Inc. is a wholly owned subsidiary of Qiagen N.V.

9. Upon information and belief, defendant Qiagen Inc. is a corporation organized under the laws of California with its principal place of business in Germantown, Maryland.

10. Upon information and belief, defendant Qiagen Inc. is licensed to do business in the Commonwealth of Massachusetts.

11. Upon information and belief, defendant Qiagen Inc. is a wholly owned subsidiary of Qiagen North American Holdings, Inc.

12. Upon information and belief, defendant Qiagen Manchester, Ltd., formerly known as DxS Ltd., is an English company.

13. Upon information and belief, defendant Qiagen Manchester, Ltd. is a wholly owned subsidiary of Qiagen N.V.

14. Qiagen GmbH, Qiagen North American Holdings, Inc., Qiagen Inc., and Qiagen Manchester, Ltd. have acted and continue to act as Qiagen N.V.'s agent and/or alter-ego with respect to the License Agreement.

JURISDICTION, VENUE AND GOVERNING LAW

15. Pursuant to Paragraph 10(g) of the License Agreement, the License Agreement is to be "governed by and construed in accordance with the laws of the Commonwealth of Massachusetts irrespective of any conflicts of law principles."

16. This Court has jurisdiction over this action based on diversity of citizenship pursuant to 28 U.S.C. § 1332. The amount in controversy, exclusive of interest and costs, is in excess of $75,000. This Court also has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

17. Venue and jurisdiction is proper in this district under 28 U.S.C. § 1391(a), (b) & (c) and § 1400 because Qiagen does business within this jurisdiction, a substantial portion of events giving rise to this action occurred within the Commonwealth of Massachusetts and Defendant has committed one or more acts of infringement in this district.

THE FACTS

18. In 2008, non-party Genzyme Corporation ("Genzyme") entered into the License Agreement with non-party DxS, Ltd. ("DxS"), a United Kingdom-based company, to allow DxS to manufacture and sell certain products utilizing certain patents set forth in Schedule

A to the License Agreement, including, but not limited to, U.S. Patent No. 7,294,468 (the "'468 Patent"), International Patent Application No. PCT/US2005/010645, and Canadian Patent Application No. 2,566,277 (collectively, the "Patents"), which provide for a method of detecting the presence of epidermal growth factor receptor or EGFR, in exchange for a royalty payment to Genzyme as calculated by the License Agreement.

19. EGFR activating gene mutations, when present, are predictive of the efficacy of certain chemotherapeutic treatments for lung cancer and other diseases.

20. In or around September 2009, Qiagen N.V. acquired DxS and, upon information and belief, as a result of the acquisition, assumed all rights and obligations under the License Agreement.

21. In or around December 2010, by way of an Asset Purchase Agreement LabCorp purchased certain assets from Genzyme, including substantially all of Genzyme's genetics testing business, including Genzyme's rights under the License Agreement and rights to the Patents (collectively with the other assets, "the Purchased Assets").

22. At the time of the purchase by LabCorp, Genzyme was a Massachusetts corporation with its principal place of business in Massachusetts.

23. In or around the time LabCorp entered into the Asset Purchase Agreement, it created EGL as a wholly-owned subsidiary to control the Purchased Assets. EGL's operations regarding the Purchased Assets were and still are located in Massachusetts.

24. EGL, therefore, is a successor in interest to the License Agreement and has all right, title and interest in the Patents.

25. The License Agreement granted Qiagen N.V. a non-exclusive sublicense to the Patent Rights, but subject to certain limitations.

26. For example, the License Agreement granted Qiagen N.V. limited rights to Licensed Products and Licensed Research Products.

27. The License Agreement defined Licensed Product(s) as:

> any article, device or composition designed for use in the Field to determine, in a patient sample, the presence or absence of specific nucleic acid variance(s) in the kinase domain of the EGFR gene for the purpose of determining the effectiveness of an EGFR targeting treatment in a patient, including reporting results thereof to a patient and/or physician, which cannot be manufactured, used, offered for sale, or sold, in whole or part without infringing one or more Valid claims under the Patent Rights and that comprises: (i) any kit, chemical and or biological reagent, or combination of chemical and/or biological reagents, testing materials and accessories sold together or separately, which are designed to detect EGFR mutations, and/or (ii) one or more analyte specific reagents sold for use in screening, chemical or biological reagents, testing materials, accessories and point of care instructions, packed and sold collectively as a sing product unit designed, promoted, marketed and sold for use as an in vitro diagnostic test.

28. Licensed Research Product(s), in turn, was defined to mean:

> any article, device or composition designed for use the Field to determine, in a sample, the presence or absence of specific nucleic acid variance(s) in the kinase domain of the EGFR gene which cannot be manufactured, used, offered for sale or sold, in whole or in part, without infringing one or more Valid Claims under the Patent Rights and that comprises: (i) one or more analyte specific reagents, and/or (ii) a combination of chemicals and/or biological reagents, testing materials, accessories and instructions packed and sold collectively as a single product unit for research use only as an *in vitro* Licensed Research Product.

29. Section 1.9 of the License Agreement specifically defined the "Field" for Licensed Research Products to mean "non-commercial research use only."

30. Per the License Agreement, until regulatory approval could be had for the EGFR mutation testing kit (the "Test Kit"), Qiagen N.V. had the right to offer for sale and to sell Licensed Research Products only and was expressly prohibited from offering EGFR Test Kits for commercial research and diagnostic testing purposes. In other words, Qiagen N.V.'s license for

EGFR testing, prior to regulatory approval, was limited to the sale of analyte specific reagents and/or combinations of chemicals, testing materials, accessories and instructions sold as a single product for non-commercial research uses only.

31. The License Agreement provides:

> 2.1 License Grant. Subject to the terms of this Agreement, Genzyme hereby grants to Licensee for use in the Field a non-exclusive license (without the right to grant sublicenses), under the Patent Rights:
>
> (b) to make sell offer for sale or have sold Licensed Research Products in the Territory. For the avoidance of doubt, Licensed Research Products shall not be manufactured, offered for sale or sold, in whole or part, for use in any clinical diagnostics with patient samples including reporting results thereof to a patient and/or physician, e.g. to determine the effectiveness of an EGFR targeting treatment in a patient.

32. Any sale of Licensed Research Products for commercial research and diagnostic testing purposes in the form of Test Kits or otherwise, by Qiagen prior to regulatory approval would be in violation of the License Agreement and EGL's patent rights.

33. During the same time period that Qiagen N.V. had the right to offer Licensed Research Products to third parties, EGL had the exclusive right to offer EGFR testing for commercial research and diagnostic testing purposes to determine the effectiveness of an EGFR targeting treatment in a patient.

34. During the term of the License Agreement, and prior to regulatory approval, Qiagen paid EGL royalties based on its purported sales of Licensed Research Products into the market.

35. For example, in 2011 and 2012, based on the royalties paid, Qiagen sold approximately 22,000 and 38,000 Test Kits, which it represented were for research only non-commercial purposes.

36. Upon information and belief, a substantial number of sales for these and other years were not for non-commercial research only purposes but rather were offered by Qiagen for commercial research and diagnostic testing purposes in violation of the License Agreement.

37. Regulatory approval for the Test Kit was received in or around July 2013. It was only at that point that Qiagen N.V. acquired the right to offer for sale and to sell Licensed Products as opposed to Licensed Research Products.

38. All sales of Test Kits for commercial research and diagnostic testing purposes by Qiagen prior to July 2013 were in violation of the License Agreement and the non-exclusive Patent Rights held by Qiagen N.V. as a sublicensee under the License Agreement.

39. Upon information and belief, many of Qiagen's sales in violation of the License Agreement took place in Massachusetts.

40. Upon information and belief, Qiagen has conducted business activities relating to the Licensing Agreement including, but not limited to, marketing and sales of Test Kits in Massachusetts and elsewhere.

41. Qiagen has communicated with EGL and LabCorp regarding the License Agreement (including regarding Qiagen's performance and breaches of the License Agreement) through Qiagen GmbH and Qiagen Manchester, Ltd. in Massachusetts.

42. Royalty reports sent pursuant to the Licensing Agreement were sent from Qiagen Manchester, Ltd. to EGL in Massachusetts.

43. Upon information and belief, Qiagen Manchester, Ltd. performed Qiagen N.V.'s obligation in the License Agreement to obtain FDA approval for the Test Kit.

44. Upon information and belief, Qiagen's sales of Test Kits for commercial research and diagnostic testing purposes prior to regulatory approval were made by employees, agents and/or representatives of Qiagen North American Holdings, Inc. and/or Qiagen Inc. in Massachusetts and elsewhere.

COUNT I.

PATENT INFRINGEMENT

45. The allegations of paragraphs 1 through 41 are incorporated as if set forth fully herein.

46. Qiagen has offered to sell and has, in fact, sold in the United States Test Kits for uses which were specifically excluded from the scope of the permissions granted to Qiagen N.V. under the License Agreement.

47. Qiagen has offered to sell and has, in fact, sold to others ("Qiagen Customers") in the United States, Test Kits for Qiagen Customers to use in ways which were specifically excluded from the scope of the permissions granted to Qiagen N.V. under the License Agreement.

48. Qiagen has offered to sell and has, in fact, sold to Qiagen Customers in the United States Test Kits for Qiagen Customers to use in ways which are covered by one or more claims of the '468 Patent and related patents.

49. Qiagen has used Licensed Research Products in ways which were specifically excluded from the scope of the permissions granted to Qiagen N.V. under the License Agreement.

50. Qiagen has offered to sell and has, in fact, sold in the United States Test Kits for commercial research and diagnostic testing purposes before regulatory approval was

obtained for uses which were specifically excluded from the scope of the permissions granted to Qiagen N.V. under the License Agreement.

51. Qiagen has offered to sell and has, in fact, sold to Qiagen Customers in the United States Test Kits for commercial research and diagnostic testing purposes before regulatory approval was obtained for Qiagen Customers to use in ways which were specifically excluded from the scope of the permissions granted to Qiagen N.V. under the License Agreement.

52. Qiagen has offered to sell and has, in fact, sold to Qiagen Customers in the United States Test Kits for commercial research and diagnostic testing purposes before regulatory approval was obtained for Qiagen Customers to use in ways which are covered by one or more claims of the '468 Patent and related patents.

53. Qiagen has used Test Kits for commercial research and diagnostic testing purposes before regulatory approval was obtained in ways which were specifically excluded from the scope of the permissions granted to Qiagen N.V. under the License Agreement.

54. The foregoing actions constitute infringement by Qiagen of one or more claims of the '468 Patent and related patents.

55. The foregoing actions constitute active inducement of infringement by Qiagen of one or more claims of the '468 Patent and related patents.

56. The foregoing actions constitute contribution by Qiagen to the infringement by Qiagen Customers of one or more claims of the '468 Patent and related patents.

57. EGL has suffered a financial loss in Massachusetts as a result of Qiagen's actions as alleged herein.

58. EGL has been damaged in Massachusetts as a result of Qiagen's actions as alleged herein.

COUNT II.

VIOLATION OF MASSACHUSETTS GENERAL LAWS CHAPTER 93A

59. The allegations of paragraphs 1 through 58 are incorporated as if set forth fully herein.

60. At all times relevant to this action, EGL and Qiagen were engaged in trade or commerce.

61. Pursuant to the License Agreement, before regulatory approval of the Test Kit was obtained, Qiagen N.V. had the right to offer for sale and to sell Licensed Research Products only.

62. Qiagen was and is aware of Qiagen N.V.'s limited rights under the License Agreement to offer for sale and to sell Test Kits only before regulatory approval of the Test Kit was obtained.

63. Pursuant to the License Agreement, Qiagen N.V. also had the right to offer for sale and to sell Test Kits for commercial research and diagnostic testing purposes only after regulatory approval of the Test Kit was obtained.

64. Qiagen was and is aware of Qiagen N.V.'s limited rights under the License Agreement to offer for sale and to sell Test Kits for commercial research and diagnostic testing purposes only after regulatory approval of the Test Kit had been obtained.

65. Qiagen acted in bad faith by offering Test Kits for sale for commercial research and diagnostic testing purposes before regulatory approval of the Test Kit was obtained.

66. Qiagen acted in bad faith by selling Test Kits for commercial research and diagnostic testing purposes before regulatory approval of the Test Kit was obtained.

67. By offering Test Kits for commercial research and diagnostic testing purposes for sale before regulatory approval of the Test Kit was obtained, Qiagen willfully and knowingly disregarded and repudiated Qiagen N.V.'s known contractual arrangements under the License Agreement and exceeded the scope of Qiagen N.V.'s rights under the License Agreement.

68. By selling Test Kits for commercial research and diagnostic testing purposes before regulatory approval of the Test Kit was obtained, Qiagen willfully and knowingly disregarded and repudiated Qiagen N.V.'s known contractual arrangements under the License Agreement and exceeded the scope of Qiagen N.V.'s rights under the License Agreement.

69. By offering for sale Test Kits for commercial research and diagnostic testing purposes before regulatory approval of the Test Kit was obtained, Qiagen intended to and did obtain the benefit of EGL's express retention in the License Agreement of the exclusive right to offer EGFR testing for commercial purposes to determine the effectiveness of an EGFR targeting treatment in a patient prior to regulatory approval.

70. By selling Test Kits for commercial research and diagnostic testing purposes before regulatory approval of the Test Kit was obtained, Qiagen intended to and did obtain the benefit of EGL's express retention in the License Agreement of the exclusive right to offer EGFR testing for commercial purposes to determine the effectiveness of an EGFR targeting treatment in a patient prior to regulatory approval.

71. EGL has suffered a financial loss in Massachusetts as a result of Qiagen's actions as alleged herein.

72. EGL has been damaged in Massachusetts as a result of Qiagen's actions as alleged herein.

COUNT III.

BREACH OF CONTRACT

73. The allegations of paragraphs 1 through 72 are incorporated as if set forth fully herein.

74. Pursuant to the License Agreement, before regulatory approval of the Test Kit was obtained, Qiagen N.V. had the right to offer for sale and to sell Licensed Research Products only.

75. Pursuant to the License Agreement, Qiagen N.V. also had the right to offer for sale and to sell Test Kits for commercial research and diagnostic testing purposes only after regulatory approval of the Test Kit was obtained.

76. Qiagen breached the Licensing Agreement by offering Test Kits for sale for commercial research and diagnostic testing purposes before regulatory approval of the Test Kit was obtained.

77. Qiagen also breached the Licensing Agreement by selling Test Kits for commercial research and diagnostic testing purposes before regulatory approval of the Test Kit was obtained.

78. EGL has been damaged in Massachusetts as a result of Qiagen's actions as alleged herein.

COUNT IV.

BREACH OF THE DUTY OF GOOD FAITH AND FAIR DEALING

79. The allegations of paragraphs 1 through 78 are incorporated as if set forth fully herein.

80. Pursuant to the License Agreement, before regulatory approval of the Test Kit was obtained, Qiagen N.V. had the right to offer for sale and to sell Licensed Research Products only.

81. Qiagen was and is aware of Qiagen N.V.'s limited rights under the License Agreement to offer for sale and to sell Test Kits only before regulatory approval of the Test Kit was obtained.

82. Pursuant to the License Agreement, Qiagen N.V. also had the right to offer for sale and to sell Test Kits for commercial research and diagnostic testing purposes only after regulatory approval of the Test Kit was obtained.

83. Qiagen was and is aware of Qiagen N.V.'s limited rights under the License Agreement to offer for sale and to sell Test Kits for commercial research and diagnostic testing purposes only after regulatory approval of the Test Kit had been obtained.

84. Qiagen acted in bad faith by offering for sale Test Kits for commercial research and diagnostic testing purposes before regulatory approval of the Test Kit was obtained.

85. Qiagen acted in bad faith by selling Test Kits for commercial research and diagnostic testing purposes before regulatory approval of the Test Kit was obtained.

86. By offering Test Kits for commercial research and diagnostic testing purposes for sale before regulatory approval of the Test Kit was obtained, Qiagen willfully and knowingly disregarded and repudiated Qiagen N.V.'s known contractual arrangements under the

License Agreement and exceeded the scope of Qiagen N.V.'s rights under the License Agreement.

87. By selling Test Kits for commercial research and diagnostic testing purposes before regulatory approval of the Test Kit was obtained, Qiagen willfully and knowingly disregarded and repudiated Qiagen N.V.'s known contractual arrangements under the License Agreement and exceeded the scope of Qiagen N.V.'s rights under the License Agreement.

88. By offering Test Kits for commercial research and diagnostic testing purposes for sale before regulatory approval of the Test Kit was obtained, Qiagen intended to and did obtain the benefit of EGL's express retention in the License Agreement of the exclusive right to offer EGFR testing for commercial purposes to determine the effectiveness of an EGFR targeting treatment in a patient prior to regulatory approval.

89. By Test Kits for commercial research and diagnostic testing purposes before regulatory approval of the Test Kit was obtained, Qiagen intended to and did obtain the benefit of EGL's express retention in the License Agreement of the exclusive right to offer EGFR testing for commercial purposes to determine the effectiveness of an EGFR targeting treatment in a patient prior to regulatory approval.

90. EGL has suffered a loss of money in Massachusetts as a result of Qiagen's actions as alleged herein.

91. EGL has been damaged in Massachusetts as a result of Qiagen's actions as alleged herein.

WHEREFORE, Plaintiff Esoterix Genetic Laboratories demands judgment in its favor and against Defendants Qiagen N.V., Qiagen GmbH, Qiagen North American Holdings, Inc., Qiagen Inc., and Qiagen Manchester, Ltd. as follows:

(a) Awarding compensatory damages to EGL in an amount that exceeds $75,000;

(b) Awarding double or treble damages;

(c) Awarding EGL's costs and attorney's fees;

(d) Finding that this case is an exceptional case and awarding EGL reasonable attorney's fees, pursuant to 35 U.S.C. § 285

(d) Awarding applicable interest to EGL on any judgment; and

(e) Awarding such other and further relief as this Court may deem just and appropriate.

JURY DEMAND

Wherefore Plaintiff demands a trial by jury on the within causes of action.

RESPECTFULLY SUBMITTED, this the 14th day of August, 2014.

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