UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ASSOCIATION FOR MOLECULAR PATHOLOGY, et at., Plaintiffs, v. UNITED STATES PATENT AND TRADEMARK OFFICE, et al., Defendants.	09 Civ. 4515 (RWS) ECF

BRIEF FOR AMICI CURIAE

American Medical Association, American Society of Human Genetics, American College of Obstetricians and Gynecologists, American College of Embryology, and The Medical Society of the State of New York

IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS AND IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Of Counsel:

Professor Lori B. Andrews
Chicago-Kent College of Law
Illinois Institute of Technology
565 West Adams Street
Chicago, IL 60661

Professor Joshua D. Sarnoff
Washington College of Law
American University
4801 Massachusetts Avenue, NW
Washington, DC 20016

Counsel of Record for Amici Curiae:

Amy L. Katz (AK2854)
Law Office of Amy L. Katz
145 Central Park West
New York, NY 10023
(212) 580-5338
AmyLKatzLaw@gmail.com

August 27, 2009

TABLE OF CONTENTS

TABLE OF AUTHORITIES ii

STATEMENT OF INTEREST OF *AMICI CURIAE* MEDICAL ASSOCIATIONS 1

PRELIMINARY STATEMENT 4

STATEMENT OF FACTS 5

ARGUMENT 14

I. Gene Sequences and Correlation Claims Are Not Patentable Inventions Within the Meaning of Article I, Section 8, Clause 8 of the U.S. Constitution and 35 U.S.C. § 101……...…..14

A. Myriad's Sequence Claims are Unpatentable Products of Nature.....17

B. Myriad's Correlation Claims are Unpatentable Laws of Nature.....19

II. Patents on Products of Nature and Laws of Nature Violate Medical and Scientific Ethical Tenets and Are Not Necessary to Promote Innovation……..22

CONCLUSION 24

TABLE OF AUTHORITIES

Cases

American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1 (1931) 4, 18

American Wood-Paper Co. v. Fibre Disintegrating Co., 90 U.S. (23 Wall.) 566 (1874) 4, 17

Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141 (1989) 21

Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293 (1884) 4, 18, 19

Diamond v. Chakrabarty, 447 U.S. 303 (1980) 4, 5, 15, 16

Diamond v. Diehr, 450 U.S. 175 (1981) ..... passim

Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948) 4, 15, 18

Gen. Elec. Co. v. DeForest Radio Co., 28 F.2d 641 (3d Cir. 1928) 19

Gottschalk v. Benson, 409 U.S. 63 (1972) 4, 16

In re Bilski, 545 F.3d 943 (Fed. Cir. 2008) 5, 20

In re Cruciferous Sprout Litig., 301 F.3d 1343 (Fed. Cir. 2002) 19

In re Grams, 888 F.2d 835 (Fed. Cir. 1989) 21

In re Schrader, 22 F.3d 290 (Fed. Cir. 1994) 21

Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124 (2006) 4, 20

Le Roy v. Tatham, 55 U.S. 156 (1853) 4

O'Reilly v. Morse, 56 U.S. 62 (1854) 4, 22

Parker v. Flook, 437 U.S. 584 (1978) 4, 19, 20, 21

Statutes

35 U.S.C. § 154 (2009) 10

35 U.S.C. § 271(a) (2009) 10

Other Authorities

A. Chetrit, et al., *Effect of BRCA1/2 Mutations on Long-Term Survival of Invasive Ovarian Cancer*, 26 J. Clin. Oncol. 20-25 (2008) 13

Albert A. Walker, Text-Book of the Patent Laws of the United States of America 2-3 (L. K. Strouse & Co., 2d ed. 1889) ..... .15

The American College of Obstetricians and Gynecologists, *ACOG Committee Opinion Number 364: Patents, Medicine, and the Interests of Patients*, 109 Obstetrics & Gynecology 1249, 1252 (May 2007)……22, 23

American Medical Association, Opinion 9.095 – The Use of Patents and Other Means to Limit Availability of Medical Procedures (1995), available at http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion9095.shtml 22

Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 Health Law J. 123 (2002) 23

CBC News, Ontario to Offer New Genetic Test for Breast, Ovarian Cancer (Jan. 8, 2003), available at http://www.cbc.ca/health/story/2003/01/06/test_genetic030106.html 11

Erik Stockstad, *Genetic Screen Misses Mutations in Women at High Risk of Breast Cancer*, 311 Science 1847 (2006)..... 14

The H. Judiciary Subcomm. on Courts, the Internet and Intellectual Property in Connection with its Hearing on "Stifling or Stimulating – The Role of Gene Patents in Research and Genetic Testing", 110th Cong. at 40 (2007)..... 12

Francis S. Collins, Eric D. Green, Alan E. Guttmacher, and Mark. S. Guyer, *A Vision for the Future of Genomics Research*, 422 Nature 835-847 (Apr. 24, 2003) 13

Issac Rabino, *How Human Geneticists in U.S. View Commercialization of the Human Genome Project*, 29 Nature Genetics 15-16 (2001) 12

Jordan Paradise, *European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics'* BRCA *Patent Controversy*, 59 Food & Drug Law J. 133-154 (2004) ……7, 17

Judy Peres, *Genetic Testing Can Save Lives – But Errors Leave Scars*, Chicago Tribune, September 26, 1999..... 11

Kimberly Blanton, *Corporate Takeover Exploiting the US Patent System, A Single Company has Gained Control Over Genetic Research and Testing for Breast Cancer and Scientists, Doctors, and Patients Have to Play by its Rules*, Boston Globe Mag., Feb. 24, 2002, at 10 12

Letter from Martin Munzer to Xavier Becerra, U.S. Congressman (May 25, 2007)..... 11

Memorandum of Law in Support of Defendants' Motion to Dismiss at 1, *Ass'n. for Molecular Pathology v. U.S. Patent and Trademark Office*, 09 Civ. 4515 (S.D.N.Y. July 13, 2009)…....19

Michael J. Czar, J. Christopher Anderson, Joel S. Bader, and Jean Peccoud, *Gene Synthesis Demystified*, 27 Trends in Biotechnology 64 (2009) 19

N.D. Kauff, *Is it Time to Stratify for BRCA Mutation Status in Therapeutic Trials in Ovarian Cancer?*, 26 J. Clin. Oncol. 9-10 (2008)..... 13

Nicholas Wade, *Cost of Decoding a Genome Is Lowered*, New York Times, August 10, 2009 . 13

17 The Parliamentary History of England col. 999 (William Cobbett ed., 1806-20) (1774)..... 20

Patents, Medicine, and the Interests of Patients, 109 Obstet Gynecol 1249-53 (2007) (Am. Coll. of Obstet. & Gynecol. Comm. Op. No. 364) 13

Phyllida Brown & Kurt Kleiner, *Patent Row Splits Breast Cancer Researchers*, New Scientist, Sept. 24, 1994, at 44..... 17

Rachel Nowak, *NIH in Danger of Losing Out on BRCA1 Patent*, 266 Science 209 (1994)..... 24

Ralf Dahm, *Discovering DNA: Friedrich Miescher and the Early Years of Nucleic Acid Research*, 122 Human Genetics 565-581, 567-8 (2008)..... 6

Robert K. Merton, On the Shoulders of Giants: A Shandean Postscript (1985) 23

Secretary's Advisory Committee on Genetics, Health, and Society, 110 *Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (March 9, 2009)..... 23

Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. Econ. Persp. 29 (1991)..... 24

Tom Walsh et al., *Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 JAMA 1379-1388 (2006)..... 10

Transcript of Oral Argument at 40, line 10-80, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006) (No. 04-607) 16

U.S. Dept. of Energy, Major Events in the U.S. Human Genome Project and Related Projects . 24

1 William C. Robinson, The Law of Patents for Useful Inventions 39 (Little, Brown 1890)..... 5

Y. Ben David, et al., *Effect of BRCA Mutations on the Length of Survival in Epithelial Ovarian Tumors*, 20 J. Clin. Oncol. 463-66 (2002) 13

STATEMENT OF INTEREST OF *AMICI CURIAE* MEDICAL ASSOCIATIONS

Amici seek to provide this Court with insight into the adverse effects on medical care and innovation that gene patents cause. These adverse effects could and should have been avoided, because genetic sequence and correlation patents – including all of the Myriad patents at issue – are not patentable inventions. These patents should never have been granted, and are not needed to create incentives for innovation. The Myriad patents on breast cancer genes, mutations, and correlations between mutations and disease have a direct, severe, and adverse impact on members of the *Amici* medical organizations and all humanity. Myriad's announced intention to aggressively enforce its patents to foreclose other diagnostic, treatment and research options deter the *Amici* health care professionals and researchers from providing appropriate medical care and diagnostic services. Myriad's patents also preclude research into better medical treatments and technologies by precluding clinical activities that would lead to additional discoveries. Myriad's patents, and other genetic sequence and biological correlation patents like them, cast a chill on important health care practices and on innovation.

***Amicus Curiae* American Medical Association (AMA)** is a private, voluntary non-profit organization of 240,000 physicians and medical students, who practice in all states and all fields of medical specialization. The AMA was founded in 1847 to promote the science and betterment of public health. From its inception, the AMA has maintained a Code of Medical Ethics, including a set of core Principles and a Code and Opinions applying those Principles. The Code has been cited by ethicists, legal scholars and courts of law, including, on numerous occasions, the U.S. Supreme Court. Several of the Ethical Opinions, as well as reports of the AMA's Council on Ethical and Judicial Affairs, address ethical issues raised by the issuance of patents on medically useful information. In the mid-1990s, the American Medical Association

amended its Code of Ethics to forbid doctors from patenting medical procedures because it found that these patents compromised patient care. Since that time, the AMA (with other medical and scientific groups) has issued numerous statements regarding the need to avoid having gene patents interfere with appropriate medical care and the development of better medical treatments and technologies, and declaring unethical any limitations on the dissemination of medical knowledge. The AMA submits this brief on its own behalf and as a representative of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition of the AMA and the medical societies of every state and the District of Columbia, formed to represent the views of organized medicine in the courts.

***Amicus Curiae* American Society of Human Genetics (ASHG)** is a non-profit, tax-exempt organization that consists of over 8,000 professionals in the field of human genetics including researchers, clinicians, academicians, ethicists, genetic counselors, and nurses whose work involves genetic testing. Its mission is to serve human genetics professionals, health care providers, and the general public by sharing genetics research through *The American Journal of Human Genetics* and its annual meeting, to advance genetic research, to enhance genetics education for genetics professionals and the general public, and to promote genetics services and support responsible social and scientific policies. ASHG has studied the gene patent issue since such patents were first granted and has found that patents on sequences and correlations interfere with research and medical care.

***Amicus Curiae* American College of Obstetricians and Gynecologists (ACOG)** is a private, non-profit, voluntary membership organization that consists of over 51,000 health care professionals dedicated to providing quality health care to women. More than ninety percent of Board-certified obstetricians and gynecologists in the U.S. are affiliated with ACOG. Its

members include both generalists and specialists in the field who offer a number of clinical services, including prenatal diagnosis and counseling regarding genetic conditions. ACOG's mission is fourfold: to advocate for accessible and quality health care for all women; to maintain high clinical standards and provide educational opportunities for professionals; to promote the involvement of patients in medical care; and to increase public awareness of unique health issues facing women. The patents at issue in this case interfere with the ability of ACOG's members to provide appropriate health care and undertake research.

Amicus Curiae **American College of Embryology (ACE)** develops and maintains professional standards for embryologists. Its mission is to develop professional training programs and certification standards for this emerging field of study. Its members offer a number of clinical services, including pre-implantation diagnosis—a technique used to test an embryo for genetic diseases before the embryo is transferred into the uterus of a woman. Its members are also involved in research on innovative treatments, such as embryo stem cell research. Patents on gene sequences and correlations have impeded embryologists' ability to study complex cellular and genetic interactions, such as those related to organ development.

Amicus Curiae **Medical Society of the State of New York (MSSNY)** is a voluntary association of approximately 27,000 licensed physicians, medical residents, and medical students in all specialties in New York. The purposes of MSSNY include enhancing the delivery of medical care of high quality to all people in the most economical manner, and acting to promote and maintain high standards in medical education and in the practice of medicine in an effort to ensure that high quality medical care is available to the public. The patents at issue in this case interfere with the mission of MSSNY.

PRELIMINARY STATEMENT

The U.S. Constitution, Article 1, Section 8, Clause 8 and the Patent Act 35 U.S.C. § 101 et seq., limit the reach of the patent system by deeming certain categories of inventions patent eligible and prohibiting patents for certain discoveries, most notably products of nature and laws of nature. In this case, Myriad's patents claim products of nature (gene sequences) and laws of nature (correlations between the existence of a mutation and the likelihood of developing cancer or between an affected tumor sample and normal tissue). They should be invalidated.

In a series of cases over the past 150 years, the U.S. Supreme Court has held that one cannot patent (1) products of nature, or materials isolated from products of nature if those materials behave in the same way they would in nature, or (2) discovered laws of nature or mathematics, or applications of those laws lacking significant (i.e., creative) "post-solution activity." *Diamond v. Diehr,* 450 U.S. 175, 191-192 (1981). *See, e.g., Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *Parker v. Flook*, 437 U.S. 584, 590 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11-12 (1931); *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 311 (1884); *American Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. (23 Wall.) 566, 594 (1874); *O'Reilly v. Morse*, 56 U.S. 62, 112-121 (1854); *Le Roy v. Tatham*, 55 U.S. 156, 175 (1853). Myriad's sequence claims improperly patent isolated products of nature that behave identically to their natural state. Myriad's correlation claims patent a law of nature. *See also Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 138 (2006) (Breyer, J., dissenting from dismissal as improvidently granted) (a diagnostic method correlation claim is an unpatentable discovery of a law of nature). Moreover, under current U.S. law, for a process claim that applies a law of nature to be patent

eligible, it also must transform an article to a different state or thing, or must use a particular machine. *See Diehr*, 450 U.S. at 184; *In re Bilski*, 545 F.3d 943, 954-56 (Fed. Cir. 2008) (en banc), *cert. granted*. Myriad's correlation claims do not require a specific machine nor transform an article to a different state or thing.

Genetic patents on natural human biology and natural human medical phenomena interfere with medical practice and violate ethical tenets. Patents are not needed to create an incentive for the discovery of human genes, and patent law does not exist to reward such scientific and medical discoveries. Rather, they must remain "free to all men and reserved exclusively to none," both to meet shared ethical commitments and to foster further scientific discovery and more rapid sequential innovation. *Chakrabarty*, 447 U.S. at 309 (quoting *Funk Bros. Seed Co.*, 333 U.S. at 130). *See* 1 William C. Robinson, The Law of Patents for Useful Inventions 39 (Little, Brown 1890) ("To benefit by the discoveries of his fellow-men is thus not only a natural right, it is also the natural duty which every man owes to himself and to society; and the mutual universal progress thence resulting is the fulfillment of the earthly destiny of the human race."). Myriad's gene sequence and correlation patent claims should be invalidated.

STATEMENT OF FACTS

1. Genes and Genetic Sequences.

Genes contain the instructions needed for an organism to develop, survive, and reproduce; they are the basic units of heredity. The sequence of a gene consists of hundreds or thousands of combinations of the four chemical bases -- adenine (A), cytosine (C), guanine (G), and thymine (T) -- which collectively form Deoxyribonucleic Acid ("DNA"). Gene sequences code for amino acids that make proteins, which are used in the growth and repair of tissues and are responsible for every inheritable trait from the color of a person's hair to whether they are

genetically predisposed to diseases.[1] A gene is represented in scientific research, medical practice, and patent applications by the information corresponding to the sequence of its DNA bases, i.e., a series of letters. For example, one segment of the hemoglobin gene looks like this: CTGAGG.

Certain natural variations in a gene ("mutations") are correlated with an increased risk of disease. These mutations (called "base mutations") can be likened to typographical errors in the spelling of the gene. Thus, a single switch of the chemical letter A to T in the hemoglobin gene sequence is correlated with a serious disease, sickle cell anemia (CCTG*A*GG is switched to CCTG*T*GG), because it changes one of the proteins made by the gene.

Beginning in 1869, scientists learned to isolate DNA from the body by removing it from the rest of the cellular material. Ralf Dahm, *Discovering DNA: Friedrich Miescher and the Early Years of Nucleic Acid Research*, 122 Human Genetics 565-581, 567-8 (2008) (documenting the activities of Dr. Miescher). A century later, in the 1970s and 1980s, scientists not only could isolate DNA from the cell, but also could string together naturally occurring nucleotides of DNA – a process know as "synthesis" – to create a mirror strand to the mRNA, known as cDNA (for complementary DNA). cDNA contains the same genetic coding information as the naturally occurring mRNA and as the naturally occurring DNA sequence. cDNA is functionally identical to its DNA counterpart in the body after the cell's natural processes remove the non-coding regions. When placed in the human body, both the cDNA and the natural DNA on which its molecular sequence is based produce identical proteins. The term

[1] The naturally occurring process of protein production makes direct use of the active coding regions of the genetic sequence, but not the non-coding regions. The natural process uses messenger RNA (mRNA), which is the functional form of the DNA gene sequence after a cellular process has removed the non-coding regions so that the sequence can produce the proteins.

"isolated DNA" refers both to the physical molecule (the DNA or cDNA) containing the genetic information and the genetic information itself.

2. <u>Myriad's Breast Cancer Genetic Sequence and Correlation Patents.</u>

Everyone has at least two genes related to breast cancer in his or her body (known as *BRCA*1 and *BRCA*2). These genes have sequences that consist of a long string of the bases A, T, C, and G. *BRCA*1 has 81,154 bases and *BRCA*2 has 84,188 bases. There are hundreds of possible naturally occurring mutations (variations) in the *BRCA*1 and *BRCA*2 DNA sequences. Some people have DNA sequences in their *BRCA*1 and *BRCA*2 genes that *do not* predispose them to breast cancer and/or ovarian cancer, and some people have mutations in the sequences that *do* predispose them to such cancers.

Shortly after a collaborative international Consortium of scientists had located the *BRCA*1 gene on chromosome 17 (of the 23 human chromosomes) and was engaged in determining its various DNA sequences, a University of Utah scientist who was part of the public consortium created Myriad to commercialize the gene once it was fully sequenced. Jordan Paradise, *European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics'* BRCA *Patent Controversy,* 59 Food & Drug Law J. 133-154, 143 (2004). Myriad's assignor patented the naturally occurring sequences for *BRCA*1 and for *BRCA*2 (the "sequence claims"), as well as the act of looking at a person's breast cancer gene sequence and comparing it to a known sequence (the "correlation claims").[2] Of course, because Myriad's patents are for "isolated DNA" or "isolated DNA molecules" and for performing the mental

[2] Although each of Myriad's patents contains numerous claims, Plaintiffs have only challenged representative claims. *See* Complaint at 30 (challenging Claims 1, 2, 5, 6, 7, and 20 of U.S. Pat. No. 5,747,282; Claims 1, 6, and 7 of U.S. Pat. No. 5,837,492; Claim 1 of U.S. Pat. No. 5,693,473; Claim 1 of U.S. Pat. No. 5,709,999; Claim 1 of U.S. Pat. No. 5,710,001; Claim 1 of U.S. Pat. No. 5,753,441; and Claims 1 and 2 of U.S. Pat. No. 6,033,857).

process of "comparing" sequences,[3] they do not prohibit people from having such sequences or information in their bodies. Rather, they prohibit people from doing anything with their DNA once it is removed from their bodies, and from doing anything useful with the genetic sequence information that such DNA contains once it is identified, even if it is identified by methods and processes that are not patented by Myriad. Further, because the patents apply to any isolated *BRCA*1 or *BRCA*2 *molecule,* they prevent anyone from simply removing such DNA from a person's body (since that would result in "isolated DNA") or analyzing a person's DNA gene sequence (since that would involve the use of "isolated DNA"). The *correlation* patents prohibit using such sequence information to diagnose disease, even if anyone could obtain the sequence information without violating Myriad's sequence patents. If that were not enough, Myriad's *sequence* patents prohibit research with any isolated natural DNA and some of the patents prohibit even thinking about those sequences for research or medical diagnosis and treatment.

Specifically, Myriad obtained a patent covering any "isolated DNA" having a sequence "coding for a *BRCA*1 polypeptide" (i.e. coding for that protein) or "at least 15 nucleotides" (DNA bases) of that sequence (claims 1 and 5 of U.S. Patent No. 5,747,282). Similarly, Myriad obtained a patent covering any "isolated DNA molecule" having a sequence "coding for a *BRCA*2 polypeptide" or having any "mutated form" associated with susceptibility to cancer (claims 1 and 6 of U.S. Patent No. 5,837,492). These patents cover naturally occurring genes removed from the cell and prevent all uses of the information the genes contain.

---

[3] Some of Myriad's patents refer to a "DNA molecule," but others refer just to "isolated DNA" or to a gene or to a cDNA "sequence." *Compare, e.g.,* 5,837,492 Claim 1 *with* U.S. Pat. No. 5,747,282, Claim 1, and U.S. Pat. No. 5,709,999, Claim 1. Other patents claim actions (e.g., "comparing") that may be performed solely with the sequence information. U.S. Pat. No. 6,033,857, Claim 1. Yet another of Myriad's patents prohibits "analyzing a sequence" of DNA, mRNA, or cDNA, which would preclude any mental or computerized identification or recognition of the information *sequence* once the individual bases are identified by chemical techniques. *See* U.S. Pat. No. 5,709,999, Claim 1.

Myriad has also obtained a patent on simply "analyzing a sequence"; its patent covers *any* method or technology for "detecting" certain mutations ("germline alteration") in the *BRCA*1 gene of any "human sample" of DNA, mRNA, or cDNA (Claim 1 of U.S. Patent No. 5,709,999). Although Myriad did not develop new methods or technology for this analysis, its improperly issued patents prevent others from using any method or technology to detect these mutations in the *BRCA*1 gene.

Further, Myriad has obtained patents on the act of "comparing" a person's breast cancer gene sequence to the normal ("wild-type") *BRCA*2 gene sequence. If the sequences are different, the patient's gene is a "mutant" gene which "indicates" a predisposition to cancer (Claim 1 and 2 of U.S. Patent No. 6,033,857). These patents prohibit others from performing the simple mental step of comparing gene sequence information.

The scope of Myriad's patent portfolio must be fully appreciated. By staking claims on all isolated versions of the *BRCA*1 and *BRCA*2 genes, Myriad effectively controls all of the naturally occurring *BRCA*1 and *BRCA*2 breast cancer genes from everyone's bodies. No woman (or man) can give her (or his) own breast cancer gene to a doctor or researcher to analyze for purposes of diagnosis or research, because once that gene is removed from the body Myriad's patent claims cover it. No clinician or scientist can perform diagnosis or research using such gene sequences or the information they contain without violating the patents.

3. <u>Adverse Effects of Myriad's Patents and Similar Genetic Patents.</u>

Myriad's patents, and patents owned by other companies, universities, and individuals, on genetic sequences and biological correlations have serious adverse impacts on *Amici* and the public that they serve. These patents hamper medical discovery and innovation, interfere with the practice of medicine, and harm patients. For 20 years from the date of the filing of the patent

application (and sometimes longer), a patent holder controls any use of its invention and can prevent anyone else from using, making, selling, or importing the invention. 35 U.S.C. §§ 154, 271(a) (2009). This ability to control all uses of an invention makes sense for a machine, such as a gene sequencer, but not for the molecule containing the gene sequence itself, which is not merely a tangible entity, but also the information code of the human body.

There is no way to "design around" these patents. Given that there are no substitutes for analyzing a patient's genetic makeup, the patent holder possesses a broad and unavoidable monopoly in the market for medical research, medical services, and patient care. Upstream of the end users and the market, the patent holder can prevent scientists and clinicians from undertaking research on the genetic disease related to that gene and from developing improved diagnostic procedures, tests, and equipment. The patent holder can charge an excessive royalty for even an inferior genetic test. Such patents prevent doctors from *properly* diagnosing even those patients willing and able to pay the excessive costs.

The patents additionally interfere with medical care because Myriad does not look for every known or possible mutation in the breast cancer gene. *Amici* are very concerned that exclusivity over the use of the *BRCA*1 and *BRCA*2 sequences, and the consequent exclusive right to perform breast cancer genetic testing, has led to the misdiagnosis of patients and has precluded the deployment of improved genetic tests. Tom Walsh et al., *Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 JAMA 1379-1388 (2006) (12% of the 300 people examined from high risk families had mutations the Myriad testing missed). Because Myriad has exclusive use of the breast cancer gene sequences, moreover, no woman can get an independent second opinion about her condition before deciding to have her healthy breasts or ovaries removed in order to avoid cancer. As a result, women may

have their breasts or ovaries removed unnecessarily when they received a false positive on a *BRCA*1 or *BRCA*2 test because they do not have access to an independent confirmatory test. *See, e.g.*, Judy Peres, *Genetic Testing Can Save Lives – But Errors Leave Scars*, Chicago Tribune, September 26, 1999.

Because of its patents, Myriad can preclude all others from looking at a person's *BRCA*1 and *BRCA*2 breast cancer gene sequences to determine if she has a mutation related to cancer. With the monopoly its patents provide, Myriad charges over $3000 per test, substantially more than the cost of those tests and consequently substantially more than competitors would charge. In 2008, Myriad spent $32,340,000 to perform molecular diagnostic tests, and had revenue for its tests totaling $222,855,000. Form 10-K, submitted by Myriad Genetics, Inc., Commission file number: 0-26642, at 27 (filed August 28, 2008). In Ontario, Canada, where the regional public healthcare plan is ignoring Myriad's patent, the testing for breast cancer is performed for a third of what it costs when done by Myriad. CBC News, Ontario to Offer New Genetic Test for Breast, Ovarian Cancer (Jan. 8, 2003), available at http://www.cbc.ca/health/story/2003/01/06/test_genetic030106.html.

The problems with genetic sequence and correlation patents extend far beyond Myriad's patents on breast cancer genes. For example, when a company obtained a patent on the hepatitis C genome, it was able to prevent other companies from offering inexpensive public health screening for hepatitis C, because the patent allowed it to, in essence, "own" the disease. Letter from Martin Munzer to Xavier Becerra, U.S. Congressman (May 25, 2007); NABV Diagnostics: Polynucleotides Useful for Screening for Hepatitis C Virus, U.S. Patent No. 6,074,816. The health consequences of failing to diagnose and treat hepatitis C are serious, not only for the infected patient but for others whom that person may unknowingly infect.

Patents on gene sequences have also resulted in people's deaths. Long QT syndrome is a disorder of the heart's electrical system that is characterized by irregular heart rhythms and a risk of sudden death. A gene associated with Long QT was patented and assigned to the University of Utah Research Foundation. U.S. Patent No. 6,207,383. The company with the exclusive license to the Long QT sequence went through corporate upheavals. For a two year period, the licensee did not offer diagnostic testing for Long QT syndrome. Other laboratories had the capability and willingness to offer the test, but were forbidden to do so by the patent licensee. During this period at least one patient, age 10, died from her undiagnosed Long QT syndrome; her death could have been prevented had testing been available. *The H. Judiciary Subcomm. on Courts, the Internet and Intellectual Property in Connection with its Hearing on "Stifling or Stimulating – The Role of Gene Patents in Research and Genetic Testing"*, 110th Cong. at 40 (2007) (statement of Dr. Marc Grodman, CEO of Bio-Reference Laboratories, Inc.).

In addition to impeding appropriate health care, the Myriad patents and similar patents related to other diseases deter medical innovation. Breast cancer researchers have been prevented by Myriad from undertaking their research. Kimberly Blanton, *Corporate Takeover Exploiting the US Patent System, A Single Company has Gained Control Over Genetic Research and Testing for Breast Cancer and Scientists, Doctors, and Patients Have to Play by its Rules*, Boston Globe Mag., Feb. 24, 2002, at 10. A survey of members of *Amicus* American Society of Human Genetics found that 49% have had to limit their research due to gene patents. Issac Rabino, *How Human Geneticists in U.S. View Commercialization of the Human Genome Project*, 29 Nature Genetics 15-16 (2001).

As increasingly more medical knowledge depends on an understanding of underlying genetic processes, continued patenting of genes (or enforcement of such gene patents) will likely

result in significant stifling of medical research in multiple disease processes. *See, e.g.*, *Patents, Medicine, and the Interests of Patients*, 109 Obstet. Gynecol. 1249-53 (2007) (Am. Coll. of Obstet. & Gynecol. Comm. Op. No. 364). As the understanding of the genetics of ovarian and related cancers expands, it has become apparent that knowledge of DNA mutation status is critical to understanding the results of therapeutic trials in ovarian cancer, as well as to appropriately caring for the participants in these trials and their family members.[4] Clinical genetic testing for *BRCA*1 and *BRCA*2 mutations through Myriad is prohibitively expensive in all but the most well-funded trials. Research testing is occasionally available, but more frequently is not performed because of the chilling effect of Myriad's patents. Even when research testing is available, it remains suboptimal due to Myriad's prohibition of sharing the test results with the research participants and their families, placing researchers in an ethically untenable position.

Soon technology will allow the sequencing of a person's entire genome of 25,000 genes for $1000. Francis S. Collins, Eric D. Green, Alan E. Guttmacher, and Mark. S. Guyer, *A Vision for the Future of Genomics Research*, 422 Nature 835-847, 846 (Apr. 24, 2003); Nicholas Wade, *Cost of Decoding a Genome Is Lowered*, New York Times, August 10, 2009, at D3. Adding even a seemingly modest royalty cost of $100 per gene would total an unaffordable $2,501,000 per test. Spending money on licenses for patents that are invalid and should never have been issued also diverts needed money from healthcare and research.

Myriad has manifested a clear intent to enforce its patent rights, and clinicians and researchers have therefore avoided infringement to the detriment of medical care and innovation.

---

[4] *See, e.g.*, A. Chetrit, et al., *Effect of BRCA1/2 Mutations on Long-Term Survival of Invasive Ovarian Cancer*, 26 J. Clin. Oncol. 20-25 (2008); N.D. Kauff, *Is it Time to Stratify for BRCA Mutation Status in Therapeutic Trials in Ovarian Cancer?*, 26 J. Clin. Oncol. 9-10 (2008); Y. Ben David, et al., *Effect of BRCA Mutations on the Length of Survival in Epithelial Ovarian Tumors*, 20 J. Clin. Oncol. 463-66 (2002).

Even Myriad recognizes the breadth and adverse consequences of its patent portfolio and aggressive litigation posture. Although the testing of the *BRCA*1 and *BRCA*2 sequences performed by Myriad does not cover all mutations, a Myriad official stated that the use of a new technology to identify mutations in a patient that Myriad missed "would probably infringe on our patents." Erik Stockstad, *Genetic Screen Misses Mutations in Women at High Risk of Breast Cancer*, 311 Science 1847 (2006).

ARGUMENT

I. Gene Sequences and Correlation Claims Are Not Patentable Inventions Within the Meaning of Article I, Section 8, Clause 8 of the U.S. Constitution and 35 U.S.C. § 101

The U.S. Constitution grants Congress the power "to promote the progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Art. I, § 8, cl. 8. However, genetic sequences and mental correlations are not "Discoveries" of "Inventors" as these terms are used in the Constitution. Accordingly, Congress could not authorize and has not authorized patents for them in 35 U.S.C. § 101. Rather, they are unpatentable products of nature and laws of nature.

The term "Discoveries" in the Constitution has a special meaning, and is synonymous with the modern term "inventions" in the restrictive sense of a human, physical creation or process. Writing in 1889, a patent law scholar noted that someone "may invent a machine, and may discover an island or law of nature. For doing the first of these things, the patent laws may reward him, because he is an inventor in doing it; but those laws cannot reward him for doing either of the others, because he is not an inventor in doing either." Albert A. Walker, Text-Book of the Patent Laws of the United States of America 2-3 (L. K. Strouse & Co., 2d ed. 1889).

The distinction between a patentable invention of biotechnology and an unpatentable natural discovery is illustrated by the seminal 1980 Supreme Court case that first authorized patents on inventions using life forms. That case involved a man-made (genetically engineered) bacterium, which the court carefully described as *not* naturally occurring. The Court stated:

> The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none…." Here, by contrast, the patentee has produced a *new* bacterium *with markedly different characteristics from any found in nature* and one having the potential for significant utility.

Chakrabarty, 447 U.S. at 309-10 (emphasis added) (quoting and contrasting *Funk Bros. Seed Co.*, 333 U.S. at 130). In *Funk Brothers Seed Co.*, the Court found the patent invalid as a product of nature, even though the patented "invention" consisted of a combination of naturally occurring bacteria that had been isolated from plants and cultured in laboratories. *See* 333 U.S. at 128-29. Finding a gene is like finding a new plant in the wild, even if isolated from surrounding flora. It is created by nature, even if discovered by humans. Similarly, the physiological fact that a naturally occurring mutation correlates to a disease is a law of nature like gravity.

To allow a patent on a gene "isolated" from the body is akin to allowing the first surgeon who removed a kidney to patent any and all "isolated" kidneys. The holder of the patent on an isolated kidney could prevent other surgeons from removing ("isolating") diseased kidneys. The patent holder could also use its exclusive rights to charge a royalty of $3,000 or more each time a person donated a kidney to a relative.

The question of patentable subject matter is not a question of usefulness, novelty or obviousness. A plant discovered in the wild or a formula like $E = MC^2$ is extremely useful, and

may be novel in the sense of not having previously been known and may be non-obvious in the sense of requiring someone to think creatively to search for it. Yet they are not patentable, because products of nature and laws of nature are not human inventions; they must be "free to all men" so as to encourage innovation and to reward only actual inventors. *Chakrabarty*, 447 U.S. at 309 (quoting *Funk Bros. Seed Co.*, 333 U.S. at 130). *See Benson*, 409 U.S. at 67 (products of nature and laws of nature are the "basic tools of scientific and technological work").

Myriad has not invented the genes that existed naturally in people's bodies; it has only removed them from those bodies and taken them out of the cellular material, using common, long-standing techniques. Nor has Myriad invented any chemical or mechanical methods of determining whether there is a mutation in a breast cancer gene. Rather, what the patentee claims to have discovered are pre-existing genetic sequences and a natural relationship (correlation) between certain mutations and breast cancer. Patenting this discovery also effectively gives Myriad control over all previously and subsequently discovered means of testing for inheritable *BRCA*1 and *BRCA*2 breast cancer mutations. Further, the relationship between gene mutations and breast cancer patented by Myriad is a law of nature that exists independent of human intervention, invention, or manipulation. This relationship existed long before it was discovered, and is neither new nor an invention, but only an existing natural phenomenon. Transcript of Oral Argument at 40, line 10-80, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006) (No. 04-607) (Scalia, J. questioning "What was made by man here?" when the patent holder claimed a similar correlation).

Nor was the incentive provided by the patents necessary to lead to the discovery of the *BRCA*1 and *BRCA*2 sequences. The international Breast Cancer Linkage Consortium was sequencing the genes in a cooperative effort and planned to make the sequences publicly

available and not patent them. Paradise, *supra*, at 143-144; Phyllida Brown & Kurt Kleiner, *Patent Row Splits Breast Cancer Researchers*, New Scientist, Sept. 24, 1994, at 44. Yet after the *BRCA*1 gene was localized by a different team in the Consortium in 1990, in 1991, Mark Skolnick, a member of the Consortium, founded Myriad Genetics in order to commercially exploit the research. *Id.* Had he not done so, the discovery would still have occurred, but the results would have been free to all men and reserved exclusively to none.

A. Myriad's Sequence Claims are Unpatentable Products of Nature

The doctrine that products of nature are not patentable has a long, unbroken history in the U.S. Supreme Court. In the 1874 case of *American Wood-Paper Co.*, the plaintiff's patent claimed a purified form of a product of nature. The Court held that the purification of a preexisting substance does not create a new, patentable product where the primary characteristics and function of the product were not significantly different from what existed in nature. 90 U.S. (23 Wall.) at 594. The Court stated:

> There are many things well known and valuable in medicine or in the arts which may be extracted from … substances. But the extract is the same, no matter from what it has been taken. A process to obtain it from a subject from which it has never been taken may be the creature of invention, but the thing itself when obtained cannot be called a new manufacture.

Id. at 593-94.

Ten years later, the Court in *Cochrane* held that the exclusions from patentable subject matter also applied to synthetic products made to mimic nature. The patentee had made a synthetic version of a dye that already existed in nature (alizarine), but with a brighter hue. The Court held that "calling it artificial alizarine *did not make it a new composition of matter, and patentable as such, by reason of its having been prepared artificially*." 111 U.S. at 311 (emphasis added). Similarly, in 1931 the Court held that treating an apple with a borax

preservative did not turn a product of nature into a patentable, human "article of manufacture," even though such treatment did not naturally occur and improved the usefulness (shelf life) of the apple. *Brogdex,* 283 U.S. at 11. *See id.* at 11-12 (the treated fruit lacked "a new or distinctive form, quality, or property" even though it was "the result of treatment, labor, and manipulation").

In the 1948 case *Funk Bros. Seed Co.*, the Supreme Court held that a mixture of isolated strains of bacteria were an unpatentable discovery because the purported invention did not involve the creation of a new bacteria or a change to any species of bacteria, and merely relied on the natural properties of the bacteria in a new combination. 333 U.S. at 131. The Court noted that "[t]he qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none." *Id*. at 130. The 1952 Patent Act, adopted shortly after *Funk Bros.*, codified in 35 U.S.C. § 101 the prior law on patentable subject matter that products of nature were not patentable.

Even though none of its claims use the term "synthesized," Myriad is apparently trying to avoid application of the products of nature doctrine by asserting that it is entitled to patents on the *BRCA*1 and *BRCA*2 genes because it has "synthesize[d] DNA corresponding to the genes in test tubes." Memorandum of Law in Support of Defendants' Motion to Dismiss at 1, *Ass'n. for Molecular Pathology v. U.S. Patent and Trademark Office*, 09 Civ. 4515 (S.D.N.Y. July 13, 2009). The process of synthesis, routinely done today by biology students, was not invented by Myriad but is merely a way to make a copy of a gene. The "synthesis" of DNA is the process of stringing together naturally existing nucleotides in the same order to function in the same way as naturally occurring DNA. Michael J. Czar, J. Christopher Anderson, Joel S. Bader, and Jean

Peccoud, *Gene Synthesis Demystified*, 27 Trends in Biotechnology 63 (2009). This is not patentable invention. *See Cochrane*, 111 U.S. at 311.

Under the U.S. Constitution and 35 U.S.C. § 101, isolated and purified genetic sequences are unpatentable. The mere fact of isolation and purification is not enough of a change, as the products *do not have any functions that they did not have already.* Similarly, "synthetic" genetic sequences that are not materially different from their naturally occurring counterparts are not patentable inventions. Myriad's patent claims to DNA molecules and gene sequences should be invalidated.

B. Myriad's Correlation Claims are Unpatentable Laws of Nature

The U.S. Supreme Court has consistently held that laws of nature are not patentable. "This Court has undoubtedly recognized limits to § 101 and every discovery is not embraced within the statutory terms. Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas." *Diehr*, 450 U.S. at 185.

A scientific principle "reveals a relationship that has always existed." *Flook*, 437 U.S. at 593 n. 15.[5] A newly-discovered phenomenon of nature, moreover, must be "treated as though it were a familiar part of the prior art" and free for all to use. *Flook*, 437 U.S. at 591-92. *See* 17 The Parliamentary History of England col. 999 (William Cobbett ed., 1806-20) (1774) (Lord Camden) (scientists are "entrusted by Providence with the delegated power of imparting to their fellow creatures that instruction which heaven meant for universal benefit; they must not be

[5] This logic is also underscored by the inherency doctrine in patent law, which was used by the U.S. Court of Appeals for the Federal Circuit to hold that a patent cannot be granted to an applicant who has discovered a natural attribute of a living entity. *In re Cruciferous Sprout Litig.*, 301 F.3d 1343 (Fed. Cir. 2002). The Court there stated that the "enzyme-inducing potential of sprouts necessarily have existed as long as sprouts themselves, which is certainly more than one year before the date of application . . . ." *In re Cruciferous Sprout Litig.*, 301 F.3d at 1350. Similarly, Myriad did not create the relationship between a mutation and breast cancer. That relationship, like the enzyme-inducing potential of certain sprouts or the strength of purified tungsten (*see Gen. Elec. Co. v. DeForest Radio Co.*, 28 F.2d 641, 643 (3d Cir. 1928), *cert. denied* 278 U.S. 656 (1929)), previously existed in nature.

niggards to the world, or hoard up for themselves the common stock"). Myriad's discovery of a relationship that has always existed between certain mutations and breast cancer is not patentable – and thus there is simply no invention left over for Myriad to patent. *See Lab. Corp. of Am. Holdings*, 548 U.S. at 138 (the step of taking a sample and analyzing it added "nothing … of significance" to the claimed correlation-based diagnostic method).

Further, in *Diehr*, the Court gave additional guidance on how to determine whether a process claim involving a law of nature is patentable subject matter. If the claim, "considered as a whole, is performing a function which the patent laws were designed to protect (*e.g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101." *Diehr*, 450 U.S. at 192. The Court in *Diehr* further stated that "transformation and reduction of an article 'to a different state or thing' is *the* clue to the patentability of a process claim that does not include particular machines." *Id.* at 184 (emphasis added and citation omitted). The U.S. Court of Appeals for the Federal Circuit in *In re Bilski* has reiterated that the machine-or-transformation test must be passed in order for there to be a patent-eligible invention. 545 F.3d 943, 954 (Fed. Cir. 2008). But Myriad's claims (1) do not include the use of any particular machines and (2) do not transform an article to a different state or thing.

Five of Myriad's correlation claims, moreover, involve only one step – "comparing" two types of information, the sequence of the patient and a known sequence. Claim 1 of U.S. Pat. No. 5,709,999, Claim 1 of U.S. Pat. No. 5,710,001, Claim 1 of U.S. Pat. No. 5,753,441, Claims 1 and 2 of U.S. Pat. No. 6,033,857.[6] These claims do not recite the use of a particular machine,

[6] The final Myriad correlation claim at issue in this case, claim 20 of U.S. Patent 5,747,282, also involves a comparison as the "act" of the process, but has additional steps of growing cells and determining growth rates. However, the act central to the claim is the comparison between growth rates. The other steps are routine laboratory techniques with insignificant extra-solution activity or data-gathering steps. *Flook*, 437 U.S. at 590; *In re Grams*, 888 F.2d 835, 839-840 (Fed. Cir. 1989); *In re Schrader*, 22 F.3d 290, 294 (Fed. Cir. 1994).

and the claimed comparison can be performed mentally by simply using the sequence disclosed in the patent, defeating the quid-pro-quo of the patent grant (the ability of the public and other inventors to use information about the patented invention) even assuming such claims were eligible. *See, e.g., Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 161 (1989). These claims do not even recite the steps (however performed) of obtaining the information for comparison, and thus cover *solely* the mental act of recognizing a similarity or a difference.

In addition, none of Myriad's correlation claims involve a "transformation and reduction of an article 'to a different state or thing.'" *Diehr*, 450 U.S. at 184 (quoting *Benson*, 409 U.S. at 70). For example, Myriad's Claim 2 of U.S. Pat. No. 6,033,857 claims "comparing" the *BRCA*2 gene sequence of a subject to the normal *BRCA*2 gene sequence, in which a difference between the two sequences indicates a higher risk of cancer in the subject. The gene sequence of the subject is not transformed, as the sequence is the same as it existed both before and after the "comparing" step. Likewise, the normal gene sequence is not transformed. Further, the subject is not transformed from having a low risk of cancer to having a high risk of cancer as a result of the performance of this claim. The level of risk the subject has for cancer is predetermined genetically, well prior to the comparison of the gene sequences.

There are additional good policy reasons for not granting a patent applicant a patent on a law of nature. The U.S. Supreme Court in *Morse*, 56 U.S. (15 How.) at 113, was concerned that granting Samuel Morse broad rights to a law of nature (the use of electromagnetic waves to write at a distance) beyond its particular application in Morse's concrete novel invention (the telegraph) would overcompensate the inventor by giving him rights to subsequent inventions by others that used the law of nature governing electromagnetic waves. *Id.* at 120-121. The Court's concern in *Morse* applies to this case, as Myriad has patented any and all uses of the law of

nature that certain mutations are correlated with breast cancer. This overcompensates Myriad by granting rights to dominate all subsequent inventions that would use that correlation, a biological fact that Myriad did not itself invent and which thus should be free for all to use.

II. Patents on Products of Nature and Laws of Nature Violate Medical and Scientific Ethical Tenets and Are Not Necessary to Promote Innovation

As *Amicus* AMA's Ethics Opinion 9.095 states, "The use of patents, trade secrets, confidentiality agreements, or other means to limit the availability of medical procedures places significant limitation on the dissemination of medical knowledge, and is therefore unethical." American Medical Association, Opinion 9.095 – The Use of Patents and Other Means to Limit Availability of Medical Procedures, (adopted June 1995), *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion9095.shtml. Similarly, *Amicus* ACOG's ethics opinion states, "Patents on medical or surgical procedures are ethically unacceptable." The American College of Obstetricians and Gynecologists, *ACOG Committee Opinion Number 364: Patents, Medicine, and the Interests of Patients*, 109 Obstetrics & Gynecology 1249, 1252 (May 2007). Additionally, "[b]ecause a patent claiming a gene as a composition of matter enables a patent holder to control future applications of the patented gene or sequence, such patents should not be granted." *Id*. Like doctors, scientists also have long-standing, historically recognized duties to freely disseminate their discoveries of products of nature and laws of nature and not to subject those discoveries to private property rights. *See, e.g.*, Robert K. Merton, On the Shoulders of Giants: A Shandean Postscript (1985). The scientists' ethical duty remains enshrined in the patent law to this day, because such natural discoveries must be treated as prior art and thus are not patentable.

Moreover, there is no need to provide patent incentives to health care professionals, clinicians, and scientists to discover and study gene sequences and the correlations at issue in this case. Indeed, a recent report by the Secretary of Health and Human Service's Advisory Committee on Genetics found that patents "do not serve as powerful incentives for either genetics research in the diagnostic arena or the development of genetic tests." Secretary's Advisory Committee on Genetics, Health, and Society, 110 *Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (March 9, 2009), at http://oba.od.nih.gov/oba/SACGHS/SACGHS Patents Consultation Draft 3 9 2009.pdf. Various members of *Amici* medical organizations are willing to identify gene sequences and correlations without patenting them, and there was no shortage of researchers who were trying to sequence the breast cancer genes without the desire to patent those sequences.

Public money – rather than private money – has been the engine for discovery of the genes at issue, as well as most human genes. A publicly-funded Consortium did most of the work to identify the *BRCA*1 and *BRCA*2 genes. Moreover, Myriad's patents' assignor utilized over $5 million of taxpayer money in the form of a direct grant from the National Institute of Health to sequence the *BRCA*1 gene. Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 Health Law J. 123, 131 (2002). A federal researcher for the National Institute of Environmental Health Sciences (NIEHS) in North Carolina also aided Myriad in its work. Rachel Nowak, *NIH in Danger of Losing Out on BRCA1 Patent*, 266 Science 209 (1994). The public thus has paid for the work underlying Myriad's patents, yet will pay hundreds of millions of dollars more in royalties each year because of the patents at issue here. Moreover, the research occurred within the Human Genome Project – an international multi-government *and* private-sector funded effort that placed

other sequences in the public domain, where they belong. *See, e.g.*, U.S. Dept. of Energy, Major Events in the U.S. Human Genome Project and Related Projects, at http://www.ornl.gov/sci/techresources/Human_Genome/project/timeline.shtml.

Patents on genes and on the correlation between mutations and disease in general, and Myriad's patents in particular, thwart rather than promote innovation. Patent law is supposed to be a bargain in which the patent holder gets a time-limited exclusive right to make, use, or sell a claimed invention of proportional scope to the inventive contribution to the field, in exchange for publishing in the patent the description of the invention that all can use to further develop the frontiers of science and technology. *See generally* Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. Econ. Persp. 29 (1991). However, the system breaks down when a patent is granted for preexisting natural phenomenon or the information disclosed by the patent itself – such as the sequence of a gene. Then the patent holder has a right to prevent others from using the disclosed information entirely.

The Myriad patents deter innovation because any new testing or treatment technology must rely on the natural materials and biological facts that were not created by Myriad but were patented by its assignor – the *BRCA*1 and *BRCA*2 genes in all of their forms, the information in the sequences that they contain, and the fact that certain *BRCA*1 and *BRCA*2 gene sequences are correlated with breast cancer.

CONCLUSION

Upholding the sequence claims and correlation claims at issue here would conflict with long-standing patent jurisprudence and would continue to thwart, not promote, "the Progress of Science and the useful Arts." This Court should follow the 150-year-long precedents of the U.S. Supreme Court that one cannot patent "laws of nature, natural phenomena, and abstract ideas."

Diehr, 450 U.S. at 185. Such a holding is in keeping with the professional and ethical tenets of medicine and reflects the long-standing ethics of science. The patent claims at issue in this case deter the *Amici* from offering the best quality and most accessible health care to their patients. It is crucial to patient care and to medical research that natural biological materials and basic scientific information be allowed to be shared, analyzed, and used in an unfettered way. The Court should therefore deny Defendants' motions to dismiss and grant Plaintiffs' motions for summary judgment.

Respectfully submitted,

Dated: August 27, 2009

s/Amy L. Katz

Amy L. Katz (AK2854)
Law Office of Amy L. Katz
145 Central Park West
New York, NY 10023
(212) 580-5338
AmyLKatzLaw@gmail.com
Counsel of Record for Amici Curiae