Edgar R. Cataxinos (7162)
Joseph A. Walkowski (5366)
H. Dickson Burton (4004)
TRASKBRITT, P.C.
P.O. Box 2550
230 South 500 East, Suite 300
Salt Lake City, Utah 84110
Tel: (801) 532-1922
Fax: (801) 531-9168

William G. Gaede, III (*pro hac vice*)
MCDERMOTT WILL & EMERY LLP
wgaede@mwe.com
275 Middlefield Road, Suite 100
Menlo Park, CA 94025
Tel: (650) 815-7435
Fax: (650) 469-1470

Attorneys for Defendant

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

UNIVERSITY OF UTAH RESEARCH FOUNDATION, a Utah nonprofit corporation; the **TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA**, a Pennsylvania nonprofit corporation; **HSC RESEARCH AND DEVELOPMENT LIMITED PARTNERSHIP**, a Canadian limited partnership organized under the laws of the Province of Ontario; **ENDORECHERCHE, INC.**, a Canadian corporation organized under the laws of the Province of Quebec; and **MYRIAD GENETICS, INC.**, a Delaware corporation; Plaintiffs, vs. **AMBRY GENETICS CORPORATION**, Defendant.	**AMBRY GENETIC CORPORATION'S ANSWER TO PLAINTIFFS' COMPLAINT; AFFIRMATIVE DEFENSES; AND COUNTERCLAIMS FOR ANTITRUST VIOLATIONS OF THE SHERMAN ACT AND DECLARATORY RELIEF OF INVALIDITY AND NONINFRINGEMENT** **JURY TRIAL DEMANDED** CASE NO. 2:13-CV-00640 RJS Judge Robert J. Shelby

Pursuant to the Federal Rules of Civil Procedure 7, 8, 12 and 15, Defendant Ambry Genetics Corporation ("Ambry"), hereby submits this Answer, Affirmative Defenses and

Counterclaims to the Complaint (Dkt. #2) of Plaintiffs University of Utah Research Foundation, the Trustees of the University of Pennsylvania, HSC Research and Development Limited Partnership, Endorecherche, Inc., and Myriad Genetics, Inc. ("Plaintiffs").

JURISDICTION AND VENUE

2. This civil action for patent infringement arises under the patent laws of the United States, specifically under Title 35 of the United States Code, Sections 271, *et seq*. Subject matter jurisdiction in this Court is founded upon 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: The statement in Paragraph 2 is neither an averment nor an allegation to which a response is required. To the extent that a response is required, Ambry admits that this Court has subject matter jurisdiction over this matter. All remaining allegations of paragraph 2 are denied.

3. This Court has personal jurisdiction over the Defendant because it regularly conducts business in this district and has committed acts in this judicial district which give rise to this action. On information and belief, Defendant sells, offers for sale, and has sold genetic testing products to residents of this jurisdiction. On information and belief, Defendant has attended, advertised, and or presented at conferences and/or meetings held in this jurisdiction in which it sells, offers for sale, has sold, and advertises its genetic testing products. On information and belief, Defendant has business relationships and/or has collaborated with multiple business and/or research entities in this district to which it sells, offers for sale, has sold, and/or advertises its genetic testing products. On information and belief, Defendant is a participating Medicaid and health insurance provider in this district.

ANSWER: Ambry admits that this Court has personal jurisdiction over the Defendant. All remaining allegations of paragraph 3 are denied.

4. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and/or 28 U.S.C. § 1400(b).

ANSWER: The statement in Paragraph 4 is neither an averment nor an allegation to which a response is required. To the extent that a response is required, Ambry admits that venue is proper in this matter. All remaining allegations of paragraph 4 are denied.

PARTIES

5. The University of Utah is a Utah nonprofit corporation with an address at 421 Wakara Way, Suite 170, Salt Lake City, Utah 84108. The University of Utah is the owner or co-owner of United States Patent Nos. 5,709,999; 5,747,282; 5,753,441; 5,837,492; and 6,033,857.

ANSWER: Upon information and belief, Ambry admits that the University of Utah is a nonprofit corporation located in Utah. All others allegations of paragraph 5 are denied.

6. The University of Pennsylvania is a Pennsylvania nonprofit corporation with an address of 3160 Chestnut Street, Suite 200, Philadelphia, Pennsylvania 19104-6283. The University of Pennsylvania is a co-owner of United States Patent Nos. 6,033,857 and 5,837,492.

ANSWER: Upon information and belief, Ambry admits that the University of Pennsylvania is a nonprofit corporation located in Pennsylvania. All others allegations of paragraph 6 are denied.

7. The Hospital for Sick Children is a Canadian limited partnership organized under the laws of the Province of Ontario, with an address of 555 University Avenue, Toronto, Ontario M5G 1X8, Canada. The Hospital for Sick Children is a co-owner of United States Patent Nos. 6,033,857 and 5,837,492.

ANSWER: Upon information and belief, Ambry admits that the Hospital for Sick Children is a limited partnership organized under the laws of the Province of Ontario, located in Toronto, Ontario, Canada. All others allegations of paragraph 7 are denied.

8. Endorecherche is Canadian corporation organized under the laws of the Province of Quebec, with a place of business at 2989 De La Promenade, Ste-Foy, Quebec,

QC G1W 2J5, Canada. Endorecherche is a co-owner of United States Patent Nos. 6,033,857 and 5,837,492.

ANSWER: Upon information and belief, Ambry admits that Endorecherche is a corporation organized under the laws of the Province of Quebec, located in Quebec, Canada. All others allegations of paragraph 8 are denied.

9. Myriad is a Delaware corporation, with its principal place of business at 320 Wakara Way, Salt Lake City, Utah 84108. Myriad owns United States Patent Nos. 5,654,155; 5,750,400; 6,051,379; 6,951,721; 7,250,497, 7,670,776; and 7,563,571. As of July 1, 2013, Myriad owns United States Patent Nos. 7,622,258; and 7,838,237. As of July 19, 2013, Myriad owns United States Patent No. 7,470,510. Further, Myriad is the exclusive licensee of United States Patent Nos. 5,709,999; 5,747,282; 5,753,441; 5,837,492; and 6,033,857.

ANSWER: Upon information and belief, Ambry admits that Myriad Genetics, Inc. is a Delaware, located in Salt Lake City, Utah. All others allegations of paragraph 8 are denied.

10. The Plaintiffs are informed and believe, and on that basis allege, that Defendant is a California corporation that has its principal place of business at 15 Argonaut, Aliso Viejo, California 92656.

ANSWER: Ambry admits the allegations of paragraph 10 of Plaintiffs' Complaint.

GENERAL ALLEGATIONS

11. Myriad is a molecular diagnostic company that develops and uses proprietary technologies that permit doctors and patients to understand the genetic basis of human disease and the role that genes play in the onset, progression and treatment of disease. Myriad's technologies result in, and guide the development of, new molecular diagnostic products that assess an individual's risk for developing disease, identify a patient's likely response to drug therapy, and assess a patient's risk of disease progression and recurrence.

ANSWER: The statement in Paragraph 11 is neither an averment nor an allegation to which a response is required. To the extent that a response is required, Ambry lacks knowledge or information sufficient to form a belief as to the truth of the statements contained in Paragraph 11 and therefore denies them.

12. For healthcare providers, Myriad offers an array of genetic tests, prognostic tests and personalized medicine tests to help healthcare providers assess a patient's increased cancer risk, disease aggressiveness and optimize efficacy of chemotherapy. Myriad's testing products provide healthcare providers with information to help make medical management decisions to reduce cancer risk and help make sure specific treatments are tailored for each individual patient.

ANSWER: The statement in Paragraph 12 is neither an averment nor an allegation to which a response is required. To the extent that a response is required, Ambry lacks knowledge or information sufficient to form a belief as to the truth of the statements contained in Paragraph 12 and therefore denies them.

13. For patients, Myriad offers tests that provide important clinical information to assist patients and their healthcare providers in assessing cancer risk so the patient can take preventative action to reduce the risk of disease and in making treatment decisions if the patient is diagnosed with cancer. Myriad improves patient care through the development of new products across multiple medical specialties.

ANSWER: The statement in Paragraph 13 is neither an averment nor an allegation to which a response is required. To the extent that a response is required, Ambry lacks knowledge or information sufficient to form a belief as to the truth of the statements contained in Paragraph 13 and therefore denies them.

14. In the early-to-mid 1990s, Plaintiffs discovered the genetic sequences of the BRCA1 and BRCA2 genes and mutations that increase a woman's risk of developing breast and ovarian cancer. Since that time, Myriad has invested over $500 million to implement this

discovery and create a molecular diagnostic test for hereditary breast and ovarian cancer related to the BRCA1 and BRCA2 genes. Likewise, Myriad has spent significant resources to create a molecular diagnostic test for hereditary colon cancer caused by mutations in the mutY homolog (MYH) gene. Plaintiffs' efforts have revolutionized patient care and provided medical diagnosis and treatment options never thought possible.

ANSWER: The statement in Paragraph 14 is neither an averment nor an allegation to which a response is required. To the extent that a response is required, Ambry denies each and every allegation in Paragraph 14.

15. Defendant offers laboratory services, including clinical diagnostic and genomic services, including testing and analysis of BRCA1, BRCA2, and MUTYH genes.

ANSWER: Ambry admits it offers laboratory services, including clinical diagnostic and genomic services. Ambry further admits that as of July 9, 2013, when the Complaint was filed, Ambry was offering to accept and was accepting samples for its *BRCA*plus, BreastNext, CancerNext, and OvaNext products. Ambry denies the remainder of this allegation.

16. Defendant began offering its BRCA1 and BRCA2 analysis as part of its cancer-testing menu on June 13, 2013. On information and belief, Defendant offers stand-alone tests comprising full gene sequencing and deletion/duplication analyses for the BRCA1, BRCA2, and MUTYH genes. On information and belief, Defendant also offers full gene sequencing and deletion/duplication analyses for the BRCA1, BRCA2, and MUTYH genes as part of multiple hereditary cancer panels that test cancer susceptibility using next-generation sequencing technology.

ANSWER: Ambry admits that as of June 13, 2013, Ambry offered to receive samples for its *BRCA*plus, BreastNext, CancerNext, and OvaNext products. Ambry admits that if implemented each of these products will determine patients' *BRCA1* and *BRCA2* and *MUTYH* sequences. Ambry admits that these products utilize next generation sequencing. Ambry admits

that each of these products include deletion/duplication analyses. Ambry denies the remainder of this allegation.

FIRST CLAIM FOR RELIEF
(By the University of Utah and Myriad for Infringement of United States Patent No. 5,709,999)

17. Plaintiffs repeat and reallege the allegations set forth in preceding paragraphs 1 through 16, inclusive.

ANSWER: The statement in Paragraph 17 is neither an averment nor an allegation to which a response is required.

18. United States Patent No. 5,709,999 (the "'999 Patent"), was duly and legally issued by the United States Patent and Trademark Office on January 20, 1998. The University of Utah is the owner and Myriad is the exclusive licensee of the '999 Patent. A true and correct copy of the '999 Patent is attached hereto and incorporated herein by reference as Exhibit 1.

ANSWER: Ambry denies that the '999 Patent was duly and legally issued by the United States Patent and Trademark Office. Ambry lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 18 and therefore denies them.

19. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '999 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold certain BRCA1, BRCA2, BRCAPlus, BreastNext, OvaNext, and CancerNext products that infringe at least the following claim of the '999 patent literally and/or under the doctrine of equivalents: Claim 6.

ANSWER: Ambry denies the allegations of paragraph 19 of Plaintiffs' Complaint.

20. Plaintiffs have been damaged and have suffered irreparable injury due to the Defendant's acts of infringement, and will continue to suffer irreparable injury unless Defendant's acts are enjoined.

ANSWER: Ambry denies the allegations of paragraph 20 of Plaintiffs' Complaint.

21. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant's acts of patent infringement as alleged herein. The University of Utah has suffered and will continue to suffer substantial damage in the form of reduced royalty payments by reason of Defendant's acts of patent infringement and the resulting reduction in Myriad's sales revenues. Plaintiffs are entitled to recover from Defendant the damages sustained as a result of Defendant's acts.

ANSWER: Ambry denies the allegations of paragraph 21 of Plaintiffs' Complaint.

22. Defendant has willfully infringed the '999 Patent.

ANSWER: Ambry denies the allegations of paragraph 22 of Plaintiffs' Complaint.

23. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Ambry denies the allegations of paragraph 23 of Plaintiffs' Complaint.

SECOND CLAIM FOR RELIEF
(By the University of Utah and Myriad for Infringement of United States Patent No. 5,747,282)

24. Plaintiffs repeat and reallege the allegations set forth in preceding paragraphs 1 through 23, inclusive.

ANSWER: The statement in Paragraph 24 is neither an averment nor an allegation to which a response is required.

25. United States Patent No. 5,747,282 (the "'282 Patent"), was duly and legally issued by the United States Patent and Trademark Office on May 5, 1998. The University of Utah, along with the Public Health Service, through the National Institutes of Health ("PHS"), are the owners, and Myriad is the exclusive licensee, of the '282 Patent. A true and correct copy of the '282 Patent is attached hereto and incorporated herein by reference as Exhibit 2.

ANSWER: Ambry denies that the ’282 Patent was duly and legally issued by the United States Patent and Trademark Office. Ambry lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 25 and therefore denies them.

26. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the ’282 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold certain BRCA1, BRCA2, BRCAPlus, BreastNext, OvaNext, and CancerNext products that infringe at least the following claims of the ’282 patent literally and/or under the doctrine of equivalents: Claims 6, 16, and 17.

ANSWER: Ambry denies the allegations of paragraph 26 of Plaintiffs’ Complaint.

27. Plaintiffs have been damaged and have suffered irreparable injury due to the Defendant’s acts of infringement, and will continue to suffer irreparable injury unless Defendant’s acts are enjoined.

ANSWER: Ambry denies the allegations of paragraph 27 of Plaintiffs’ Complaint.

28. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant’s acts of patent infringement as alleged herein. The University of Utah has suffered and will continue to suffer substantial damage in the form of reduced royalty payments by reason of Defendant’s acts of patent infringement and the resulting reduction in Myriad’s sales revenues. Plaintiffs are entitled to recover from Defendant the damages sustained as a result of Defendant’s acts.

ANSWER: Ambry denies the allegations of paragraph 28 of Plaintiffs’ Complaint.

29. Defendant has willfully infringed the ’282 Patent.

ANSWER: Ambry denies the allegations of paragraph 29 of Plaintiffs’ Complaint.

30. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Ambry denies the allegations of paragraph 30 of Plaintiffs' Complaint.

THIRD CLAIM FOR RELIEF
(By the University of Utah and Myriad for Infringement of United States Patent No. 5,753,441)

31. Plaintiffs repeat and reallege the allegations set forth in preceding paragraphs 1 through 30, inclusive.

ANSWER: The statement in Paragraph 31 is neither an averment nor an allegation to which a response is required.

32. United States Patent No. 5,753,441 (the "'441 Patent"), was duly and legally issued by the United States Patent and Trademark Office on May 19, 1998. The University of Utah and PHS are the owners, and Myriad is the exclusive licensee, of the '441 Patent. A true and correct copy of the '441 Patent is attached hereto and incorporated herein by reference as Exhibit 3.

ANSWER: Ambry denies that the '441 Patent was duly and legally issued by the United States Patent and Trademark Office. Ambry lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 32 and therefore denies them.

33. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '441 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold certain BRCA1, BRCA2, BRCAPlus, BreastNext, OvaNext, and CancerNext products that infringe at least the following claims of the '441 patent literally and/or under the doctrine of equivalents: Claims 7, 8, 12, 23, and 26.

ANSWER: Ambry denies the allegations of paragraph 33 of Plaintiffs' Complaint.

34. Plaintiffs have been damaged and have suffered irreparable injury due to the Defendant's acts of infringement, and will continue to suffer irreparable injury unless Defendant's acts are enjoined.

ANSWER: Ambry denies the allegations of paragraph 34 of Plaintiffs' Complaint.

35. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant's acts of patent infringement as alleged herein. The University of Utah has suffered and will continue to suffer substantial damage in the form of reduced royalty payments by reason of Defendant's acts of patent infringement and the resulting reduction in Myriad's sales revenues. Plaintiffs are entitled to recover from Defendant the damages sustained as a result of Defendant's acts.

ANSWER: Ambry denies the allegations of paragraph 35 of Plaintiffs' Complaint.

36. Defendant has willfully infringed the '441 Patent.

ANSWER: Ambry denies the allegations of paragraph 36 of Plaintiffs' Complaint.

37. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Ambry denies the allegations of paragraph 37 of Plaintiffs' Complaint.

FOURTH CLAIM FOR RELIEF
(By the University of Utah, the University of Pennsylvania, and the Hospital for Sick Children, Endorecherche, and Myriad for Infringement of United States Patent No. 5,837,492)

38. Plaintiffs repeat and reallege the allegations set forth in preceding paragraphs 1 through 37, inclusive.

ANSWER: The statement in Paragraph 38 is neither an averment nor an allegation to which a response is required.

39. United States Patent No. 5,837,492 (the "'492 Patent"), was duly and legally issued by the United States Patent and Trademark Office on November 17, 1998. The

University of Utah, the University of Pennsylvania, the Hospital for Sick Children, and Endorecherche are the owners, and Myriad is the exclusive licensee, of the '492 Patent. A true and correct copy of the '492 Patent is attached hereto and incorporated herein by reference as Exhibit 4.

ANSWER: Ambry denies that the '492 Patent was duly and legally issued by the United States Patent and Trademark Office. Ambry lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 39 and therefore denies them.

40. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '492 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold certain BRCA1, BRCA2, BRCAPlus, BreastNext, OvaNext, and CancerNext products that infringe at least the following claims of the '492 patent literally and/or under the doctrine of equivalents: Claims 29 and 30.

ANSWER: Ambry denies the allegations of paragraph 40 of Plaintiffs' Complaint.

41. Plaintiffs have been damaged and have suffered irreparable injury due to the Defendant's acts of infringement, and will continue to suffer irreparable injury unless Defendant's acts are enjoined.

ANSWER: Ambry denies the allegations of paragraph 41 of Plaintiffs' Complaint.

42. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant's acts of patent infringement as alleged herein. The University of Utah, the University of Pennsylvania, the Hospital for Sick Children, and Endorecherche have suffered and will continue to suffer substantial damage in the form of reduced royalty payments by reason of Defendant's acts of patent infringement and the

resulting reduction in Myriad's sales revenues. Plaintiffs are entitled to recover from Defendant the damages sustained as a result of Defendant's acts.

ANSWER: Ambry denies the allegations of paragraph 42 of Plaintiffs' Complaint.

43. Defendant has willfully infringed the '492 Patent.

ANSWER: Ambry denies the allegations of paragraph 43 of Plaintiffs' Complaint.

44. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Ambry denies the allegations of paragraph 44 of Plaintiffs' Complaint.

FIFTH CLAIM FOR RELIEF

(By the University of Utah, the University of Pennsylvania, the Hospital for Sick Children, Endorecherche, and Myriad for Infringement of United States Patent No. 6,033,857)

45. Plaintiffs repeat and reallege the allegations set forth in preceding paragraphs 1 through 44, inclusive.

ANSWER: The statement in Paragraph 45 is neither an averment nor an allegation to which a response is required.

46. United States Patent No. 6,033,857 (the "'857 Patent"), was duly and legally issued by the United States Patent and Trademark Office on March 7, 2000. The University of Utah, the University of Pennsylvania, the Hospital for Sick Children, and Endorecherche are the owners, and Myriad is the exclusive licensee, of the '857 Patent. A true and correct copy of the '857 Patent is attached hereto and incorporated herein by reference as Exhibit 5.

ANSWER: Ambry denies that the '857 Patent was duly and legally issued by the United States Patent and Trademark Office. Ambry lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 46 and therefore denies them.

47. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '857 patent by making, manufacturing, promoting, marketing, advertising,

distributing, offering for sale and selling and/or causing to be offered or sold certain BRCA1, BRCA2, BRCAPlus, BreastNext, OvaNext, and CancerNext products that infringe at least the following claim of the ’857 patent literally and/or under the doctrine of equivalents: Claim 4.

ANSWER: Ambry denies the allegations of paragraph 47 of Plaintiffs’ Complaint.

48. Plaintiffs have been damaged and have suffered irreparable injury due to the Defendant’s acts of infringement, and will continue to suffer irreparable injury unless Defendant’s acts are enjoined.

ANSWER: Ambry denies the allegations of paragraph 48 of Plaintiffs’ Complaint.

49. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant’s acts of patent infringement as alleged herein. The University of Utah, the University of Pennsylvania, the Hospital for Sick Children, and Endorecherche have suffered and will continue to suffer substantial damage in the form of reduced royalty payments by reason of Defendant’s acts of patent infringement and the resulting reduction in Myriad’s sales revenues. Plaintiffs are entitled to recover from Defendant the damages sustained as a result of Defendant’s acts.

ANSWER: Ambry denies the allegations of paragraph 49 of Plaintiffs’ Complaint.

50. Defendant has willfully infringed the ’857 Patent.

ANSWER: Ambry denies the allegations of paragraph 50 of Plaintiffs’ Complaint.

51. Defendant’s acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Ambry denies the allegations of paragraph 51 of Plaintiffs’ Complaint.

SIXTH CLAIM FOR RELIEF

(By Myriad for Infringement of United States Patent No. 5,654,155)

52. Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 51, inclusive.

ANSWER: The statement in Paragraph 52 is neither an averment nor an allegation to which a response is required.

53. United States Patent No. 5,654,155 (the "'155 Patent"), was duly and legally issued by the United States Patent and Trademark Office on August 5, 1997. Myriad is the owner of the '155 Patent. A true and correct copy of the '155 Patent is attached hereto and incorporated herein by reference as Exhibit 6.

ANSWER: Ambry denies that the '155 Patent was duly and legally issued by the United States Patent and Trademark Office. Ambry lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 53 and therefore denies them.

54. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '155 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold certain BRCA1, BRCA2, BRCAPlus, BreastNext, OvaNext, and CancerNext products that infringe at least the following claims of the '155 patent literally and/or under the doctrine of equivalents: Claims 2, 3, and 4.

ANSWER: Ambry denies the allegations of paragraph 54 of Plaintiffs' Complaint.

55. Myriad has been damaged and has suffered irreparable injury due to the Defendant's acts of infringement, and Myriad will continue to suffer irreparable injury unless Defendant's acts are enjoined.

ANSWER: Ambry denies the allegations of paragraph 55 of Plaintiffs' Complaint.

56. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant's acts of patent infringement as

alleged herein, and Myriad is entitled to recover from Defendant the damages sustained as a result of Defendant's acts.

ANSWER: Ambry denies the allegations of paragraph 56 of Plaintiffs' Complaint.

57. Defendant has willfully infringed the '155 Patent.

ANSWER: Ambry denies the allegations of paragraph 57 of Plaintiffs' Complaint.

58. Defendant's acts make this an exceptional case within the meaning of 35 U .S.C. § 285.

ANSWER: Ambry denies the allegations of paragraph 58 of Plaintiffs' Complaint.

SEVENTH CLAIM FOR RELIEF
(By Myriad for Infringement of United States Patent No. 5,750,400)

59. Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 58, inclusive.

ANSWER: The statement in Paragraph 59 is neither an averment nor an allegation to which a response is required.

60. United States Patent No. 5,750,400 (the "'400 Patent"), was duly and legally issued by the United States Patent and Trademark Office on May 12, 1998. Myriad is the owner of the '400 Patent. A true and correct copy of the '400 Patent is attached hereto and incorporated herein by reference as Exhibit 7.

ANSWER: Ambry denies that the '400 Patent was duly and legally issued by the United States Patent and Trademark Office. Ambry lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 60 and therefore denies them.

61. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '400 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold certain BRCA1, BRCA2, BRCAPlus, BreastNext, OvaNext, and CancerNext products that infringe at least the

following claims of the ’400 patent literally and/or under the doctrine of equivalents: Claims 2, 3, 4, 5, 6, and 7.

ANSWER: Ambry denies the allegations of paragraph 61 of Plaintiffs’ Complaint.

62. Myriad has been damaged and has suffered irreparable injury due to the Defendant’s acts of infringement, and Myriad will continue to suffer irreparable injury unless Defendant’s acts are enjoined.

ANSWER: Ambry denies the allegations of paragraph 62 of Plaintiffs’ Complaint.

63. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant’s acts of patent infringement as alleged herein, and Myriad is entitled to recover from Defendant the damages sustained as a result of Defendant’s acts.

ANSWER: Ambry denies the allegations of paragraph 63 of Plaintiffs’ Complaint.

64. Defendant has willfully infringed the ’400 Patent.

ANSWER: Ambry denies the allegations of paragraph 64 of Plaintiffs’ Complaint.

65. Defendant’s acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Ambry denies the allegations of paragraph 65 of Plaintiffs’ Complaint.

EIGHTH CLAIM FOR RELIEF

66. Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 65, inclusive.

ANSWER: The statement in Paragraph 66 is neither an averment nor an allegation to which a response is required.

67. United States Patent No. 6,051,379 (the “’379 Patent”), was duly and legally issued by the United States Patent and Trademark Office on April 18, 2000. Myriad is the

owner of the ’379 Patent. A true and correct copy of the ’379 Patent is attached hereto and incorporated herein by reference as Exhibit 8.

ANSWER: Ambry denies that the ’379 Patent was duly and legally issued by the United States Patent and Trademark Office. Ambry lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 67 and therefore denies them.

68. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the ’379 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold certain BRCA1, BRCA2, BRCAPlus, BreastNext, OvaNext, and CancerNext products that infringe at least the following claims of the ’379 patent literally and/or under the doctrine of equivalents: Claims 32 and 33.

ANSWER: Ambry denies the allegations of paragraph 68 of Plaintiffs’ Complaint.

69. Myriad has been damaged and has suffered irreparable injury due to the Defendant’s acts of infringement, and Myriad will continue to suffer irreparable injury unless Defendant’s acts are enjoined.

ANSWER: Ambry denies the allegations of paragraph 69 of Plaintiffs’ Complaint.

70. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant’s acts of patent infringement as alleged herein, and Myriad is entitled to recover from Defendant the damages sustained as a result of Defendant’s acts.

ANSWER: Ambry denies the allegations of paragraph 70 of Plaintiffs’ Complaint.

71. Defendant has willfully infringed the ’379 Patent.

ANSWER: Ambry denies the allegations of paragraph 71 of Plaintiffs’ Complaint.

72. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Ambry denies the allegations of paragraph 72 of Plaintiffs' Complaint.

NINTH CLAIM FOR RELIEF
(By Myriad for Infringement of United States Patent No. 6,951,721)

73. Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 72, inclusive.

ANSWER: The statement in Paragraph 73 is neither an averment nor an allegation to which a response is required.

74. United States Patent No. 6,951,721 (the "'721 Patent"), was duly and legally issued by the United States Patent and Trademark Office on October 5, 2005. Myriad is the owner of the '721 Patent. A true and correct copy of the '721 Patent is attached hereto and incorporated herein by reference as Exhibit 9.

ANSWER: Ambry denies that the '721 Patent was duly and legally issued by the United States Patent and Trademark Office. Ambry lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 74 and therefore denies them.

75. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '721 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold certain BRCA1, BRCA2, BRCAPlus, BreastNext, OvaNext, and CancerNext products that infringe at least the following claim of the '721 patent literally and/or under the doctrine of equivalents: Claim 5.

ANSWER: Ambry denies the allegations of paragraph 75 of Plaintiffs' Complaint.

76. Myriad has been damaged and has suffered irreparable injury due to the Defendant's acts of infringement, and Myriad will continue to suffer irreparable injury unless Defendant's acts are enjoined.

ANSWER: Ambry denies the allegations of paragraph 76 of Plaintiffs' Complaint.

77. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant's acts of patent infringement as alleged herein, and Myriad is entitled to recover from Defendant the damages sustained as a result of Defendant's acts.

ANSWER: Ambry denies the allegations of paragraph 77 of Plaintiffs' Complaint.

78. Defendant has willfully infringed the '721 Patent.

ANSWER: Ambry denies the allegations of paragraph 78 of Plaintiffs' Complaint.

79. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Ambry denies the allegations of paragraph 79 of Plaintiffs' Complaint.

TENTH CLAIM FOR RELIEF
(By Myriad for Infringement of United States Patent No. 7,250,497)

80. Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 79, inclusive.

ANSWER: The statement in Paragraph 80 is neither an averment nor an allegation to which a response is required.

81. United States Patent No. 7,250,497 (the "'497 Patent"), was duly and legally issued by the United States Patent and Trademark Office on July 31, 2007. Myriad is the owner of the '497 Patent. A true and correct copy of the '497 Patent is attached hereto and incorporated herein by reference as Exhibit 10.

ANSWER: Ambry denies that the '497 Patent was duly and legally issued by the United States Patent and Trademark Office. Ambry lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 81 and therefore denies them.

82. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '497 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold certain BRCA1, BRCA2, BRCAPlus, BreastNext, OvaNext, and CancerNext products that infringe at least the following claims of the '497 patent literally and/or under the doctrine of equivalents: Claims 3, 4, 5, 6, 7, 8, 11, 14, 17, 18, and 19.

ANSWER: Ambry denies the allegations of paragraph 82 of Plaintiffs' Complaint.

83. Myriad has been damaged and has suffered irreparable injury due to the Defendant's acts of infringement, and Myriad will continue to suffer irreparable injury unless Defendant's acts are enjoined.

ANSWER: Ambry denies the allegations of paragraph 83 of Plaintiffs' Complaint.

84. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant's acts of patent infringement as alleged herein, and Myriad is entitled to recover from Defendant the damages sustained as a result of Defendant's acts.

ANSWER: Ambry denies the allegations of paragraph 84 of Plaintiffs' Complaint.

85. Defendant has willfully infringed the '497 Patent.

ANSWER: Ambry denies the allegations of paragraph 85 of Plaintiffs' Complaint.

86. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Ambry denies the allegations of paragraph 86 of Plaintiffs' Complaint.

ELEVENTH CLAIM FOR RELIEF

(By Myriad for Infringement of United States Patent No. 7,470,510)

87. Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 86, inclusive.

ANSWER: The statement in Paragraph 87 is neither an averment nor an allegation to which a response is required.

88. United States Patent No. 7,470,510 (the "'510 Patent"), was duly and legally issued by the United States Patent and Trademark Office on December 30, 2008. Myriad is the owner of the '510 Patent. A true and correct copy of the '510 Patent is attached hereto and incorporated herein by reference as Exhibit 11.

ANSWER: Ambry denies that the '510 Patent was duly and legally issued by the United States Patent and Trademark Office. Ambry lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 88 and therefore denies them.

89. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '510 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold certain BreastNext, OvaNext, CancerNext, ColoNext, MUTYH-Associated Polyposis, and Familial Adenomatous Polyposis Panel products that infringe at least the following claims of the '510 patent literally and/or under the doctrine of equivalents: Claims 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, and 18.

ANSWER: Ambry denies the allegations of paragraph 89 of Plaintiffs' Complaint.

90. Myriad has been damaged and has suffered irreparable injury due to the Defendant's acts of infringement, and Myriad will continue to suffer irreparable injury unless Defendant's acts are enjoined.

ANSWER: Ambry denies the allegations of paragraph 90 of Plaintiffs' Complaint.

91. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant's acts of patent infringement as

alleged herein, and Myriad is entitled to recover from Defendant the damages sustained as a result of Defendant's acts.

ANSWER: Ambry denies the allegations of paragraph 91 of Plaintiffs' Complaint.

92. Defendant has willfully infringed the '510 Patent.

ANSWER: Ambry denies the allegations of paragraph 92 of Plaintiffs' Complaint.

93. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Ambry denies the allegations of paragraph 93 of Plaintiffs' Complaint.

TWELFTH CLAIM FOR RELIEF
(By Myriad for Infringement of United States Patent No. 7,622,258)

94. Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 93, inclusive.

ANSWER: The statement in Paragraph 94 is neither an averment nor an allegation to which a response is required.

95. United States Patent No. 7,622,258 (the "'258 Patent"), was duly and legally issued by the United States Patent and Trademark Office on November 24, 2009. Myriad is the owner of the '258 Patent. A true and correct copy of the '258 Patent is attached hereto and incorporated herein by reference as Exhibit 12.

ANSWER: Ambry denies that the '258 Patent was duly and legally issued by the United States Patent and Trademark Office. Ambry lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 95 and therefore denies them.

96. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '258 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold certain BreastNext, OvaNext, CancerNext, ColoNext, MUTYH-Associated Polyposis, and Familial Adenomatous

Polyposis Panel products that infringe at least the following claims of the '258 patent literally and/or under the doctrine of equivalents: Claims 10, 11, 15, 16, 17, and 19.

ANSWER: Ambry denies the allegations of paragraph 96 of Plaintiffs' Complaint.

97. Myriad has been damaged and has suffered irreparable injury due to the Defendant's acts of infringement, and Myriad will continue to suffer irreparable injury unless Defendant's acts are enjoined.

ANSWER: Ambry denies the allegations of paragraph 97 of Plaintiffs' Complaint.

98. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant's acts of patent infringement as alleged herein, and Myriad is entitled to recover from Defendant the damages sustained as a result of Defendant's acts.

ANSWER: Ambry denies the allegations of paragraph 98 of Plaintiffs' Complaint.

99. Defendant has willfully infringed the '258 Patent.

ANSWER: Ambry denies the allegations of paragraph 99 of Plaintiffs' Complaint.

100. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Ambry denies the allegations of paragraph 100 of Plaintiffs' Complaint.

THIRTEENTH CLAIM FOR RELIEF
(By Myriad for Infringement of United States Patent No. 7,838,237)

101. Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 100, inclusive.

ANSWER: The statement in Paragraph 101 is neither an averment nor an allegation to which a response is required.

102. United States Patent No. 7,838,237 (the "'237 Patent"), was duly and legally issued by the United States Patent and Trademark Office on November 23, 2010. Myriad is the

owner of the ’237 Patent. A true and correct copy of the ’237 Patent is attached hereto and incorporated herein by reference as Exhibit 13.

ANSWER: Ambry denies that the ’237 Patent was duly and legally issued by the United States Patent and Trademark Office. Ambry lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 102 and therefore denies them.

103. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the ’237 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold certain BreastNext, OvaNext, CancerNext, ColoNext, MUTYH-Associated Polyposis, and Familial Adenomatous Polyposis Panel products that infringe at least the following claims of the ’237 patent literally and/or under the doctrine of equivalents: Claims 2, 8, and 16.

ANSWER: Ambry denies the allegations of paragraph 103 of Plaintiffs’ Complaint.

104. Myriad has been damaged and has suffered irreparable injury due to the Defendant’s acts of infringement, and Myriad will continue to suffer irreparable injury unless Defendant’s acts are enjoined.

ANSWER: Ambry denies the allegations of paragraph 104 of Plaintiffs’ Complaint.

105. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant’s acts of patent infringement as alleged herein, and Myriad is entitled to recover from Defendant the damages sustained as a result of Defendant’s acts.

ANSWER: Ambry denies the allegations of paragraph 105 of Plaintiffs’ Complaint.

106. Defendant has willfully infringed the ’237 Patent.

ANSWER: Ambry denies the allegations of paragraph 106 of Plaintiffs’ Complaint.

107. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Ambry denies the allegations of paragraph 107 of Plaintiffs' Complaint.

FOURTEENTH CLAIM FOR RELIEF
(By Myriad for Infringement of United States Patent No. 7,670,776)

108. Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 107, inclusive.

ANSWER: The statement in Paragraph 108 is neither an averment nor an allegation to which a response is required.

109. United States Patent No. 7,670,776 (the "'776 Patent"), was duly and legally issued by the United States Patent and Trademark Office on March 2, 2010. Myriad is the owner of the '776 Patent. A true and correct copy of the '776 Patent is attached hereto and incorporated herein by reference as Exhibit 14.

ANSWER: Ambry denies that the '776 Patent was duly and legally issued by the United States Patent and Trademark Office. Ambry lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 109 and therefore denies them.

110. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the '776 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold certain BreastNext, OvaNext, CancerNext, ColoNext, MUTYH-Associated Polyposis, and Familial Adenomatous Polyposis Panel products that infringe at least the following claims of the '776 patent literally and/or under the doctrine of equivalents: Claims 2, 3, 5, 9, 10, and 12.

ANSWER: Ambry denies the allegations of paragraph 110 of Plaintiffs' Complaint.

111. Myriad has been damaged and has suffered irreparable injury due to the Defendant's acts of infringement, and Myriad will continue to suffer irreparable injury unless Defendant's acts are enjoined.

ANSWER: Ambry denies the allegations of paragraph 111 of Plaintiffs' Complaint.

112. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant's acts of patent infringement as alleged herein, and Myriad is entitled to recover from Defendant the damages sustained as a result of Defendant's acts.

ANSWER: Ambry denies the allegations of paragraph 112 of Plaintiffs' Complaint.

113. Defendant has willfully infringed the '776 Patent.

ANSWER: Ambry denies the allegations of paragraph 113 of Plaintiffs' Complaint.

114. Defendant's acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Ambry denies the allegations of paragraph 114 of Plaintiffs' Complaint.

FIFTEENTH CLAIM FOR RELIEF

(By Myriad for Infringement of United States Patent No. 7,563,571)

115. Plaintiff Myriad repeats and realleges the allegations set forth in preceding paragraphs 1 through 114, inclusive.

ANSWER: The statement in Paragraph 115 is neither an averment nor an allegation to which a response is required.

116. United States Patent No. 7,563,571 (the "'571 Patent"), was duly and legally issued by the United States Patent and Trademark Office on July 21, 2009. Myriad is the owner of the '571 Patent. A true and correct copy of the '571 Patent is attached hereto and incorporated herein by reference as Exhibit 15.

ANSWER: Ambry denies that the ’571 Patent was duly and legally issued by the United States Patent and Trademark Office. Ambry lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 116 and therefore denies them.

117. Defendant is infringing, contributing to the infringement of, and/or inducing others to infringe the ’571 patent by making, manufacturing, promoting, marketing, advertising, distributing, offering for sale and selling and/or causing to be offered or sold certain BreastNext, OvaNext, CancerNext, ColoNext, MUTYH-Associated Polyposis, and Familial Adenomatous Polyposis Panel products that infringe at least the following claims of the ’571 patent literally and/or under the doctrine of equivalents: Claims 2 and 7.

ANSWER: Ambry denies the allegations of paragraph 117 of Plaintiffs’ Complaint.

118. Myriad has been damaged and has suffered irreparable injury due to the Defendant’s acts of infringement, and Myriad will continue to suffer irreparable injury unless Defendant’s acts are enjoined.

ANSWER: Ambry denies the allegations of paragraph 118 of Plaintiffs’ Complaint.

119. Myriad has suffered and will continue to suffer substantial damage to its business, including, without limitation, lost profits, loss of business reputation, loss of business opportunities, and loss of market share, by reason of Defendant’s acts of patent infringement as alleged herein, and Myriad is entitled to recover from Defendant the damages sustained as a result of Defendant’s acts.

ANSWER: Ambry denies the allegations of paragraph 119 of Plaintiffs’ Complaint.

120. Defendant has willfully infringed the ’571 Patent.

ANSWER: Ambry denies the allegations of paragraph 120 of Plaintiffs’ Complaint.

121. Defendant’s acts make this an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Ambry denies the allegations of paragraph 121 of Plaintiffs' Complaint.

PRAYER FOR RELIEF

Ambry denies that Plaintiff is entitled to any relief from the court.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

122. Ambry incorporates by reference Paragraphs 17 – 121 of this Answer as if fully set forth herein.

123. Plaintiffs' allegations fail to state a claim against Ambry for which relief may be granted.

SECOND AFFIRMATIVE DEFENSE
(Invalidity Under 35 U.S.C. § 102)

124. Ambry incorporates by reference Paragraphs 17-121 of this Answer as if fully set forth herein.

125. On information and belief, one or more claims of United States Patent Nos. 5,654,155; 5,750,400; 6,051,379; 6,951,721; 7,250,497; 7,670,776; 7,563,571; 7,622,258; 7,838,237; 7,470,510; 5,709,999; 5,747,282; 5,753,441; 5,837,492; and 6,033,857 (collectively the "patents-in-suit") are invalid for failure to comply with one or more conditions of patentability set forth in 35 U.S.C. § 102.

THIRD AFFIRMATIVE DEFENSE
(Invalidity Under 35 U.S.C. § 103)

126. Ambry incorporates by reference Paragraphs 17 – 121 of this Answer as if fully set forth herein.

127. On information and belief, one or more claims of the patents-in-suit are invalid for failure to comply with one or more conditions of patentability set forth in 35 U.S.C. § 103.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity Under 35 U.S.C. § 112)

128. Ambry incorporates by reference Paragraphs 17-121 of this Answer as if fully set forth herein.

129. On information and belief, one or more claims of the patents-in-suit are invalid for failure to comply with one or more conditions of patentability set forth in 35 U.S.C. § 112.

FIFTH AFFIRMATIVE DEFENSE
(Non-infringement)

130. Ambry incorporates by reference Paragraphs 17-121 of this Answer as if fully set forth herein.

131. Ambry does not directly infringe any claim of the patents-in-suit literally or under the doctrine of equivalents.

132. Ambry does not induce infringement of any claim of the patents-in-suit.

133. Ambry does not willfully infringe any claim of any of the patents-in-suit.

SIXTH AFFIRMATIVE DEFENSE
(Subject Matter Not Patentable Under 35 U.S.C. § 101)

134. Ambry incorporates by reference Paragraphs 17-121 of this Answer as if fully set forth herein.

135. On information and belief, one or more claims of the patents-in-suit are invalid for failure to comply with 35 U.S.C. § 101.

SEVENTH AFFIRMATIVE DEFENSE
(Patent Misuse)

136. Ambry incorporates by reference Paragraphs 17-121 of this Answer as if fully set forth herein.

137. On information and belief, one or more claims of the patents-in-suit are unenforceable under the doctrine of patent misuse.

RESERVATION OF DEFENSES

138. Ambry hereby reserves any and all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent Laws, and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and/or further factual investigation during this litigation.

COUNTERCLAIMS

Ambry Genetics Corporation ("Ambry") asserts the following counterclaims against Plaintiffs University of Utah Research Foundation, the Trustees of the University of Pennsylvania, HSC Research and Development Limited Partnership, Endorecherche, Inc., and Myriad Genetics, Inc. ("Plaintiffs" or "Counter-defendants").

THE PARTIES

1. Ambry is a corporation organized under the laws of the State of California and has its principal place of business at 15 Argonaut, Aliso Viejo, California 92656. Ambry is a CAP-accredited, CLIA-certified commercial clinical laboratory, a recognized leader in diagnostic and contract genomic services specializing in the application of new technologies to molecular diagnostics and genetics research.

2. Upon information and belief, the University of Utah is a Utah nonprofit corporation with an address at 421 Wakara Way, Suite 170, Salt Lake City, Utah 84108.

3. Upon information and belief, the University of Pennsylvania is a Pennsylvania nonprofit corporation with an address of 3160 Chestnut Street, Suite 200, Philadelphia, Pennsylvania 19104-6283.

4. Upon information and belief, the Hospital for Sick Children is a Canadian limited partnership organized under the laws of the Province of Ontario, with an address of 555 University Avenue, Toronto, Ontario M5G 1X8, Canada.

5. Upon information and belief, Endorecherche, Inc. is a Canadian corporation organized under the laws of the Province of Quebec, with a place of business at 2989 De La Promenade, Ste-Foy, Quebec, QC G1W 2J5, Canada.

6. Upon information and belief, Myriad Genetics, Inc. is a Delaware corporation, with its principal place of business at 320 Wakara Way, Salt Lake City, Utah 84108.

NATURE OF THE ACTION

7. Ambry brings this action pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26, and federal question jurisdiction over Ambry's claims is based on 28 U.S.C. §§ 1321 and 1337. Ambry seeks to recover treble damages and injunctive relief under the Sherman Act, 15 U.S.C. § 2.

8. This is an action for declaratory judgment under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, that U.S. Patent Nos. 5,654,155 (the "'155 Patent"), 5,750,400 (the "'400 Patent"), 6,051,379 (the "'379 Patent"), 6,951,721 (the "'721 Patent"), 7,250,497 (the "'497 Patent"), 7,670,776 (the "'776 Patent"), 7,563,571 (the "'571 Patent), 7,622,258 (the "'258 Patent), 7,838,237 (the "'237 Patent), 7,470,510 (the "'510 Patent), 5,709,999 (the "'999 Patent), 5,747,282 (the "'282 Patent), 5,753,441 (the "'441 Patent), 5,837,492 (the "'492 Patent), and 6,033,857 (the "'857 Patent) (collectively the "patents-in-suit") are invalid and not infringed by Ambry directly or through inducement.

JURISDICTION

9. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

10. This Court has personal jurisdiction over the Plaintiffs by its choice of forum.

11. This Court has jurisdiction over Ambry's claims pursuant to 15 U.S.C. §§ 15 and 26, as an action brought by a person injured in its business or property by violation of the antitrust laws, and as an action for injunctive relief against a violation of the antitrust laws.

VENUE

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)-(c), 1400(b).

BACKGROUND

13. On July 9, 2013, Counter-defendants herein filed a Complaint alleging infringement by Ambry of certain claims of the patents-in-suit.

14. Counter-defendants allege in their Complaint that The University of Utah is the owner or co-owner of United States Patent Nos. 5,709,999; 5,747,282; 5,753,441; 5,837,492; and 6,033,857. Counter-defendants allege in their Complaint that the University of Pennsylvania is a co-owner of United States Patent Nos. 6,033,857 and 5,837,492. Counter-defendants allege in their Complaint that the Hospital for Sick Children is a co-owner of United States Patent Nos. 6,033,857 and 5,837,492. Counter-defendants allege in their Complaint that Endorecherche, Inc. is a co-owner of United States Patent Nos. 6,033,857 and 5,837,492. Counter-defendants allege in their Complaint that Myriad owns United States Patent Nos. 5,654,155; 5,750,400; 6,051,379; 6,951,721; 7,250,497; 7,670,776; 7,563,571; 7,622,258; 7,838,237; and 7,470,510. Counter-defendants allege in their Complaint that Myriad is the exclusive licensee of United States Patent Nos. 5,709,999; 5,747,282; 5,753,441; 5,837,492; and 6,033,857.

15. An actual and justiciable controversy has arisen and presently exists between the parties with respect to the '155, '400, '379, '721, '497, '776, '571, '258, '237, '510, '999, '282, '441, '492, and '857 Patents in as much as Counter-defendants have alleged that Ambry is infringing certain claims the patents-in-suit. Ambry denies this allegation. Ambry alleges that it in fact does not infringe any claim of the patents-in-suit and the claims are invalid. Ambry is

entitled to a declaratory judgment that the ’155, ’400, ’379, ’721, ’497, ’776, ’571, ’258, ’237, ’510, ’999, ’282, ’441, ’492, and ’857 Patents are invalid and not infringed.

ALLEGATIONS

Myriad Is Maintaining Its Monopoly In Violation Of The Antitrust Laws Through Its Bad Faith Enforcement Of Its Patents

16. Myriad has in bad faith brought this lawsuit against Ambry on patent claims that it knows are invalid under two Supreme Court decisions and Federal Circuit authority. In doing so, Myriad continues a practice of using sharp and overreaching practices to wrongfully monopolize the diagnostic testing of human *BRCA1* and *BRCA2* genes in the United States and to attempt to injure any competitor who dares to challenge Myriad’s monopoly, including Ambry. These practices include (1) using research funded by public money to file patents over alleged inventions that the Supreme Court and the Federal Circuit have confirmed never should have been patented, (2) using those patents to intimidate and chill competition in the *BRCA1* and *BRCA2* genetic screening markets in the late 1990s to ensure monopoly profits, (3) taking patients’ personal *BRCA1* and *BRCA2* genetic sequence data and depriving the public of access to that data to inhibit competition, and (4) using sales and marketing tactics with genetic counselors and payors to intentionally misrepresent the accuracy and reimbursement of Ambry’s *BRCA1* and *BRCA2* diagnostic tests.

Sequencing Of The *BRCA1* And *BRCA2* Genes

17. Beginning in the 1970s, women began to articulate their displeasure with treatments for breast cancer. At that time, mastectomy was the only accepted surgical option for treatment. (Today, breast-conserving surgery followed by local radiation therapy has replaced

mastectomy as the preferred surgical approach for treating early-stage breast cancer.) By 1975, clinical evaluations of hormonal treatments for breast cancer were just underway.

18. In the 1980s, breast cancer patients began to mobilize in large numbers to increase government and public attention to the breast cancer epidemic. As a result, federal funding of breast cancer research has increased significantly, from under $90 million in FY1990 to more than $2.1 billion by FY2008.

19. Prior to 1990, it was known that human breast cancer is usually caused by mutations in the cells of the breast. It was also observed that patients could inherit susceptibility to breast cancer.

20. Several international research teams became involved in the search for the gene(s) that could be inherited and that correlated with a higher risk of breast cancer. In the United States, the two main groups were Dr. Mary Claire King's laboratory at the University of California at Berkeley and Dr. Mark Skolnick's group at the University of Utah. Several international laboratories also were using standard genomic identification techniques to locate the genes, including laboratories from the United Kingdom, France, Belgium, the Netherlands, and Canada.

21. Dr. King's group pointed the way. In 1990, she announced at the American Society of Human Genetics Meeting that her laboratory had located on human chromosome 17 the gene that became known as *BRCA1* (breast cancer 1). This finding, which was later published in *Science*, was the first evidence of the existence of genes for hereditary forms of breast cancer. The results from Dr. King's laboratory were confirmed by Gilbert Lenoir and Steven Narod, two researchers from Canada who had collaborated with Dr. Skolnick.

22. Collaborations were common during this period. For example, Dr. King and Dr. Skolnick collaborated, but only for a short while because they could not agree on how to conduct the research. Dr. Skolnick also collaborated with teams from Canada and France, as well as two researchers from the National Institutes of Environmental Health Sciences (NIEHS), one of the federally funded National Institutes of Health.

23. As part of this effort among researchers to increase collaboration, in or about 1988, the Breast Cancer Linkage Consortium (the "Consortium") first brought together several international research groups to compile later stage research and to speed up the pace of identifying relevant genetic mutations. In or about 1990, the Consortium was able to demonstrate that the *BRCA1* gene was particularly associated with families in which both breast and ovarian cancer occurred frequently.

24. The Consortium gathered and shared evidence that also indicated that genes other than *BRCA1* might be involved in hereditary breast cancer, as only 45% of the breast cancers in families with a high incidence of hereditary cancer could be explained by *BRCA1* alone. Members of the Consortium met frequently to compile their research and to provide a composite map of the region believed to contain *BRCA1*, in part to help identify mutations. Ambry is informed and believes that Dr. Skolnick and/or his collaborators attended at least some of these meetings.

25. Researchers continued to use these known gene location techniques to identify the precise location of the *BRCA1* gene in chromosome 17. Once its location was identified, standard and well-known techniques could be used to sequence the gene.

26. Dr. Skolnick's group at the University of Utah was among those researchers. His lab had developed a database of an extensive pedigree of Mormon families that contained information on 200,000 families and most of the 1.6 million descendants of the initial 10,000 Utah settlers. Dr. Skolnick linked his database to the Utah cancer registry, which resulted in 40,000 cross-linked entries that spurred much of his future research. Although the University of Utah always had control of the database, Dr. Skolnick was in a unique position to utilize it.

27. Access to this database gave Dr. Skolnick (and later Myriad) an advantage because it provided the raw natural data Myriad's team could use to more quickly determine the likely physical location of *BRCA1* based on the general chromosome location Dr. King and other groups published.

28. In 1991, Dr. Skolnick formed Myriad as a spin-off from the University of Utah Center for Genetic Epidemiology with the aim of obtaining additional funding necessary to locate the precise location of the *BRCA1* gene. According to Dr. Skolnick, his group required additional resources to compete with Dr. Francis Collins' group, which had just received a substantial grant from the NIH. Myriad obtained funding from Eli Lilly and Company and the National Institutes of Health ($5 million). Altogether, Myriad received at least $22 million in funding from public and private sources: $5 million in 1992, $8 million in 1993, and $9 million in 1994.

29. After spinning off Myriad, Dr. Skolnick continued to rely on collaborations. The search for precise location of the *BRCA1* gene involved more than forty researchers from public and private entities including: the University of Utah, McGill University in Montreal, the

NIEHS, Eli Lilly and Myriad. Dr. Skolnick and his collaborators published their sequence of *BRCA1* in *Science* on October 7, 1994.

30. Researchers also searched for the *BRCA2* gene. Building on the work of the Consortium which had data indicating the existence of other *BRCA* genes, as well as the work of Mike Stratton's group which in 1994 showed the existence of *BRCA2* on chromosome 13, there was a major push to identify using known and standard techniques to identify the precise location of the *BRCA2* and to sequence it.

31. Dr. Skolnick collaborated with many other laboratories, including labs at the University of Laval in Quebec, the Hospital for Sick Children in Toronto, and the University of Pennsylvania in this search to identify the precise location of *BRCA2*. Myriad also collaborated with Mike Stratton's group for some time, though Dr. Stratton ended the collaboration after learning that Myriad planned to patent the genes.

32. In December 1995, Mike Stratton's group announced they had mapped and sequenced *BRCA2*. Dr. Stratton's group communicated its discovery in a manuscript to the journal *Nature*. The day before the Stratton group's sequence was published in *Nature*, Myriad announced that it had sequenced *BRCA2*.

Myriad Files For Patents Covering *BRCA1* And *BRCA2* And Uses Those Patents To Monopolize The Entire *BRCA1/2* Genetic Screening Market

33. Myriad quickly set out to commercialize its discoveries. On August 12, 1994, Myriad applied for patents covering the *BRCA1* gene and its mutations – nearly two months before it published its sequence in *Science*. The first patent issued on December 2, 1997. Named as inventors were scientists each Myriad, le Centre de recherché du CHUL (which Ambry is informed and believes is now known as plaintiff Endorecherché, Inc.) and the Cancer Institute in

Tokyo. Subsequently, five more patents issued for *BRCA1* and its mutations. In April 1996 Myriad applied for patents related to the *BRCA2* DNA, mutations and diagnosis.

34. These patents rest on patenting the isolated DNA sequence of the *BRCA1* and *BRCA2* genes. The claims at issue in this case do not cover novel diagnostic tools or methods used in genetic testing. Nor are they analogous to patents on novel medical instruments. Rather, these claims attempt to confer upon Myriad the exclusive right to read human *BRCA1* and *BRCA2* sequences.

35. The claims either attempt to assert broad ownership over all human DNA sequences that can be used to amplify and sequence *BRCA1* and *BRCA2*, or merely append routine steps to the patent claims, which would necessarily be conducted while assessing the biological relationships between mutations in the *BRCA1* and or *BRCA2* genes and the predisposition to cancer.

36. The claim strategy is an overt attempt to convert these natural biological phenomena into patentable inventions using the patent language of a "method" or "process." In other words, the patent claims are directed to routine biological procedures and correlations generically such that it is effectively impossible for anyone in the United States in any meaningful way to "make" or "use" natural forms of isolated DNA molecules encoding the *BRCA1* and *BRCA2* genes in humans without infringing Myriad's patents.

37. In late 1996, and armed with its pending patent applications, Myriad set up a $30 million diagnostics laboratory. It began marketing three principle tests: (1) the $2400 Comprehensive BRACAnalysis, which involved full sequence testing of both *BRCA1* and *BRCA2*; (2) the $395 Single Site BRACAnalysis test (testing for only a single mutation that was

previously identified in another family member); and (3) the Multisite three BRACAnalysis, which identifies mutations that are particularly prominent in the Ashkenazi Jewish population. Myriad also put together a group of laboratories, health insurers, sales teams and doctors to market and sell its tests. Myriad hired genetic counselors to train physicians to identify candidates for its tests. Myriad's tests were successful from the beginning: from 1Q97 through 3Q97, Myriad earned more than $20 million in revenue.

38. Despite that some estimate that the NIH provided a third of the funding for the discovery of *BRCA1*, including funding to both Myriad and the University of Utah, and that NIH researchers directly participated in the discovery, Myriad did not identify the NIH researchers as co-inventors. In 1994, NIH complained that Myriad had failed to give credit and inventorship to the six NIEHS researchers who worked on the *BRCA1* sequencing project. The NIH filed a concurrent patent application naming its researchers as co-inventors. Eventually Myriad added to its applications the NIEHS researchers and the NIH withdrew its application. Myriad also agreed to pay the researchers royalties, but at least as of 2005, Ambry is informed and believes, none had been paid.

39. While Myriad's patents were pending, other laboratories were screening patient samples for *BRCA1* and *BRCA2* mutations. Once Myriad's patents issued, Myriad threatened to sue and did sue laboratories that were screening human *BRCA1* and/or *BRCA2* genes.

40. As one example, Myriad was able to stop researchers at the Genetic Diagnostic Testing Laboratory ("GDL") and the University of Pennsylvania from screening samples for *BRCA1* and *BRCA2* mutations.

41. During the mid-to-late 1990s, Drs. Kazazian and Ganguly at the GDL offered screening services for *BRCA1* and *BRCA2* that differed from the testing method used by Myriad, but which involved using DNA purified from patient samples. At least some of GDL's testing was conducted for Dr. Barbara, a principal investigator on the Cancer Genetics Network Project supported by the National Cancer Institute, which is part of the NIH.

42. Dr. Skolnick advised Drs. Kazazian and Ganguly that Myriad planned to stop the *BRCA1/2* testing being conducted at the GDL. Myriad offered Dr. Ganguly a cooperative license that would allow GDL to perform the single mutation test (which cost $395 if run by Myriad) or multiple mutation panels of up to four mutations to allow for testing of patients of Ashkenazi Jewish descent. Myriad did not offer Dr. Ganguly a license to screen for all *BRCA1* and *BRCA2* mutations, which, when done by Myriad, cost $2400 at that time.

43. Myriad sued the University of Pennsylvania – its collaborator in the effort to sequence *BRCA2* - in November 1998 for patent infringement. In June 1999, Myriad's general counsel sent a letter to the University of Pennsylvania seeking written assurances that Dr. Kazazian and the University of Pennsylvania had ceased *BRCA1* and *BRCA2* testing. This demand was repeated in a September 1999 letter from Myriad to the University of Pennsylvania. As a result of Myriad's efforts to enforce its patents against the University of Pennsylvania, the GDL no longer conducts *BRCA1* and *BRCA2* screening for research or as part of its clinical practice.

44. Myriad was also able to stop or prevent other laboratories from performing analysis of *BRCA* sequences. In 1998, Myriad stopped Dr. Ostrer from performing *BRCA1* and *BRCA2* screening. In 2000, Myriad also was able to stop the Yale Diagnostics Lab from

performing *BRCA* screening. In 2005, Dr. Matloff of Yale sought permission from Myriad for the Yale DNA Diagnostics Lab to conduct screening for mutations caused by large rearrangements, which Myriad was not conducting at the time. Myriad denied that request.

45. Myriad also sought to keep other commercial entities out of the marketplace. While Myriad's patents were pending, OncorMed, a company based in Maryland, also applied for and received a patent for the consensus sequence of *BRCA1*. OncorMed's patent issued in August 1997, four months before Myriad's first patent issued. OncorMed had been active in the *BRCA* gene discovery field and had developed its own testing service based in part on licenses from Dr. King's and Dr. Stratton's groups. Eventually, after they each acquired *BRCA* patents, OncorMed and Myriad sued each other for patent infringement. Ultimately, the litigation settled and Myriad bought OncorMed's patents to extend its monopoly.

Myriad Eschews Considerations Of Affordability, Test Accuracy, And Recommendations For Genetic Testing

46. Myriad and OncorMed differed in their approaches to *BRCA* testing. Patients wanting to screen for all *BRCA1* and *BRCA2* mutations by Myriad had to buy its $2400 test. OncorMed, on the other hand, offered a tiered approach designed to save patients money. For $500, a patient sample could be screened for all frequently occurring mutations. If that test was negative, the patient could pay an additional $800 for a second test for other mutations in regions of the genes where mutations were likely to be found. If that test were negative, OncorMed would sequence the rest of the genes for $800, for a total of $2100. Myriad did not offer a similar tiered approach.

47. In March 1996, the Federal Task Force on Genetic Testing ("Task Force") issued recommendations for the regulation of genetic testing. The Task Force advocated the position

that pre-existing regulations of testing centers did not suffice to assess the clinical validity of genetic tests. The report recommended expanding the regulatory criteria under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), a statute that governs laboratories. The Task Force also sought to ensure quality of informed consent, genetic counseling, and test utility, and not just whether the test measured what it claimed.

48. In 1996, OncorMed was the first to market with a *BRCA* test. OncorMed complied with the Task Force's recommendations. OncorMed tested only in research protocols approved by institutional review boards, and testing was accompanied by consumer education and informed consent. OncorMed required pre- and post-test genetic counseling. OncorMed directed its marketing to physicians involved in research. OncorMed also had very strict family risk criteria that women interested in testing would need to meet prior to testing, to avoid undue psychological, emotional, or financial risk, and to avoid overutilization of an expensive test that low-risk women did not necessarily need.

49. Myriad took a different approach. Myriad marketed its test outside research protocols and utilized direct-to-consumer advertising. Myriad did not refuse to test based on inappropriate patient selection. Nor did Myriad require a copy of signed consent (the health care provider was responsible for securing consent). Myriad also did not require verification of the availability of qualified counselors to assist the patient or that counseling had taken place.

50. In February 1996, the American Society of Clinical Oncology ("ASCO") also adopted guidelines for genetic testing for cancer susceptibility. The ASCO guidelines were published in the May 1996 issue of *Journal of Clinical Oncology* and were as follows: (1) "Cancer risk counseling as part of the mission of clinical oncologists"; (2) "Educational

opportunities for physicians for pre- and post-testing counseling"; (3) "The need for informed consent"; and (4) "indications for genetic testing." The fourth recommendation sought to limit genetic testing for cancer susceptibility to only those patients with indicators, such as a family history for the disease:

> ASCO recommends that cancer predisposition testing be offered only when: 1) the person has a strong family history of cancer or very early age of onset of disease; 2) the test can be adequately interpreted; and 3) the results will influence the medical management of the patient or family member. As clinical testing becomes more widely available, the Society encourages oncologists to utilize laboratories committed to the validation of testing methodologies, and to facilitate families' participation in long-term outcome studies.

51. ASCO "recognize[d] the need for ongoing research, rigorous quality assurance of genetic testing, and continued medical education."

52. Reponses from the National Breast Cancer Foundation ("NBCF"), the National Action Plan on Breast Cancer ("NAPBC"), and Dr. Skolnick were published in the same issue of the *Journal of Oncology*.

53. NBCF and NAPBC took positions consistent with ASCO's proposed guidelines. NBCF concluded that the "standard of care should be that genetic screening should only be available to individuals who agree to join peer-reviewed, approved research protocols." Likewise, NAPBC supported the principle that genetic testing should occur only within "hypothesis-driven research, institutional review board approved, research studies," indicating that "[t]he lack of scientific knowledge about *BRCA1* and *BRCA2* makes clinical uses of the mutation testing premature outside of research protocols." Myriad refused to follow these recommendations.

54. Myriad claimed that its monopoly was in the interests of patients and that it was offering the state-of-the-art test. But that was not true. In 2006, commentary in the *Journal of the American Medical Association* questioned the quality of Myriad's tests and their inability to detect certain types of mutations, called genomic rearrangements, insertions and deletions. Specifically, it was determined that Myriad's test missed up to 12% of these types of mutations.

55. In congressional testimony from October 30, 2007, Drs. Mark Grodman and Wendy Chung attributed this problem to Myriad's sole provider status and patent monopoly, concluded that the delay in addressing this issue would not have occurred but for Congressional and industry pressure, since Myriad had no competitors on its wrongly obtained patents:

> It was only after considerable pressure from the scientific community that the company added methods to detect these deletions, insertions, and re-arrangements in 2006, over 10 years after they first introduced clinical genetic testing, and barred anyone else from performing the tests. In a competitive marketplace, this delay never would have occurred.

There Exists Significant Opposition To Myriad's Business Model of Patenting Gene Sequences And Establishing A Private Database

56. In addition to obtaining patents on the *BRCA* sequences, in 1996 Myriad established a public database to collect and organize data and personal and family cancer histories of the patients that had purchased Myriad's tests to understand whether they had any mutations in their *BRCA1* and *BRCA2* genes. Mr. Richard Marsh, the Executive Vice President of Myriad, explained in 2012 that Myriad set up the database to "educate" others, *i.e.*, collect information on *BRCA1* and *BRCA2* mutations and identify them as harmful, harmless, or of unknown clinical significance.

57. In November 2004, Myriad made its last major deposit of data to the public databases.

58. In 2005, Myriad stated that it had decided to stop sharing data because of the difficulties in matching data formats, but later adopted a deliberate policy of retaining the patients' data as a trade secret. Myriad also keeps secret the algorithms it uses to determine whether mutations in the *BRCA1* and *BRCA2* genes are harmful or harmless.

59. Politicians, clinicians, breast cancer advocacy groups and commentators all have voiced their opposition to Myriad's business model of patenting DNA sequences and keeping secret its database of *BRCA1* and *BRCA2* mutations that comes from the patients' (public's) genes.

60. For example, in response to the loss of open access to Myriad's database, clinicians and researchers have started a not-for-profit grass roots effort called the "Sharing Clinical Reports Project." The goal of SCRP is to obtain test results from medical providers who have ordered Myriad's *BRCA1* and *BRCA2* tests and to add them to the public database.

61. Advocacy groups have voiced their opposition to Myriad as well. In 2009, the ACLU filed a lawsuit in the District Court for the Southern District of New York on behalf of professional societies, patients, breast cancer advocacy groups, and doctors seeking to invalidate a number of Myriad's patent claims to *BRCA1* and *BRCA2* DNA sequences. That case culminated in the Supreme Court's June 2013 decision in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*[1]

[1] Hereinafter the Supreme Court decision will be referred to as "*Myriad*," and the litigation from the district court level until the Supreme Court's *Myriad* decision will be referred to as the "Myriad Litigation."

Myriad's Is Aware That Its Asserted Claims On *BRCA1* And *BRCA2* Genes Are Invalid Under Recent Supreme Court And Federal Circuit Cases

62. Two decisions by the Supreme Court, issued before plaintiffs brought this suit, rebut the presumption by Myriad that it brought this suit in good faith: *Myriad*, 133 S.Ct. 2107 (2013); and *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289 (2012) ("*Prometheus*").

Judge Sweet Grants Summary Judgment Against Myriad

63. The Myriad Litigation began in 2009 in the United States District Court for the Southern District of New York before Judge Robert W. Sweet. The case involved summary judgment, two appeals to the Federal Circuit and two appeals to the Supreme Court, the latter from which the *Myriad* decision was rendered.

64. The plaintiffs in the Myriad Litigation sought declaratory relief of invalidity of numerous claims of patents owned or exclusively licensed by Myriad for failure to claim patentable subject matter as required by 35 U.S.C. § 101.

65. On March 29, 2010, Judge Sweet granted summary judgment to plaintiffs, finding that both the composition and method claims at issue failed to recite patentable subject matter as required by 35 U.S.C. § 101.

66. Section 101 provides "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." The Supreme Court had held many years prior to the initiation of the Myriad Litigation that the laws of nature, physical phenomena, and abstract ideas are not patentable.

67. The composition claims at issue in the Myriad Litigation were drawn to an isolated DNA molecule that contained all or part of the *BRCA1* and/or *BRCA2* sequence. This sequence could be either in whole or in part of the genomic sequence or a cDNA sequence derived from the transcribed natural mRNA sequence of the gene using standard techniques to create the cDNA.

68. Judge Sweet found as unpatentable these claims directed to isolated *BRCA1* and *BRCA2* sequences. Judge Sweet reasoned that "the clear line of Supreme Court precedent and accompanying lower court authorities…establishes that purification of a product from nature, without more, cannot transform it into patentable subject matter" unless the purified product "possesses markedly different characteristics." Judge Sweet determined that DNA isolated from a patient sample, regardless of what type of DNA (*i.e.*, genomic DNA or cDNA) was not markedly different than the DNA that appears in nature.

69. The method claims at issue in the Myriad Litigation covered the process of identifying the existence of certain specific mutations in *BRCA1* or *BRCA2* by analyzing the sequence obtained from a human sample. Judge Sweet determined that independent claim 1 of the '999 patent is representative:

> A method for detecting a germline alteration in the *BRCA1* gene, said alteration selected from a group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human which comprises analyzing a sequence of a *BRCA1* gene or *BRCA1* RNA from a human sample or analyzing a sequence of *BRCA1* cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1.

70. Judge Sweet recognized that the state of the law was that "an application of a law of nature or mathematical formula to a known structure or process may well be deserving of

patent protection," and that the Federal Circuit had set forth "the definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than pre-empt the principle itself," the so-called "machine or transformation test."

71. Under this test, a "claimed process is surely patent eligible under § 101 if (1) it is tied to a particular machine or apparatus, or (2) transforms a particular article into a different state or thing." Judge Sweet also noted that the case law required that "the use of a specific machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility," and the "involvement of the machine or transformation in the claimed process must not merely be an insignificant extra-solution activity." Judge Sweet also observed that the case law provided that "[a] requirement simply that data inputs be gathered – without specifying how – is a meaningless limit on a claim to an algorithm because every algorithm inherently requires the gathering of data inputs."

72. Judge Sweet determined that method claims involving "analyzing" or "comparing" nucleotide sequences are patent ineligible, because they are directed only to abstract mental processes of comparing sequences. Judge Sweet acknowledged that these claims involved isolating DNA, but that the process of isolating DNA constituted no more than "data-gathering step[s]" that are "not central to the purpose of the claimed process."

The Supreme Court Instructs The Federal Circuit To Consider The *Prometheus* Decision

73. The defendants appealed Judge Sweet's decision to the Federal Circuit. On July 29, 2011, the Federal Circuit reversed in part and affirmed in part.

74. On or about December 7, 2011, the plaintiffs applied for *certiorari* before the Supreme Court. On March 26, 2012, the Supreme Court vacated the Federal Circuit's decision and remanded the case to the Federal Circuit for further consideration in light of the Supreme Court's decision in *Prometheus*, which the Supreme Court decided on March 20, 2012 while plaintiffs' application for *certiorari* was pending.

75. With *Prometheus*, the Supreme Court addressed the patent eligibility of method claims. Specifically, at issue were method claims wherein each claim recited (i) an "administering step," telling a doctor to administer a drug to a patient; (ii) a "determining step," telling the doctor to measure the resulting metabolite levels in the blood; and (iii) a "wherein" step, describing the concentrations above which there is a likelihood of harmful side-effects and below which it is likely that the drug dosage is ineffective, and informing the doctor that metabolite concentrations above or below these thresholds "indicate a need" to decrease or increase, respectively, the drug dosage.

76. The Supreme Court held that these method claims are invalid for failure to recite patentable subject matter as required by 35 U.S.C. § 101. While the Court recognized that an application of a natural law may be patentable if it involves some additional inventive concepts, if the steps in the claimed processes (apart from the natural laws themselves) involve merely well-understood, routine, conventional activity previously engaged in by researchers in the field, then the subject matter is not patentable.

The Federal Circuit's Post-*Prometheus* Opinion In The Myriad Litigation

77. On August 16, 2012, the Federal Circuit rendered its second opinion in the Myriad Litigation. The Federal Circuit again reversed Judge Sweet's ruling that the composition

claims are not patent eligible. The panel reasoned that *Prometheus* did not control the issue of patent-eligibility of composition claims, since it dealt only with method claims, and that natural or synthesized DNA that was "isolated" from a cell, and cDNA synthesized to reflect only the exons, are patent eligible: "While, as we have held, all of the claimed isolated DNAs are eligible for patent as compositions of matter distinct from natural DNA, the claimed cDNAs are especially distinctive, lacking the noncoding introns present in naturally occurring chromosomal DNA."

78. The Federal Circuit agreed with Judge Sweet that the method claims are not patent eligible. According to the Federal Circuit, with *Prometheus* the Supreme Court "made clear that such diagnostic methods in that case essentially claim natural laws that are not eligible for patent." The court also observed that "[a]lthough the *application* of a formula or abstract idea in a process may describe patent eligible subject matter, Myriad's claims do not apply the step of comparing two nucleotide sequences in a process. Rather, the step of comparing two DNA sequences is the entire process that is claimed."

The Plaintiffs Appeal The Federal Circuit's Holding That Myriad's Composition Claims Are Patent Eligible

79. The plaintiffs appealed the Federal Circuit's decision to affirm the patent eligibility of isolated DNA (including DNA synthesized in a laboratory) and cDNA that reflected a gene's coding region.

80. Myriad did not appeal the Federal Circuit's holding that its method claims are patent ineligible.

81. On June 13, 2013, the Supreme Court unanimously reversed the Federal Circuit's holding that isolated DNA is patent eligible subject matter. Instead, the Court found that isolated DNA is not patent eligible:

> Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry. … Myriad found the location of the *BRCA1* and *BRCA2* genes, but that discovery, by itself, does not render the *BRCA* genes "new ... composition[s] of matter," § 101, that are patent eligible.
>
> Indeed, Myriad's patent descriptions highlight the problem with its claims. For example, a section of the '282 patent's Detailed Description of the Invention indicates that Myriad found the location of a gene associated with increased risk of breast cancer and identified mutations of that gene that increase the risk. In subsequent language Myriad explains that the location of the gene was unknown until Myriad found it among the approximately eight million nucleotide pairs contained in a subpart of chromosome. The '473 and '492 patents contain similar language as well. Many of Myriad's patent descriptions simply detail the "iterative process" of discovery by which Myriad narrowed the possible locations for the gene sequences that it sought. Myriad seeks to import these extensive research efforts into the § 101 patent-eligibility inquiry. But extensive effort alone is insufficient to satisfy the demands of § 101.

82. The Supreme Court also found that "Myriad's claims are not saved by the fact that isolating DNA from the human genome severs the chemical bonds that bind gene molecules together." The Court noted that the claims focus entirely on the information contained in *BRCA1* and *BRCA2* and not in terms of a chemical composition: "[The] claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the *BRCA1* and *BRCA2* genes." *Id.* at 2117.

83. The Supreme Court also held that some synthetically created DNA known as complementary DNA (cDNA) is patent eligible if the sequence is not found in natural DNA. The Supreme Court precluded from patent-eligibility synthetically created cDNA that is indistinguishable from the natural DNA sequence:

> cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. As already explained, creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring. Petitioners concede that cDNA differs from natural DNA in that "the non-coding regions have been removed." They nevertheless argue that cDNA is not patent eligible because "[t]he nucleotide sequence of cDNA is dictated by nature, not by the lab technician." 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.***

The Asserted Composition Claims Are Not Patent Eligible

84. Claims 16 and 17 of the asserted U.S. Patent No. 5,747,282 patent are representative of the asserted composition claims:

> 16. A pair of single-stranded DNA primers for determination of a nucleotide sequence of a *BRCA1* gene by a polymerase chain reaction the sequence of said primers being derived from human chromosome 17q wherein the use of said primers in a polymerase chain reaction results in the synthesis of all or part of the sequence of the *BRCA1* gene.
>
> 17. The pair of primers of claims 16 wherein said *BRCA1* gene has the nucleotide sequence of SEQ ID NO:1.

85. When read in connection with *Myriad*, the claims on their faces fail to recite patentable subject matter. The Court in *Myriad* unequivocally excluded from patentable subject

matter synthetic DNA "that may be indistinguishable from natural DNA." The claims on their face address subject matter of DNA primers whose sequence is indistinguishable from the natural DNA sequence. Moreover, as Myriad represented to the Supreme Court, probes and primers constituted "isolated" DNA within the meaning of the claims that the Court ultimately struck down. This is so even though the probe or the primer may have been synthesized in a laboratory, so long as it mirrors, in whole or in part, the genomic DNA of the *BRCA1* or *BRCA2* genes. Myriad is wrongfully attempting to enforce claims that have common subject matter to the invalidated claims in defiance of the Supreme Court's opinion.

The Asserted Method Claims Are Not Patent Eligible

86. Plaintiffs are also asserting method claims that are facially invalid in view of *Prometheus* and the Federal Circuit's *Myriad* decisions. Claim 8 of U.S. Patent No. 5,753,441, which depends from invalid claim 1, is representative:

> 1. A method for screening germline of a human subject for an alteration of a *BRCA1* gene which comprises comparing germline sequence of a *BRCA1* gene or *BRCA1* RNA from a tissue sample from said subject or a sequence of *BRCA1* cDNA made from mRNA from said sample with germline sequences of wild-type *BRCA1* gene, wild-type *BRCA1* RNA or wild-type *BRCA1* cDNA, wherein a difference in the sequence of the *BRCA1* gene, *BRCA1* RNA or *BRCA1* cDNA of the subject from wild-type indicates an alteration in the *BRCA1* gene in said subject.
>
> 8. The method of claim 1 wherein a germline nucleic acid sequence is compared by amplifying all or part of a *BRCA1* gene from said sample using a set of primers to produce amplified nucleic acids and sequencing the amplified nucleic acids.

87. These claims recite two biochemical processes: amplification and sequencing. According to the specification of the patent, these two processes were well known in the art:

> Detection of point mutations may be accomplished by molecular cloning of the *BRCA1* allele(s) and ***sequencing the allele(s) using techniques well known in the art. Alternatively, the gene sequences can be amplified directly from a genomic DNA preparation from the tumor tissue, using known techniques.*** The DNA sequence of the amplified sequences can then be determined.
>
> ***
>
> "Amplification of Polynucleotides" utilizes methods such as the polymerase chain reaction (PCR), ligation amplification (or ligase chain reaction, LCR) and amplification methods based on the use of Q-beta replicase. ***These methods are well known and widely practiced in the art.*** See, e.g., U.S. Pat. Nos. 4,683,195 and 4,683,202 and Innis et al., 1990 (for PCR); and Wu et al., 1989a (for LCR). Reagents and hardware for conducting PCR are commercially available. Primers useful to amplify sequences from the *BRCA1* region are preferably complementary to, and hybridize specifically to sequences in the *BRCA1* region or in regions that flank a target region therein. *BRCA1* sequences generated by amplification may be sequenced directly. Alternatively, but less desirably, the amplified sequence(s) may be cloned prior to sequence analysis. A method for the direct cloning and sequence analysis of enzymatically amplified genomic segments has been described by Scharf, 1986.

88. The remainder of the claim recites the mental process of comparing the sequence obtained from a patient sample with wild-type (normal) *BRCA1* DNA sequence to determine whether there is "an alteration" (mutation) in the patient's DNA.

89. These method claims are not patent eligible under *Prometheus*. Just as the steps in the claims in *Prometheus* that are patent ineligible, the steps in the asserted method claims, "apart from the natural laws themselves" (the sequence of *BRCA1*), "involve well-understood, routine, conventional activity previously engaged in by researchers in the field," namely DNA amplification and sequencing. Myriad did not invent sequencing or gene amplification, nor does

its asserted method claims add any new "inventive concepts" to the application of the natural and unpatentable phenomena.

90. Because the *BRCA* genes and the information they encode are not patentable subject matter, Myriad has no right to exclude others from making or using same. The act of copying and sequencing the genetic material for purposes of determining its natural composition and the information it encodes is central to the unpatentable biological material's fundamental purpose. Myriad's patent claims attempt to impede access to the genes' nucleic acid sequence information by claiming the only available (and obvious) laboratory means needed to determine it. As a result, Myriad now seeks to wrongfully enforce a *de facto* monopoly on the unpatentable genes to the detriment of women in the United States.

91. Myriad's decision to bring this lawsuit and attempt to prevent competition has been widely criticized. For example, on July 12, 2013, Senator Patrick J. Leahy, Chairman of U.S. Senate Committee on the Judiciary, sent a letter to the NIH urging the NIH to use its "march-in rights" under the Bayh-Dole Act either to force Myriad to license its patents on reasonable terms or, if Myriad refuses, for the NIH itself to license Myriad's patents. Mr. Leahy points out that Myriad's patents were based in part on federally funded research, that Myriad is the only provider of the test due to its patent protection, that millions of women are potentially affected by *BRCA1* and *BRCA2* mutations, and that for many women, the $3,000 to $4,000 charge for the test is simply cost prohibitive.

Myriad Filed This Lawsuit To Enforce Its Invalid Patents In Bad Faith In Order To Keep Competitors From Entering The Market

92. Statements from Myriad's Application for a Preliminary Injunction ("Application") confirm that Myriad's main goal in filing the lawsuit is to maintain the "status

quo," *i.e.*, its wrongful monopoly of the market for *BRCA* testing and reporting services. For example, Myriad argues that unless Ambry is enjoined, Myriad will suffer irreparable harm in the forms of "price erosion and the loss of the benefit of Myriad's established pricing strategy" and "the loss of market share." All of these alleged "harms" actually are the beneficial results of healthy competition.

93. As another example, Myriad makes clear that it filed this lawsuit and Application to stifle competition and protect its monopoly, while characterizing as harmful the benefits of healthy competition that result from Ambry entering the market:

> Until a couple of weeks ago, Myriad was the only company that offered a full sequence test for the *BRCA1* and 2 genes in the United States. Ambry unambiguously declared its intent to compete directly with Myriad when it announced on June 13, 2013, mere hours after the [*Myriad*] decision, that it is now offering its own *BRCA*Plus test that includes *BRCA1* and *BRCA2* testing. At the same time, Ambry released a Cancer Test Requisition Form that invites members of the public to purchase various tests, four of which (BreastNext, *BRCA*Plus, CancerNext and OvaNext) offer *BRCA1* and/or *BRCA2* testing. Ambry further indicated that it will offer its *BRCA*Plus test for $2,280, significantly below the price for Myriad's competing test, which is priced at $4,040. Thus, Ambry has entered the market not only as a direct competitor of Myriad, but at a significantly discounted price.
>
> ***If Ambry is allowed to proceed, market prices will decline.*** This is largely because third-party payors (such as insurors and HMO's) are primarily responsible for deciding whether they will reimburse or pay for testing, rather than the physician or the patient. Those payors will exert pressure on Myriad to lower its prices in response to Ambry, and Myriad would be forced to do so in some instances. This could lead to a competitive response by Ambry and even lower market prices. Additionally, other competitors potentially could enter the market at even lower prices. As a consequence, Myriad's market share will decline to the extent it does not match Ambry's price. In either case, Myriad will lose significant amounts of revenue.

94. Myriad also seeks to keep competitors from duplicating the data in its proprietary database of *BRCA* mutations built from the natural gene sequences of patients who purchased the Myriad test. According to Myriad's Executive Vice President Richard Marsh, it has contributed 80% of the data that is in the public databases. Presumably Myriad's proprietary database includes all information in the public databases (including the 20% not contributed by Myriad) in addition to its gene sequence data of thousands of patients that it has not shared with the public. The only way the public can duplicate Myriad's database is if other entities, such as Ambry, screen patient samples and deposit that data into the public databases.

95. Ambry is informed and believes that Myriad filed this lawsuit in part because Ambry has committed to depositing into the public databases the *BRCA1* and *BRCA2* sequence information obtained from performing its tests, further enabling competition in the *BRCA1* and *BRCA2* sequencing markets.

96. Myriad uses its database built on human gene sequences to more easily determine whether a patient has a harmful or harmless mutation, or a mutation that has an unknown clinical significance (called "variants of unknown [or uncertain] significance," or "VUS"). Mr. Marsh explained, in his testimony before the U.S.P.T.O. on March 3, 2012, the importance of returning fewer VUS results and why doing so is better for the patient:

> And from day one, in answer to your second question, we have always had a process of anytime we identify a VUS we contact the patient and we let them know you have a VUS. We do not yet have enough information about this variant to classify it. And the clinical advice is given to a patient, so once again, there's no uncertainty, oh, what do I do; I have this VUS. The medical process and procedure is because it's a VUS they're instructed that you need to base your medical management decisions not based on these test results because it's unknown but on the general management treatment that you would have based on your

> personal family history that (inaudible) situation. So there's clear specific guidance.
>
> Then the next step that Myriad does is we go out and we test. For free, we contact the patient and say would you please have any of your family members who have – we'd like to test all of them because it's a hereditary condition to see what other individuals in the family have that same mutation and then look at their information. Did sister have cancer? Did mother have cancer? Did grandmother have cancer? And we can then collect enough information to determine whether or not it is a deleterious mutation or not. And hence, in time, we classify the gene. We keep a database and we track all our patients. And the day we reclassify -- not reclassify but classify for the first time in the VUS -- we contact the health care provider who ordered the test and we advise them. Generally, that's a difficult question how long it takes. It really depends on how -- the common frequency of the VUS. Today, our VUS rate is 3 percent. So we have seen enough mutations enough of the time that we're very accurate and are able to do it.

97. Thus, Myriad is using its invalid patents to maintain as secret patients' gene sequences (which do not belong to Myriad) in an attempt to limit competition.

98. Ambry also is informed and believes that Myriad filed this baseless lawsuit and Application to keep all competitors – not just Ambry – from the market.

99. Ambry is informed and believes that many companies either have delayed launching *BRCA* screening services or have decided to suspend their *BRCA* screening services because of this lawsuit and pending Application.

100. Ambry is informed and believes that, just after the Supreme Court *Myriad* decision was rendered, many companies signaled their intent to launch *BRCA* screening services.

101. Ambry is informed and believes that Prevention Genetics offered full length *BRCA* testing services but currently does not offer them due to this lawsuit and the pending Application. Ambry is informed and believes that Pathway Genomics announced plans to offer

full length testing for *BRCA1* and *BRCA2*, but is delaying launch of those tests due to this lawsuit and impending Application.

102. Ambry is informed and believes that Myriad filed this lawsuit and applied for a preliminary injunction to enable it to appropriate the goodwill associated with Ambry's superior screening services, which utilize more sensitive, efficient and cost-effective next-generation sequencing technologies. Ambry's screening services use RainDance Technologies, Inc.'s PCR methods, which are compatible with next-generation sequencing technologies. Ambry is informed and believes that Myriad's current BRACAnalysis services do not utilize RainDance's PCR methods or any other methods compatible with next-generation sequencing technologies.

103. Ambry is informed and believes that on or about April 17, 2013, Myriad became a new strategic equity investor in RainDance.

104. Ambry is informed and believes that on or about April 17, 2013, Myriad signed a multi-year supply agreement where RainDance will supply Myriad with systems, reagents, gene panels and consumables.

105. Ambry is informed and believes that Myriad has begun incorporating RainDance technologies into its *BRCA* screening services.

106. Ambry is informed and believes that Myriad intends to use a technology similar to Ambry's insofar as Ambry utilizes RainDance's PCR methods and next-generation sequencing.

107. Ambry is informed and believes that Myriad is using this lawsuit and the pending Application to replace Ambry's superior screening services with its own.

Myriad Has Market Power And Has Harmed The Market

108. The relevant product market is genetic testing for patients seeking analysis of their full *BRCA1* and *BRCA2* gene sequences.

109. There are no products that are reasonably interchangeable substitutes for the genetic tests described immediately above. The only way a mutation in the full-length DNA sequence of *BRCA1* or *BRCA2* that is correlated with an elevated risk of developing hereditary breast or ovarian cancer can be detected is through genetic screening of the entire sequences utilizing amplification, hybridization, and/or gene sequencing techniques. Gene sequences are not visible to the human eye, even when using an electron microscope. Genetic mutations are not detectable by mammography, for example. Thus, a mammogram, which is an X-ray picture of a breast, cannot reveal a gene sequence. There is no test for blood metabolites that can reveal genetic mutations. There are tests that can detect specific mutations, but those tests cannot detect additional mutations other than those specific mutations.

110. Methods exist that detect whether a *BRCA* mutation results in a truncated protein, but those methods cannot detect a single nucleotide mutation that may result in a nonfunctional full-length protein. Sequencing of the full gene is required to detect those types of mutations.

111. The relevant geographic market is the United States. Foreign suppliers are unable to compete effectively. Payors (insurers) effectively determine where patient samples are sent for screening. Where an insurer pays for the screening, it also will dictate which laboratory will do the screening. In this instance, the insurer has only one choice of laboratory: Myriad. Genetic counselors cannot send samples to laboratories unless the laboratories have been certified according to the High Complexity CLIA guidelines. CLIA certification typically takes up to a

year or longer for foreign laboratories, and it is difficult for foreign laboratories to obtain High Complexity CLIA certification. In addition, all laboratories, including both foreign and domestic, are subject to state regulations applicable to genetic tests performed on human specimens. Furthermore, payors will not reimburse the costs associated with genetic analyses performed by laboratories outside the United States.

112. Myriad's monopoly pricing and other anticompetitive behaviors have been protected by high barriers to entry. The barriers new entrants faced included the various patents Myriad holds, the technological know-how for designing and running genetic tests to identify mutations in *BRCA1* and *BRCA2*, and establishing relationships with genetic counselors and hospitals, many of which are already heavily utilizing Myriad's tests.

113. As Myriad explains in its Application, Myriad is the only supplier in the U.S. of genetic testing for patients seeking analysis of their full *BRCA1* and *BRCA2* gene sequences. Ambry is informed and believes that Myriad has over 90% market share in the relevant market. Myriad possesses the power to control prices and exclude competitors. Myriad's genetic tests for full *BRCA1* and *BRCA2* gene sequences are nearly 100% higher ($4,040) than what Ambry is charging for its genetic tests for full *BRCA1* and *BRCA2* gene sequences ($2,280).

114. Ambry is informed and believes that in 2007 Myriad's full length *BRCA* screening services cost approximately $3,000.

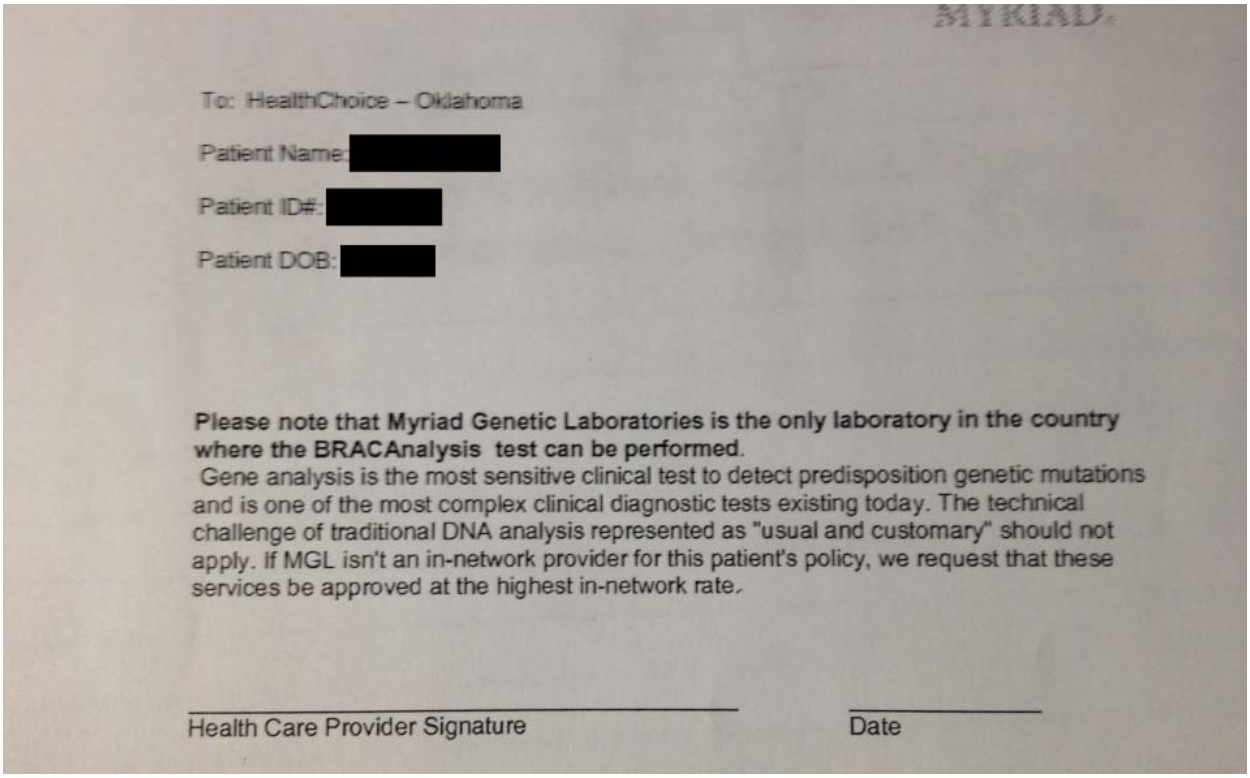
115. Ambry is informed and believes that in 2007 Dr. Skolnick said that one day Myriad's full length screening services would only cost hundreds of dollars and that Myriad would contemplate decreasing the cost of the service. As noted above, Myriad's full length *BRCA* screening services cost more today than they did in 2007.

116. Ambry is informed and believes that after Ambry launched its competing panel of tests following the Supreme Court's June 13, 2013 decision, Myriad employees told genetic counselors that Ambry's tests infringe Myriad's patents, despite the awareness that Myriad's patents are no longer enforceable due to effect of the *Myriad* and *Prometheus* decisions. Ambry is informed and believes that the intent in doing so is to maintain its monopoly in the market.

117. Ambry is informed and believes that Myriad employees have represented to genetic counselors that Ambry's test results in VUS rates are between 10-30%. Ambry is informed and believes that Myriad's employees are aware that this representation is patently false.

118. Ambry is informed and believes that Myriad employees are contacting genetic counselors and urging them not to send their samples to Ambry for testing, misrepresenting that Ambry will bill the patient the balance of any difference between the retail price of Ambry's test and the price negotiated with the insurer (so-called "balance billing"). Ambry has never balance billed. Ambry is informed and believes that Myriad's employees are misrepresenting Ambry's billing policies to discourage genetic counselors from using Ambry's testing services.

119. Ambry is informed and believes that Myriad employees are misrepresenting that "Myriad Genetic Laboratories is the only laboratory in the country where BRACAnalysis test can be performed":



MYRIAD

To: HealthChoice – Oklahoma

Patient Name: [redacted]

Patient ID#: [redacted]

Patient DOB: [redacted]

Please note that Myriad Genetic Laboratories is the only laboratory in the country where the BRACAnalysis test can be performed.
Gene analysis is the most sensitive clinical test to detect predisposition genetic mutations and is one of the most complex clinical diagnostic tests existing today. The technical challenge of traditional DNA analysis represented as "usual and customary" should not apply. If MGL isn't an in-network provider for this patient's policy, we request that these services be approved at the highest in-network rate.

Health Care Provider Signature _____ Date _____

120. Ambry does not offer a test called "BRACAnalysis." However, Ambry is informed and believes that Myriad employees are disseminating the above message with the intent to confuse genetic counselors and health care providers into believing that Myriad is the only laboratory in the country that offers *BRCA* genetic screening.

121. Myriad's false statements to such entities concerning Ambry and its *BRCA1* and *BRCA2* panels is intended to injure Ambry as it exercises its rights to compete.

122. Ambry is informed and believes that the anticompetitive conduct of Myriad's employees is systemic and has been carried out under the direction of Myriad's management.

123. Ambry is informed and believes that the Plaintiffs in this action are aware of the anticompetitive and exclusionary conduct by Myriad. Ambry is informed and believes that each and every Plaintiff is aware that the claims of the asserted patents are facially invalid. Ambry is

informed and believes that each and every plaintiff was involved in the decision to bring this lawsuit, notwithstanding that the asserted claims are facially invalid.

COUNT I
SECTION 2 OF THE SHERMAN ACT: MONOPOLIZATION
(Against Myriad Only)

124. Ambry repeats and incorporates by reference the allegations contained in paragraphs 1 through 123 of its Counterclaims as if fully set forth herein.

125. Myriad has over 90% market share in the relevant market for genetic testing for patients seeking analysis of their full *BRCA1* and *BRCA2* gene sequences.

126. Myriad is willfully maintaining its monopoly through exclusionary conduct as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident. Myriad seeks to maintain its monopoly position through various anticompetitive conducts described above, including through the bad faith enforcement of its facially invalid patents.

127. Myriad was aware before filing its Complaint in this action that the claims it was asserting are invalid per *Myriad* and *Prometheus*.

128. Through its exclusionary and anticompetitive conduct, Myriad has acquired and maintained its monopoly in the relevant market for genetic testing for patients seeking analysis of their full *BRCA1* and *BRCA2* gene sequences. Myriad has operated in this manner free from competition because of the high barriers to entry that exist in the market, including Myriad's invalid patents, the technological know-how to design and run genetic tests, and the actions of Myriad's employees.

129. Ambry has suffered substantial injury to its business and property as a result of Myriad's exclusionary and anticompetitive conduct. Ambry is being excluded from the market by Myriad's bad faith and illegal enforcement of its asserted patents and by the misrepresentations made by Myriad's employees.

130. Competition in the relevant market has suffered as a result of Myriad's exclusionary and anticompetitive conduct. Due to Myriad's anticompetitive conduct, customers must pay significantly higher prices for Myriad's products in the relevant market, often nearly twice as high as the price of Ambry's products and those of other competitors. Myriad's bad faith and illegal enforcement of the asserted patents has ensured that customers have virtually nowhere to turn but Myriad and its monopoly-priced products. Customers desire and are entitled to alternative sources of genetic testing to identify all mutations in the *BRCA1* and *BRCA2* gene sequences, through the utilization of amplification, hybridization, and/or gene sequencing, which, but for Myriad's anticompetitive conduct, could be supplied by Ambry and others.

COUNT II
SECTION 2 OF THE SHERMAN ACT: ATTEMPTED MONOPOLIZATION
(Against Myriad Only)

131. Ambry repeats and incorporates by reference the allegations contained in paragraphs 1 through 130 of its Counterclaims as if fully set forth herein.

132. Myriad has over 90% market share in the relevant market genetic testing for patients seeking analysis of their full *BRCA1* and *BRCA2* gene sequences.

133. Myriad has engaged in anticompetitive conduct with a specific intent to monopolize the relevant market through the assertion of facially invalid patent claims and the anticompetitive conduct of its employees. Myriad was aware before filing the complaint in this

action that the claims it was asserting are invalid per *Myriad* and *Prometheus*. Myriad is aware of its employees' anti-competitive conduct.

134. As evidenced by its >90% market share and power over price, to the extent it has not already, Myriad has a dangerous probability of achieving monopoly power in the relevant market. Myriad has operated in this manner free from competition because of high barriers to entry that exist in the relevant market, including Myriad's facially invalid patents, the technological know-how required to perform *BRCA* testing, and the actions of Myriad's employees.

135. Ambry has suffered substantial injury to its business and property as a result of Myriad's exclusionary and anticompetitive conduct. Ambry has largely been excluded from the market by virtue of Myriad's bad faith assertion of facially invalid patents and the actions of its employees.

136. Competition in the relevant market has suffered as a result of Myriad's exclusionary and anticompetitive conduct. Due to Myriad's anticompetitive conduct, customers must pay significantly higher prices for Myriad's products in the relevant market, often nearly twice as high as the price of Ambry's products and those of other competitors. Myriad's bad faith enforcement of patent claims that are facially patent ineligible has ensured that customers have virtually nowhere to turn but Myriad and its monopoly-priced products. Customers desire and are entitled to a second source of *BRCA* testing, which, but for Myriad's anticompetitive conduct, could be supplied by Ambry.

COUNT III
DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 5,654,155

137. Ambry hereby incorporates by reference paragraphs 1 through 136 of its Counterclaims as if fully set forth herein.

138. As a result of Counter-defendants' actions and statements and the totality of circumstances detailed above, there is an actual, immediate, and justiciable controversy that exists between Counter-defendants and Ambry concerning whether Ambry infringes any valid claim of the '155 Patent.

139. Ambry does not and will not infringe, literally or by the doctrine of equivalents, directly or by inducement, any valid claim of the '155 Patent.

140. One or more claims of the '155 Patent are invalid for failing to satisfy the requirements of Title 35 of the United States Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

141. Upon information and belief, the claims of the '155 patent are invalid for obviousness-type double patenting.

142. Ambry is entitled to a Declaratory Judgment that the '155 Patent is invalid and/or not infringed by Ambry directly or through inducement.

COUNT IV
DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 5,750,400

143. Ambry hereby incorporates by reference paragraphs 1 through 142 of its Counterclaims as if fully set forth herein.

144. As a result of Counter-defendants' actions and statements and the totality of circumstances detailed above, there is an actual, immediate, and justiciable controversy that exists between Counter-defendants and Ambry concerning whether Ambry infringes any valid claim of the '400 Patent.

145. Ambry does not and will not infringe, literally or by the doctrine of equivalents, directly or by inducement, any valid claim of the ’400 Patent.

146. One or more claims of the ’400 Patent are invalid for failing to satisfy the requirements of Title 35 of the United States Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

147. Upon information and belief, the claims of the ’400 patent are invalid for obviousness-type double patenting.

148. Ambry is entitled to a Declaratory Judgment that the ’400 Patent is invalid and/or not infringed by Ambry directly or through inducement.

COUNT V
DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 6,051,379

149. Ambry hereby incorporates by reference paragraphs 1 through 148 of its Counterclaims as if fully set forth herein.

150. As a result of Counter-defendants’ actions and statements and the totality of circumstances detailed above, there is an actual, immediate, and justiciable controversy that exists between Counter-defendants and Ambry concerning whether Ambry infringes any valid claim of the ’379 Patent.

151. Ambry does not and will not infringe, literally or by the doctrine of equivalents, directly or by inducement, any valid claim of the ’379 Patent.

152. One or more claims of the ’379 Patent are invalid for failing to satisfy the requirements of Title 35 of the United States Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

153. Upon information and belief, the claims of the ’379 patent are invalid for obviousness-type double patenting.

154. Ambry is entitled to a Declaratory Judgment that the ’379 Patent is invalid and/or not infringed by Ambry directly or through inducement.

COUNT VI
DECLARATORY JUDGMENT FOR NON-INFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 6,951,721

155. Ambry hereby Ambry hereby incorporates by reference paragraphs 1 through 154 of its Counterclaims as if fully set forth herein.

156. As a result of Counter-defendants’ actions and statements and the totality of circumstances detailed above, there is an actual, immediate, and justiciable controversy that exists between Counter-defendants and Ambry concerning whether Ambry infringes any valid claim of the ’721 Patent.

157. Ambry does not and will not infringe, literally or by the doctrine of equivalents, directly or by inducement, any valid claim of the ’721 Patent.

158. One or more claims of the ’721 Patent are invalid for failing to satisfy the requirements of Title 35 of the United States Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

159. Upon information and belief, the claims of the ’721 patent are invalid for obviousness-type double patenting.

160. Ambry is entitled to a Declaratory Judgment that the ’721 Patent is invalid and/or not infringed by Ambry directly or through inducement.

COUNT VII
DECLARATORY JUDGMENT FOR NON-INFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 7,250,497

161. Ambry hereby incorporates by reference paragraphs 1 through 160 of its Counterclaims as if fully set forth herein.

162. As a result of Counter-defendants’ actions and statements and the totality of circumstances detailed above, there is an actual, immediate, and justiciable controversy that

exists between Counter-defendants and Ambry concerning whether Ambry infringes any valid claim of the ’497 Patent.

163. Ambry does not and will not infringe, literally or by the doctrine of equivalents, directly or by inducement, any valid claim of the ’497 Patent.

164. One or more claims of the ’497 Patent are invalid for failing to satisfy the requirements of Title 35 of the United States Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

165. Upon information and belief, the claims of the ’497 patent are invalid for obviousness-type double patenting.

166. Ambry is entitled to a Declaratory Judgment that the ’497 Patent is invalid and/or not infringed by Ambry directly or through inducement.

COUNT VIII
DECLARATORY JUDGMENT FOR NON-INFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 7,670,776

167. Ambry hereby incorporates by reference paragraphs 1 through 166 of its Counterclaims as if fully set forth herein.

168. As a result of Counter-defendants’ actions and statements and the totality of circumstances detailed above, there is an actual, immediate, and justiciable controversy that exists between Counter-defendants and Ambry concerning whether Ambry infringes any valid claim of the ’776 Patent.

169. Ambry does not and will not infringe, literally or by the doctrine of equivalents, directly or by inducement, any valid claim of the ’776 Patent.

170. One or more claims of the ’776 Patent are invalid for failing to satisfy the requirements of Title 35 of the United States Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

171. Upon information and belief, the claims of the ’776 patent are invalid for obviousness-type double patenting.

172. Ambry is entitled to a Declaratory Judgment that the ’776 Patent is invalid and/or not infringed by Ambry directly or through inducement.

COUNT IX
DECLARATORY JUDGMENT FOR NON-INFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 7,563,571

173. Ambry hereby incorporates by reference paragraphs 1 through 172 of its Counterclaims as if fully set forth herein.

174. As a result of Counter-defendants’ actions and statements and the totality of circumstances detailed above, there is an actual, immediate, and justiciable controversy that exists between Counter-defendants and Ambry concerning whether Ambry infringes any valid claim of the ’571 Patent.

175. Ambry does not and will not infringe, literally or by the doctrine of equivalents, directly or by inducement, any valid claim of the ’571 Patent.

176. One or more claims of the ’571 Patent are invalid for failing to satisfy the requirements of Title 35 of the United States Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

177. Upon information and belief, the claims of the ’571 patent are invalid for obviousness-type double patenting.

178. Ambry is entitled to a Declaratory Judgment that the ’571 Patent is invalid and/or not infringed by Ambry directly or through inducement.

COUNT X
DECLARATORY JUDGMENT FOR NON-INFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 7,622,258

179. Ambry hereby incorporates by reference paragraphs 1 through 178 of its Counterclaims as if fully set forth herein.

180. As a result of Counter-defendants' actions and statements and the totality of circumstances detailed above, there is an actual, immediate, and justiciable controversy that exists between Counter-defendants and Ambry concerning whether Ambry infringes any valid claim of the '258 Patent.

181. Ambry does not and will not infringe, literally or by the doctrine of equivalents, directly or by inducement, any valid claim of the '258 Patent.

182. One or more claims of the '258 Patent are invalid for failing to satisfy the requirements of Title 35 of the United States Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

183. Upon information and belief, the claims of the '258 patent are invalid for obviousness-type double patenting.

184. Ambry is entitled to a Declaratory Judgment that the '258 Patent is invalid and/or not infringed by Ambry directly or through inducement.

COUNT XI
DECLARATORY JUDGMENT FOR NON-INFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 7,838,237

185. Ambry hereby incorporates by reference paragraphs 1 through 184 of its Counterclaims as if fully set forth herein.

186. As a result of Counter-defendants' actions and statements and the totality of circumstances detailed above, there is an actual, immediate, and justiciable controversy that exists between Counter-defendants and Ambry concerning whether Ambry infringes any valid claim of the '237 Patent.

187. Ambry does not and will not infringe, literally or by the doctrine of equivalents, directly or by inducement, any valid claim of the '237 Patent.

188. One or more claims of the ’237 Patent are invalid for failing to satisfy the requirements of Title 35 of the United States Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

189. Upon information and belief, the claims of the ’237 patent are invalid for obviousness-type double patenting.

190. Ambry is entitled to a Declaratory Judgment that the ’237 Patent is invalid and/or not infringed by Ambry directly or through inducement.

COUNT XII
DECLARATORY JUDGMENT FOR NON-INFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 7,470,510

191. Ambry hereby incorporates by reference paragraphs 1 through 190 of its Counterclaims as if fully set forth herein.

192. As a result of Counter-defendants’ actions and statements and the totality of circumstances detailed above, there is an actual, immediate, and justiciable controversy that exists between Counter-defendants and Ambry concerning whether Ambry infringes any valid claim of the ’510 Patent.

193. Ambry does not and will not infringe, literally or by the doctrine of equivalents, directly or by inducement, any valid claim of the ’510 Patent.

194. One or more claims of the ’510 Patent are invalid for failing to satisfy the requirements of Title 35 of the United States Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

195. Upon information and belief, the claims of the ’510 patent are invalid for obviousness-type double patenting.

196. Ambry is entitled to a Declaratory Judgment that the ’510 Patent is invalid and/or not infringed by Ambry directly or through inducement.

COUNT XIII
DECLARATORY JUDGMENT FOR NON-INFRINGEMENT INVALIDITY OF U.S. PATENT NO. 5,709,999

197. Ambry hereby incorporates by reference paragraphs 1 through 196 of its Counterclaims as if fully set forth herein.

198. As a result of Counter-defendants' actions and statements and the totality of circumstances detailed above, there is an actual, immediate, and justiciable controversy that exists between Counter-defendants and Ambry concerning whether Ambry infringes any valid claim of the '999 Patent.

199. Ambry does not and will not infringe, literally or by the doctrine of equivalents, directly or by inducement, any valid claim of the '999 Patent.

200. One or more claims of the '999 Patent are invalid for failing to satisfy the requirements of Title 35 of the United States Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

201. Upon information and belief, the claims of the '999 patent are invalid for obviousness-type double patenting.

202. Ambry is entitled to a Declaratory Judgment that the '999 Patent is invalid and/or not infringed by Ambry directly or through inducement.

COUNT XIV
DECLARATORY JUDGMENT FOR NON-INFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 5,747,282

203. Ambry hereby incorporates by reference paragraphs 1 through 202 of its Counterclaims as if fully set forth herein.

204. As a result of Counter-defendants' actions and statements and the totality of circumstances detailed above, there is an actual, immediate, and justiciable controversy that exists between Counter-defendants and Ambry concerning whether Ambry infringes any valid claim of the '282 Patent.

205. Ambry does not and will not infringe, literally or by the doctrine of equivalents, directly or by inducement, any valid claim of the ’282 Patent.

206. One or more claims of the ’282 Patent are invalid for failing to satisfy the requirements of Title 35 of the United States Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

207. Upon information and belief, the claims of the ’282 patent are invalid for obviousness-type double patenting.

208. Ambry is entitled to a Declaratory Judgment that the ’282 Patent is invalid and/or not infringed by Ambry directly or through inducement.

COUNT XV
DECLARATORY JUDGMENT FOR NON-INFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 5,753,441

209. Ambry hereby incorporates by reference paragraphs 1 through 208 of its Counterclaims as if fully set forth herein.

210. As a result of Counter-defendants’ actions and statements and the totality of circumstances detailed above, there is an actual, immediate, and justiciable controversy that exists between Counter-defendants and Ambry concerning whether Ambry infringes any valid claim of the ’441 Patent.

211. Ambry does not and will not infringe, literally or by the doctrine of equivalents, directly or by inducement, any valid claim of the ’441 Patent.

212. One or more claims of the ’441 Patent are invalid for failing to satisfy the requirements of Title 35 of the United States Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

213. Upon information and belief, the claims of the ’441 patent are invalid for obviousness-type double patenting.

214. Ambry is entitled to a Declaratory Judgment that the ’441 Patent is invalid and/or not infringed by Ambry directly or through inducement.

COUNT XVI
DECLARATORY JUDGMENT FOR NON-INFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 5,837,492

215. Ambry hereby incorporates by reference paragraphs 1 through 214 of its Counterclaims as if fully set forth herein.

216. As a result of Counter-defendants’ actions and statements and the totality of circumstances detailed above, there is an actual, immediate, and justiciable controversy that exists between Counter-defendants and Ambry concerning whether Ambry infringes any valid claim of the ’492 Patent.

217. Ambry does not and will not infringe, literally or by the doctrine of equivalents, directly or by inducement, any valid claim of the ’492 Patent.

218. One or more claims of the ’492 Patent are invalid for failing to satisfy the requirements of Title 35 of the United States Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

219. Upon information and belief, the claims of the ’492 patent are invalid for obviousness-type double patenting.

220. Ambry is entitled to a Declaratory Judgment that the ’492 Patent is invalid and/or not infringed by Ambry directly or through inducement.

COUNT XVII
DECLARATORY JUDGMENT FOR NON-INFRINGEMENT AND INVALIDITY OF U.S. PATENT NO. 6,033,857

221. Ambry hereby incorporates by reference paragraphs 1 through 220 of its Counterclaims as if fully set forth herein.

222. As a result of Counter-defendants’ actions and statements and the totality of circumstances detailed above, there is an actual, immediate, and justiciable controversy that

exists between Counter-defendants and Ambry concerning whether Ambry infringes any valid claim of the ’857 Patent.

223. Ambry does not and will not infringe, literally or by the doctrine of equivalents, directly or by inducement, any valid claim of the ’857 Patent.

224. One or more claims of the ’857 Patent are invalid for failing to satisfy the requirements of Title 35 of the United States Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

225. Upon information and belief, the claims of the ’857 patent are invalid for obviousness-type double patenting.

226. Ambry is entitled to a Declaratory Judgment that the ’857 Patent is invalid and/or not infringed by Ambry directly or through inducement.

DEMAND FOR JURY TRIAL

Ambry demands a trial by jury on all matters herein so triable.

PRAYER FOR RELIEF

WHEREFORE, Ambry Genetics Corporation respectfully requests the Court enter judgment against Defendant as follows:

1. A declaration that Myriad has violated Section 2 of the Sherman Act for Monopolization through its bad faith and illegal enforcement of the ’155, ’400, ’379, ’721, ’497, ’776, ’571, ’258, ’237, ’510, ’999, ’282, ’441, ’492, and ’857 Patents;

2. A declaration that Myriad has violated Section 2 of the Sherman Act for Attempted Monopolization through its bad faith and illegal enforcement of the ’155, ’400, ’379, ’721, ’497, ’776, ’571, ’258, ’237, ’510, ’999, ’282, ’441, ’492, and ’857 Patents;

3. An injunction, pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, enjoining Myriad from enforcing the ’155, ’400, ’379, ’721, ’497, ’776, ’571, ’258, ’237, ’510, ’999, ’282, ’441, ’492, and ’857 Patents;

4. An award to Ambry of damages, such amount to be trebled pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15, together with prejudgment interest thereon and attorneys' fees and costs;

5. A declaration that the manufacture, use, sale, or offer to sell of Ambry's *BRCA1*, *BRCA2*, *BRCA*Plus, BreastNext, OvaNext, and CancerNext products would not and will not directly (either literally or under the doctrine of equivalents) or indirectly infringe (either contributorily or by inducement) any valid claim of the '155, '400, '379, '721, '497, '776, '571, '258, '237, '510, '999, '282, '441, '492, and '857 Patents;

6. A declaration that the claims of the '155, '400, '379, '721, '497, '776, '571, '258, '237, '510, '999, '282, '441, '492, and '857 Patents are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103 and/or 112;

7. An injunction against Counter-defendant and their affiliates, subsidiaries, assigns, employees, agents or anyone acting in privity or concert with Counter-defendant from asserting infringement or instituting any legal action for infringement of the '155, '400, '379, '721, '497, '776, '571, '258, '237, '510, '999, '282, '441, '492, and '857 Patents against Ambry, customers of Ambry, or affiliates of Ambry;

8. An award to Ambry of its reasonable costs and attorneys' fees incurred in bringing this action pursuant to 35 U.S.C. § 285; and

9. An award of such other and further relief as the Court may deem just and proper.

Respectfully Submitted,

DATED this 5th day of August, 2013.

/s/ Edgar R. Cataxinos
Edgar R. Cataxinos
Joseph A. Walkowski
H. Dickson Burton
TRASKBRITT, PC
230 South 500 East, Suite 300
Salt Lake City, Utah 84110

Attorneys for Defendant

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 5th day of August 2013, a true and correct copy of the foregoing was electronically filed with the Clerk of the Court and delivered by CM/ECF and by the method(s) indicated below to the following:

David G. Mangum
Email: dmangum@parsonsbehle.com
C. Kevin Spears
Email: ecf@parsonsbehle.com
Kristine E. Johnson
Email: ecf@parsonsbehle.com
Michael R. McCarthy
Email: ecf@parsonsbehle.com
PARSONS BEHLE & LATIMER
201 S MAIN ST STE 1800
PO BOX 45898
SALT LAKE CITY, UT 84145-0898
Tele: (801) 532-1234

__X__ ECF Delivery
_____ United States Mail
_____ Federal Express
_____ Email

_/s/ Edgar R. Cataxinos
Edgar R. Cataxinos