

1 PILLSBURY WINTHROP SHAW PITTMAN LLP
KIRKE M. HASSON (SBN 61446)
2 kirke.hasson@pillsburylaw.com
RICHARD L. BLAYLOCK (SBN 212947)
3 richard.blaylock@pillsburylaw.com
COLIN T. KEMP (SBN 215408)
4 colin.kemp@pillsburylaw.com
Four Embarcadero Center, 22nd Floor
5 Post Office Box 2824
San Francisco, CA 94126-2824
6 Telephone: (415) 983-1000
Facsimile: (415) 983-1200
7
8 Attorneys for Plaintiff,
INVITAE CORPORATION

9

10 UNITED STATES DISTRICT COURT
11 NORTHERN DISTRICT OF CALIFORNIA

12

13	_____)	<u>E-FILING</u>
14	INVITAE CORPORATION, a Delaware)	Case No.
	corporation,)	
15)	<u>COMPLAINT FOR DECLARATORY</u>
	Plaintiff,)	<u>JUDGMENT</u>
16	vs.)	
17	MYRIAD GENETICS, INC., a Delaware)	<u>DEMAND FOR JURY TRIAL</u>
	corporation,)	
18)	
	Defendant.)	
19	_____)	

20

21 Plaintiff INVITAE CORPORATION (“Invitae”) by way of its Complaint for
22 Declaratory Judgment against MYRIAD GENETICS, INC. (“Myriad”) alleges the following:

23

PARTIES

24

25 1. Invitae is a Delaware corporation with its principal place of business at
26 458 Brannan Street, San Francisco, California 94107.

27

28 2. On information and belief, Myriad is a Delaware corporation, with its principal
place of business at 320 Wakara Way, Salt Lake City, Utah 84108. On information and belief,
Myriad is the owner or exclusive licensee of the following United States Patents related to

1 Breast Cancer Susceptibility Gene 1 (“BRCA1”) and/or Breast Cancer Susceptibility Gene 2
2 (“BRCA2”) (together “BRCA1/2”) or the mutY homolog gene (“MUTYH”): U.S. Patent
3 Nos. 5,747,282; 5,753,441; 6,033,857; 6,051,379; 6,951,721; 7,250,497; 7,470,510; 7,622,258;
4 7,838,237; 7,670,776; and 7,563,571. The foregoing patents are referred to herein collectively
5 as the “Myriad Patents,” and each Myriad Patent is attached hereto. *See* Exhibits 1-11.

6 JURISDICTION AND VENUE

7 3. This action arises under the Patent Laws of the United States, 35 U.S.C. section
8 100, *et seq.*, and the Declaratory Judgments Act, 28 U.S.C. sections 2201 and 2202.

9 4. This Court has subject matter jurisdiction of this action pursuant to 28 U.S.C.
10 sections 1331, 1338(a), 2201(a) and 2202.

11 5. Venue is proper in this judicial district pursuant to 28 U.S.C. sections 1391(b)
12 and (c) and 1400(b), because a substantial part of the events giving rise to Invitae’s claims
13 occurred in this district.

14 INTRADISTRICT ASSIGNMENT

15 6. Pursuant to Civil Local Rule 3-2(c), this action is properly assigned to any of the
16 divisions in this district because it is an intellectual property action.

17 GENERAL ALLEGATIONS

18 7. This is an action to declare the Myriad Patents invalid and not infringed by
19 Invitae.

20 8. Invitae is a genetic diagnostics company with a Clinical Laboratory Improvement
21 Amendments-certified laboratory that offers customizable, clinically-relevant next-generation
22 sequencing-based genetic testing services. One of Invitae’s key innovations is that its genetic
23 test uses state-of-the-art advances in genetic testing to provide a single test for numerous genes
24 of interest at less than the cost of most single gene tests today. Thus, Invitae’s comprehensive
25 test offers the sequencing of over 200 human genes, all for less than the cost of what others
26 might charge for a test that sequences one or two.

27
28

1 9. Among the 200+ genes of an individual that can be sequenced in Invitae’s
2 groundbreaking all-in-one test are the BRCA1/2 and MUTYH genes. But Invitae performs its
3 sequencing using a very different approach than that claimed by the Myriad Patents.

4 10. Nevertheless, Myriad asserts that Invitae’s genetic sequencing test infringes the
5 Myriad Patents. Indeed, just yesterday, November 25, 2013, Myriad sued Invitae in the United
6 States District Court for the District of Utah, asserting infringement by Invitae of the Myriad
7 Patents. *See University of Utah Research Foundation, et al. v. Invitae Corporation*, Case No.
8 13-cv-01049-EJF (United States District Court, District of Utah) (the “Utah Action”). Invitae
9 intends to move to dismiss the Utah Action, and believes that such a motion will be granted.

10 11. Myriad’s filing of the Utah Action, however, makes it inescapably clear that an
11 actual and justiciable controversy has arisen and presently exists between the parties with
12 respect to the validity and infringement by Invitae of the Myriad Patents.

13 12. On the one hand, Myriad has expressly accused Invitae of infringing the Myriad
14 Patents.

15 13. On the other hand, Invitae asserts that it does not infringe the Myriad Patents,
16 asserts that those patents are invalid, and denies Myriad’s claims to the contrary. For example,
17 over half of the Myriad Patents relate to the BRCA1/2 genes; mutations or alterations of those
18 genes as indicators of enhanced susceptibility to cancer; compositions and tools made of those
19 genes (or fragments thereof); and methods for detecting the presence or absence of
20 mutations/alterations in the sequence of a patient’s BRCA1/2 gene sequence. But the very
21 different approach taken by Invitae for its BRCA1/2 genetic test is not covered by any valid
22 claim of a Myriad Patent.

23 14. For example, certain Myriad Patents merely claim DNA “primers.”¹ *See, e.g.,*
24 Patent No. 5,747,282, claims 16 and 17 (primer claims); Patent No. 5,837,492, claims 29 and 30
25 (primer claims). Still others require as elements the use of DNA primers to hybridize to and
26 amplify certain genomic DNA sequences (*e.g.*, the sequence or a fragment of the sequence of

27 _____
28 ¹ “DNA” is the abbreviation for deoxyribonucleic acid.

1 BRCA2). *See, e.g.*, Patent No. 6,033,857, claim 4 (requiring “(e) amplifying all or part of the
2 BRCA2 gene from said tissue sample using primers for a specific BRCA2 mutant allele”). But
3 Invitae’s tests do not use any such DNA primers, making non-infringement clear.

4 15. Moreover, the Myriad Patents are invalid. A vast portion of the landscape
5 purportedly claimed by the Myriad Patents has been washed away in the wake of the Federal
6 Circuit and Supreme Court’s decisions in *Association for Molecular Pathology v. Myriad*
7 *Genetics, Inc.*, 689 F.3d 1303 (Fed. Cir. 2012) (“*Myriad 1*”), *Association for Molecular*
8 *Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (“*Myriad 2*”) and *Mayo*
9 *Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012) (“*Mayo*”).

10 16. In *Myriad 2*, for example, the Supreme Court held that “naturally occurring DNA
11 segment is a product of nature and not patent eligible merely because it has been isolated[.]”
12 *Myriad 2*, 133 S. Ct. at 2111. The Court therefore invalidated the following DNA segment
13 claims of the Myriad Patents: claims 1, 5, and 6 of U.S. Patent No. 5,747,282. Based on
14 *Myriad 2*, all similar claims of the Myriad Patents should similarly be held invalid.

15 17. Furthermore, the mere method of “comparing” or “analyzing” (i) the genetic
16 sequence data from a patient with (ii) another sequence, such as a reference or wild type
17 sequence, or a sequence having a known mutation, is patent ineligible as an abstract idea (*see*
18 *Myriad 1*, 689 F.3d at 1334-35), and also patent ineligible as a law of nature. *See Mayo*, 132 S.
19 Ct. at 1298. Thus, in *Myriad 1*, the Federal Circuit invalidated the following method claims of
20 the Myriad Patent: claim 1 of U.S. Patent No. 5,753,441; and claims 1 and 2 of U.S. Patent
21 No. 6,033,857. Myriad did not appeal or petition for review of the Federal Circuit’s decision in
22 *Myriad 1* as to these method claims, so the Federal Circuit’s decision with respect to those
23 claims is final. Based on *Myriad 1*, all similar method claims of the Myriad Patents should
24 similarly be held invalid. *See, e.g.*, claims 2, 3, 5, 8, 13-15, 17-20, 23, 30 and 33 of U.S. Patent
25 No. 5,753,441; claims 3-8 of U.S. Patent No. 6,033,857; claims 32, 33 and 44 of U.S. Patent
26 No. 6,051,379; and claims 1-18 of U.S. Patent No. 6,951,721.

27
28

1 and is not directly or indirectly infringing any valid claim of the '282 patent through any of its
2 activities, including those related to the tests identified in Paragraph 23, above.

3 26. Given the actual controversy between the parties, a judicial determination of their
4 respective rights with respect to infringement of the '282 patent is necessary and appropriate
5 pursuant to 28 U.S.C. section 2201.

6 SECOND CLAIM FOR RELIEF

7 (Declaratory Judgment of Invalidity of U.S. Patent No. 5,747,282)

8 (22 U.S.C. § 2201)

9 27. Invitae realleges and incorporates the allegations of Paragraphs 1-26, above, as if
10 fully set forth herein.

11 28. An actual, immediate, and justiciable controversy exists between the parties
12 regarding whether the '282 patent is valid.

13 29. On the one hand, Myriad contend that the '282 patent is valid.

14 30. On the other hand, Invitae contends that the asserted claim(s), and other claims,
15 of the '282 patent are invalid for failure to meet one or more of the requirements of patentability
16 under the Patent Act (35 U.S.C. section 100, *et seq.*), including but not limited to 35 U.S.C.
17 sections 101, 102, 103 and/or 112, and/or under the judicially created doctrine of obviousness-
18 type double patenting.

19 31. Invitae therefore seeks a declaration that such claims of the '282 patent are
20 invalid.

21 32. A judicial determination of the parties' respective rights with respect to the
22 validity of the '282 patent is necessary and appropriate pursuant to 28 U.S.C. section 2201.

23 THIRD CLAIM FOR RELIEF

24 (Declaratory Judgment of Non-Infringement of U.S. Patent No. 5,753,441)

25 (22 U.S.C. § 2201)

26 33. Invitae realleges and incorporates the allegations of Paragraphs 1-32, above, as if
27 fully set forth herein.

28 34. An actual, immediate, and justiciable controversy exists between the parties

1 regarding whether Invitae infringes the ‘441 patent. A true and correct copy of the ‘441 patent
2 is attached as Exhibit 2.

3 35. On the one hand, Myriad contends that Invitae infringes, directly or indirectly,
4 literally or under the doctrine of equivalents, claims 7, 8, 12, 22 and 26 of the ‘441 patent by
5 making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and
6 selling and/or causing to be offered or sold the following tests: “Hereditary Breast and Ovarian
7 Cancer Syndrome,” “High-Risk Hereditary Breast Cancers,” “Women’s Hereditary Cancers,”
8 and “Hereditary Cancer Syndromes.”

9 36. On the other hand, Invitae expressly denies Myriad’s aforesaid claim of
10 infringement, as well as any claim that Invitae infringes the ‘441 patent on the basis of any other
11 Invitae test.

12 37. Invitae therefore seeks a declaration that it has not directly or indirectly infringed
13 and is not directly or indirectly infringing any valid claim of the ‘441 patent through any of its
14 activities, including those related to the tests identified in Paragraph 35, above.

15 38. Given the actual controversy between the parties, a judicial determination of their
16 respective rights with respect to infringement of the ‘441 patent is necessary and appropriate
17 pursuant to 28 U.S.C. section 2201.

18 FOURTH CLAIM FOR RELIEF

19 (Declaratory Judgment of Invalidity of U.S. Patent No. 5,753,441)

20 (22 U.S.C. § 2201)

21 39. Invitae realleges and incorporates the allegations of Paragraphs 1-38, above, as if
22 fully set forth herein.

23 40. An actual, immediate, and justiciable controversy exists between the parties
24 regarding whether the ‘441 patent is valid.

25 41. On the one hand, Myriad contend that the ‘441 patent is valid.

26 42. On the other hand, Invitae contends that the asserted claim(s), and other claims,
27 of the ‘441 patent are invalid for failure to meet one or more of the requirements of patentability
28 under the Patent Act (35 U.S.C. section 100, *et seq.*), including but not limited to 35 U.S.C.

1 sections 101, 102, 103 and/or 112, and/or under the judicially created doctrine of obviousness-
2 type double patenting.

3 43. Invitae therefore seeks a declaration that such claims of the ‘441 patent are
4 invalid.

5 44. A judicial determination of the parties’ respective rights with respect to the
6 validity of the ‘441 patent is necessary and appropriate pursuant to 28 U.S.C. section 2201.

7 FIFTH CLAIM FOR RELIEF

8 (Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,033,857)

9 (22 U.S.C. § 2201)

10 45. Invitae realleges and incorporates the allegations of Paragraphs 1-44, above, as if
11 fully set forth herein.

12 46. An actual, immediate, and justiciable controversy exists between the parties
13 regarding whether Invitae infringes the ‘857 patent. A true and correct copy of the ‘857 patent
14 is attached as Exhibit 3.

15 47. On the one hand, Myriad contends that Invitae infringes, directly or indirectly,
16 literally or under the doctrine of equivalents, claim 4 of the ‘857 patent by making,
17 manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling
18 and/or causing to be offered or sold the following tests: “Hereditary Breast and Ovarian Cancer
19 Syndrome,” “High-Risk Hereditary Breast Cancers,” “Women’s Hereditary Cancers,”
20 “Hereditary Cancer Syndromes,” and “Fanconi Anemia.”

21 48. On the other hand, Invitae expressly denies Myriad’s aforesaid claim of
22 infringement, as well as any claim that Invitae infringes the ‘857 patent on the basis of any other
23 Invitae test.

24 49. Invitae therefore seeks a declaration that it has not directly or indirectly infringed
25 and is not directly or indirectly infringing any valid claim of the ‘857 patent through any of its
26 activities, including those related to the tests identified in Paragraph 47, above.

27 50. Given the actual controversy between the parties, a judicial determination of their
28 respective rights with respect to infringement of the ‘857 patent is necessary and appropriate

1 pursuant to 28 U.S.C. section 2201.

2 SIXTH CLAIM FOR RELIEF

3 (Declaratory Judgment of Invalidity of U.S. Patent No. 6,033,857)

4 (22 U.S.C. § 2201)

5 51. Invitae realleges and incorporates the allegations of Paragraphs 1-50, above, as if
6 fully set forth herein.

7 52. An actual, immediate, and justiciable controversy exists between the parties
8 regarding whether the '857 patent is valid.

9 53. On the one hand, Myriad contend that the '857 patent is valid.

10 54. On the other hand, Invitae contends that the asserted claim(s), and other claims,
11 of the '857 patent are invalid for failure to meet one or more of the requirements of patentability
12 under the Patent Act (35 U.S.C. section 100, *et seq.*), including but not limited to 35 U.S.C.
13 sections 101, 102, 103 and/or 112, and/or under the judicially created doctrine of obviousness-
14 type double patenting.

15 55. Invitae therefore seeks a declaration that such claims of the '857 patent are
16 invalid.

17 56. A judicial determination of the parties' respective rights with respect to the
18 validity of the '857 patent is necessary and appropriate pursuant to 28 U.S.C. section 2201.

19 SEVENTH CLAIM FOR RELIEF

20 (Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,051,379)

21 (22 U.S.C. § 2201)

22 57. Invitae realleges and incorporates the allegations of Paragraphs 1-56, above, as if
23 fully set forth herein.

24 58. An actual, immediate, and justiciable controversy exists between the parties
25 regarding whether Invitae infringes the '379 patent. A true and correct copy of the '379 patent
26 is attached as Exhibit 4.

27 59. On the one hand, Myriad contends that Invitae infringes, directly or indirectly,
28 literally or under the doctrine of equivalents, claims 32 and 33 of the '379 patent by making,

1 manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling
2 and/or causing to be offered or sold the following tests: “Hereditary Breast and Ovarian Cancer
3 Syndrome,” “High-Risk Hereditary Breast Cancers,” “Women’s Hereditary Cancers,”
4 “Hereditary Cancer Syndromes,” and “Fanconi Anemia.”

5 60. On the other hand, Invitae expressly denies Myriad’s aforesaid claim of
6 infringement, as well as any claim that Invitae infringes the ‘379 patent on the basis of any other
7 Invitae test.

8 61. Invitae therefore seeks a declaration that it has not directly or indirectly infringed
9 and is not directly or indirectly infringing any valid claim of the ‘379 patent through any of its
10 activities, including those related to the tests identified in Paragraph 59, above.

11 62. Given the actual controversy between the parties, a judicial determination of their
12 respective rights with respect to infringement of the ‘379 patent is necessary and appropriate
13 pursuant to 28 U.S.C. section 2201.

14 EIGHTH CLAIM FOR RELIEF

15 (Declaratory Judgment of Invalidity of U.S. Patent No. 6,051,379)

16 (22 U.S.C. § 2201)

17 63. Invitae realleges and incorporates the allegations of Paragraphs 1-62, above, as if
18 fully set forth herein.

19 64. An actual, immediate, and justiciable controversy exists between the parties
20 regarding whether the ‘379 patent is valid.

21 65. On the one hand, Myriad contend that the ‘379 patent is valid.

22 66. On the other hand, Invitae contends that the asserted claim(s), and other claims,
23 of the ‘379 patent are invalid for failure to meet one or more of the requirements of patentability
24 under the Patent Act (35 U.S.C. section 100, *et seq.*), including but not limited to 35 U.S.C.
25 sections 101, 102, 103 and/or 112, and/or under the judicially created doctrine of obviousness-
26 type double patenting.

27 67. Invitae therefore seeks a declaration that such claims of the ‘379 patent are
28 invalid.

1 TENTH CLAIM FOR RELIEF

2 (Declaratory Judgment of Invalidity of U.S. Patent No. 6,951,721)

3 (22 U.S.C. § 2201)

4 75. Invitae realleges and incorporates the allegations of Paragraphs 1-74, above, as if
5 fully set forth herein.

6 76. An actual, immediate, and justiciable controversy exists between the parties
7 regarding whether the '721 patent is valid.

8 77. On the one hand, Myriad contend that the '721 patent is valid.

9 78. On the other hand, Invitae contends that the asserted claim(s), and other claims,
10 of the '721 patent are invalid for failure to meet one or more of the requirements of patentability
11 under the Patent Act (35 U.S.C. section 100, *et seq.*), including but not limited to 35 U.S.C.
12 sections 101, 102, 103 and/or 112, and/or under the judicially created doctrine of obviousness-
13 type double patenting.

14 79. Invitae therefore seeks a declaration that such claims of the '721 patent are
15 invalid.

16 80. A judicial determination of the parties' respective rights with respect to the
17 validity of the '721 patent is necessary and appropriate pursuant to 28 U.S.C. section 2201.

18 ELEVENTH CLAIM FOR RELIEF

19 (Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,250,497)

20 (22 U.S.C. § 2201)

21 81. Invitae realleges and incorporates the allegations of Paragraphs 1-80, above, as if
22 fully set forth herein.

23 82. An actual, immediate, and justiciable controversy exists between the parties
24 regarding whether Invitae infringes the '497 patent. A true and correct copy of the '497 patent
25 is attached as Exhibit 6.

26 83. On the one hand, Myriad contends that Invitae infringes, directly or indirectly,
27 literally or under the doctrine of equivalents, claims 3-8, 11, 14, and 17-19 of the '497 patent by
28 making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and

1 selling and/or causing to be offered or sold the following tests: “Hereditary Breast and Ovarian
2 Cancer Syndrome,” “High-Risk Hereditary Breast Cancers,” “Women’s Hereditary Cancers,”
3 and “Hereditary Cancer Syndromes.”

4 84. On the other hand, Invitae expressly denies Myriad’s aforesaid claim of
5 infringement, as well as any claim that Invitae infringes the ‘497 patent on the basis of any other
6 Invitae test.

7 85. Invitae therefore seeks a declaration that it has not directly or indirectly infringed
8 and is not directly or indirectly infringing any valid claim of the ‘497 patent through any of its
9 activities, including those related to the tests identified in Paragraph 83, above.

10 86. Given the actual controversy between the parties, a judicial determination of their
11 respective rights with respect to infringement of the ‘497 patent is necessary and appropriate
12 pursuant to 28 U.S.C. section 2201.

13 TWELFTH CLAIM FOR RELIEF

14 (Declaratory Judgment of Invalidity of U.S. Patent No. 7,250,497)

15 (22 U.S.C. § 2201)

16 87. Invitae realleges and incorporates the allegations of Paragraphs 1-86, above, as if
17 fully set forth herein.

18 88. An actual, immediate, and justiciable controversy exists between the parties
19 regarding whether the ‘497 patent is valid.

20 89. On the one hand, Myriad contend that the ‘497 patent is valid.

21 90. On the other hand, Invitae contends that the asserted claim(s), and other claims,
22 of the ‘497 patent are invalid for failure to meet one or more of the requirements of patentability
23 under the Patent Act (35 U.S.C. section 100, *et seq.*), including but not limited to 35 U.S.C.
24 sections 101, 102, 103 and/or 112, and/or under the judicially created doctrine of obviousness-
25 type double patenting.

26 91. Invitae therefore seeks a declaration that such claims of the ‘497 patent are
27 invalid.

28 92. A judicial determination of the parties’ respective rights with respect to the

1 validity of the '497 patent is necessary and appropriate pursuant to 28 U.S.C. section 2201.

2 THIRTEENTH CLAIM FOR RELIEF

3 (Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,470,510)

4 (22 U.S.C. § 2201)

5 93. Invitae realleges and incorporates the allegations of Paragraphs 1-92, above, as if
6 fully set forth herein.

7 94. An actual, immediate, and justiciable controversy exists between the parties
8 regarding whether Invitae infringes the '510 patent. A true and correct copy of the '510 patent
9 is attached as Exhibit 7.

10 95. On the one hand, Myriad contends that Invitae infringes, directly or indirectly,
11 literally or under the doctrine of equivalents, claims 5-18 of the '510 patent by making,
12 manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling
13 and/or causing to be offered or sold the following tests: "Hereditary Colon Cancers," "High
14 Risk Hereditary Colon Cancers," "Hereditary Cancer Syndromes," and "Women's Hereditary
15 Cancers."

16 96. On the other hand, Invitae expressly denies Myriad's aforesaid claim of
17 infringement, as well as any claim that Invitae infringes the '510 patent on the basis of any other
18 Invitae test.

19 97. Invitae therefore seeks a declaration that it has not directly or indirectly infringed
20 and is not directly or indirectly infringing any valid claim of the '510 patent through any of its
21 activities, including those related to the tests identified in Paragraph 95, above.

22 98. Given the actual controversy between the parties, a judicial determination of their
23 respective rights with respect to infringement of the '510 patent is necessary and appropriate
24 pursuant to 28 U.S.C. section 2201.

25 FOURTEENTH CLAIM FOR RELIEF

26 (Declaratory Judgment of Invalidity of U.S. Patent No. 7,470,510)

27 (22 U.S.C. § 2201)

28 99. Invitae realleges and incorporates the allegations of Paragraphs 1-98, above, as if

1 fully set forth herein.

2 100. An actual, immediate, and justiciable controversy exists between the parties
3 regarding whether the ‘510 patent is valid.

4 101. On the one hand, Myriad contend that the ‘510 patent is valid.

5 102. On the other hand, Invitae contends that the asserted claim(s), and other claims,
6 of the ‘510 patent are invalid for failure to meet one or more of the requirements of patentability
7 under the Patent Act (35 U.S.C. section 100, *et seq.*), including but not limited to 35 U.S.C.
8 sections 101, 102, 103 and/or 112, and/or under the judicially created doctrine of obviousness-
9 type double patenting.

10 103. Invitae therefore seeks a declaration that such claims of the ‘510 patent are
11 invalid.

12 104. A judicial determination of the parties’ respective rights with respect to the
13 validity of the ‘510 patent is necessary and appropriate pursuant to 28 U.S.C. section 2201.

14 FIFTEENTH CLAIM FOR RELIEF

15 (Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,622,258)

16 (22 U.S.C. § 2201)

17 105. Invitae realleges and incorporates the allegations of Paragraphs 1-104, above, as
18 if fully set forth herein.

19 106. An actual, immediate, and justiciable controversy exists between the parties
20 regarding whether Invitae infringes the ‘258 patent. A true and correct copy of the ‘258 patent
21 is attached as Exhibit 8.

22 107. On the one hand, Myriad contends that Invitae infringes, directly or indirectly,
23 literally or under the doctrine of equivalents, claims 10, 11, 15-17, and 19 of the ‘258 patent by
24 making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and
25 selling and/or causing to be offered or sold the following tests: “Hereditary Colon Cancers,”
26 “High Risk Hereditary Colon Cancers,” “Hereditary Cancer Syndromes,” and “Women’s
27 Hereditary Cancers.”

28 108. On the other hand, Invitae expressly denies Myriad’s aforesaid claim of

1 infringement, as well as any claim that Invitae infringes the ‘258 patent on the basis of any other
2 Invitae test.

3 109. Invitae therefore seeks a declaration that it has not directly or indirectly infringed
4 and is not directly or indirectly infringing any valid claim of the ‘258 patent through any of its
5 activities, including those related to the tests identified in Paragraph 107, above.

6 110. Given the actual controversy between the parties, a judicial determination of their
7 respective rights with respect to infringement of the ‘258 patent is necessary and appropriate
8 pursuant to 28 U.S.C. section 2201.

9 SIXTEENTH CLAIM FOR RELIEF

10 (Declaratory Judgment of Invalidity of U.S. Patent No. 7,622,258)

11 (22 U.S.C. § 2201)

12 111. Invitae realleges and incorporates the allegations of Paragraphs 1-110, above, as
13 if fully set forth herein.

14 112. An actual, immediate, and justiciable controversy exists between the parties
15 regarding whether the ‘258 patent is valid.

16 113. On the one hand, Myriad contend that the ‘258 patent is valid.

17 114. On the other hand, Invitae contends that the asserted claim(s), and other claims,
18 of the ‘258 patent are invalid for failure to meet one or more of the requirements of patentability
19 under the Patent Act (35 U.S.C. section 100, *et seq.*), including but not limited to 35 U.S.C.
20 sections 101, 102, 103 and/or 112, and/or under the judicially created doctrine of obviousness-
21 type double patenting.

22 115. Invitae therefore seeks a declaration that such claims of the ‘258 patent are
23 invalid.

24 116. A judicial determination of the parties’ respective rights with respect to the
25 validity of the ‘258 patent is necessary and appropriate pursuant to 28 U.S.C. section 2201.

26
27
28

1 SEVENTEENTH CLAIM FOR RELIEF

2 (Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,838,237)

3 (22 U.S.C. § 2201)

4 117. Invitae realleges and incorporates the allegations of Paragraphs 1-116, above, as
5 if fully set forth herein.

6 118. An actual, immediate, and justiciable controversy exists between the parties
7 regarding whether Invitae infringes the ‘237 patent. A true and correct copy of the ‘237 patent
8 is attached as Exhibit 9.

9 119. On the one hand, Myriad contends that Invitae infringes, directly or indirectly,
10 literally or under the doctrine of equivalents, claims 2, 8 and 16 of the ‘237 patent by making,
11 manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling
12 and/or causing to be offered or sold the following tests: “Hereditary Colon Cancers,” “High
13 Risk Hereditary Colon Cancers,” “Hereditary Cancer Syndromes,” and “Women’s Hereditary
14 Cancers.”

15 120. On the other hand, Invitae expressly denies Myriad’s aforesaid claim of
16 infringement, as well as any claim that Invitae infringes the ‘237 patent on the basis of any other
17 Invitae test.

18 121. Invitae therefore seeks a declaration that it has not directly or indirectly infringed
19 and is not directly or indirectly infringing any valid claim of the ‘237 patent through any of its
20 activities, including those related to the tests identified in Paragraph 119, above.

21 122. Given the actual controversy between the parties, a judicial determination of their
22 respective rights with respect to infringement of the ‘237 patent is necessary and appropriate
23 pursuant to 28 U.S.C. section 2201.

24 EIGHTEENTH CLAIM FOR RELIEF

25 (Declaratory Judgment of Invalidity of U.S. Patent No. 7,838,237)

26 (22 U.S.C. § 2201)

27 123. Invitae realleges and incorporates the allegations of Paragraphs 1-122, above, as
28 if fully set forth herein.

1 Invitae test.

2 133. Invitae therefore seeks a declaration that it has not directly or indirectly infringed
3 and is not directly or indirectly infringing any valid claim of the ‘776 patent through any of its
4 activities, including those related to the tests identified in Paragraph 131, above.

5 134. Given the actual controversy between the parties, a judicial determination of their
6 respective rights with respect to infringement of the ‘776 patent is necessary and appropriate
7 pursuant to 28 U.S.C. section 2201.

8 TWENTIETH CLAIM FOR RELIEF

9 (Declaratory Judgment of Invalidity of U.S. Patent No. 7,670,776)

10 (22 U.S.C. § 2201)

11 135. Invitae realleges and incorporates the allegations of Paragraphs 1-134, above, as
12 if fully set forth herein.

13 136. An actual, immediate, and justiciable controversy exists between the parties
14 regarding whether the ‘776 patent is valid.

15 137. On the one hand, Myriad contend that the ‘776 patent is valid.

16 138. On the other hand, Invitae contends that the asserted claim(s), and other claims,
17 of the ‘776 patent are invalid for failure to meet one or more of the requirements of patentability
18 under the Patent Act (35 U.S.C. section 100, *et seq.*), including but not limited to 35 U.S.C.
19 sections 101, 102, 103 and/or 112, and/or under the judicially created doctrine of obviousness-
20 type double patenting.

21 139. Invitae therefore seeks a declaration that such claims of the ‘776 patent are
22 invalid.

23 140. A judicial determination of the parties’ respective rights with respect to the
24 validity of the ‘776 patent is necessary and appropriate pursuant to 28 U.S.C. section 2201.

25 TWENTY-FIRST CLAIM FOR RELIEF

26 (Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,563,571)

27 (22 U.S.C. § 2201)

28 141. Invitae realleges and incorporates the allegations of Paragraphs 1-140, above, as

1 if fully set forth herein.

2 142. An actual, immediate, and justiciable controversy exists between the parties
3 regarding whether Invitae infringes the ‘571 patent. A true and correct copy of the ‘571 patent
4 is attached as Exhibit 11.

5 143. On the one hand, Myriad contends that Invitae infringes, directly or indirectly,
6 literally or under the doctrine of equivalents, claims 2 and 7 of the ‘571 patent by making,
7 manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling
8 and/or causing to be offered or sold the following tests: “Hereditary Colon Cancers,” “High
9 Risk Hereditary Colon Cancers,” “Hereditary Cancer Syndromes,” and “Women’s Hereditary
10 Cancers.”

11 144. On the other hand, Invitae expressly denies Myriad’s aforesaid claim of
12 infringement, as well as any claim that Invitae infringes the ‘571 patent on the basis of any other
13 Invitae test.

14 145. Invitae therefore seeks a declaration that it has not directly or indirectly infringed
15 and is not directly or indirectly infringing any valid claim of the ‘571 patent through any of its
16 activities, including those related to the tests identified in Paragraph 143, above.

17 146. Given the actual controversy between the parties, a judicial determination of their
18 respective rights with respect to infringement of the ‘571 patent is necessary and appropriate
19 pursuant to 28 U.S.C. section 2201.

20 TWENTY-SECOND CLAIM FOR RELIEF

21 (Declaratory Judgment of Invalidity of U.S. Patent No. 7,563,571)

22 (22 U.S.C. § 2201)

23 147. Invitae realleges and incorporates the allegations of Paragraphs 1-146, above, as
24 if fully set forth herein.

25 148. An actual, immediate, and justiciable controversy exists between the parties
26 regarding whether the ‘571 patent is valid.

27 149. On the one hand, Myriad contend that the ‘571 patent is valid.

28 150. On the other hand, Invitae contends that the asserted claim(s), and other claims,

1 of the '571 patent are invalid for failure to meet one or more of the requirements of patentability
2 under the Patent Act (35 U.S.C. section 100, *et seq.*), including but not limited to 35 U.S.C.
3 sections 101, 102, 103 and/or 112, and/or under the judicially created doctrine of obviousness-
4 type double patenting.

5 151. Invitae therefore seeks a declaration that such claims of the '571 patent are
6 invalid.

7 152. A judicial determination of the parties' respective rights with respect to the
8 validity of the '571 patent is necessary and appropriate pursuant to 28 U.S.C. section 2201.

9 PRAYER FOR RELIEF

10 WHEREFORE, Invitae respectfully prays for judgment against Defendants as follows:

11 A. For a declaration under 28 U.S.C. section 2201 that Invitae has not infringed any
12 valid claim of the Myriad Patents;

13 B. For a declaration under 28 U.S.C. section 2201 that each claim of the Myriad
14 Patents is invalid under the Patent Act, 35 U.S.C. section 100, *et seq.*;

15 C. For a declaration that this is an exceptional case under 35 U.S.C. section 285 and
16 that Invitae be and is awarded its attorney's fees and costs incurred herein; and

17 ///
18 ///
19 ///
20 ///
21 ///
22 ///
23 ///
24 ///
25 ///
26 ///
27 ///
28 ///

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

DEMAND FOR JURY TRIAL

TO THE COURT, AND TO DEFENDANTS AND THEIR ATTORNEYS OF RECORD:

Plaintiff INVITAE CORPORATION hereby demands a trial by jury to decide all issues so triable in this action.

Dated: November 26, 2013.

PILLSBURY WINTHROP SHAW PITTMAN LLP
KIRKE M. HASSON (SBN 61446)
kirke.hasson@pillsburylaw.com
RICHARD L. BLAYLOCK (SBN 212947)
richard.blaylock@pillsburylaw.com
COLIN T. KEMP (SBN 215408)
colin.kemp@pillsburylaw.com
Four Embarcadero Center, 22nd Floor
Post Office Box 2824
San Francisco, CA 94126-2824

By _____ /s/ Kirke M. Hasson
Kirke M. Hasson
Attorneys for Plaintiff,
INVITAE CORPORATION