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Attorneys for Plaintiff
COUNSYL, INC.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

COUNSYL, INC.,

Plaintiff,

v.

MYRIAD GENETICS, INC.; UNIVERSITY OF
UTAH RESEARCH FOUNDATION; the
TRUSTEES OF THE UNIVERSITY OF
PENNSYLVANIA; HSC RESEARCH AND
DEVELOPMENT LIMITED PARTNERSHIP;
and ENDORECHERCHE, INC.,

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5776 Defendants.

Case No. 5:13-cv-04391-EJD

Related to MDL Case No. 2:14-MD-02510-RJS
(D. Utah)

**SECOND AMENDED COMPLAINT FOR
DECLATORY JUDGMENT**

JURY TRIAL DEMANDED

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Plaintiff Counsyl, Inc. (“Counsyl”), for its Complaint against Defendants Myriad Genetics, Inc. (“Myriad”), the University of Utah Research Foundation (“U. Utah”), the Trustees of the University of Pennsylvania (“U. Penn.”); HSC Research and Development Limited Partnership (“HSC”); and Endorecherche, Inc. (“Endorecherche”) (collectively, “Defendants”) alleges as follows:

NATURE OF THE ACTION

1. This is an action brought by Counsyl to obtain declaratory judgment that Defendants have no rights against Counsyl regarding the following patents pursuant to Federal Rules of Civil Procedure 57 and 28 U.S.C. § 2201:

a. U.S. Patent No. 6,951,721, entitled “METHOD FOR DETERMINING THE HAPLOTYPE OF A HUMAN *BRCA1* GENE,” issued on October 4, 2005 (“the ’721 patent”). A true and correct copy of the ’721 patent is attached as Exhibit 3.

b. U.S. Patent No. 7,250,497, entitled “LARGE DELETIONS IN HUMAN *BRCA1* GENE AND USE THEREOF,” issued on July 31, 2007 (“the ’497 patent”). A true and correct copy of the ’497 patent is attached as Exhibit 4.

c. U.S. Patent No. 6,033,857, entitled “CHROMOSOME 13-LINKED BREAST CANCER SUSCEPTIBILITY GENE,” issued on March 7, 2000 (“the ’857 patent”). A true and correct copy of the ’857 patent is attached as Exhibit 5.

d. U.S. Patent No. 6,051,379, entitled “CANCER SUSCEPTIBILITY MUTATIONS OF *BRCA2*,” issued on April 18, 2000 (“the ’379 patent”). A true and correct copy of the ’379 patent is attached as Exhibit 6.

THE PARTIES

2. Counsyl is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 180 Kimball Way, South San Francisco, California 94080.

Counsyl is a technology company in the United States focusing on the development of genetic testing and services for various hereditary diseases and traits, including, but not limited to, the development of genetic testing and services in connection with breast and/or ovarian cancer.

3. On information and belief, Myriad is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 320 Wakara Way, Salt Lake City, Utah

84108. On information and belief, Myriad is an owner or co-owner of the '721, '497, and '379 patents and is an exclusive licensee of the '857 patent.

4. On information and belief, U. Utah is a nonprofit corporation organized and existing under the laws of the State of Utah with its principal place of business at 421 Wakara Way, Suite 170, Salt Lake City, Utah 84108. On information and belief, U. Utah is an owner or co-owner of the '857 patent.

5. On information and belief, U. Penn. is a nonprofit corporation organized and existing under the laws of the State of Pennsylvania with its principal place of business at 3160 Chestnut Street, Suite 200, Philadelphia, Pennsylvania 19104-6283. On information and belief, U. Penn. is an owner or co-owner of the '857 patent.

6. On information and belief, HSC is a Canadian limited partnership organized and existing under the laws of the Province of Ontario with its principal place of business at 555 University Avenue, Toronto, Ontario M5G 1X8, Canada. On information and belief, HSC is a co-owner of the '857 patent.

7. On information and belief, Endorecherche is a Canadian corporation organized and existing under the laws of the Province of Quebec with its principal place of business at 2989 De La Promenade, Ste-Foy, Quebec, QC G1W 2J5, Canada. On information and belief, Endorecherche is a co-owner of the '857 patent.

BACKGROUND

8. Counsyl is a technology company with the goal of making the human genome practically useful for individuals making decisions about their life, family, and health.

9. Counsyl has developed and provides genetic tests and related services related to sequencing and analysis of *BRCA1* and *BRCA2* genes.

10. Prior to the priority dates of the '721, '497, '857, and '379 patents, it was discovered that alterations in human *BRCA1* and *BRCA2* genes are associated with an increased risk of breast and/or ovarian cancer.

11. On information and belief, Defendants contend that one or more claims of the '721, '497, '857, and/or '379 patents cover isolated fragments of human *BRCA1* and *BRCA2* genes, as well as methods of using the human *BRCA1* and *BRCA2* genes to screen and/or detect alterations in those genes

1 or to diagnose a predisposition for breast and/or ovarian cancer. On information and belief, Defendants
 2 contend that one or more claims of the '721, '497, '857, and/or '379 patents cover methods of using
 3 *BRCA1* and/or *BRCA2* genes in genetic tests and related services, such as the sequencing and analysis of
 4 *BRCA1* and/or *BRCA2* genes.

5 12. Defendants have asserted that they own and/or have the sole right(s) to enforce the '721,
 6 '497, '857, and '379 patents.

7 13. Myriad itself claims that, by offering its allegedly patented testing services to breast
 8 and/or ovarian cancer patients and their family members, and by excluding any potential competitors
 9 from being able to offer women any alternatives to the Myriad test, Myriad has created an extensive
 10 database of genetic variants of *BRCA1* and *BRCA2*. Since 2005, however, Myriad has kept the vital
 11 public health information in this database a secret, and has refused to share it with healthcare workers
 12 and the public. Thus, Myriad, along with the other Defendants, have effectively hindered the medical
 13 community from being able to use patient data to further medical research and impeded the ability of
 14 clinicians to interpret genomic data.

15 14. Defendants have asserted that any company that makes, uses, sells, or offers to sell genetic
 16 tests and related services using the *BRCA1* and/or *BRCA2* genes, such as the sequencing and analysis of
 17 *BRCA1* and/or *BRCA2* genes, faces the risk of suit for infringement of one or more claims of the '721,
 18 '497, '857, and '379 patents.

19 15. Certain claims of the '857 patent have been the subject of a prior patent litigation, which
 20 culminated in the review of the validity of those claims by the Supreme Court. *Association for*
 21 *Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107, 2013 WL 2631062 (June 13, 2013). In the
 22 proceedings leading up to the Supreme Court decision, the Federal Circuit had reviewed claims 1 and 2
 23 of the '857 patent directed to methods of using human *BRCA2* genes to identify a mutant sequence and to
 24 diagnosis a predisposition for breast cancer and held that those claims are invalid for lack of patentable
 25 subject matter under 35 U.S.C. § 101. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark*
 26 *Office*, 689 F.3d 1303, 1329 (Fed. Cir. 2012). That decision was not appealed by either party.

27 16. Notwithstanding these rulings, Myriad has stated that it still intends to aggressively and
 28 vigorously enforce the '721, '497, '857, and '379 patents, along with the other Defendants, against any

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entity that makes, uses, sells, or offers to sell genetic tests and related services using the *BRCA1* and/or *BRCA2* genes, such as the sequencing and analysis of *BRCA1* and/or *BRCA2* genes.

17. Numerous clinicians and entities performing research on *BRCA1* and/or *BRCA2* genes have stated that Defendants have sent them cease and desist letters, effectively prohibiting routine screening of *BRCA1* and/or *BRCA2* genes for research or clinical practice without a license to the '721, '497, '857, and '379 patents.

18. After the Supreme Court decision, two other entities, Ambry Genetics Corp. and Gene by Gene Ltd., publicly stated on June 13, 2013, that they would begin offering their respective genetic tests and related services that included sequencing and analysis of the *BRCA1* and/or *BRCA2* genes. In response, Defendants sued Ambry and Gene by Gene on July 9, 2013, and July 10, 2013, respectively, for infringement of certain claims of the '721, '497, '857, and '379 patents. *See Univ. of Utah Research Found. v. Ambry Genetics, Inc.*, No. 2:13-cv-000640 (D. Utah filed July 9, 2013) and *Univ. of Utah Research Found. v. Gene by Gene*, No. 2:13-cv-000640 (D. Utah filed July 10, 2013). While Defendants and Gene by Gene subsequently settled their dispute around February 2014, Defendants' suit against Ambry is still pending in the District of Utah, Central Division.

19. Defendants' conduct, including Defendants' litigation history, puts at risk Counsyl's legal rights and ability to market its genetic tests and related services related to sequencing and analysis of *BRCA1* and *BRCA2* genes.

20. Counsyl has made a substantial research and development investment in improving genetic tests and providing more access at lower cost to related services connected with sequencing and analysis of *BRCA1* and *BRCA2* genes. Accordingly, Counsyl seeks and is lawfully entitled to a declaratory judgment that at least one of the following claims is invalid and/or not infringed: claim 5 of the '721 patent, claims 4-8 and 19 of the '497 patent, claim 4 of the '857 patent, and claims 32 and 33 of the '379 patent.

21. There is a definite, concrete, real and substantial controversy between Counsyl and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of at least one of claim 5 of the '721 patent, claims 4-8 and 19 of the '497 patent, claim 4 of the '857 patent, and claims 32 and 33 of the '379 patent. A declaration of rights between the parties is both appropriate

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and necessary to establish that Counsyl does not infringe any valid claim of the '721, '497, '857, and '379 patents.

JURISDICTION AND VENUE

22. This lawsuit is a civil action arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 35 U.S.C. § 2201. Accordingly, this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

23. This Court has personal jurisdiction over Myriad, by virtue of, *inter alia*, it having conducted business in California, having availed itself of the rights and benefits of California law, and having engaged in substantial and continuing contacts with California.

24. On information and belief, Myriad conducts substantial business in this judicial district and regularly solicits business from, does business with, and derives value from goods and services provided to customers in this judicial district. For example, Myriad employs a significant sales and marketing force in this District, markets its tests to thousands of residents within this District, generates significant revenues from this District, and has made significant investments in this District, including a \$25 million strategic investment in Crescendo Bioscience based in South San Francisco, California, in 2011. *See, e.g., Myriad Genetics Makes Strategic Debt Investment With Exclusive Option to Acquire Crescendo Bioscience*, Myriad Investor Relations Press Releases (Sept. 8, 2011), <http://investor.myriad.com/releasedetail.cfm?ReleaseID=604160>.

25. This Court has personal jurisdiction over U. Utah, by virtue of, *inter alia*, it having availed itself of the rights and benefits of California law, and having engaged in substantial and continuing contacts with California.

26. This Court has personal jurisdiction over U. Penn., by virtue of, *inter alia*, it having availed itself of the rights and benefits of California law, and having engaged in substantial and continuing contacts with California.

27. This Court has personal jurisdiction over HSC, by virtue of, *inter alia*, it having availed itself of the rights and benefits of California law, and having engaged in substantial and continuing contacts with California.

28. This Court has personal jurisdiction over Endorecherche, by virtue of, *inter alia*, it having

availed itself of the rights and benefits of California law, and having engaged in substantial and continuing contacts with California.

29. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

COUNT I

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '721 PATENT

30. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-29.

31. An actual controversy exists between Counsyl and Defendants with respect to Counsyl's noninfringement of claim 5 of the '721 patent.

32. Counsyl has not directly or indirectly infringed and is not directly or indirectly infringing claim 5 of the '721 patent as defined by 35 U.S.C. § 271.

33. Counsyl hereby seeks a declaration that the manufacture, use, offer for sale, or sale of its genetic sequencing and analysis of the *BRCA1* gene does not directly or indirectly infringe claim 5 of the '721 patent.

COUNT II

DECLARATORY JUDGMENT OF INVALIDITY OF THE '721 PATENT

34. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-33.

35. An actual controversy exists between Counsyl and Defendants with respect to the invalidity of claim 5 of the '721 patent.

36. Claim 5 of the '721 patent fails to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 101-103, 112, *et seq.*, and/or under the judicially created doctrine of obviousness-type double patenting.

37. Counsyl hereby seeks a declaration that claim 5 of the '721 patent is invalid.

COUNT III

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '497 PATENT

38. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-37.

39. An actual controversy exists between Counsyl and Defendants with respect to Counsyl's noninfringement of at least one of claims 4-8 and 19 of the '497 patent.

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40. Counsyl has not directly or indirectly infringed and is not directly or indirectly infringing claims 4-8 and 19 of the '497 patent as defined by 35 U.S.C. § 271.

41. Counsyl hereby seeks a declaration that the manufacture, use, offer for sale, or sale of its genetic sequencing and analysis of the *BRCA1* gene does not directly or indirectly infringe claims 4-8 and 19 of the '497 patent.

COUNT IV

DECLARATORY JUDGMENT OF INVALIDITY OF THE '497 PATENT

42. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-41.

43. An actual controversy exists between Counsyl and Defendants with respect to the invalidity of at least one of claims 4-8 and 19 of the '497 patent.

44. Claims 4-8 and 19 of the '497 patent fail to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 101-103, 112, *et seq.*, and/or under the judicially created doctrine of obviousness-type double patenting.

45. Counsyl hereby seeks a declaration that claims 4-8 and 19 of the '497 patent are invalid.

COUNT V

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '857 PATENT

46. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-45.

47. An actual controversy exists between Counsyl and Defendants with respect to Counsyl's noninfringement of claim 4 of the '857 patent.

48. Counsyl has not directly or indirectly infringed and is not directly or indirectly infringing claim 4 of the '857 patent as defined by 35 U.S.C. § 271.

49. Counsyl hereby seeks a declaration that the manufacture, use, offer for sale, or sale of its genetic sequencing and analysis of the *BRCA2* gene does not directly or indirectly infringe claim 4 of the '857 patent.

COUNT VI

DECLARATORY JUDGMENT OF INVALIDITY OF THE '857 PATENT

50. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-49.

51. An actual controversy exists between Counsyl and Defendants with respect to the invalidity of claim 4 of the '857 patent.

52. Claim 4 of the '857 patent fails to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 101-103, 112, *et seq.*, and/or under the judicially created doctrine of obviousness-type double patenting.

53. Counsyl hereby seeks a declaration that claim 4 of the '857 patent is invalid.

COUNT VII

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '379 PATENT

54. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-53.

55. An actual controversy exists between Counsyl and Defendants with respect to Counsyl's noninfringement of at least one of claims 32 and 33 of the '379 patent.

56. Counsyl has not directly or indirectly infringed and is not directly or indirectly infringing claims 32 and 33 of the '379 patent as defined by 35 U.S.C. § 271.

57. Counsyl hereby seeks a declaration that the manufacture, use, offer for sale, or sale of its genetic sequencing and analysis of the *BRCA2* gene does not directly or indirectly infringe claims 32 and 33 of the '379 patent.

COUNT VIII

DECLARATORY JUDGMENT OF INVALIDITY OF THE '379 PATENT

58. Counsyl incorporates by reference the preceding averments set forth in paragraphs 1-57.

59. An actual controversy exists between Counsyl and Defendants with respect to the invalidity of at least one of claims 32 and 33 of the '379 patent.

60. Claims 32 and 33 of the '379 patent fail to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 101-103, 112, *et seq.*, and/or under the judicially created doctrine of obviousness-type double patenting.

61. Counsyl hereby seeks a declaration that claims 32 and 33 of the '379 patent are invalid.

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PRAYER FOR RELIEF

WHEREFORE, Counsyl respectfully requests that:

A. Judgment be entered declaring that Counsyl has not infringed, induced infringement of, or contributed to the infringement of and is not infringing, inducing the infringement of, or contributing to the infringement of any one of the following claims: claim 5 of the '721 patent, claims 4-8 and 19 of the '497 patent, claim 4 of the '857 patent, and claims 32 and 33 of the '379 patent;

B. Judgment be entered declaring that claim 5 of the '721 patent, claims 4-8 and 19 of the '497 patent, claim 4 of the '857 patent, and claims 32 and 33 of the '379 patent are invalid;

C. Judgment be entered finding that this is an exceptional case entitling Counsyl to an award of attorneys' fees for bringing and prosecuting this action, together with interest, and costs of the action under 35 U.S.C. § 285; and

D. Such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiff hereby requests a trial by jury, pursuant to Federal Rule of Civil Procedure 38(b), on all issues so triable.

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1 Dated: November 10, 2014

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10 By: /s/ Nicholas Groombridge

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12 *Attorneys for Plaintiff*

13 COUNSYL, INC.

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CERTIFICATE OF SERVICE

On this 10th day of November, 2014, I certify that I served the foregoing document through the CM/ECF system of the United States District Court for the District of Utah, where the above-captioned case has been transferred for pre-trial proceedings in connection with a multi-district litigation. That Court's Cm/ECF system will deliver an electronic copy of the foregoing document to counsel of record for all parties in the above-captioned litigation.

/s/ Jess M. Krannich

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