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14 Attorneys for Plaintiffs
15 QUEST DIAGNOSTICS INCORPORATED
and QUEST DIAGNOSTICS NICHOLS INSTITUTE
16

17 **IN THE UNITED STATES DISTRICT COURT**
18 **CENTRAL DISTRICT OF CALIFORNIA**

19
20 QUEST DIAGNOSTICS
INCORPORATED and
21 QUEST DIAGNOSTICS NICHOLS
INSTITUTE,

22 Plaintiffs,

23
24 v.

25 MYRIAD GENETICS, INC.,

26 Defendant.
27
28

Case No. 13-cv-1587

**COMPLAINT FOR
DECLARATORY
JUDGMENT**

JURY TRIAL DEMANDED

Complaint served:
Current response date:

1 Plaintiffs Quest Diagnostics Incorporated (“Quest Diagnostics”) and Quest
2 Diagnostics Nichols Institute (“Nichols Institute”), by and through their
3 undersigned counsel, for their claim for relief against Defendant Myriad Genetics,
4 Inc. (“Myriad”), allege as follows:

5 **NATURE OF THIS ACTION**

6 1. Quest Diagnostics and Nichols Institute, (collectively referred to as
7 “Quest”) bring this action for a declaration that Quest does not directly or indirectly
8 infringe each of the claims of U.S. Patent Nos. 5,747,282; 5,693,473; 5,709,999;
9 5,710,001; 5,753,441; 5,837,492; 6,033,857; 7,250,497; 6,083,698; 5,750,400;
10 5,654,155; 6,951,721; 6,492,109; and 6,051,379 (together, the “patents-in-suit”)
11 and that each and every claim of the patents-in-suit is invalid.

12 **THE PARTIES**

13 2. Quest Diagnostics is a corporation organized and existing under the laws
14 of the State of Delaware with its principal place of business at 3 Giralda Farms,
15 Madison, New Jersey 07940. Quest is the world’s leading provider of diagnostic
16 information services, and is a pioneer in developing innovative diagnostic tests and
17 advanced healthcare information technology solutions that help improve patient
18 care.

19 3. Nichols Institute is a corporation organized and existing under the laws
20 of the State of California with its principal place of business at 33608 Ortega
21 Highway, San Juan Capistrano, California 92690. Nichols Institute is a world
22 leader in highly specialized laboratory testing. Over the last three decades, Nichols
23 Institute has pioneered many new tests and technologies and has often been first in
24 providing access to advances in laboratory testing.

25 4. Upon information and belief, Myriad is a corporation organized and
26 existing under the laws of the State of Delaware with its principal place of business
27 at 320 Wakara Way, Salt Lake City, Utah 84108.
28

JURISDICTION AND VENUE

1
2 5. This action arises under the Declaratory Judgment Act, 28 U.S.C §§ 2201
3 and 2202 and the United States Patent Law, 35 U.S.C. § 100 et seq. The claims in
4 this lawsuit pertain to non-infringement and invalidity of U.S. patents, and
5 therefore, this Court has subject matter jurisdiction over this action pursuant to 28
6 U.S.C. §§ 1331 and 1338.

7 6. This Court has personal jurisdiction over Myriad because Myriad
8 conducts substantial business in the State of California including in the Central
9 District of California and elsewhere in California. Myriad has made significant
10 strategic investments in the state, and regularly derives value from services
11 provided to California consumers. Myriad employs a significant sales and
12 marketing force in this judicial district, from which it generates significant revenues
13 from sales made in this district. Myriad either employs or intends to employ
14 persons in Los Angeles and Orange counties having the title of “Institutional
15 Account Executive.” Upon information and belief, Myriad specifically markets and
16 sells genetic tests related to sequencing and analysis of BRCA1 and BRCA2 genes
17 to citizens of Los Angeles and Orange counties, and throughout the state of
18 California. Upon information and belief, Myriad claims that its BRCA1/BRCA2
19 genetic tests are covered by one or more of the patents-in-suit in this lawsuit.

20 7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and
21 1400 because Nichols Institute, the testing laboratory where the non-infringing
22 BRCA1/BRCA2 genetic test was developed, and where Quest intends that
23 information obtained from those tests will be analyzed, is located in Orange County
24 California. Therefore, a substantial part of the events giving rise to the claims
25 herein have occurred and are occurring in Orange County. Moreover, Myriad
26 regularly conducts business in this judicial district relating to BRCA1 and BRCA2
27 genetic testing.

THE PATENTS IN SUIT

1
2 8. U.S. Patent No. 5,747,282 (“the ’282 patent”), titled “17Q-LINKED
3 BREAST AND OVARIAN CANCER SUSCEPTIBILITY GENE,” issued on May
4 5, 1998. A true and correct copy of the ’282 patent is attached as Exhibit 1.

5 9. Myriad purports to be the exclusive licensee of the ’282 patent, and
6 Myriad has asserted that it has the sole right to enforce the ’282 patent.

7 10. U.S. Patent No. 5,693,473, titled (“the ’473 patent”), titled “LINKED
8 BREAST AND OVARIAN CANCER SUSCEPTIBILITY GENE,” issued on Dec.
9 2, 1997. A true and correct copy of the ’473 patent is attached as Exhibit 2.

10 11. Myriad has purported to have sufficient rights to enforce the ’473 patent.

11 12. U.S. Patent No. 5,709,999, titled “LINKED BREAST AND OVARIAN
12 CANCER SUSCEPTIBILITY GENE,” issued on January 20, 1998 (“the ’999
13 patent”). A true and correct copy of the ’999 patent is attached as Exhibit 3.

14 13. Myriad purports to be the exclusive licensee of the ’999 patent, and
15 Myriad has asserted that it has the sole right to enforce the ’999 patent.

16 14. U.S. Patent No. 5,710,001 (“the ’001 patent”), titled “17Q-LINKED
17 BREAST AND OVARIAN CANCER SUSCEPTIBILITY GENE,” issued on Jan.
18 20, 1998. A true and correct copy of the ’001 patent is attached as Exhibit 4.

19 15. Myriad purports to be the exclusive licensee of the ’001 patent, and
20 Myriad has asserted that it has the sole right to enforce the ’001 patent.

21 16. U.S. Patent No. 5,753,441 (“the ’441 patent”), titled “17Q-LINKED
22 BREAST AND OVARIAN CANCER SUSCEPTIBILITY GENE,” issued on May
23 19, 1998. A true and correct copy of the ’441 patent is attached as Exhibit 5.

24 17. Myriad purports to be the exclusive licensee of the ’441 patent, and
25 Myriad has asserted that it has the sole right to enforce the ’441 patent.

26 18. U.S. Patent No. 5,837,492 (“the ’492 patent”), titled “CHROMOSOME
27 13-LINKED BREAST CANCER SUSCEPTIBILITY GENE,” issued on Nov. 17,
28 1998. A true and correct copy of the ’492 patent is attached as Exhibit 6.

1 19. Myriad purports to be the exclusive licensee of the '492 patent, and
2 Myriad has asserted that it has the sole right to enforce the '492 patent.

3 20. U.S. Patent No. 6,033,857 ("the '857 patent"), titled "CHROMOSOME
4 13-LINKED BREAST CANCER SUSCEPTIBILITY GENE," issued on Mar. 7,
5 2000. A true and correct copy of the '857 patent is attached as Exhibit 7.

6 21. Myriad purports to be the exclusive licensee of the '857 patent, and
7 Myriad has asserted that it has the sole right to enforce the '857 patent.

8 22. U.S. Patent No. 7,250,497 ("the '497 patent"), titled "LARGE
9 DELETIONS IN HUMAN BRCA1 GENE AND USE THEREOF," issued on Jul.
10 31, 2007. A true and correct copy of the '497 patent is attached as Exhibit 8.

11 23. Myriad purports to own the '497 patent.

12 24. U.S. Patent No. 6,083,698 ("the '698 patent"), titled "CANCER
13 SUSCEPTIBILITY MUTATIONS OF BRCA1," issued on Jul. 4, 2000. A true and
14 correct copy of the '698 patent is attached as Exhibit 9.

15 25. Myriad purports to be either the assignee or the exclusive licensee of the
16 '698 patent, and Myriad has the sole right to enforce the '698 patent.

17 26. U.S. Patent No. 5,750,400 ("the '400 patent"), titled "CODING
18 SEQUENCES OF THE HUMAN BRCA1 GENE," issued on May 12, 1998. A
19 true and correct copy of the '400 patent is attached as Exhibit 10.

20 27. Myriad purports to own the '400 patent.

21 28. U.S. Patent No. 5,654,155 ("the '155 patent"), titled "CONSENSUS
22 SEQUENCE OF THE HUMAN BRCA1 GENE," issued on Aug. 5, 1997. A true
23 and correct copy of the '155 patent is attached as Exhibit 11.

24 29. Myriad purports to own the '155 patent.

25 30. U.S. Patent No. 6,951,721 ("the '721 patent"), titled "METHOD FOR
26 DETERMINING THE HAPLOTYPE OF A HUMAN BRCA1 GENE," issued on
27 Oct. 4, 2005. A true and correct copy of the '721 patent is attached as Exhibit 12.

28 31. Myriad purports to own the '721 patent.

1 32. U.S. Patent No. 6,492,109 (“the ’109 patent”), titled “SUSCEPTIBILITY
2 MUTATION 6495DELGC OF BRCA2,” issued on Dec. 10, 2002. A true and
3 correct copy of the ’109 patent is attached as Exhibit 13.

4 33. Myriad purports to be either the assignee or the exclusive licensee of the
5 ’109 patent, and purports to have the sole right to enforce the ’109 patent.

6 34. U.S. Patent No. 6,051,379 (“the ’379 patent”), titled “CANCER
7 SUSCEPTIBILITY MUTATIONS OF BRCA2,” issued on Apr. 18, 2000. A true
8 and correct copy of the ’379 patent is attached as Exhibit 14.

9 35. Myriad purports to own the ’379 patent.

10 **BACKGROUND**

11 **A. SCREENING ASSAYS FOR GENETIC ABNORMALITIES IN BRCA GENES**

12 36. BRCA1 and BRCA2 are human genes that encode specific proteins
13 responsible for repairing damaged DNA in cells. Alterations or mutations in either
14 of those genes may impact a cell’s ability to repair DNA damage, leading to
15 additional genetic alterations that can lead to cancer. Specific inherited mutations
16 in BRCA1 and BRCA2 genes are associated with an increased risk of breast and
17 ovarian cancers. It is estimated that 55 to 65 percent of women who inherit a
18 harmful *BRCA1* mutation and around 45 percent of women who inherit a harmful
19 *BRCA2* mutation will develop breast cancer by age 70.

20 37. BRCA1/BRCA2 screening assays identify particular harmful gene
21 mutations in DNA obtained from a blood or saliva sample. These assays have
22 emerged as an important tool in the diagnosis of a woman’s risk of contracting
23 breast and ovarian cancer. BRCA1/BRCA2 screening enables women with a
24 positive test to make an informed decision about medical treatment options, and
25 possibly take steps to reduce their cancer risk. This screening is particularly
26 valuable for women who have a familial history of breast cancer or who have
27 previously contracted cancer; a significant public health issue given that breast
28 cancer is the most common cancer among American women, with more than

1 200,000 women diagnosed each year.

2 **B. MYRIAD’S HISTORY OF ENFORCING THE PATENTS-IN-SUIT**

3 38. Myriad has asserted that any company that makes, uses, sells or offers to
4 sell genetic tests and related services using the BRCA1 and/or BRCA2 genes, such
5 as the sequencing and analysis of BRCA1 and/or BRCA2 genes, will face a patent
6 infringement lawsuit.

7 39. Before the patents-in-suit issued, other laboratories screened patient
8 DNA samples to assess natural mutations in BRCA1 and BRCA2 genes and
9 correlate those mutations with a risk of developing breast or ovarian cancer. For
10 example, throughout the mid- and late-1990s, researchers at the Genetics
11 Diagnostic Testing Laboratory at the University of Pennsylvania performed
12 BRCA1 and BRCA2 genetic testing services for hundreds of patients each year.
13 Researchers at the Molecular Genetics Laboratory at New York University also
14 performed BRCA1 and BRCA2 genetic testing.

15 40. Myriad sent cease and desist letters to those other laboratories,
16 threatening patent infringement lawsuits unless that activity stopped. In response to
17 Myriad’s threats, these laboratories, including the Genetics Diagnostic Testing
18 Laboratory at the University of Pennsylvania and the Molecular Genetics
19 Laboratory at New York University, stopped performing BRCA1 and BRCA2
20 testing and analysis on or around 1999. As a result, Myriad became the only
21 provider of BRCA1 and BRCA2 related genetic screening and testing services in
22 the United States.

23 41. In 2009, the American Civil Liberties Union and an organization called
24 PubPat, acting on behalf medical associations, doctors, universities and individuals
25 named as plaintiffs, sued Myriad Genetics in the Southern District of New York,
26 seeking a declaratory judgment that certain claims among the patents-in-suit were
27 invalid for failing to meet one or more requirements of the Patent Act (hereinafter,
28 the “ACLU Case”). This case ultimately led to a decision from the United States

1 Supreme Court in June of 2013.

2 42. The plaintiffs in the ACLU Case sought a declaration that numerous
3 composition and method claims in patents owned or exclusively licensed by Myriad
4 (including claims from several of the patents-in-suit in the present action) were
5 invalid for claiming ineligible subject matter. The composition claims at issue in
6 the ACLU Case covered isolated DNA from the BRCA1 and BRCA2 genes, as
7 well as synthesized complementary DNA (“cDNA”). The method claims at issue
8 were drawn to the process of identifying mutations within BRCA1 or BRCA2 using
9 well-known techniques, such as gene sequencing. The district court found all of the
10 composition and method claims at issue invalid.

11 43. Myriad appealed the district court’s decision to the Federal Circuit, and
12 the Federal Circuit ultimately issued an opinion on August 16, 2012, affirming-in-
13 part and reversing-in-part. Specifically, the Federal Circuit reversed the District
14 Court with respect to the composition claims, finding that the claims for isolated
15 DNA and cDNA were patent eligible. However, the Federal Circuit affirmed the
16 District Court’s finding that the method claims were invalid. In so doing, the
17 Federal Circuit invalidated the following method claims from the patents-in-suit:
18 claim 1 of the ‘999 patent, claim 1 of the ‘441 patent, claims 1 and 2 of the ‘857
19 patent. These claims are directed to methods of using human BRCA1 and BRCA2
20 genes to detect alterations or to screen for alterations. The Federal Circuit agreed
21 that those claims are directed to patent-ineligible subject matter, do not satisfy the
22 requirements of 35 U.S.C. § 101, and are therefore invalid. *Ass’n for Molecular*
23 *Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1329 (Fed. Cir.
24 2012).

25 44. The plaintiffs in the ACLU Case appealed to the Supreme Court, arguing
26 that the Federal Circuit was wrong to conclude that the composition claims directed
27 to isolated DNA and cDNA contained patent eligible subject matter and were valid.

28 45. Myriad did not appeal the Federal Circuit’s holding that the method

1 claims are patent ineligible under § 101. Accordingly, those method claims are, and
2 remain, invalid.

3 46. On June 13, 2013, the Supreme Court invalidated certain composition
4 claims in Myriad's patents on appeal. In its decision, the Supreme Court
5 unanimously held that isolated DNA is not patent eligible and, therefore, at least
6 claims 1 and 5 of the '282 patent and claims 1 and 6 of the '492 patent directed to
7 isolated human BRCA1 and BRCA2 genes are invalid under 35 U.S.C. § 101.
8 *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107
9 (2013).

10 47. The Supreme Court also held that, under some circumstances,
11 composition claims for synthetically created cDNA are patent eligible. The
12 Supreme Court explained

13 cDNA does not present the same obstacles to patentability
14 as naturally occurring, isolated DNA segments. As
15 already explained, creation of a cDNA sequence from
16 mRNA results in an exons-only molecule that is not
17 naturally occurring. Petitioners concede that cDNA
18 differs from natural DNA in that "the non-coding regions
19 have been removed." They nevertheless argue that cDNA
20 is not patent eligible because "[t]he nucleotide sequence
21 of cDNA is dictated by nature, not by the lab technician."
22 That may be so, but the lab technician unquestionably
creates something new when cDNA is made. cDNA
retains the naturally occurring exons of DNA, but it is
distinct from the DNA from which it was derived. As a
result, cDNA is not a "product of nature" and is patent
eligible under §101, except insofar as very short series of
DNA may have no intervening introns to remove when
creating cDNA. In that situation, a short strand of cDNA
may be indistinguishable from natural DNA.

23 *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107
24 (2013). As stated by the Supreme Court, synthetically created cDNA that is
25 indistinguishable from natural DNA sequences is not patent eligible.

26 48. After the Supreme Court decision, several entities announced that they
27 would begin offering genetic tests and related services that included sequencing and
28 analysis of the BRCA1 and/or BRCA2 genes.

1 49. On June 13, 2013, Ambry Genetics Corporation announced that it would
2 begin offering BRCA1 and BRCA2 testing and analysis services.

3 50. In response, Myriad sued Ambry Genetics Corporation in the United
4 States District Court for the District of Utah on July 9, 2013, alleging infringement
5 of certain claims of the '999, '282, '441, '721, 155', '400, '497, '492, '857, and
6 '379 patents. *See Univ. of Utah Research Found. v. Ambry Genetics, Inc.*, No. 2:
7 13-cv-000640 (D. Utah filed July 9, 2013).

8 51. On June 13, 2013, Gene by Gene Limited announced its intention to
9 begin offering BRCA1 and BRCA2 testing and analysis services to the public.

10 52. In response, Myriad sued Gene by Gene Limited in the United States
11 District Court for the District of Utah on July 10, 2013, alleging infringement of
12 certain claims of the '999, '282, '441, '721, 155', '400, '497, '492, and '857 patents.
13 *Univ. of Utah Research Found, v. Gene by Gene*, No. 2: 13-cv-000640 (D. Utah
14 filed July 10, 2013).]

15 53. Myriad's aggressive conduct has deterred other competitors from
16 entering the BRCA1/BRCA2 genetic testing market for fear of being sued. For
17 example, on June 13, 2013, Pathway Genomics announced plans to offer testing for
18 BRCA1 and BRCA2. However, after Myriad filed suits against Ambry Genetics
19 Corp. and Gene by Gene limited, Pathway Genomics stated that it is delaying
20 launch of those tests.

21 **C. QUEST'S BRCA1/BRCA2 GENETIC TESTING COMMERCIAL**
22 **OFFERINGS**

23 54. Quest Diagnostics is the world's leading provider of diagnostic
24 information services, and is the world's leader in cancer diagnostics, which include,
25 among other approaches, genetic screening assays to detect alterations in naturally
26 occurring genes.

27 55. After years of research and development, and a financial commitment of
28 millions of dollars, Quest will soon commercially launch of a novel two-part assay

1 to detect hereditary alterations in two human genes, BRCA1 and BRCA2, that
2 correlate with an increased risk for breast and/or ovarian cancer (“Quest’s BRCA
3 Assay”). The types of hereditary alterations detected by Quest’s BRCA Assay
4 include alterations in DNA copy number, deletions, duplications or rearrangements
5 in BRCA1 and BRCA2. After launch, Quest’s BRCA Assay will be made available
6 to doctors and patients as part of the complete portfolio Quest offers as part of its
7 diagnostic testing services.

8 56. Quest’s BRCA Assay does not make or use cloned DNA, replicative
9 cloning vectors, expression systems or host cells comprising BRCA1 or BRCA2
10 DNA, does not make or use BRCA1 or BRCA2 polypeptides, and does not make
11 use of any BRCA1 or BRCA2 specific primers—subject matter covered by various
12 claims of the patents-in suit.

13 57. On June 13, 2013, Quest publicly announced that it planned to market its
14 BRCA Assay. Following this announcement and Myriad’s suits against Ambry and
15 Gene by Gene, several commentators have publicly speculated that Quest may be
16 sued by Myriad for patent infringement.

17 **D. MYRIAD’S CONTINUED AGGRESSIVE ENFORCEMENT STRATEGY**

18 58. Myriad’s conduct, including Myriad’s litigation history, threatens
19 Quest’s legal rights and ability to market Quest’s BRCA Assay.

20 59. Myriad’s conduct demonstrates that it intends to continue aggressively
21 enforcing its patent portfolio. Myriad has explained that it will vigorously defend
22 method claims that cover its BRACAnalysis testing against competitors who launch
23 competing tests. Even after the prior court decisions invalidating claims from
24 several of Myriad’s patents, Myriad has emphasized the alleged strength of its
25 patent portfolio and claimed that its BRACAnalysis testing is covered by 24 valid
26 and enforceable patents.

27 60. Myriad has developed a marketing strategy designed to maintain and
28 even expand its market share with respect to BRCA1 and BRCA2 testing and

1 analysis. Competitors like Quest that enter the BRCA1/BRCA2 testing market are a
2 threat to Myriad.

3 61. Quest, as the largest entrant to the BRCA1/BRCA2 genetic testing
4 market since the Supreme Court's June decision, has specific reason to believe that
5 it will be the target of a patent infringement lawsuit from Myriad. For example, on
6 July 10, 2013, and only one day after Myriad sued Ambry and the same day it sued
7 Gene by Gene, Nicolas J. Conti, PhD, Vice President Licensing and Alliances for
8 Quest, conferred with Sam LaBrie, Vice President of Corporate Development of
9 Myriad RBM.

10 62. Mr. LaBrie knew that Dr. Conti was a representative of Quest. He knew
11 that, unless told otherwise, his comments would be perceived by Dr. Conti and
12 Quest as representative of the positions of Myriad.

13 63. Mr. LaBrie explained Myriad's business tactics and strategy. His
14 detailed discussion about Myriad's tactics and strategy, including marketing and
15 pricing strategy, made it clear to Dr. Conti that Mr. LaBrie was fully aware of
16 Myriad's positions regarding any laboratories that would offer tests for BRCA1 or
17 BRCA2. It was also clear to Dr. Conti that Mr. LaBrie knew Myriad's strategy for
18 responding to any companies that offered BRCA1 and BRCA2 tests without first
19 seeking permission from Myriad.

20 64. Mr. LaBrie specifically discussed with Dr. Conti the status of the Myriad
21 patents after the Supreme Court invalidated some of those claims. In that
22 conversation, Mr. LaBrie indicated that the public does not understand how strong
23 Myriad's patent claims are. He further stated that the notion that Quest would enter
24 the market "scared the [Myriad] team" and he confirmed that Myriad would be
25 "sending letters" to any labs who offered BRCA1 or BRCA2 tests. When making
26 that statement, Mr. LaBrie knew that Quest was planning to offer some sort of
27 BRCA testing. Therefore, upon information and belief, he intended to advise that
28 Quest would also receive a letter from Myriad objecting to Quest's offer of those

1 tests. Moreover, the above statements applied to any BRCA1 and BRCA2 testing
2 and related services. When making the above statements, Mr. LaBrie did not
3 concede that any BRCA1 or BRCA2 tests would not infringe.

4 65. Upon information and belief, when Mr. LaBrie made the above
5 statements directly to Dr. Conti, he knew that Dr. Conti, as a representative of
6 Quest, would understand that Myriad would promptly assert its patents against
7 Quest in conjunction with the launch of Quest's BRCA 1 and BRCA2 tests and
8 related services.

9 66. Quest has made a substantial research and development investment in
10 providing Quest's BRCA Assay—an accurate and cost-effective diagnostic test for
11 analyzing BRCA1 and BRCA2 genes in a patient sample. Accordingly, Quest seeks
12 and is lawfully entitled to a declaratory judgment that each of the claims of the
13 patents-in-suit is invalid and/or not infringed. There is a definite, concrete, real and
14 substantial controversy between Quest and Myriad of sufficient immediacy and
15 reality to warrant the issuance of a declaratory judgment of the same. A declaration
16 of rights between the parties is both appropriate and necessary to confirm Quest's
17 present understanding that it may continue pursuing its lawful activities unhindered
18 by the patents-in-suit.

19 **COUNT I**

20 **DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '282**
21 **PATENT**

22 67. Quest re-alleges and incorporates by reference the allegations contained
23 in paragraphs 1-66.

24 68. Quest seeks a declaration that it has not directly or indirectly infringed
25 and is not directly or indirectly infringing any claim of the '282 patent through any
26 activities related to Quest's BRCA Assay.

27 69. An actual controversy exists between Quest and Myriad with respect to
28 the non-infringement of the claims of the '282 patent, and a judicial declaration to

1 this effect is appropriate and necessary.

2 **COUNT II**

3 **DECLARATORY JUDGMENT OF INVALIDITY OF THE '282 PATENT**

4 70. Quest re-alleges and incorporates by reference the allegations contained
5 in paragraphs 1-69.

6 71. Upon information and belief, each claim of the '282 patent fails to meet
7 one or more of the statutory requirements and/or conditions for patentability under
8 the Patent Laws of the United States, 35 U.S.C. § 100 et seq., including but not
9 limited to 35 U.S.C. §§ 101-103 and 112, and/or under the judicially created
10 doctrine of obviousness-type double patenting.

11 72. An actual controversy exists between Quest and Myriad with respect to
12 the invalidity of the claims of the '282 patent, and a judicial declaration to this
13 effect is appropriate and necessary.

14 **COUNT III**

15 **DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '473**
16 **PATENT**

17 73. Quest re-alleges and incorporates by reference the allegations contained
18 in paragraphs 1-72.

19 74. Quest seeks a declaration that it has not directly or indirectly infringed
20 and is not directly or indirectly infringing any claim of the '473 patent through any
21 activities related to Quest's BRCA Assays.

22 75. An actual controversy exists between Quest and Myriad with respect to
23 the non-infringement of the claims of the '473 patent, and a judicial declaration to
24 this effect is appropriate and necessary.

25 **COUNT IV**

26 **DECLARATORY JUDGMENT OF INVALIDITY OF THE '473 PATENT**

27 76. Quest re-alleges and incorporates by reference the allegations contained
28 in paragraphs 1-75.

1 77. Upon information and belief, each claim of the '473 patent fails to meet
2 one or more of the statutory requirements and/or conditions for patentability under
3 the Patent Laws of the United States, 35 U.S.C. § 100 et seq., including but not
4 limited to 35 U.S.C. §§ 101-103 and 112, and/or under the judicially created
5 doctrine of obviousness-type double patenting.

6 78. An actual controversy exists between Quest and Myriad with respect to
7 the invalidity of the claims of the '473 patent, and a judicial declaration to this
8 effect is appropriate and necessary.

9 **COUNT V**

10 **DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '999**
11 **PATENT**

12 79. Quest re-alleges and incorporates by reference the allegations contained
13 in paragraphs 1-78.

14 80. Quest seeks a declaration that it has not directly or indirectly infringed
15 and is not directly or indirectly infringing any claim of the '999 patent through any
16 activities related to Quest's BRCA Assays.

17 81. An actual controversy exists between Quest and Myriad with respect to
18 the non-infringement of the claims of the '999 patent, and a judicial declaration to
19 this effect is appropriate and necessary.

20 **COUNT VI**

21 **DECLARATORY JUDGMENT OF INVALIDITY OF THE '999 PATENT**

22 82. Quest re-alleges and incorporates by reference the allegations contained
23 in paragraphs 1-81.

24 83. Upon information and belief, each claim of the '999 patent fails to meet
25 one or more of the statutory requirements and/or conditions for patentability under
26 the Patent Laws of the United States, 35 U.S.C. § 100 et seq., including but not
27 limited to 35 U.S.C. §§ 101-103 and 112, and/or under the judicially created
28 doctrine of obviousness-type double patenting.

1 84. An actual controversy exists between Quest and Myriad with respect to
2 the invalidity of the claims of the '999 patent, and a judicial declaration to this
3 effect is appropriate and necessary.

4 **COUNT VII**

5 **DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '001**
6 **PATENT**

7 85. Quest re-alleges and incorporates by reference the allegations contained
8 in paragraphs 1-84.

9 86. Quest seeks a declaration that it has not directly or indirectly infringed
10 and is not directly or indirectly infringing any claim of the '001 patent through any
11 activities related to Quest's BRCA Assays.

12 87. An actual controversy exists between Quest and Myriad with respect to
13 the non-infringement of the claims of the '001 patent, and a judicial declaration to
14 this effect is appropriate and necessary.

15 **COUNT VIII**

16 **DECLARATORY JUDGMENT OF INVALIDITY OF THE '001 PATENT**

17 88. Quest re-alleges and incorporates by reference the allegations contained
18 in paragraphs 1-87.

19 89. Upon information and belief, each claim of the '001 patent fails to meet
20 one or more of the statutory requirements and/or conditions for patentability under
21 the Patent Laws of the United States, 35 U.S.C. § 100 et seq., including but not
22 limited to 35 U.S.C. §§ 101-103 and 112, and/or under the judicially created
23 doctrine of obviousness-type double patenting.

24 90. An actual controversy exists between Quest and Myriad with respect to
25 the invalidity of the claims of the '001 patent, and a judicial declaration to this
26 effect is appropriate and necessary.

27 **COUNT IX**

28 **DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '441**

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PATENT

91. Quest re-alleges and incorporates by reference the allegations contained in paragraphs 1-90.

92. Quest seeks a declaration that it has not directly or indirectly infringed and is not directly or indirectly infringing any claim of the '441 patent through any activities related to Quest's BRCA Assays.

93. An actual controversy exists between Quest and Myriad with respect to the non-infringement of the claims of the '441 patent, and a judicial declaration to this effect is appropriate and necessary.

COUNT X

DECLARATORY JUDGMENT OF INVALIDITY OF THE '441 PATENT

94. Quest re-alleges and incorporates by reference the allegations contained in paragraphs 1-93.

95. Upon information and belief, each claim of the '441 patent fails to meet one or more of the statutory requirements and/or conditions for patentability under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., including but not limited to 35 U.S.C. §§ 101-103 and 112, and/or under the judicially created doctrine of obviousness-type double patenting.

96. An actual controversy exists between Quest and Myriad with respect to the invalidity of the claims of the '441 patent, and a judicial declaration to this effect is appropriate and necessary.

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COUNT XI

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '492 PATENT

97. Quest re-alleges and incorporates by reference the allegations contained

1 in paragraphs 1-96.

2 98. Quest seeks a declaration that it has not directly or indirectly infringed
3 and is not directly or indirectly infringing any claim of the '492 patent through any
4 activities related Quest's BRCA Assays.

5 99. An actual controversy exists between Quest and Myriad with respect to
6 the non-infringement of the claims of the '492 patent, and a judicial declaration to
7 this effect is appropriate and necessary.

8 **COUNT XII**

9 **DECLARATORY JUDGMENT OF INVALIDITY OF THE '492 PATENT**

10 100. Quest re-alleges and incorporates by reference the allegations contained
11 in paragraphs 1-99.

12 101. Upon information and belief, each claim of the '492 patent fails to meet
13 one or more of the statutory requirements and/or conditions for patentability under
14 the Patent Laws of the United States, 35 U.S.C. § 100 et seq., including but not
15 limited to 35 U.S.C. §§ 101-103 and 112, and/or under the judicially created
16 doctrine of obviousness-type double patenting.

17 102. An actual controversy exists between Quest and Myriad with respect to
18 the invalidity of the claims of the '492 patent, and a judicial declaration to this
19 effect is appropriate and necessary.

20 **COUNT XIII**

21 **DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '857**
22 **PATENT**

23 103. Quest re-alleges and incorporates by reference the allegations contained
24 in paragraphs 1-102.

25 104. Quest seeks a declaration that it has not directly or indirectly infringed
26 and is not directly or indirectly infringing any claim of the '857 patent through any
27 activities related Quest's BRCA Assays.

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COUNT XVI

DECLARATORY JUDGMENT OF INVALIDITY OF THE '497 PATENT

112. Quest re-alleges and incorporates by reference the allegations contained in paragraphs 1-111.

113. Upon information and belief, each claim of the '497 patent fails to meet one or more of the statutory requirements and/or conditions for patentability under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., including but not limited to 35 U.S.C. §§ 101-103 and 112, and/or under the judicially created doctrine of obviousness-type double patenting.

114. An actual controversy exists between Quest and Myriad with respect to the invalidity of the claims of the '497 patent, and a judicial declaration to this effect is appropriate and necessary.

COUNT XVII

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '698 PATENT

115. Quest re-alleges and incorporates by reference the allegations contained in paragraphs 1-114.

116. Quest seeks a declaration that it has not directly or indirectly infringed and is not directly or indirectly infringing any claim of the '698 patent through any activities related Quest's BRCA Assays.

117. An actual controversy exists between Quest and Myriad with respect to the non-infringement of the claims of the '698 patent, and a judicial declaration to this effect is appropriate and necessary.

COUNT XVIII

DECLARATORY JUDGMENT OF INVALIDITY OF THE '698 PATENT

118. Quest re-alleges and incorporates by reference the allegations contained in paragraphs 1-117.

1 119. Upon information and belief, each claim of the '698 patent fails to meet
2 one or more of the statutory requirements and/or conditions for patentability under
3 the Patent Laws of the United States, 35 U.S.C. § 100 et seq., including but not
4 limited to 35 U.S.C. §§ 101-103 and 112, and/or under the judicially created
5 doctrine of obviousness-type double patenting.

6 120. An actual controversy exists between Quest and Myriad with respect to
7 the invalidity of the claims of the '497 patent, and a judicial declaration to this
8 effect is appropriate and necessary.

9 **COUNT XIX**

10 **DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '400**
11 **PATENT**

12 121. Quest re-alleges and incorporates by reference the allegations contained
13 in paragraphs 1-120.

14 122. Quest seeks a declaration that it has not directly or indirectly infringed
15 and is not directly or indirectly infringing any claim of the '400 patent through any
16 activities related to Quest's BRCA Assays.

17 123. An actual controversy exists between Quest and Myriad with respect to
18 the non-infringement of the claims of the '400 patent, and a judicial declaration to
19 this effect is appropriate and necessary.

20 **COUNT XX**

21 **DECLARATORY JUDGMENT OF INVALIDITY OF THE '400 PATENT**

22 124. Quest re-alleges and incorporates by reference the allegations contained
23 in paragraphs 1-123.

24 125. Upon information and belief, each claim of the '400 patent fails to meet
25 one or more of the statutory requirements and/or conditions for patentability under
26 the Patent Laws of the United States, 35 U.S.C. § 100 et seq., including but not
27 limited to 35 U.S.C. §§ 101-103 and 112, and/or under the judicially created
28 doctrine of obviousness-type double patenting.

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PATENT

133. Quest re-alleges and incorporates by reference the allegations contained in paragraphs 1-132.

134. Quest seeks a declaration that it has not directly or indirectly infringed and is not directly or indirectly infringing any claim of the '721 patent through any activities related to Quest's BRCA Assays.

135. An actual controversy exists between Quest and Myriad with respect to the non-infringement of the claims of the '721 patent, and a judicial declaration to this effect is appropriate and necessary.

COUNT XXIV

DECLARATORY JUDGMENT OF INVALIDITY OF THE '721 PATENT

136. Quest re-alleges and incorporates by reference the allegations contained in paragraphs 1-135.

137. Upon information and belief, each claim 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, 35 U.S.C. § 100 et seq., including but not limited to 35 U.S.C. §§ 101-103 and 112, and/or under the judicially created doctrine of obviousness-type double patenting.

138. An actual controversy exists between Quest and Myriad with respect to the invalidity of the claims of the '721 patent, and a judicial declaration to this effect is appropriate and necessary.

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COUNT XXV

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '109 PATENT

139. Quest re-alleges and incorporates by reference the allegations contained in paragraphs 1-138.

1 140. Quest seeks a declaration that it has not directly or indirectly infringed
2 and is not directly or indirectly infringing any claim of the '109 patent through any
3 activities related to Quest's BRCA Assays.

4 141. An actual controversy exists between Quest and Myriad with respect to
5 the non-infringement of the claims of the '109 patent, and a judicial declaration to
6 this effect is appropriate and necessary.

7 **COUNT XXVI**

8 **DECLARATORY JUDGMENT OF INVALIDITY OF THE '109 PATENT**

9 142. Quest re-alleges and incorporates by reference the allegations contained
10 in paragraphs 1-141.

11 143. Upon information and belief, each claim of the '109 patent fails to meet
12 one or more of the statutory requirements and/or conditions for patentability under
13 the Patent Laws of the United States, 35 U.S.C. § 100 et seq., including but not
14 limited to 35 U.S.C. §§ 101-103 and 112, and/or under the judicially created
15 doctrine of obviousness-type double patenting.

16 144. An actual controversy exists between Quest and Myriad with respect to
17 the invalidity of the claims of the '109 patent, and a judicial declaration to this
18 effect is appropriate and necessary.

19 **COUNT XXVII**

20 **DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '379**
21 **PATENT**

22 145. Quest re-alleges and incorporates by reference the allegations contained
23 in paragraphs 1-144.

24 146. Quest seeks a declaration that it has not directly or indirectly infringed
25 and is not directly or indirectly infringing any claim of the '379 patent through any
26 activities related to Quest's BRCA Assays.

1 October 10, 2013

Respectfully submitted,

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ROBINS, KAPLAN, MILLER & CIRESI L.L.P.

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By: /s/ David Martinez

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DAVID MARTINEZ

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Attorneys for Plaintiffs

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QUEST DIAGNOSTICS

INCORPORATED and QUEST

DIAGNOSTICS NICHOLS INSTITUTE

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DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure and Local Rule 38-1 of this Court, Plaintiffs hereby demand a trial jury as to all issues so triable.

October 10, 2013

Respectfully submitted,
ROBINS, KAPLAN, MILLER & CIRESI L.L.P.

By: /s/ David Martinez
DAVID MARTINEZ

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