No. 12-398

In The Supreme Court of the United States

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, ET AL.,
Petitioners,

v.

MYRIAD GENETICS, INC., ET AL.,
Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF AMICUS CURIAE AARP IN SUPPORT OF PETITIONERS

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INTEREST OF AMICUS CURIAE[1]

AARP is a nonpartisan, nonprofit organization dedicated to addressing the needs and interests of people age fifty and older. AARP seeks through education, advocacy, and service to enhance the quality of life for all by promoting independence, dignity, and purpose. In its efforts to promote independence, AARP works to foster the health and economic security of individuals as they age by attempting to ensure the availability of quality and economical health coverage. AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality.

Access to affordable health care is particularly important to the older population, which has higher rates of chronic and serious health conditions. Genetic tests are capable of diagnosing a variety of diseases, assessing the risk of future disease, and enabling treatment to be tailored to individual genetic variations. Patents such as those present in this case significantly elevate the cost of genetic testing, prohibit diagnosis and treatment based on second medical opinions. In light of the significance of the issue presented in this case, AARP respectfully

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[1] In accordance with Supreme Court Rule 37.6, AARP states that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than AARP, its members and its counsel have made a monetary contribution to the preparation or submission of this brief. All parties have received at least ten days notice of AARP's intent to file a brief. Written consent of the parties has been obtained and will be filed with the Clerk of the Court pursuant to Supreme Court Rule 37.2.

submits this amicus curiae brief urging the Court to grant the petition for writ of certiorari.

SUMMARY OF THE ARGUMENT

The Federal Circuit erred in holding that isolated DNA was patentable. DNA molecules and human genetic sequences are natural phenomena that when discovered are not the kind of "discovery" that Section 101 protects. If the Federal Circuit's decision is permitted to stand, there will be grave public health implications. Specifically, patients will be prevented from seeking a second opinion from another laboratory before making potentially life-altering decisions to undergo prophylactic mastectomies or receive other medical treatment.

Additionally, the monopoly created by the patents in this case has allowed the patent holder to charge fees that are unaffordable to many people effectively denying them life-saving medical treatment. While the patent system involves a delicate balance between the need for innovators to recoup research and development expenditures and protecting the public, the ultimate object of the patent laws has always been to benefit, not harm the public.

ARGUMENT

I. The Court Should Grant Certiorari Because The Federal Circuit Refused To Even Consider The Public Health Impact That Results From Denying High-Risk Patients A Second Medical Opinion.

The Court has long recognized that "the rights and welfare of the community must be fairly dealt with and effectually guarded" in the patent system *Kendall v. Winsor*, 62 U.S. 322, 329 (1859). More recently, the Court held that courts must consider the public impact when considering injunctive relief in patent cases. *eBay Inc. v. MercExchange, L.L.C.,* 547 U.S. 388, 391. The Federal Circuit erred when it essentially held that whether or not women would be denied a second medical opinion was irrelevant. Specifically, the Federal Circuit dismissed the serious health consequences of its decision by erroneously holding that this case "…is not about whether individuals suspected of having an increased risk of developing breast cancer are entitled to a second opinion". *Ass'n For Molecular Pathology v. United States PTO,* 689 F.3d 1303, 1324 (Fed.Cir. 2012). Unfortunately, that is precisely what this case is about and the Federal Circuit committed reversible error by refusing to even consider the public health consequences of its decision.

The patent system involves a delicate balance between the need for innovators to recoup research and development expenditures and the protection of the public. Public interest in the patent system must

take into account public health. The ultimate object of the patent laws has always been to benefit, not harm the public. *See Kendall v. Winsor*, *supra.* "A patent by its very nature is affected with a public interest. As recognized by the Constitution, it is a special privilege designed to serve the public purpose of promoting the 'Progress of Science and useful Arts.'" *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 815-16 (1945). *See also* U.S. Const. art. I, § 8.

Patents should not be used to deprive the public of the best and safest medical treatment. *See e.g., Hybritech, Inc. v. Abbott Labs.,* 849 F.2d 1446, 1458 (Fed. Cir. 1988)(noting that while there exists a public interest in protecting rights secured by valid patents, the public's needs must also be considered)[2];*Vitamin Technologists, Inc. v. Wis. Alumni Research Found.*, 146 F.2d 941 (9th Cir. 1945) (holding that patents that limited low income persons' access to a vitamin that combats rickets were invalid). It is a principle of general application that courts can consider the public interest when granting equitable relief and these principles apply equally to patent cases. *See, eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

Gene patents, such as Myriad's, significantly harm the public interest by maintaining an environment in which patients are unable to obtain a

[2] The preliminary injunction standards were revised on other grounds in *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7 (2008). *See also eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

second opinion when other laboratories are precluded from conducting genetic tests due to patents. Additionally, the monopoly created by the patent has allowed the patent holder to charge excessive fees and effectively deny many people life-saving medical treatment.

A. Gene Patents Impede The Ability Of Patients To Obtain The Best Medical Care.

Information gained from genetic tests can have a profound impact on medical decision-making. For many, the results from genetic testing can inform crucial life-altering decisions such as whether to undergo prophylactic mastectomy, or take a particular drug. Kathy L. Hudson et al., *Oversight of US Genetic Testing Laboratories*, 24 Nature Biotechnology 1083, 1083 (2006). Research released this year indicates that BRCA2 mutation carriers may be at a heightened risk of cardiac failure if certain chemotherapy treatments are used. Krishna K. Singh et al., *BRCA2 Deficiency Exaggerates Doxorubicin-Induced Cardiomyocyte Apoptosis and Cardiac Failure*, J. Biological Chemistry, 287 J. of Biological Chemistry 6604 (2012). If treating physicians are not aware of a patient's BRCA2 deficiency, they might prescribe chemotherapy that increases the risk of cardiac failure. *Id.* In order to receive proper treatment it is crucial that both patients and the medical professionals treating them have full access to genetic tests including confirmatory tests at different laboratories.

Referencing the present case, the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) noted in an April 2010 report that "an exclusive rights holder's clearance of the market denies all patients of the ability to access a confirmatory genetic test from a different laboratory." U.S. Dep't of Health & Human Servs., *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests: Report of the Secretary's Advisory Committee on Genetics, Health, and Society* 44 (2010), [hereinafter SACGHS 2010 Report], http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf. The Committee stated that the ability to obtain a confirmatory test from a second laboratory is "the laboratory equivalent to the time-honored practice of obtaining a second opinion from a clinician." *Id.* In the absence of a second opinion, laboratory errors and inaccurate test results can result in "misdiagnosis, inappropriate and/or delayed treatment, anxiety and in rare cases, even death." Hudson, *supra*, at 1089. Independent confirmatory testing is especially important, given the "implications for major medical decisions, such as whether to have a mastectomy or surgical removal of the ovaries." SACGHS 2010 Report, *supra*, at 44.

A 2008 study of decision-making in 338 women who underwent BRCA testing determined that risk-averse women who are high-risk and test positive for a BRCA1/2 mutation are likely to opt for more invasive and irreversible preventative procedures, such as a prophylactic mastectomy (*i.e.*, preemptive breast removal surgery). Sandra van Dijk et al.,

Decision Making Regarding Prophylactic Mastectomy: Stability of Preferences and the Impact of Anticipated Feelings of Regret, 26 J. Clinical Oncology 2358, 2360 (2008). The study determined that fear of a future cancer diagnosis is often a factor in the decision-making process regarding treatment options and that decisions regarding treatment options cause very high levels of anxiety, particularly for women who fear that choosing anything short of the most aggressive treatment option may leave their children motherless. *Id.* at 2362.

Under the Federal Circuit's ruling, exclusive rights holders such as Myriad deny patients access to a second opinion by preventing other laboratories from offering confirmatory testing. A study of more than 130 genetics laboratories found that 25 percent had no choice but to stop performing or developing a clinical genetic test due to the exclusionary effects of a gene patent. 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). While Myriad has allowed others to perform basic research on BRCA1 and BRCA2 "participation in research studies is not an adequate substitute for providing the most effective and thorough clinical genetic testing." Tom Walsh et al., *Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 J. Am. Med. Ass'n 1379, 1386 (2006). Only reports from Clinical Laboratory Improvement certified laboratories can be reported to patients or used in clinical care and it may take months or even years before patients receive their results from

research laboratories, if at all. *See e.g.*, Ebony B. Bookman et al., *Reporting Genetic Results in Research Studies: Summary and Recommendations of an NHLBI Working Group*, 140 Am. J. Med. Genetics 1033, 1034 (2006); Misha Angrist et al., *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Long QT Syndrome*, 12 Genetics Med. S111, S127 (2010).

With genetic tests, the need for access to a second opinion is especially critical because studies have shown that Myriad's BRCA tests do not detect all known mutations. Tom Walsh et al., *supra* at 1380. A study at the University of Pennsylvania further found that 8 percent of non-Ashkenazi Jewish test subjects carried a BRCA mutation not detectable by Myriad's standard test. Maurizia Dalla Palma et al., *The Relative Contribution of Point Mutations and Genomic Rearrangements in* BRCA1 *and* BRCA2 *in High-Risk Breast Cancer Families*, 68 Cancer Research 7006, 7011 (2008).

Not only do Myriad's tests underrepresent cancer risks, at least one study suggests that the mutation prediction models used by Myriad to counsel patients regarding whether to even obtain BRCA1/2 testing can be grossly inaccurate among portions of the population. Allison W. Kurian et al., *Performance of BRCA1/2 Mutation Prediction Models in Asian Americans*, 26 J. Clinical Oncology 4752, 4756 (2008). The study found that the models used by Myriad significantly underestimate the prevalence of BRCA1/2 mutations among Asian American women. *See id.* at 4754-55.

The treatment options available to a patient with a high risk of developing breast or ovarian cancer are invasive, expensive, and often carry a heavy emotional and psychological cost. Multiple genetic tests have reached different conclusions than Myriad's, and the science governing genetic testing continues to advance. Eileen M. Kane, *Patent-Mediated Standards in Genetic Testing*, 2008 Utah L. Rev. 835, 849 (2008). Since the implications of incorrect genetic test results are grave, it is imperative that patients not be prevented from seeking a second opinion.

II. Patents On Genetic Sequences Interfere With The Practice Of Medicine And Harm Patients.

Gene patents force millions of Americans with limited health care coverage and personal resources to forgo potentially life-saving testing. They allow sole providers of a genetic test to exclude other laboratories from serving patients. Access to genetic testing is particularly difficult for large segments of the Latin American/Hispanic population who are disproportionately poor and uninsured or underinsured. Lloyd Runser, Cabrina Eagan, & Danielle Olds, *The Uninsured and Underinsured*, http://www.case.edu/med/epidbio/mphp439/Safety_Nets.htm (last visited Oct. 26, 2012).[3] Recent data

[3] *See also* Office of the Assistant Sec'y for Planning & Evaluation, U.S. Dep't of Health & Human Servs., *Overview of the Uninsured in the U.S.: An analysis of the 2005 Current PopulationSurvey* (2005), http://aspe.hhs.gov/health/reports/05/uninsured-cps/index.htm#race.

released by Myriad indicates that Hispanic patients who need BRCA testing need the full range and more costly BART analysis. *See* Myriad Genetic Labs., Inc., *BRCA1 and BRCA2 Prevalence Tables for Mutations Detected by Sequencing, the 5-Site Rearrangement Panel (LRP) and the BRACAnalyis Large Rearrangement Test (BART) in High Risk Patients*, http://www.myriad.com/lib/brac/BART-table-faq.pdf (last visited Oct. 26, 2012).[4]

Gaining access to genetic testing is also particularly challenging for Medicare and Medicaid patients because gene patents allow exclusive rights holders to place limits on the forms of insurance that they will accept. Clinicians have reported access problems "when an exclusive rights holder does not accept a particular insurance, but enforces its patents to narrow or clear the market." SACGHS 2010 Report, *supra*, at 43. Specifically, two Emory University genetic counselors commented that "there are also labs [that are exclusive licensees or patent holders] that choose not to contract with Medicaid or Medicare at all." *Id.* SACGHS concluded in its April 2010 report that "patient access problems . . . are caused not by any behavior by health insurers, but by an exclusive rights holder's decisions" and that "[i]f other laboratories could offer [these genetic tests] . . . patients would have a greater chance of obtaining access . . . ." SACGHS 2010 Report, *supra*, at 44-45.

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[4] *See also* Yale Cancer Genetic Counseling, *An Open Letter to Myriad Genetics* (July 22, 2011), http://yalecancergenetic counseling.blogspot.com/2011/07/open-letter-to- myriad-genetic s.html.

In the present case, while Myriad does have a financial assistance program, neither Medicaid nor Medicare recipients are eligible to apply. Myriad Genetic Labs., Inc., *Billing & Payment Options*, https://www.myriadpro.com/billing-insurance/reimbursement-payment-options (last visited Oct. 26, 2012) ("Due to regulatory limitations, patients who are recipients of government funded programs [i.e. Medicaid, Medicare] or those that have any third-party insurance are not eligible to apply for MFAP.").

The lack of competition also keeps "costs of tests comparatively high." Cancer Council Austl., Clinical Oncological Soc'y of Austl., *Senate Inquiry into Gene Patents* 6 (2009), http://bit.ly/Rd5fGd (noting that costs can remain high despite advances in technology or efficiency elsewhere in the system).[5] There are an estimated 226,870 new cases of invasive breast cancer in women and about 39,570 deaths from breast cancer each year. *See* Am. Cancer Soc'y, *Breast Cancer Facts and Figures 2012* 9 (2011). Those at risk for cancer often have no choice but to forgo potentially life-saving health care treatment because they lack health care coverage or the resources to pay for genetic testing out-of-pocket. "[T]he failure to obtain health care in a timely

[5] *See also* Joshua Sarnoff et al., *Submission of American Patent and Health Law Professors on Australian Senate Community Affairs Committee Inquiry Into Gene Patents*, March 18, 2009 ("Gene patents increase the cost of the diagnosis and treatment of genetic diseases. For up to twenty years, a gene patent holder controls *any* use of 'its' gene. The patent holder can charge whatever it wants for any test analyzing the patented gene—even if that test uses a technology that was not invented by the patent holder.").

fashion is associated with negative outcomes, including more costly care, delays in diagnosis or treatment and poorer health outcomes, and premature death." Stefanie Mollborn et al., *Delayed Care and Unmet Needs Among Health Care System Users: When Does Fiduciary Trust in a Physician Matter?*, 40 Health Services Research 1898, 1899 (2005) (citations omitted).

A. Gene Patents Limit Access To Genetic Testing For Patients Covered by Medicare.

Medicare is the largest health insurance provider in the United States, serving approximately 49 million older and disabled Americans.[6] *See* U.S. Dep't of Health & Human Servs., *Coverage And Reimbursement of Genetic Tests and Services: Report of the Secretary's Advisory Committee on Genetics, Health, and Society* 4 (2006), [hereinafter Coverage and Reimbursement], http://oba.od.nih.gov/oba/sacghs/reports/CR_report.pdf; Kaiser Family Found., *Medicare Spending and Financing Fact Sheet* 1 (Sept. 2011), http://www.kff.org/medicare/upload/7305-06.pdf. In 2010, the median annual income of Medicare beneficiaries was $21,183. Kaiser Family Found., *Projecting Income and Assets: What Might the Future Hold for the Next Generation of Medicare Beneficiaries?* 1 (June 2011), http://www.kff.org/medicare/upload/8172.pdf. Additionally, one in four beneficiaries spend 30 percent or more of their income on health expenses. Kaiser Family Found.,

[6] "Older" under Medicare is age 65 or older.

Medicare Spending and Financing Fact Sheet 2 (Sept. 2011), http://www.kff.org/medicare/upload/7305-06.pdf.

Gene patents preclude a substantial portion of the Medicare population from accessing potentially life-saving genetic tests. Medicare policy limits coverage of BRCA tests to Medicare recipients with a personal history of cancer who meet additional criteria despite U.S. Preventive Services Task Force recommendations to test women with a family history of cancer who have not yet contracted cancer. *See e.g*, Grace Wang et al., *Eligibility Criteria in Private and Public Coverage Policies for BRCA Genetic Testing and Genetic Counseling*, 13 Genetics Med. 1045 (2011). Currently Medicare's coverage of the actual BRCA test is more limited than private insurance companies. Wang, et al, *supra.* Requiring Medicare patients to actually contract cancer before covering the BRCA1/2 test eliminates the primary benefit of predictive testing. Further, individuals who do not meet the criteria for the test are forced to either pay the exorbitant expense of the test out-of-pocket or forgo testing altogether.

B. Gene Patents Limit Access To Genetic Testing For Patients Covered by Medicaid.

Medicaid beneficiaries often suffer from similar problems of access and affordability, due to gene patents, as those experienced by Medicare beneficiaries. "Overall, Medicaid beneficiaries are much poorer and in markedly worse health than low-

income people with private insurance." Kaiser Family Found., *MEDICAID: A Primer, Key Information on Our Nation's Health Coverage for Low-Income People* 7 (2010), *available at* http://www.kff.org/Medicaid/upload/7334-04.pdf. Coverage for genetic testing varies from State to State, often depending on the States' respective revenues and political climates. House Budget Comm. on the Budget, *The Path to Prosperity: Restoring America's Promise* 25 (2011), *available at* http://budget.house.gov/UploadedFiles/PathToProsperityFY2012.pdf (indicating the Medicaid system is "broken"); Coverage and Reimbursement, *supra*, at 32. Some Medicaid programs do not consider BRCA testing to be a covered service. Wang et al., *supra*, at 1048. Individual State fiscal policies make "it extremely difficult for the Medicaid population to secure access to new [genetic] tests and services over the long term." Coverage and Reimbursement, *supra*, at 32. *See also* Ryan Crowley, American Coll. of Physicians, *Medicaid and Health Care Reform* 4-5, http://www.acponline.org/advocacy/where_we_stand/policy/reform_medicaid.pdf (highlighting the financial constraints limiting state Medicaid coverage). These differences in State Medicaid coverage "may constitute a significant source of disparate access to genetic tests and services, especially since Medicaid beneficiaries may not have other health insurance coverage or be able to pay for care out-of-pocket." Coverage and Reimbursement, *supra*, at 32.

With this uncertain health care framework in place for Medicaid beneficiaries, the access problems

created by exclusive gene patents are acute for these low-income individuals. Even Medicaid recipients who live in states that cover BRCA testing have difficulty getting testing because Myriad refuses to accept their Medicaid. Lisbeth Ceriani, one of the plaintiffs, spoke candidly in the District Court about how Myriad Genetics holds Medicaid recipients' fate and future in its administrative hands because it could choose to accept or reject her Medicaid insurance.

> I am currently insured through MassHealth, a Medicaid insurance program for low-income people in Massachusetts. Although my health insurance covers genetic testing done through contracted laboratories, Myriad refuses to contract with MassHealth. I was told that Myriad refuses to accept the $1599 reimbursement rate that MassHealth offers for the test. Myriad is the only laboratory in the U.S. that provides full BRCA gene sequencing, so it is impossible for MassHealth to "contract" with another laboratory to cover this test for its insured.

Ceriani Decl., filed in U.S. Dist. Ct. for the S.D of N.Y., at 2, ECF No. 53.

Patents granting exclusive rights to perform genetic tests exacerbate problems with coverage and reimbursement in the health care system. *See e.g.*, Misha Angrist et al., *supra,* at S127 (2010). Patents additionally create unique issues of access for the Medicaid and Medicare recipients who need genetic

tests. These problems are not limited to Myriad's BRCA1/2 test, but actually arise with other genetic tests offered by patent rights holders. SACGHS 2010 Report, *supra*, at 42-44. Patients are seeking access now, but gene patents are creating difficulties that health care reforms cannot resolve. Therefore, it is important that gene patents, such as those owned by Myriad, be rejected.

III. The Federal Circuit Erred In Holding That Isolated DNA Is Patent Eligible Under 35 U.S.C. § 101.

DNA molecules and human genes are natural phenomena that when discovered are not the kind of "discovery" that Section 101 protects. "Laws of nature, natural phenomena, and abstract ideas' are not patentable." *Mayo Collaborative Services v. Prometheus, Inc.,* 566 U.S. __, 132 S. Ct. 1289, 1293 (2012) (quoting *Diamond v. Diehr,* 450 U.S. 175, 185). The relevant distinction for purposes of Section 101 is "…between products of nature…and human-made inventions". *Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980) "The laws of nature, physical phenomena, and abstract ideas have been held not patentable." Id. at 309; *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). "Mere recognition" of an already existing phenomenon is not patentable. *Parker v. Flook*, 437 U.S. 584, 593 n. 15 (1978) ("Patentable subject matter must be new [novel]; not merely heretofore unknown."). Further, insignificant physical steps such as isolating and removing DNA cannot transform unpatentable natural phenomena into a patentable invention. In *Wood-Paper Patent*, 90 U.S.

566 (1874), the Court found that merely removing pulp from straw, wood, or other natural sources did not make it a patentable new composition of matter: "A process to obtain it [an extract] 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." *Wood-Paper Patent*, 90 U.S. at 593-94. Similarly, isolating a gene or DNA from the human body does not then make the isolated DNA itself patentable. DNA molecules, regardless of whether they are isolated and cleaved, are natural phenomena and are not patent eligible under 35 U.S.C. § 101.

CONCLUSION

For the foregoing reasons, AARP respectfully urges the Court to grant the petition for *writ of certiorari*.

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October 30, 2012