Docket No. 2010-1406

In the

United States Court of Appeals

For the

Federal Circuit

THE ASSOCIATION FOR MOLECULAR PATHOLOGY,
THE AMERICAN COLLEGE OF MEDICAL GENETICS,
THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY,
THE 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, and KATHLEEN RAKER,

Plaintiffs-Appellees,

v.

UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendant,

(Caption Continued Inside Cover)

Appeal from the United States District Court for the Southern District of New York in Case No. 09-CV-4515 · Senior Judge Robert W. Sweet

BRIEF OF AMICI CURIAE THE NATIONAL WOMEN'S HEALTH NETWORK, REPRODUCTIVE HEALTH TECHNOLOGIES PROJECT, FORWARD TOGETHER, THE CENTER FOR GENETICS AND SOCIETY THE PRO-CHOICE ALLIANCE FOR RESPONSIBLE RESEARCH, ALLIANCE FOR HUMAN BIOTECHNOLOGY, G. MICHAEL ROYBAL, MD, MPH AND ANNE L. PETERS, MD IN SUPPORT OF APPELLEES

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and

MYRIAD GENETICS, INC.,

Defendant-Appellant,

and

LORRIS BETZ, ROGER BOYER, JACK BRITTAIN, ARNOLD B. COMBE, RAYMOND GESTELAND, JAMES U. JENSEN, JOHN KENDALL MORRIS, THOMAS PARKS, DAVID W. PERSHING, and MICHAEL K. YOUNG, in their official capacity as Directors of the University of Utah Research Foundation,

Defendants-Appellants.

CERTIFICATE OF INTEREST

Counsel for *Amici* National Women's Health Network, et al, certifies the following:

1. The full name of every party or amicus represented by me is:

The National Women's Health Network, Reproductive Health Technologies Project, Forward Together, The Center for Genetics and Society, The Pro-Choice Alliance for Responsible Research, Alliance for Human Biotechnology, G. Michael Roybal, MD, MPH, and Anne L. Peters, MD.

2. The name of the real party in interest represented by me is:

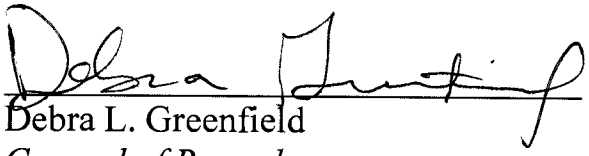
The National Women's Health Network, Reproductive Health Technologies Project, Forward Together, The Center for Genetics and Society, The Pro-Choice Alliance for Responsible Research, Alliance for Human Biotechnology, G. Michael Roybal, MD, MPH, and Anne L. Peters, MD.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of any party or amicus curiae represented by me are:

None.

4. The names of all law firms and the partners or associates that appeared for any party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Dated: June 12, 2012



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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici Curiae are women's health and social justice advocates, experts in policy issues concerning women's health and health disparities for women of particular ethnic and racial backgrounds and socio-economically disadvantaged women. They educate community-based organizations about the implications of genetic technologies for women's health, and advocate for just public policy. *Amici Curiae* also include physicians/researchers who, as experts in the clinical care and treatment of underserved populations, understand the importance of genetic technologies for preventative medicine, treatment, and possible cures. *Amici Curiae* recognize that Myriad's exclusive and broad patents on isolated DNA/cDNA molecules are natural laws and scientific principles whose preemption from public use inhibits innovative work in research and treatments for breast and ovarian cancer, with resultant harms for the communities and patients they serve.

Amicus Curiae **The National Women's Health Network (NWHN)** aspires to a health care system that is guided by social justice and reflects the needs of women from diverse communities. Developing and promoting a critical analysis of health issues which affect policy and support consumer decision-making, the NWHN provides evidence-based information free from corporate influence.

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[1] The Court has invited filing of amicus briefs without consent or leave of court. No part of this brief was authored or funded by counsel for any Party, person, or organization besides Amici and their counsel.

The NWHN has particular expertise in women's health issues as a result of their research and evaluation of emerging drugs, devices and treatments and their impact on women's health.

Amicus Curiae **Reproductive Health Technologies Project (RHTP)** is a national non-profit advocacy organization working on behalf of women to achieve access to the safest and most effective methods for protecting their health. Bringing together experts, using solid science and clinical data, and seeking consensus among diverse communities, RHTP ensures that new technologies are developed and introduced with appropriate safeguards, a well-informed consumer constituency, and broad based public support.

Amicus Curiae **Forward Together (FW)** is a nonprofit community-based multi-racial organization that engages in grass-roots action and training community leaders. FW works with communities of color to ensure that women and adolescents have the information they need to improve their own health status, and believe in policy that enables *all* people to have the economic, social, and political power and resources necessary for decision-making regarding their bodies.

Amicus Curiae **The Center for Genetics and Society (CGS)** is a nonprofit public affairs organization working to encourage responsible uses and effective societal governance of genetic, reproductive and biomedical technologies. Providing accurate information regarding these technologies, CGS works with civil

society leaders, health professionals, scientists, and others to advance the public interest in the development of policy regarding human biotechnologies.

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

Amicus Curiae **Alliance for Human Biotechnology** is a non-profit association that conducts outreach and education on the social implications of human genetics and works towards a culture of science that places the health and welfare of people above financial interests.

Amicus Curiae **G. Michael Roybal, MD, MPH** is the Medical Director of the Roybal Comprehensive Health Center (CHC), which was established to address the inequity of communities and individuals without access to affordable healthcare. Dr. Roybal has spent his career working with the Department of Health Services for Los Angeles County, focusing on healthcare redesign and reform in an attempt to improve healthcare delivery for underserved populations.

Amicus Curiae **Anne L. Peters, MD**, is the Director of the Diabetes Clinic at the Roybal Comprehensive Health Center (CHC) and a Professor at the USC Keck School of Medicine. An internationally known expert in the field of treatment for diabetes, her work at the CHC provides over 80,000 yearly patient visits, mostly for the uninsured. She developed a similar program which is situated at five additional safety-net sites in Los Angeles County.

ARGUMENT

I. *Mayo* is Applicable to Myriad's Isolated DNA/ cDNA Claims.

"Excluded from patent protection are laws of nature, natural phenomenon, and abstract ideas." *Diamond v.Diehr*, 450 U.S.175, 185 (1981). Phenomenon of nature, though just discovered... are not patentable, as they are the basic tools of scientific and technical work." *Gottschalk* v. *Benson,* 409 U.S. 63, 67 (1972).

In *Mayo v. Prometheus*, 132 S. Ct. 1289 (2012) the Court considered whether a process for measuring the relationship between concentrations of metabolites in the blood and a likelihood that a certain dosage of a drug would prove ineffective or cause harm, was patentable subject matter according to 35 U.S.C. § 101. The Court held that the method was essentially for the relationship itself, a prohibited non-statutory Law of Nature, even as applied within a process. *Id.* at 1305. *Mayo*'s prohibition is applicable to Myriad's patented isolated DNA/ cDNA molecules, non-statutory laws of nature.

Although the method in *Mayo* involved human action, i.e. administering a drug to trigger the manifestation of the relationship, the relationship existed in principle apart from any human action, and was an entirely natural process." *Id.* at 1297. The Court noted that, "... a patent that simply describes that relation sets forth a natural law," *id,* and held that the method claimed "the underlying laws of nature themselves," and thus was invalidated. *Id.* at 1305.

The embodied informational content of the claimed isolated DNA/cDNA molecules is similarly, a relationship, a law of nature. DNA is a chemical molecule composed of four standard repeating chemical units, adenine, thymine, cytosine, and quinine (aka, A, T, C, G) known as "nucleotides" or "bases." *Ass'n. for Molecular Pathology v. U.S Patent and Trademark Office,* 702 F. Supp. 2d 181, 192-200 (2010) at 193. The ordering of these bases is described as nucleotide sequences, DNA sequences, or gene sequences. *Id.* at 194. Gene sequences constitute biological information, describing the structural and chemical properties of a particular DNA molecule that is the cellular "blueprint" for the production of proteins, *id,* and are of a double nature: they are "chemical substances or molecules as well as physical carriers of information, i.e., where the actual biological function of this information is coding for proteins." *Id.* at 228, citing Strauss Decl. P 20.

The actual three dimensional configuration of the DNA molecule encodes this information *see* Dan Burk, *The Problem of Process in Biotechnology,* 43 Hous. L.

Rev. 561, 582-87 (2006), which is *only* useful for purposes of patenting when embodied in such structures: no one is interested in the 'letters' of the sequence rather, "... they are interested in ... building informational structures-the molecules that are the conduit for information transfer." *Id.* at 586-87. These informational structures are the sole content of Myriad's isolated DNA/cDNA claims, the specified nucleotide sequences relating to the BRCA 1& 2 genes. *See,* e.g. claims 2, 5, 6, 7 of U.S. Patent No. 5,747,282; claims 1, 6, 7 of U.S. Patent No. 5,837,492. *Ass'n.*, 702 F. Supp. 2d at 212.

This ordering of the chemical bases, the arrangement of nucleotides which comprise the BRCA 1 & 2 genes can be considered a relationship, analogous to the correlation in *Mayo*. The relationship established by the structure of the nucleotides in the molecule enables the instructions for the building of proteins in the human body or identical DNA. This ordering is similarly "fixed by nature," an "entirely natural process." These pre-determined relationships that reveal a genetic susceptibility to breast and ovarian cancers in the BRCA 1 & 2 genes exist "in principle" unchanged and apart from the technical isolation/replication processes. The claims "simply describe the relations" between the nucleotides, and their resulting chemical and structural content. "One cannot patent the physical entity without claiming the scientific relationship the genetic material represents or deciphers in its natural state." *See,* Debra Greenfield, *Intangible or Embodied*

Information: The Non-Statutory Nature of Human Genetic Material, 25 Santa Clara Computer & High Tech. L. J. 467, 488 (2009).

The Court in *Mayo* determined whether the steps involved in the questioned process transformed the natural correlations into patentable applications, *Mayo,* 132 S. Ct. at 1298, by looking at cases where processes "embodied the equivalent of natural laws." *Id.* An equation in *Diehr*; an algorithm in *Flook*; and a mathematic principle in *Benson* were recognized as underlying laws of nature, unsuitable subject matter for patent protection. *Id.* Myriad's claims to the isolated DNA/ cDNA molecules are analogous. The mathematical ordering of the chemical base pairs is an equation; a formula for the production of proteins; an algorithm which dictates biological processes. The fixed nature of the relationship of the nucleotides arranged in the BRCA 1 & 2 genes revealing a susceptibility to breast or ovarian cancer is a pre-existing scientific principle. As such, per the holding in *Mayo*, Myriad's claims on isolated DNA / cDNA are laws of nature, ineligible for patent protection.

II. *Mayo's* Rationale, Prohibiting the Preemption of Laws of Nature is Applicable to the Present Case. The Denial of Access to the Isolated DNA/ cDNA Molecules Stifles Innovation in Biomedical Research and Treatment Creating Harms for Women's Health, Particularly for Women of Particular Racial or Ethnic Backgrounds or Socio-Economically Disadvantaged Women.

Mayo recognized that "Patent law not inhibit further discovery by improperly tying up future use of laws of nature," *Mayo,* 132 S. Ct. at 1301,

warning against claims that "preempt the use of a natural law." *id*, citing *Morse, supra,* at 112-120, 15 How. 62, 14 L. Ed. 601. These laws were considered "... basic tools of scientific and technical work," whose monopolization or preemption might "tend to impede innovation more than it would tend to promote it." *Mayo,* 132 S. Ct. at 1294.

The patenting of Myriad's isolated DNA /cDNA molecules preempt broad and essential laws of nature. The patents are exclusive grants given for *all uses* of the informational content embodied in their chemical structures. Thus, access to basic scientific principles is denied- impeding innovation and discouraging the implementation of new technological advances in the fields of genetic and biomedical research and treatment. As a result, the public, particularly women, women of ethnic and racial minorities, and socio-economically disadvantaged women, are deprived of benefits from innovations in research and healthcare.

Clinical researchers and laboratory directors have expressed real fears that they will be prevented from doing their work by patent holders. *See,* Richard Gold and Julia Carbonne, *Myriad Genetics: In the Eye of the Policy Storm*, 12 Genetics in Medicine S39 (2010) [hereinafter "Gold"]. Despite claiming that they do not enforce their patents against researchers, Myriad has not confirmed this in writing in a public form or clarified the concept of 'infringing activities.' *Secretary's Advisory Committee on Genetics, Health & Society: Gene Patents and Licensing*

Practices and their Impact on Patient Access to Genetic Tests, 4-2010, at A26-27 [hereinafter "*Report*"]. This creates ambiguity which may stifle basic or clinical research as scientists avoid the work or "are wary of public reporting results." *Id.* at A27.

Researchers ceased studying the BRCA genes when they became aware of potential liability, and Myriad reportedly enforced their patents in nine instances *id.* at 7, citing Mildred K. Cho, et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services,* 5 J. Molecular Diagnostics 3, 5 (2003), including the receipt of "cease and desist" letters by two laboratories. Gold, *supra* at S44. Following the issuance of Myriad's BRCA claims, scientists expressed concerns about contributing their research on the BRCA genes to public databases. One university researcher was specifically told *not* to contribute his findings of new mutations (which would be covered by Myriad's broad patents). *Id.* In 2004, Myriad stopped contributing data concerning "variations of unknown significance" (VUS) accumulated as a result of their exclusive testing, to the NIH open access Breast Cancer Information Core (BIC) mutation database. John Conley, Dan Vorhaus, Robert Cook-Deegan: Genomics Law Report, March 1, 2011: *How Will Myriad Respond to the Next Generation of BRCA Testing? available at* http://www.genomicslawreport.com/index.php/2011/03/01/how-will-

myriad-respond-to-t. This denial of access to new information regarding possible mutations in the BRCA 1 & 2 genes impedes vital biomedical research.

Because of the preemption of the broad informational content of their BRCA patents, Myriad is the sole provider of genetic testing in the U.S. *Report* at 40. The patents cover both known and unknown mutations for increased susceptibility to breast and ovarian cancer, e.g., Claim 6 of the '492 patent, "directed to any DNA nucleotide encoding any mutant BRCA 2 protein that is associated with breast cancer" *Ass'n.,* at 213, decreasing the likelihood of investment in developing alternative or improved testing methods. 53% of clinical laboratories do not develop new or improved genetic tests in light of patents, see Cho, *supra* at 3-5, and researchers have stated that Myriad prevented the development of improved BRCA 1 & 2 tests. See Gold, *supra* at S44.

Thus, access to genetic testing for breast and ovarian cancer is severely limited as a result of Myriad's broad composition claims. Methods which might be more cost effective are prohibited: "...the average cost per mutation using the Myriad approach was five times as high," as those developed and used in Europe. *Report* at A-27. Myriad's test utilizing the whole BRCA sequence differs from tests used in Europe, and as such establishes the "standard of care" in the United States, precluding the use of testing methods which might also be more efficient. *Id.* at A-28. The monopolization of the informational content of Myriad's isolated

DNA/cDNA patents eliminates the possibility of a patient's access to a confirmatory second opinion, a test from a different laboratory.

Innovation in the quality of genetic tests is similarly inhibited by Myriad's patents. Clinical geneticists outside of Myriad's laboratories cannot determine whether the Myriad test is accurate in identifying mutations in the BRCA genes or predicting a patient's risk for breast or ovarian cancer. 10-20% of false negatives in Myriad's test were found in patients at high risk in a study conducted by non-clinical researchers. Walsh T., Casadei S., Coat KH et al., *Spectrum of Mutations in BRCA 1, BRCA 2, CHEK and TP 53 in Families at High Risk of Breast Cancer*, 295 JAMA 1379 (2006) [hereinafter "Walsh"]. Using an alternative molecular testing method one study found that Myriad's test missed up to 12% of large genomic deletions or duplications. *Id* at 1380.

Myriad's patents prevent laboratories from offering more rapid and cost effective methods, such as genomic capture and massive parallel sequencing for multiple breast and ovarian cancer susceptibility genes. Walsh, Lee, Casadei, Thorton, Stray, Pennil, Nord, Mandell, Swisher, and Mary-Claire King; PNAS Early Edition, *Detection of Inherited Mutations for Breast and Ovarian Cancer Using Genomic Capture and Massive Parallel Sequencing,* www.pnas.org/cg/10.1073/pnas [hereinafter "King"]. If a result based upon the Myriad test is negative, testing for *other* breast or ovarian cancer genes are done

selectively, costing thousands of dollars beyond the costs of Myriad's tests. *Id.* Myriad's test is also less accurate than these new methods, one of which evaluated multiple genes in addition to BRCA 1 & 2, identifying a wide range of mutations in a variety of genes. *Id.* Six large deletions and duplications were identified which could have been missed using Myriad's standard test. *Id.* These innovative new tests cannot be done on the BRCA 1 & 2 sequences without infringing Myriad's patents on isolated DNA.

Problems created by broad patents including "patent thickets, blocking patents, and high transactions costs'" threaten the use of next generation innovations in genetic testing, such as whole genome sequencing (WGS) which evaluate multiple genes." *Report* at 50-51. Laboratories using multiplex tests are not reporting results to patients or sending clinicians the results of tests involving patent protected genes, for fear of infringement liability. *Id.* Broad patents such as Myriad's isolated DNA/ cDNA claims create uncertainty leading to high transaction costs, potentially affecting the use of WGS in assessing for risk or existence of disease, and thus, patient care. National Society of Genetic Counselors, Position Statement of Human Gene Patents, available at: http://www.nsgc.org/Advocacy/PositionStatements/tabid/107/Default.aspx (2010).

Myriad's patents on the BRCA 1 & 2 genes deter innovation in breast and ovarian cancer research and treatment, diseases which primarily affect women.

See, American Cancer Society, *Breast Cancer Facts and Figures 2009-2011.* Numerous cancer patients with BRCA 1 & 2 mutations have a negative family history, and do not qualify for testing according to Myriad's criteria. King, *supra* at 4. However, the development of specific treatments, inhibitors which effectively kill BRCA 1 & 2 mutated carcinomas having *therapeutic* as well as preventive applications, necessitates an increased need for identifying BRCA 1 & 2 mutations through testing, which is limited by Myriad's exclusive test on the patented sequences. *Id.*

Socio-economically disadvantaged women are disproportionately harmed by Myriad's exclusive and broad patents. There is less access to genetic testing for underserved ethnic and racial minorities than for those in the white population. Armstrong K., Micco E., Carney A. et al, *Racial Differences in the Use of BRCA 1/2 Testing Among Women with a Family History of Breast or Ovarian Cancer,* 293 JAMA 1729 (2005). Socio-economic forces create these health disparities and the price of Myriad's test ($3000) is necessarily prohibitive. Access to Myriad's test is severely limited for those without insurance, *Report* at 38, and even for the insured, the coverage for BRCA testing has been inconsistent and reimbursement is limited to those at high risk. *Id* at 37-38.

Myriad's patents also affect the quality of the tests for ethnic and racial minority women. Large genomic deletions or duplications, known as large genetic

rearrangements will be found in approximately 12% of patients with both breast cancer and a "severe" family history who test negative for the BRCA genes. K.M. Shannon et al., *Which Individuals Undergoing BRCA Analysis Need BART Testing?* 204 Cancer Genetics 416 (2011). Data from Myriad suggests that these large rearrangements BRCA mutations are over-represented and account for a larger percentage of mutations than previously thought in some populations, e.g., 20% of Latina women. *An Open Letter to Myriad Genetics,* Friday, July 22, 2011, *available at* http://yalecancergeneticcounseling.blogspot.com/2011_07_11 archive. html.

Lack of access to Myriad's tests for underserved racial and ethnic populations diminishes the quality of the test itself. Michael J. Hall, Olufunmilay I. Olopade, *Disparities in Genetic Testing: Thinking Outside the BRCA Box,* 24. J. Clin. Oncol. 2197 (2006). Models to assess risk used in BRCA testing need accurate estimates of the prevalence in specific populations to estimate probabilities in particularly high risk genotypes. *Id.* However the prevalence of Ashkenazi groups in testing shows a 10 fold increased prevalence in this group compared with estimates for the remaining U.S. population. *Id.* Without accurate estimates of mutation prevalence in minority subgroups, the reliability of these models is compromised. *Id.*

Thus, the preemption of the informational content, the knowledge regarding the isolated DNA/cDNA molecules which comprise the BRCA 1 & 2 genes deters rather than promotes innovation in both research and treatment. This denial of access to critical information has serious and harmful implications for the health of women, particularly women who are underserved and socio-economically disadvantaged, as well as women of ethnic and racial minorities.

CONCLUSION

We respectfully request this Court to hold that, in accordance with the decision in *Mayo,* Myriad's claimed isolated DNA/cDNA are molecules ineligible for patenting under 35 U.S.C. §101. They are non-statutory laws of nature, whose preemption as a result of exclusionary patents deters innovation in biomedical research and treatment.

Dated: June 12, 2012 Respectfully submitted,

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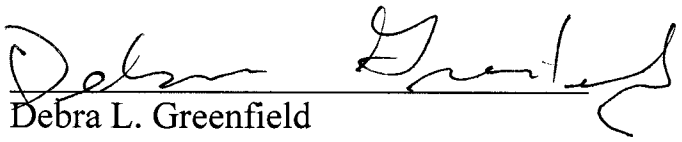
Dated: June 12, 2012 Respectfully submitted,



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