

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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ASSOCIATION FOR MOLECULAR
PATHOLOGY, et al., :

Plaintiffs, :

v. :

UNITED STATES PATENT AND TRADEMARK
OFFICE, et al., :

Defendants. :

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: **ANSWER**
: 09 Civ. 4515 (RWS)

Defendant United States Patent and Trademark Office (“USPTO”), by its attorney Preet Bharara, United States Attorney for the Southern District of New York, answers the complaint on information and belief as follows:

1. Admits the allegations in the first and second sentences of paragraph 1 of the complaint. The allegations in the third sentence of paragraph 1 constitute a characterization of the claims in the action to which no response is required; to the extent a response is required, denies the allegations.
2. The allegations in paragraph 2 of the complaint constitute a characterization of the claims in the action to which no response is required; to the extent a response is required, denies the allegations.
3. The allegations in paragraph 3 of the complaint constitute a characterization of the claims in the action to which no response is required; to the extent a response is required, denies the allegations.
4. The allegations in paragraph 4 of the complaint constitute legal conclusions to which no

- response is required; to the extent a response is required, denies the allegations.
5. Denies the allegations in paragraph 5 of the complaint.
 6. The allegations in paragraph 6 of the complaint constitute legal conclusions to which no response is required; to the extent a response is required, denies the allegations.
 7. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 7 of the complaint.
 8. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 8 of the complaint.
 9. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 9 of the complaint.
 10. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 10 of the complaint.
 11. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 11 of the complaint.
 12. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 12 of the complaint.
 13. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 13 of the complaint.
 14. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 14 of the complaint.
 15. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 15 of the complaint.

16. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 16 of the complaint.
17. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 17 of the complaint.
18. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 18 of the complaint.
19. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 19 of the complaint.
20. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 20 of the complaint.
21. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 21 of the complaint.
22. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 22 of the complaint.
23. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 23 of the complaint.
24. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 24 of the complaint.
25. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 25 of the complaint.
26. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 26 of the complaint.

27. Admits the allegations in the first two sentences of paragraph 27 of the complaint. The allegations in the third sentence of paragraph 27 constitute a characterization of plaintiffs' claims to which no response is required.
28. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 28 of the complaint.
29. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 29 of the complaint.
30. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 30 of the complaint.
31. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 31 of the complaint, except admits that the USPTO issued patents to Myriad relating to the human genes known as *BRCA1* and *BRCA2*.
32. The allegations in paragraph 32 of the complaint constitute a characterization of the claims in the action to which no response is required.
33. Denies the allegations in paragraph 33 of the complaint, except admits the allegations in the first and fifth sentences of paragraph 33, and admits that most cells in the body contain a nucleus and that the nucleus contains DNA, and that DNA encodes instructions that may be used by the body to construct RNA, which in turn may be used to make proteins.
34. Denies the allegations in paragraph 34 of the complaint, except admits that DNA is a chemical made by cells; that DNA encodes instructions that may be used by the body to construct RNA, which in turn may be used to make proteins; and that genetic sequences

may be informational for researchers and clinicians.

35. Admits the allegations in paragraph 35 of the complaint.
36. Denies the allegations in the first sentence of paragraph 36 of the complaint, except admits that one way to determine whether a person has a genetic mutation is to look at the sequence of an individual's genes. Admits the allegations in the second, third, and fourth sentences of paragraph 36. The allegations in the final sentence of paragraph 36 state a conclusion of law to which no response is required.
37. The allegations in the first sentence of paragraph 37 of the complaint state legal conclusions to which no response is required. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in the second and fourth sentences of paragraph 37. Admits the allegations in the third sentence of paragraph 37.
38. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 38 of the complaint.
39. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 39 of the complaint.
40. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 40 of the complaint.
41. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 41 of the complaint.
42. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 42 of the complaint.

43. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 43 of the complaint, except admits that Myriad filed and obtained patents associated with the *BRCA1* gene.
44. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 44 of the complaint.
45. Denies the allegations in paragraph 45 of the complaint, except admits that Myriad filed and obtained patents associated with the *BRCA2* gene.
46. Denies the allegations in paragraph 46 of the complaint, except admits that Myriad did not invent the human *BRCA1* and *BRCA2* genes as they exist in human chromosomes and that *BRCA1* and *BRCA2* genes naturally exist in human chromosomes in human cells.
47. The allegations in paragraph 47 of the complaint state legal conclusions to which no response is required, except admits that Myriad did not invent the differences found in the human *BRCA1* and *BRCA2* genes.
48. The allegations in paragraph 48 of the complaint state legal conclusions to which no response is required. To the extent a response is required, denies the allegations.
49. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 49 of the complaint.
50. The allegations in paragraph 50 of the complaint state conclusions of law to which no response is required. The USPTO respectfully refers the Court to the USPTO guidelines issued January 5, 2001, set forth at 66 Fed. Reg. 1092, for a true and accurate statement of their contents.
51. Denies the allegations contained in paragraph 51 of the complaint.

52. Denies the allegations contained in paragraph 52 of the complaint.
53. Denies the allegations contained in paragraph 53 of the complaint.
54. Denies the allegations contained in paragraph 54 of the complaint.
55. The allegations in paragraph 55 of the complaint state legal conclusions to which no response is required.
56. The allegations in paragraph 56 of the complaint state legal conclusions to which no response is required.
57. The allegations in paragraph 57 of the complaint state legal conclusions to which no response is required.
58. The allegations in paragraph 58 of the complaint state legal conclusions to which no response is required.
59. The allegations in paragraph 59 of the complaint state legal conclusions to which no response is required.
60. The allegations in paragraph 60 of the complaint state legal conclusions to which no response is required.
61. The allegations in paragraph 61 of the complaint state legal conclusions to which no response is required.
62. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 62 of the complaint, except that the allegations as to the scope of Myriad's patents state a legal conclusion to which no response is required.
63. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 63 of the complaint, except that the allegations as to

- the scope of Myriad's patents state a legal conclusion to which no response is required.
64. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 64 of the complaint, except that the allegations as to the scope of Myriad's patents state a legal conclusion to which no response is required.
 65. The allegations in paragraph 65 of the complaint state legal conclusions to which no response is required.
 66. The allegations in paragraph 66 of the complaint state legal conclusions to which no response is required.
 67. The allegations in paragraph 67 of the complaint state legal conclusions to which no response is required.
 68. The allegations in paragraph 68 of the complaint state legal conclusions to which no response is required.
 69. The allegations in paragraph 69 of the complaint state legal conclusions to which no response is required.
 70. The allegations in paragraph 70 of the complaint state legal conclusions to which no response is required.
 71. The allegations in paragraph 71 of the complaint state legal conclusions to which no response is required.
 72. The allegations in paragraph 72 of the complaint state legal conclusions to which no response is required.
 73. The allegations in paragraph 73 of the complaint state legal conclusions to which no response is required.

74. The allegations in paragraph 74 of the complaint state legal conclusions to which no response is required.
75. The allegations in paragraph 75 of the complaint state legal conclusions to which no response is required.
76. The allegations in paragraph 76 of the complaint state legal conclusions to which no response is required.
77. The allegations in paragraph 77 of the complaint state legal conclusions to which no response is required.
78. The allegations in paragraph 78 of the complaint state legal conclusions to which no response is required.
79. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 79 of the complaint.
80. The allegations in paragraph 80 of the complaint state legal conclusions to which no response is required.
81. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 81 of the complaint.
82. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 82 of the complaint
83. The allegations in paragraph 83 of the complaint state legal conclusions to which no response is required, except denies knowledge or information sufficient to form a belief as to the truth of the allegations in the fourth sentence of paragraph 83.
84. Denies knowledge or information sufficient to form a belief as to the truth of the

allegations contained in the first sentence of paragraph 84 of the complaint. The remaining allegations in paragraph 84 state legal conclusions to which no response is required.

85. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 85 of the complaint.
86. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 86 of the complaint.
87. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 87 of the complaint.
88. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 88 of the complaint.
89. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 89 of the complaint.
90. The allegations in the first sentence of paragraph 90 of the complaint state legal conclusions to which no response is required. Denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 90.
91. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 91 of the complaint.
92. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 92 of the complaint.
93. Denies knowledge or information sufficient to form a belief as to the truth of the

- allegations contained in paragraph 93 of the complaint.
94. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 94 of the complaint.
 95. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 95 of the complaint.
 96. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 96 of the complaint.
 97. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 97 of the complaint.
 98. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 98 of the complaint.
 99. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 99 of the complaint.
 100. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 100 of the complaint.
 101. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 101 of the complaint.
 102. Denies the allegations contained in paragraph 102 of the complaint.
 103. Denies the allegations contained in paragraph 103 of the complaint.

FIRST DEFENSE

The Complaint fails to state a claim against the USPTO upon which relief may be granted.

SECOND DEFENSE

The Court lacks jurisdiction over the subject matter of this action.

THIRD DEFENSE

Plaintiffs lack standing to sue the USPTO on the complaint.

FOURTH DEFENSE

Sovereign immunity bars the action against the USPTO.

FIFTH DEFENSE

All or some of plaintiffs' claims may be barred by the doctrine of laches.

WHEREFORE, Defendant USPTO demands judgment against plaintiffs dismissing the complaint, and request that it be granted such other and further relief as this Court deems just and proper.

Dated: New York, New York
November 20, 2009

PREET BHARARA
United States Attorney for the
Southern District of New York
Attorney for Defendant USPTO

By: _____/s/_____
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