UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ASSOCIATION FOR MOLECULAR PATHOLOGY; AMERICAN COLLEGE OF MEDICAL GENETICS; AMERICAN SOCIETY FOR CLINICAL PATHOLOGY; COLLEGE OF AMERICAN PATHOLOGISTS; HAIG KAZAZIAN, MD; ARUPA GANGULY, PhD; WENDY CHUNG, MD, PhD; HARRY OSTRER, MD; DAVID LEDBETTER, PhD; STEPHEN WARREN, PhD; ELLEN MATLOFF, M.S.; ELSA REICH, M.S.; BREAST CANCER ACTION; BOSTON WOMEN'S HEALTH BOOK COLLECTIVE; LISBETH CERIANI; RUNI LIMARY; GENAE GIRARD; PATRICE FORTUNE; VICKY THOMASON; KATHLEEN PARKER, Plaintiffs,	:	Civil Action No. 09 Civ. 4515 (RWS)
v.	:	ECF Case
UNITED STATES PATENT AND TRADEMARK OFFICE; MYRIAD GENETICS; LORRIS BETZ, ROGER BOYER, JACK BRITTAIN, ARNOLD B. COMBE, RAYMOND GESTELAND, JAMES U. JENSEN, JOHN KENDAL MORRIS; THOMAS PARKS, DAVID W. PERSHING, and MICHAEL K. YOUNG, in their official capacity as Directors of the University of Utah Research Foundation, Defendants.	:	

BRIEF FOR *AMICI CURIAE*

National Women's Health Network
Asian Communities for Reproductive Justice
Center for Genetics and Society
Generations Ahead
Pro-Choice Alliance for Responsible Research

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

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

INTEREST OF *AMICI CURIAE*

Amici Curiae are women's health and social justice advocates with expertise in public policy, women's health, and health disparities as they impact the health and well-being of women, and in particular women of color and low income women. Collectively, *Amici* conduct research, advocate for just public policy, and educate community-based organizations about the implications of new technologies for women's health and rights. *Amici* have the expertise to illustrate to the Court how patents on genes and gene mutations prevent women at risk for breast and ovarian cancer from obtaining the information they need about their own bodies to take steps to improve their health outcomes, and possibly save their own lives and the lives of their children.

Amicus Curiae **The National Women's Health Network** is a nonprofit organization that improves the health of all women by developing and promoting a critical analysis of health issues in order to affect policy and support consumer decision-making. The Network aspires to a health care system that is guided by social justice and reflects the needs of diverse women. Part of the Network's mission is to support individual decision-making by providing evidence-based information free from corporate influence. The Network has particular expertise in research and evaluation of emerging drugs, devices and treatments and their impact on women's health.

Amicus Curiae **Asian Communities for Reproductive Justice (ACRJ)** is a nonprofit community-based organization that promotes and protects reproductive justice. ACRJ believes that reproductive justice will be achieved when all people have the economic, social and political power and resources to make health decisions about their gender, bodies and sexuality for themselves, their families, and their communities. ACRJ works in communities of color to ensure that women and adolescents have the information they need to improve their own health

status.

Amicus Curiae **The Center for Genetics and Society (CGS)** is a nonprofit information and public affairs organization working to encourage responsible uses and effective societal governance of genetic, reproductive and biomedical technologies. CGS works with a growing network of civil society leaders, health professionals, scientists, and others who share a commitment to advancing the public interest in the development of policy regarding human biotechnologies.

Amicus Curiae **Generations Ahead (GA)** is a nonprofit community-based organization that brings different communities together to expand the public debate and promote policies on genetic technologies that protect human rights and affirm our shared humanity. By looking at the benefits and risks of these technologies for diverse communities including African-Americans, Latinos, Asian-Pacific Islanders, Native Americans, and people with disabilities, GA promotes policies that ensure full respect and human rights for all people.

Amicus Curiae **The Pro-Choice Alliance for Responsible Research (PCARR)** is a coalition of reproductive rights and justice advocates, bioethicists, academics, and community leaders working together to promote accountability, safety and social justice in bio-medical research from a women's rights perspective. PCARR believes that justice, safety, and dignity for women must be paramount in public policy and private practice in emerging biotechnologies. Since 2004, PCARR has been providing research and legal analysis to policymakers and consumers, and engaging with administrative agencies to ensure that women's health outcomes are protected in the implementation of new biotechnologies.

INTRODUCTION

Rapid advancements in the understanding of the human genome and the role that genes, gene sequences, and gene mutations play in health and well-being have the potential to improve the health status of people around the globe. Fulfilling that potential depends, however, on ensuring that knowledge and information are maintained in the public domain. As former British Prime Minister Tony Blair and former President Bill Clinton stated, "To realize the full promise of this research, raw fundamental data on the human genome including the human DNA sequence and its variations, should be made freely available to scientists everywhere." World Health Organization, *Genetics, Genomics and the Patenting of DNA* 5 (2000).

That "full promise" is especially significant for women's health. Breast cancer is the second highest cause of death for women in the United States. The American Cancer Society estimated over 240,000 new cases of breast cancer in 2008. American Cancer Society, *Breast Cancer Facts and Figures 2007-08* (2007). The discovery of the role that certain variants of the BRCA1 and BRCA2 genes play in increased risk of breast and ovarian cancer in women offers the opportunity for women with those genetic variants to take steps to improve the chances of survival for themselves and their children.

The Constitutional purpose of the patent system is to "promote the Progress of Science and the useful Arts" U.S. Const., Art. I, § 8, cl. 8. *Amici* believe that denying access to the resources of the human genome is contrary to that fundamental goal. In addition, genes and gene variants like those of BRCA1 and BRCA2, and correlations between these sequences and predisposition to diseases, are both unpatentable products of nature. While they have only recently been identified by scientists, they have evolved along with the human species. The Myriad BRCA1 and BRCA2 patents remove this important information from the public domain contrary to

established law with real-life health consequences for women.

ARGUMENT

I. Patents on the BRCA Genes and Genetic Sequences and their Correlations to Genetic Conditions or Diseases are Exceptions to Suitable Subject Matter According to the Patent Statute

The Constitution grants Congress broad power to legislate 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." U.S. Const. Art. I § 8, cl. 8. Under the statute enabling the grant of such an exclusive right,

> "Whoever 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."

35 U.S.C. § 101. Section 101 is a general statement of the type of subject matter that is eligible for patent protection. However subject matter per §101 is limited: "The laws of nature, physical phenomenon, and abstract ideas have been held not patentable. See *Parker v. Flook,* 437 U. S. 584 (1978)*; Gottschalk v. Benson,* 409 U.S. 63, 67 (1972)*; Funk Brothers Seed Co. v. Kalo Inoculant Co.,* 333 U.S. 127, 130 (1948)*; O'Reilly v. Morse,* 56 U.S. 62 (1853); *LeRoy v. Tatham,* 55 U.S. 156, 175 (1852*).* 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=mc2; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of …nature, free to all men and reserved exclusively to none.' *Funk, supra,* at 130.'" *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

Human genetic material and information, including correlations between genetic sequences and diseases are not suitable subject matter for patenting under 35 U.S.C. § 101, but instead are representative of the clear limitations to subject matter patentability the U.S. Supreme

Court has described. Like new minerals found in the earth or plants in the wild, gene sequences are phenomena of nature, products of nature. Like relativity or gravity, the correlations between mutations in the gene sequences and cancer are also synonymous with laws of nature. The Court should prohibit the patenting of these manifestations of nature, human genetic sequences, as they are not subject matter suitable for patenting according to 35 U.S.C. § 101.

A. Gene Sequences are a Product of Nature Unsuitable for Patent Protection

Subject matter that is "a non-naturally occurring manufacture or composition of matter - a product of human ingenuity 'having a distinctive name, character [and] use' *Hartranft v. Wiegmann*, 121 U. S. 609, 615 (1887)," is suitable subject matter for patent protection, whereas claims to 'hitherto unknown natural phenomenon' are not so qualified. *Chakrabarty,* 447 U.S. at 309-310. The BRCA 1 and BRCA2 genes and their mutations are natural phenomena, products of nature, and thus should not be considered patentable according to the statute.

Proponents of patents issued on gene sequences dispute that they are products of nature, and instead argue that they are different from the DNA sequences occurring naturally in the human body because genes and their sequences have been removed from their natural environment (isolated), or have been "purified," or made synthetically, thus rendering them suitable subject matter for a grant of a patent. However, "isolated and purified" human genes and their sequences are not substantially different from those found in their natural environment. They possess the same inherent characteristics and qualities of naturally occurring human genes, and they perform the same essential function of human genes found in nature.

In *Funk Brothers,* the Court considered the subject matter of patents issued to an inventor who remedied a long-standing agricultural problem. Legumes can produce natural fertilizers when their roots contain several species of a particular bacteria Rhizobium. The roots become

infected and form nodules which attach nitrogen from the air. Each species of Rhizobium infected only a particular legume group, but when applied in combination, the different species exhibited a mutually inhibiting effect that reduced the nitrogen fixing efficiency of the bacteria. *Id.* at 128. By selection and testing, the applicant found that particular strains of each of the bacteria species did not have the same inhibiting effect, and sought patents on these mixed culture inoculants of the Rhizobium. *Id.*

The Supreme Court held that under 35 U.S.C. § 31 of the precursor to the current patent statute, there was no invention or discovery. *Funk Brothers,* 333 U.S. at 132. The mutual non-inhibiting qualities of the bacteria had not been invented; rather, "The qualities of these bacteria, like the heat of the sun, electricity, and the qualities of metals, are part of the storehouse of knowledge of all men." *Id.* at 130. In examining whether the product of nature had been applied in a way as to make it suitable subject matter for a patent, the Court noted that the bacteria "perform in their natural way" and that "they serve the ends nature originally provided and act quite independently of any effort of the patentee." *Id.* at 131. Without any new biological function, the cultures were not patentable.

Products of nature are not suitable subject matter for patent protection as required by 35 U.S.C. § 101. When claimed inventions are indistinguishable from a naturally occurring phenomenon; when they are not substantially different than things found in nature and possess the same inherent characteristics and qualities of things found in nature; or when they perform the same essential function as they do in nature, they have been found to be "phenomenon of nature," *Gottschalk*, 409 U.S. at 67, "free to all men and reserved exclusively to none." *Funk Brothers,* 333 U.S. at 130. An isolated, purified, or synthesized genetic sequence is indistinguishable from its naturally occurring counterpart. Like the bacterium in *Funk Brothers,*

the claimed genetic sequences are not substantially different from what is found in nature and possesses the same inherent characteristics and qualities. Most importantly the genes perform the identical function - code for the production of proteins - and should not be subject to the grant of a patent.

B. A Correlation Between Particular Genes and Gene Sequences and a Predisposition to Conditions or Illnesses is a Manifestation of a Law of Nature. It is Information, a Scientific Truth or Principle, and Ultimately, a Research Tool, and Thus an Exception to Statutory Subject Matter

The Court has recognized limits to subject matter patentability under 35 U.S.C. § 101; "every discovery is not embraced within the statutory terms. Excluded from such patent protection are laws of nature, natural phenomenon and abstract ideas." *Diamond v. Diehr*, 450 U.S. 175 (1981). The Court has given examples, including Newton's law of gravitation describing the gravitational force between two objects as a function of their distance and mass, *Flook,* at 593 n.15 (1978); Einstein's law for the inter-conversion of energy and mass, *Chakrabarty,* at 309; the formula for determining the circumference of a circle*, Flook,* at 595; the Arrhenius equation, *Diehr,* at 188; and the multiplication tables, *Flook,* at 598. According to the Court, these laws reveal "a relationship that has always existed." *Flook,* at 593.

Contemporary cases dealing with the uses of algorithms in computer technology have described the laws of nature doctrine. The Court in *Gottschalk* questioned whether a method for converting numerical information was a process according to the statute. The claimed invention was described by the Court as an "algorithm," "a procedure for solving a given mathematical problem," *Id.* at 66, and was a variation on the ordinary arithmetic that a human could do. *Id.* at 67. The Court recognized that, "A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right." *Id. citing Le Roy v. Tatham,* at 175.

In *Flook*, the Court determined that a method for updating alarm limits during the process of catalytic conversion was not suitable subject matter for the grant of a patent. The Court noted that "the rule that the discovery of a law of nature cannot be patented rests, not on the notion that a natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of discoveries that the statute was enacted to protect." *Id.* at 592. In a footnote, the Court expounded upon the rationale:

> "The underlying notion is that a scientific principle, such as that expressed in respondent's algorithm, reveals a relationship that has always existed… Such 'mere' recognition of a theretofore existing phenomenon or relationship carries with it no rights to exclude others from enjoyment… Patentable subject matter must be new (novel); not merely heretofore unknown. There is a very compelling reason for this rule. The reason is founded upon the proposition that in granting patent rights, the public must not be deprived of any rights that it theretofore freely enjoyed."

Id. at 593, n.15.

Correlations between human genetic sequences and susceptibility to illness, such as the claimed Myriad correlation patents, and like the claimed algorithms underlying the processes of *Benson*, are similarly pre-existent scientific principles, laws of nature and non-statutory subject matter under 35 U.S.C. § 101. Like the mathematical formula in *Benson*, the issuance of a specific correlation patent "wholly pre-empts" the information. No one may use a specific correlation without infringing a correlation patent. Similar to the algorithm in *Flook*, claims to these correlations contain "no other inventive concepts." *Flook,* at 594. These correlations have pre-existed in the natural environment, and are not suitable subject matter for a grant of a patent according to the statute.

Thus, the Myriad Genetics BRCA1 and BRCA2 patents should be invalidated because genes, gene mutations, and correlations, such as those granted to Myriad, are products of nature and laws of nature, and are not patentable.

II. Gene Patents Cause Harm to Patients, in Particular to Women, by Inappropriately Stifling Innovation and Competition and Interfering with Access to Healthcare

Patents on non-statutory products and laws of nature have removed from the public domain vital resources important for medical research and patient care. Gene patents such as the Myriad patents on BRCA1 and BRCA2 restrict patients' access to information in several ways that interfere with health care and increase health disparities.

A. Gene Patents Impede Access to Information Necessary for Informed Medical Decision-Making and Interfere with Patient Access to Medical Testing, Diagnosis and Treatment

While particular tests on a gene or gene variant may be patentable subject matter, genes themselves are not. Gene patents like those that Myriad holds on the "breast cancer genes" known as BRCA1 and BRCA2 preclude the development of alternative or related tests. Researchers who wish to develop a different (possibly superior or less expensive) method of testing for gene variations would violate the Myriad patents. Under the terms of the existing Myriad patents, this violation would occur even if someone were to develop tests for potential variations of the BRCA1 and BRCA2 genes that have not yet been identified. As Darnovsky and Reynolds point out, "Patents are meant to provide an incentive to build a better mousetrap, but human gene patents, in effect, claim the entire concept of catching mice." Marcy Darnovsky and Jesse Reynolds, *The Battle to Patent Your Genes: The Meaning of the Myriad Case*, 5 The American Interest 56 (Oct./Sept. 2009).

Patents on human genes thus stifle innovation in health care and raise the costs of existing health care products and services. Cost is a serious barrier to access to health care. Costs and lack of insurance are the most frequently reported reasons for delaying care, but the cost barrier is not just a function of whether or not a person is covered by health insurance. In the U.S., 61% of adults with health insurance report difficulty paying their medical bills. For

example, after an acute myocardial infarction (heart attack), patients with financial barriers faced significantly higher health risks. They experienced higher rates of angina before hospitalization, higher rates of re-hospitalization, and decreased quality of life. A.R. Rahimi, et al., *Financial Barriers to Health Care and Outcomes After Acute Myocardial Infarction*, 297 JAMA 1063 (Mar. 14, 2007).

Breast cancer is largely a disease suffered by women, and ovarian cancer affects only women. Data show that cost is a greater barrier for women generally, and for women of color in particular. Women are more likely to delay or go without care due to cost (24%) than men (20%). Among women of color, one-third of Latinas (32%) and African American women (32%) report delaying or forgoing needed care in the past year, as did 25% of white women. Alina Salganicoff et.al., *Women and Health Care: A National Profile, Key Findings from the Kaiser Women's Health Survey*, 28 Kaiser Family Foundation (July 2005).

A recent study published in the New England Journal of Medicine found that among women enrolled in a Medicare managed care plan, even a small co-payment (more than $10) resulted in a significant decrease in mammography screenings. Amal N. Trivedi et al., *Effect of Cost Sharing on Screening Mammography in Medicare Health Plans*, 358 N. Engl. J. Med. 375 (Jan. 24, 2008).

Amici are not suggesting that *tests* for gene mutations using novel machines or chemicals should not be patentable. However, the Myriad BRCA1 and BRCA2 patents on the genes and gene mutations themselves create a monopoly that allows Myriad to prevent the development of alternative gene tests, and thus to set prices without market pressure to compete. In Canada and Europe, alternative tests for variants of the BRCA1 and BRCA2 genes have in fact been developed (by researchers in jurisdictions that are not fully enforcing Myriad's patents) that are

significantly less expensive than Myriad's. Myriad's higher prices create an insurmountable barrier to needed testing for many women at risk of breast and ovarian cancer.

Lack of access to the genetic information contained in their bodies deprives individuals of the opportunity to take steps to improve their health and reduce their health risks. While a genetic predisposition cannot in and of itself be changed by behaviors, knowledge of such genetic risk can allow people to take preventive steps. For example, a woman who knows she has mutations of the BRCA1 or BRCA2 genes that are associated with cancer could change her diet, stop smoking, reduce her exposure to environmental hazards, and get timely mammograms and other tests to increase the chance of early detection of any cancer that begins to develop or have prophylactic surgery. The Myriad patents rob her of that opportunity to improve her chances of survival.

Gene patents also limit the type of information and the exactness of the information that is available to patients. Rather than stimulating innovation and increasing knowledge in the public domain, the Myriad BRCA patents have slowed the pace of medical progress by the limitations of its own testing processes. Without competition, Myriad has been slow to make data available to researchers, to develop new testing methodologies, and to investigate ambiguous results, referred to as "variants of unknown significance." Women of color are disproportionately given these ambiguous results and are left without definitive information that they need in order to take steps to improve their health outcomes. *Statement Submitted by Dr. Marc C. Grodman to the House Judiciary Subcommittee on Courts, the Internet, and Intellectual Property* (Oct. 25, 2007). In addition, Myriad's patents prevent anyone else from studying these ambiguous results, meaning definitive information for these patients is not available.

The Myriad patents also interfere with the physician-patient relationship by preventing physicians from fulfilling their ethical and medical obligations to their patients. The American College of Obstetricians and Gynecologists practice guidelines require that physicians refer their patients who are at high risk for breast and ovarian cancer for genetic counseling and testing. American College of Obstetricians and Gynecologists, *Hereditary Breast and Ovarian Cancer Syndrome Practice Bulletin #103* (April 2009). This requirement creates an ethical dilemma for the physician who knows that her patient cannot afford the counseling or the test.

In addition, under the Myriad patents, only Myriad Genetics or its limited number of licensed laboratories can perform the analysis of the tissue samples collected during a BRCA1 or BRCA2 genetic test. Myriad requires that samples from tests performed all over the world be sent to Myriad laboratories for analysis. In fact, the Myriad database contains more than 95% of the entire BRCA1/2 testing data in the entire United States. Michael J. Hall et al., *BRCA1 and BRCA2 Mutations in Women of Different Ethnicities Undergoing Testing for Hereditary Breast-Ovarian Cancer*, 115 Cancer 2222, at 2223 (May 15, 2009). As a result, not only does the Myriad patent given it a monopoly on the genes and their mutations, but further, that monopoly allows it to control who can perform research using that data and what types of research can be performed.

One of the important missions of *Amici Curiae* is to provide women with comprehensive information about their health options by analyzing and assessing biomedical research pertaining to diagnostic tests, drugs, and treatments. A centerpiece of that information is the recommendation that women obtain a second opinion when faced with a diagnosis of a serious medical condition. Myriad's patents, however, prevent patients with ambiguous or other results from double-checking those results through the standard medical practice of obtaining a second

opinion. The American Medical Association Code of Medical Ethics states, "Physicians should recommend that patients obtain a second opinion whenever they believe it would be helpful in the care of the patient." American Medical Association, *Code of Medical Ethics Opinion 8.041* (Issued June 1992; updated June 1996). The Myriad patents prevent women who have been tested for BRCA1 and BRCA2, in particular those women whose results are ambiguous, from obtaining a second opinion on the test results.

B. Gene Patents Increase Health Disparities for Women and for Racial and Ethnic Minorities

Originally, it was thought that only or primarily women of Jewish European Ashkenazi descent were at risk for the BRCA1 and BRCA2 gene mutations that indicated an elevated risk for breast or ovarian cancer. More recent research suggests that there are not racial differences in the risk for carrying the BRCA genes mutations, and that high-risk (having a family or personal history of breast or ovarian cancer) African-American, Latina, and Asian women have a similar risk for carrying the genetic mutation as other women with a similar history. BRCA mutations were found in 12.5% of women tested across ethnic groups. Michael J. Hall, *BRCA1 and BRCA2,* at 2222.

Racial and ethnic minorities continue to experience poorer health outcomes than Caucasians. These health disparities occur in the larger context of social and economic disparities: people of color are disproportionately poor, less likely to have access to a regular source of care, more likely to experience bias and prejudice in the health care system, and less likely to get full and complete health education. These disparities continue to exist even when controlled for factors such as income and insurance status, and may be attributable to stress from long-standing racial bias and discrimination. *See* The Institute of Medicine, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care* (2003).

Racial and ethnic minorities comprise nearly one-third of American women. Health disparities between white women and women of color, as well as disparities between racial and ethnic groups, are well documented. For example, white women are most likely to be diagnosed with breast cancer, but African American women are most likely to die from the disease. American Cancer Society, *Breast Cancer Facts and Figures 2007-08* (2007).

By limiting access to genetic tests, preventing women from obtaining second opinions on their test results, and thereby interfering with the ability of women to obtain full and complete information about their health conditions, Myriad contributes to increased health disparities among women of color.

C. Gene Patents Stifle Competition and Prevent Innovation that Can Reduce Costs, Improve Health Care, and Reduce Health Disparities

Progress in the development of new drugs, tests and treatments is achieved by a balance of granting exclusive control for a limited amount of time to reward the inventor and by ensuring the potential for competition. Development of new drugs and therapies depends on many companies having access to genes so that they can compete in developing drugs and treatments based on the information contained in those genes. According to Craig Venter, founder of Celera Genomics, who raced with the Human Genome Project to decipher the human genome, "Blocking another biotech or a pharmaceutical company from trying to come up with a cure for a disease really does block research, and the public loses. Why should one company say that's their unique source of biology?" Matthew Herper, *Genome Scientists: Gene Patents are Bad*, Forbes, http://www.forbes.com/2002/06/26/0626targets.html (June 26, 2002).

Gene patents inhibit the sharing of information between researchers. Twenty-eight percent of geneticists were unable to duplicate published results because scientists refused to share information. When asked why they would not share information, 20% of the scientists

responded that they were protecting their commercial interests. Lori B. Andrews, The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs, 2 Hous. J. Health L. & Pol'y 65, 80-81 (2002)

In another study, 25% of laboratories reported that they stopped providing a test or service because of notification from a patent holder, and 53% responded that they decided not to develop or perform a test because of a patent. Mildred Cho et.al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. Molecular Diagnostics 5 (Feb. 2003). These concerns are felt intensely in the international medical community. Dr Anders Milton, chairman of the World Medical Association (WMA), said: "There is a growing alarm among physicians about the patenting of the human genome because of the potential limitation on the availability of new treatments for patients and on the restrictions this might place on the transfer of knowledge. The WMA is calling on its national medical association members to approach their governments as a matter of urgency to prevent this from happening." World Medical Association, *World Medical Association Council Meeting Press Release* (May 8, 2000).

Prior to the granting of the Myriad patent on the BRCA1 and BRCA2 breast and ovarian cancer gene mutations, Canadian researchers at Genetic Diagnostic Laboratories in British Columbia, Canada provided a similar genetic test licensed and covered by the British Columbia Ministry of Health and Long-Term Care. The tests were offered through the British Columbia Cancer Agency (BCCA) for about 1,200 Canadian Dollars (CND) per test. Testing was halted in 2001 after Myriad obtained its patent on the genes and served a cease and desist order on the provincial Ministry of Health that it intended to assert its patent against BCCA and would be charging 3,850 CND for the test, more than three times the cost of the Canadian test. Heather Kent, *Patenting Move Ends BC's Gene-Testing Program*, 165 Can. Med. Assoc. J. 812 (Sept. 18,

2001). BCCA later decided to continue using its own test but moved the testing services from British Columbia to Ontario, Canada in order to continue to serve women in need. Heather Kent, *BC Sidesteps Patent Claim, Transfers BRCA Gene Testing to Ontario*, 168 Can. Med. Assoc. J. 211 (Jan. 21, 2003).

Mike Harris, then-Premier of Ontario, stated, "Benefits of a world-wide effort such as the human genome project should not be the property of a handful of people or companies. Our genetic heritage belongs to everyone. We must share the benefits fairly and do what we can to make genetic tests and therapies affordable and accessible." Timothy Caulfield, *Policy Conflicts: Gene Patents and Health Care in Canada*, 8 Community Genet. 223 (2005).

The Myriad patents also stifle research into other mutations of the BRCA1 and BRCA2 genes. One study of African-American women found four variants of undetermined pathology of the BRCA genes. Yet, only Myriad-licensed researchers can investigate those gene mutations. Until and unless Myriad decides to pursue that avenue of research, African American women will continue to be denied critical information about their own genes. Tuya Pal, et.al., *BRCA1 and BRCA2 Mutations in a Study of African American Breast Cancer Patients*, 13 Cancer Epidemiol. Biomarkers Prev. 1794 (Nov. 2004).

III. Human Genes are Part of the Common Heritage of Humanity and Should Not be Removed from the Public Domain According to International Treaties and the Public Trust Doctrine

Human genes and their informational content should not be patented or subject to exclusive control because they are part of the common heritage of humanity. This principle, the inability of an individual, a nation, or in the present case, a corporation to appropriate what should belong to everyone equally, is of particular importance to the *Amici*. The resources of the Human Genome, so necessary for the progress of modern science and modern medicine, should

be guaranteed to all, and women and minorities should be able to share in the benefits of research based upon this body of knowledge known as the Human Genome. The "common heritage of humanity" or "common heritage of mankind" principle is an international legal concept which conveys equal property interests to all people. Melissa L. Sturges, *Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind*, 13 Am. U. Int'l L. Rev. 219, 245 (1997). U.S. law also provides protections for some things that are considered public goods or part of a "commons," or part of humanity's common heritage. These protections include restrictions on the ability to appropriate or exercise intellectual property rights over our common heritage.

A. The Human Genome is Part of the Common Heritage of Humanity

The "common heritage of humanity" principle has been applied by international bodies and agreements to the deep seabeds, Antarctica, the moon, and other celestial bodies. These treaties consider those territories as parts of the natural world that should be protected from exploitation by nations or private entities, and that should be held in trust for the public as a whole and for future generations. Other examples of humanity's common heritage include the atmosphere, fresh water, and outer space.

The human genome is another example of our common heritage as human beings. Genes are pieces of DNA, the basic building blocks of all biological organisms. Human genes help to determine who we are and how we function. Although individuals' genes differ in a few respects, the human genome that each of us inherits – the result of millions of years of natural evolution – links us closely to each other. The information encoded in our genes represents our shared human history, the blueprint for a human being that connects those of us in the present with our collective ancestors and our future descendants. In this sense, the case that the human

genome is part of the common heritage of humanity is even stronger than traditional applications of the common heritage concept.

While things that constitute part of our common heritage can (and should) be managed and regulated for the public benefit, attempts to "enclose the commons" or to exclude others from their use and benefits are not permitted. The common heritage concept "would convey property rights of the genome to all people by recognizing that the genome is integral to every human being. [It] gives the responsibility for regulating the uses of the genome, as well as the benefits of the project, to all of humanity." Sturges, *Who Should Hold Property Rights to the Human Genome?*, at 223-4.

The consequences of such attempts to assert exclusionary rights to our common heritage often involve harms to others. Attorney and philosopher David Koepsell asks us to "[i]magine a tax on air, or a levy on sunlight, or some corporation claiming ownership of the open seas and demanding royalties for their use. Imagine a world where ideas could be owned, and thinking ideas held by others was prohibited or subject to fees, taxes or royalties." David Koepsell, *Who Owns You*?, Wiley-Blackwell at 133 (2009). He points out that the "human genome is a constantly evolving object that involves every member of the species" and that "[g]ranting exclusionary rights to discoverers of genes that are part of that genome interferes with our common rights as beneficiaries and possessors of parts of the human genome." http://whoownsyou-drkoepsell.blogspot.com (Aug. 21, 2009 posting; last accessed Aug. 27, 2009).

A number of international organizations have recognized the human genome as the common heritage of humanity. The United Nations Educational, Scientific and Cultural Organization declared that the human genome "underlies the fundamental unity of all members

of the human family" and is thus "[i]n a symbolic sense, the heritage of humanity." UNESCO Declaration on the Human Genome and Human Rights, Article 1. The World Medical Association has stated that "human genes must be seen as mankind's common heritage" and that information derived from the human genome "should be general property… Therefore no patents should be given for the human genome or parts of it." World Medical Association, *World Medical Association Council Meeting Press Release*, May 8, 2000; World Medical Association, *Declaration on the Human Genome Project*, Sept. 1992. The Human Genome Organization, the international scientific coordinating body for the Human Genome Project, recognizes that "the human genome is part of the common heritage of humanity." Human Genome Organization, Ethical, Legal, and Social Issues Committee, *Statement on the Principled Conduct of Genetics Research* (1996).

The United States has also tacitly recognized the human genome as the shared heritage of humanity, spending billions of public dollars on an international project to explore and understand it. The Human Genome Project involved the collaborative efforts of 18 countries to map the human genome, and the U.S. Human Genome Project, a multi-billion dollar public project, was spearheaded by the Department of Energy and the National Institutes of Health. *See generally*, National Human Genome Research Institute, National Institutes of Health, *An Overview of the Human Genome Project*, http://www.genome.gov/25019879 (Reviewed Nov. 7, 2008; accessed August 28, 2009). Such a significant public expenditure in a collaborative international effort reflects the understanding of the human genome as the shared property and common heritage of humankind.

B. Patenting Human Genes and Gene Sequences is Contrary to International Law and Treaties

International and U.S. law include longstanding protections against private ownership or individual rights of exclusion afforded to the common heritage of humanity. The United Nations recognizes the deep sea as the "common heritage of mankind." The United Nations Convention on the Law of the Sea. Treaties also recognize outer space, the moon and Antarctica as part of the common heritage of humanity. *See* Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, including the Moon and Other Celestial Bodies; Antarctic Treaty System. These treaties require that humanity's common heritage not be appropriated by individuals or states because "all rights in the resource…are vested in mankind as a whole." *See* The United Nations Convention on the Law of the Sea, article 137.2. States cannot exclude other states from accessing humanity's common heritage and any use of the heritage must be for the common good, and not simply private interests. These restrictions would prohibit patenting any part of the human genome, because otherwise, patent holders could exclude access to information about our common genetic ancestry and our common genetic make-up as not only individuals, but as a species. Any patent that could be used to restrict access to that information, as is the case with the BRCA1 and BRCA2 gene patents, would violate common heritage protections.

C. Patenting Human Genes and Gene Sequences is Contrary to the Public Trust Doctrine

U.S. courts have provided protections to the common heritage of humanity through the public trust doctrine. The public trust doctrine has proven to be a "dynamic common-law principle flexible enough to meet diverse modern needs" and is used to protect and preserve public lands, waterways, and the animals and plants that inhabit them, among other things.

District of Columbia v. Air Florida, Inc., 750 F.2d 1077, 1083 (D.C. Cir. 1984). Originally, the doctrine prevented the alienation of publicly owned land, but now is recognized to impose positive duties on the state as well. *Id.* The public trust is "an affirmation of the duty of the state to protect the people's common heritage." *Nat'l Audubon Soc'y v. Superior Court*, 658 P.2d 709, 724 (Cal. 1983). Public property must be used for public purposes, and the state cannot give private entities property rights in public lands unless it benefits the common good. *Id.* at 723. This would suggest that interpretations of patent law that limit public access to vital medical information, as the patents covering the BRCA1 and BRCA2 genes do, violate the public trust.

CONCLUSION

Amici Curiae appreciate the opportunity to provide information to the Court about the patentability of genes and gene mutations, and their impact on the health and well-being of vulnerable women. For the reasons set out above, *Amici Curiae* respectfully urge the Court to deny the defendant's motion to dismiss, and to grant the plaintiff's motion for summary judgment.

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