

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

ASSOCIATION FOR MOLECULAR PATHOLOGY;
AMERICAN COLLEGE OF MEDICAL GENETICS;
AMERICAN SOCIETY FOR CLINICAL PATHOLOGY;
COLLEGE OF AMERICAN PATHOLOGISTS; HAIG
KAZAZIAN, MD; ARUPA GANGULY, PhD; WENDY
CHUNG, MD, PhD; HARRY OSTRER, MD; DAVID
LEDBETTER, PhD; STEPHEN WARREN, PhD; ELLEN
MATLOFF, M.S.; ELSA REICH, M.S.; BREAST CANCER
ACTION; BOSTON WOMEN'S HEALTH BOOK
COLLECTIVE; LISBETH CERIANI; RUNI LIMARY;
GENAE GIRARD; PATRICE FORTUNE; VICKY
THOMASON; KATHLEEN RAKER,

Plaintiffs,

-against-

UNITED STATES PATENT AND TRADEMARK OFFICE;
MYRIAD GENETICS; LORRIS BETZ, ROGER BOYER,
JACK BRITTAIN, ARNOLD B. COMBE, RAYMOND
GESTELAND, JAMES U. JENSEN, JOHN KENDALL
MORRIS, THOMAS PARKS, DAVID W. PERSHING, and
MICHAEL K. YOUNG, in their official capacity as Directors of
the University of Utah Research Foundation,

Defendants.

No. 09 Civ. 4515 (RWS)

ECF Case

ANSWER TO COMPLAINT

Defendants Myriad Genetics (“Myriad”) and Lorris Betz, Roger Boyer, Jack Brittain, Arnold B. Combe, Raymond Gesteland, James U. Jensen, John Kendall Morris, Thomas Parks, David W. Pershing, and Michael K. Young in their official capacity, or alleged to have been named in their official capacity, as directors of the University of Utah Research Foundation (the “Directors”) (collectively, Myriad and the Directors are referred to as the “Defendants”), by and

through their undersigned counsel, respectfully submit this Answer to Plaintiffs' Complaint ("Complaint").

1. Defendants deny the allegations contained in paragraph 1, except to admit that human bodies contain genes and that genes can be inherited.

2. Defendants deny the allegations contained in paragraph 2, except to admit that the Complaint purports to assert causes of action with respect to United States Patent Numbers 6,033,857 (the "'857 patent"), 5,753,441 (the "'441 patent"), 5,837,492 (the "'492 patent"), 5,747,282 (the "'282 patent"), 5,710,001 (the "'001 patent"), 5,709,999 (the "'999 patent"), and 5,693,473 (the "'473 patent"), hereinafter referred to as the "Patents-in-Suit."

3. Defendants deny the allegations contained in paragraph 3, and respectfully refer to the claims of the Patents-in-Suit with respect to what "[t]he patents cover."

4. Defendants deny the allegations contained in paragraph 4.

5. Defendants deny the allegations contained in paragraph 5.

6. Defendants admit the allegations contained in paragraph 6.

7. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 7 and, therefore, deny them.

8. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 8 and, therefore, deny them.

9. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 9 and, therefore, deny them.

10. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 10 and, therefore, deny them.

11. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 11 with respect to Dr. Kazazian's employment and research activities and, therefore, deny them. Defendants deny the remaining allegations contained in paragraph 11.

12. Defendants deny the allegation contained in paragraph 12 that Dr. Kazazian received a cease-and-desist letter from defendant Myriad. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 12 and, therefore, deny them.

13. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 13 with respect to Dr. Chung's employment and research activities and what she is ready, willing, and able to do and, therefore, deny them. Defendants deny the remaining allegations contained in paragraph 13.

14. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 14 with respect to Dr. Ostrer's employment and research activities and what he is ready, willing, and able to do and, therefore, deny them. Defendants deny the remaining allegations contained in paragraph 14.

15. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 15 with respect to Dr. Ledbetter's employment and research activities and what he is ready, willing, and able to do and, therefore, deny them. Defendants deny the remaining allegations contained in paragraph 15.

16. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 16 with respect to Dr. Warren's

employment and research activities and what he is ready, willing, and able to do and, therefore, deny them. Defendants deny the remaining allegations contained in paragraph 16.

17. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 17 with respect to Ms. Matloff's employment and genetic counseling activities and what she is ready, willing, and able to do and, therefore, deny them. Defendants deny the remaining allegations contained in paragraph 17.

18. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 18 with respect to Ms. Reich's employment and genetic counseling activities and what she is ready, willing, and able to do and, therefore, deny them. Defendants deny the remaining allegations contained in paragraph 18.

19. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 19 and, therefore, deny them.

20. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 20 and, therefore, deny them.

21. Myriad admits the allegation contained in paragraph 21 that it received a sample submitted on behalf of Ms. Ceriani. Myriad denies the allegation contained in paragraph 21 that it will not accept MassHealth coverage. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 21 and, therefore, deny them.

22. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 22 and, therefore, deny them.

23. Myriad admits the allegation contained in paragraph 23 that it tested a sample from Ms. Girard and that the test result was positive for a deleterious mutation in the *BRCA2*

gene. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 23 and, therefore, deny them.

24. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 24 and, therefore, deny them.

25. Myriad admits the allegation contained in paragraph 25 that Ms. Thomason obtained *BRCA1/BRCA2* genetic testing from Myriad in 2007 and was found to be negative for mutations covered by that test. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 25 and, therefore, deny them.

26. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 26 and, therefore, deny them.

27. Defendants admit the allegations contained in paragraph 27 that the United States Patent and Trademark Office is an agency of the Commerce Department of the United States and that its principal office is in Alexandria, Virginia. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 27 and, therefore, deny them.

28. Defendants deny the allegations contained in paragraph 28, except to admit that Myriad is a for-profit corporation, that Myriad's principal place of business is in Salt Lake City, Utah, that Myriad is incorporated in Delaware, that Myriad formerly was a co-owner of some of the Patents-in-Suit, that Myriad is the exclusive licensee of the Patents-in-Suit, and that Myriad is the sole provider of full sequencing of *BRCA1* and *BRCA2* genes in the United States on a commercial basis.

29. Defendants deny the allegations contained in paragraph 29, except to admit that Lorris Betz, Roger Boyer, Jack Brittain, Arnold B. Combe, James U. Jensen, David W. Pershing, and Michael K. Young are Directors of the University of Utah Research Foundation, and that the University of Utah Research Foundation is an owner or part-owner of each of the Patents-in-Suit.

30. Defendants deny the allegations contained in paragraph 30, except to admit that Endo Recherche, Inc., of Sainte-Foy, Canada, HSC Research & Development Limited Partnership of Toronto, Canada, and the Trustees of the University of Pennsylvania are additional owners of the '492 patent and the '857 patent, and that the United States of America, as represented by the Secretary of the Department of Health and Human Services, is an additional owner of the '001 patent, the '441 patent, United States Patent No. 6,162,897, and the '282 patent.

31. Defendants deny the allegations contained in paragraph 31, except to admit that Myriad is the exclusive licensee of the Patents-in-Suit.

32. Defendants deny the allegations contained in paragraph 32, except to admit that Plaintiffs purport to challenge the following claims of the following patents: claims 1, 2, 5, and 6 of the '282 patent; claim 1 of the '492 patent; claim 1 of the '473 patent; claim 7 of the '282 patent; claims 6 and 7 of the '492 patent; claim 1 of the '999 patent; claim 1 of the '001 patent; claim 1 of the '441 patent; claims 1 and 2 of the '857 patent; and claim 20 of the '282 patent.

33. Defendants deny the allegations contained in paragraph 33, except to admit that every person's body is composed of cells.

34. Defendants deny the allegations contained in paragraph 34, except to admit that DNA is deoxyribonucleic acid.

35. Defendants deny the allegations contained in paragraph 35, except to admit that genetic sequences can vary and that such variations can be inherited or acquired during a lifetime.

36. Defendants deny the allegations contained in paragraph 36.

37. Defendants deny the allegations contained in paragraph 37, except to admit that *BRCA1* and *BRCA2* are human breast and ovarian cancer predisposing genes and that some alleles of these genes cause susceptibility to cancer, in particular, breast, ovarian, prostate and pancreatic cancer.

38. Defendants admit the allegations contained in paragraph 38.

39. Defendants deny the allegations contained in paragraph 39, except to admit that *BRCA1* and *BRCA2* are human breast and ovarian cancer predisposing genes and that some alleles of these genes cause susceptibility to cancer, in particular, breast and ovarian cancer.

40. Defendants deny the allegations contained in paragraph 40, except to admit that a *BRCA1* and *BRCA2* genetic test result can be a factor that a woman considers in making medical decisions.

41. Defendants deny the allegations contained in paragraph 41, except to admit that research was being done in the 1990's regarding a human breast and ovarian cancer predisposing gene.

42. Defendants deny the allegations contained in paragraph 42, except to admit that efforts to isolate the *BRCA1* gene have proceeded since it was first mapped to chromosome 17 in 1990.

43. Defendants deny the allegations contained in paragraph 43.

44. Defendants deny the allegations contained in paragraph 44, except to admit that scientific research was being conducted for years to isolate and detect the human *BRCA2* gene.

45. Defendants deny the allegations contained in paragraph 45, except to refer to the '857 and the '492 patents with respect to the techniques and methodology used to isolate and detect the human *BRCA2* gene.

46. Defendants deny the allegations contained in paragraph 46.

47. Defendants deny the allegations contained in paragraph 47.

48. Defendants deny the allegations contained in paragraph 48.

49. Defendants deny the allegations contained in paragraph 49.

50. With respect to the allegations contained in paragraph 50, Defendants admit that the Patents-in-Suit were obtained from the United States Patent and Trademark Office pursuant to applicable laws and regulations. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 50 and, therefore, deny them.

51. Defendants deny the allegations contained in paragraph 51.

52. Defendants deny the allegations contained in paragraph 52.

53. With respect to the allegations contained in paragraph 53, Defendants admit that the Patents-in-Suit were obtained from the United States Patent and Trademark Office pursuant to applicable laws and regulations. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 53 and, therefore, deny them.

54. Defendants deny the allegations contained in paragraph 54.

55. Defendants deny the allegations contained in paragraph 55, except to refer to the claims of the Patents-in-Suit with respect to what “the claims in Myriad’s patents cover.”

56. Defendants deny the allegations contained in paragraph 56, except to refer to the ’282 patent with respect to what claim 1 of the ’282 patent “covers.”

57. Defendants deny the allegations contained in paragraph 57, except to refer to the ’282 patent with respect to what claim 2 of the ’282 patent “covers.”

58. Defendants deny the allegations contained in paragraph 58, except to refer to the ’282 patent with respect to what claim 5 of the ’282 patent “covers.”

59. Defendants deny the allegations contained in paragraph 59, except to refer to the ’282 patent with respect to what claim 6 of the ’282 patent “covers.”

60. Defendants deny the allegations contained in paragraph 60, except to refer to the ’492 patent with respect to what claim 1 of the ’492 patent “covers.”

61. Defendants deny the allegations contained in paragraph 61, except to refer to the respective patents with respect to what claim 1 of the ’473 patent, claim 7 of the ’282 patent, and claims 6 and 7 of the ’492 patent “claim.”

62. Myriad denies the allegations contained in paragraph 62, except to refer to the Patents-in-Suit with respect to what activities the named inventors of the Patents-in-Suit performed. The Directors lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 62 and, therefore, deny them.

63. Defendants deny the allegations contained in paragraph 63, except to refer to the ’473 patent with respect to what claim 1 of the ’473 patent “claims.”

64. Defendants deny the allegations contained in paragraph 64, except to refer to the ’282 patent with respect to what claim 7 of the ’282 patent “claims.”

65. Defendants deny the allegations contained in paragraph 65, except to refer to the '492 patent with respect to what claim 6 of the '492 patent "covers."

66. Defendants deny the allegations contained in paragraph 66, except to refer to the '492 patent with respect to what claim 7 of the '492 patent "claims."

67. Defendants deny the allegations contained in paragraph 67, except to refer to the respective patents as to what claim 1 of the '473 patent, claim 7 of the '282 patent, and claims 6 and 7 of the '492 patent "include."

68. Defendants deny the allegations contained in paragraph 68.

69. Defendants deny the allegations contained in paragraph 69, except to refer to the '999 patent with respect to what claim 1 of the '999 patent "covers."

70. Defendants deny the allegations contained in paragraph 70.

71. Defendants deny the allegations contained in paragraph 71, except to refer to the Patents-in-Suit with respect to what the claims of the Patents-in-Suit "include."

72. Defendants deny the allegations contained in paragraph 72, except to refer to the '001 patent with respect to what claim 1 of the '001 patent "involves."

73. Defendants deny the allegations contained in paragraph 73, except to refer to the '441 patent with respect to what claim 1 of the '441 patent "covers."

74. Defendants deny the allegations contained in paragraph 74, except to refer to the '857 patent with respect to what claim 1 of the '857 patent "involves."

75. Defendants deny the allegations contained in paragraph 75, except to refer to the '857 patent with respect to what claim 2 of the '857 patent "involves."

76. Defendants deny the allegations contained in paragraph 76, except to refer to the '282 patent with respect to what claim 20 of the '282 patent "involves."

77. Defendants deny the allegations contained in paragraph 77, except to refer to the Patents-in-Suit with respect to what the claims of the Patents-in-Suit “include.”

78. Defendants deny the allegations contained in paragraph 78, except to refer to the Patents-in-Suit with respect to what the claims of the Patents-in-Suit are “limited to.”

79. Defendants deny the allegations contained in paragraph 79, except to refer to the Patents-in-Suit with respect to what activities the applicants of the Patents-in-Suit performed.

80. Defendants deny the allegations contained in paragraph 80, except to refer to the Patents-in-Suit with respect to what the claims of the Patents-in-Suit are “limited to.”

81. Defendants deny the allegations contained in paragraph 81, except to admit that Myriad offers a test to assess a woman’s risk of developing breast or ovarian cancer based on detection of mutations in the *BRCA1* and *BRCA2* genes.

82. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 82 and, therefore, deny them, except to admit that Myriad is the exclusive licensee of the Patents-in-Suit.

83. Defendants deny the allegations contained in paragraph 83.

84. Defendants deny the allegations contained in paragraph 84, except to admit that Myriad is the exclusive licensee of the Patents-in-Suit.

85. Defendants deny the allegations contained in paragraph 85, except to admit that Myriad is the exclusive licensee of the Patents-in-Suit.

86. Defendants deny the allegations contained in paragraph 86, except to admit that Myriad maintains a database of data relating to the *BRCA1* and *BRCA2* genes.

87. Defendants deny the allegations contained in paragraph 87.

88. Defendants deny the allegations contained in paragraph 88.

89. Defendants deny the allegations contained in paragraph 89.

90. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 90 with respect to Ms. Girard, Ms. Limary, and “any other women” and, therefore, deny them. Defendants deny the remaining allegations contained in paragraph 90, except to admit that Myriad is the exclusive licensee of the Patents-in-Suit.

91. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 91 with respect to “laboratories, such as that operated by Dr. Ledbetter” and, therefore, deny them. Defendants deny the remaining allegations contained in paragraph 91.

92. Defendants deny the allegations contained in paragraph 92, except to admit that the list price of Myriad’s BRAC*Analysis*® test is more than \$3,000.

93. Myriad denies the allegation in paragraph 93 that it will not accept the insurance of plaintiffs Ceriani and Fortune. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 93 and, therefore, deny them.

94. Defendants admit the allegation contained in paragraph 94 that Myriad offers a test called BRAC*Analysis*® Rearrangement Test (or “BART”) that is designed to detect large rearrangements. Defendants further admit the allegations contained in paragraph 94 that Myriad will conduct BART testing for some women who meet its criteria at no additional cost and that other women must pay an additional price of approximately \$650 for BART testing. Defendants deny the remaining allegations contained in paragraph 94.

95. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 95 with respect to the medical histories and advice given to “women, including plaintiffs Thomason and Raker” and, therefore, deny them. Defendants deny the remaining allegations contained in paragraph 95.

96. Defendants deny the allegations contained in paragraph 96.

97. Defendants deny the allegations contained in paragraph 97, except to admit that Myriad has not opposed non-commercial research related to the *BRCA1* and *BRCA2* genes.

98. Defendants deny the allegations contained in paragraph 98.

99. Defendants lack sufficient knowledge or information to form a belief as to the truth or falsity of the allegations contained in paragraph 99 with respect to the research activities of plaintiffs Dr. Chung and Dr. Ostrer and, therefore, deny them. Defendants deny the remaining allegations contained in paragraph 99.

100. Defendants deny the allegations contained in paragraph 100.

101. Defendants deny the allegations contained in paragraph 101.

102. Defendants deny the allegations contained in paragraph 102.

103. Defendants deny the allegations contained in paragraph 103.

104. To the extent any allegations are not addressed above, they are denied.

AFFIRMATIVE DEFENSES

- i. This Court lacks subject-matter jurisdiction over this case.
- ii. This Court lacks personal jurisdiction over the Directors.
- iii. Plaintiffs’ claims are barred by the doctrine of laches, waiver, and equitable estoppel.
- iv. The Complaint fails to state a claim upon which relief can be granted.

DEFENDANTS' PRAYER FOR RELIEF

WHEREFORE, Defendants pray that the Court:

- a. Dismiss the Complaint with prejudice;
- b. Award Defendants attorney's fees and costs; and
- c. Award Defendants such other and further relief as the Court may deem proper.

Dated: New York, New York
November 20, 2009

JONES DAY

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CERTIFICATE OF SERVICE

This is to certify that on November 20, 2009, a true and correct copy of the foregoing document has been served on all counsel of record via the court's ECF system.

/s/ Lynda Q. Nguyen

Lynda Q. Nguyen