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 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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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

CASES

CONSTITUTION & FEDERAL STATUTES

OTHER AUTHORITIES

MISCELLANEOUS

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, and prohibit diagnosis and treatment based on second medical opinions. In light of the significance of the issue presented in this case, AARP

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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. Written consent of the parties has been obtained and will be filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

respectfully submits this amicus curiae brief in support of the petitioners.

SUMMARY OF THE ARGUMENT

Gene patents threaten public health by chilling scientific research and preventing patients from obtaining necessary diagnostic procedures and treatments. Additionally, the monopoly created by gene patents allows the patent holder to charge fees that are unaffordable to many people, effectively denying them life-saving medical treatment.

DNA molecules and human genetic sequences are natural phenomena that, when discovered, are not the kinds of "discover[ies]" that 35 U.S.C. § 101 protects. Gene patents do not promote the progress of science and are not in the public interest.

ARGUMENT

I. Gene Patents Threaten Public Health and Are Not in the Public Interest

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. (21 How.) 322, 329 (1858). 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 (2006).

The ultimate object of the patent laws has always been to benefit, not harm, the public. *See Kendall*, 62 U.S. at 329 ("Considerations of individual emolument can never be permitted to operate to the injury of [the rights and welfare of the community]."). "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, 816 (1945) (quoting U.S. Const. art. I, § 8, cl. 8).

A. Gene Patents Have a Chilling Effect on Scientific Research

Unfortunately, gene patents and the omnipresent threat of multi-million dollar patent lawsuits can significantly inhibit genetic research. An example of how gene patents can stymie research—even when defendants succeed in defeating the patents—are the multiple suits brought by the Alzheimer's Institute of America, Inc. ("AIA") concerning research and testing of early onset Alzheimer's Disease. The AIA reportedly purchased a patent from Michael Mullan, a biomedical researcher, who patented a human DNA sequence used in mouse models of early-onset Alzheimer's disease. Erika C. Hayden, *Patent Dispute Threatens US Alzheimer's Research*, 472 Nature 20, 20 (2011), *available at* http://www.nature.com/news/2011/110405/pdf/472020a.pdf. The sequence encodes a mutation which causes early-onset Alzheimer's. *Id.*

The AIA sued private companies, academic institutions, and federally funded laboratories for infringing this patent. *See Alzheimer's Inst. of Am., Inc. v. Avid RadioPharmaceuticals, et al.*, No. 2:10-cv-06908-TJS (E.D. Pa. filed Nov. 24, 2010); *Alzheimer's Inst. of Am., Inc. v. Elan Pharmaceuticals, Inc.*, No. 3:10-cv-00482-EDL (N.D. Cal. filed Feb. 2, 2010); *Alzheimer's Inst. of Am., Inc. v. CoMentis, Inc.*, No. 5:09-cv-01366-F (W.D. Okla. filed Dec. 14, 2009); *Alzheimer's Inst. of Am., Inc. v. Pfizer, Inc.*, No. 4:09-cv-01026-CAS (E.D. Mo. filed June 30, 2009). In the *Avid RadioPharmaceuticals* case, Avid's counsel indicated that Avid incurred over $6.5 million in attorney's fees and $222,000 in costs trying the case, which resulted in a defense verdict. Bill of Costs, *Avid RadioPharmaceuticals, et al.*, No. 2:10-cv-06908-TJS, ECF No.: 318-1; Decl. of L. Scott Burwell, *Avid RadioPharmaceuticals, et al.*, No. 2:10-cv-06908-TJS, ECF No.: 317-4. Even in the AIA cases dismissed before trial, cost bills alone filed by defendants totalled over $130,000, exclusive of attorney's fees. *See* Bill of Costs of Elan, *Elan Pharmaceuticals, Inc.*, No. 3:10-cv-00482-EDL, ECF No.: 323 ($57,555.80); Bill of Costs of Elie Lilly, *Elan Pharmaceuticals, Inc.*, No. 3:10-cv-00482-EDL, ECF No.: 319 ($3,710.59); Bill of Costs*, CoMentis, Inc.*, No. 5:09-cv-01366-F, ECF No.: 182 ($69,482.53). These costs and fees can be devastating—particularly for universities and other non-profit institutions. As one Alzheimer's researcher noted, these lawsuits "'constitute a large drain on valuable scientific resources at a time when scientific funds are increasingly tight.'" Hayden, *supra*, at 20 (quoting

Benjamin Wolozin, Alzheimer's researcher, Boston University).

Not surprisingly, then, gene patents have made laboratories hesitant to conduct promising genetic research. A survey of more than 130 genetic laboratories revealed that fifty-three percent of respondents elected to forgo developing or performing a genetic test for clinical or research purposes because of a pre-existing 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); *see also* John F. Merz, *Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine*, 45 Clinical Chemistry 324, 327 (1999) ("The knowledge that a patent application has been filed can influence the decision to spend the time and resources to develop a clinical test because of the uncertain risk that a patent holder will later prevent the laboratory from continuing to provide this service."); Alzheimer Research Forum, *Workshop Explores Intellectual Property Issues in Alzheimer's Disease* (Nov. 4, 2003), http://www.alzforum.org/new/detail.asp?id=901 (hypothesizing that "academic investigators may feel constrained from crossing a patented AD mouse model with other strains, even though such experiments might help uncover additional genes involved in neurodegeneration. Further, investigators and their institutions may be concerned about sharing or providing a mouse model that may be covered by a patent to their colleagues, who might use the model to identify a promising drug for AD."). Invalidating gene patents would eliminate the

significant risk of costly patent litigation, thereby encouraging genetic research. The research is particularly important for Alzheimer's Disease because there is currently no known curative measure available. Alzheimer's Ass'n, *2012 Alzheimer's Disease Facts and Figures* 12 (2012), http://www.alz.org/downloads/facts_figures_2012.pdf.

B. Gene Patents Impede the Ability of Patients to Obtain a Second Opinion

Information gained from genetic tests can have a profound impact on medical decision-making. For many, the results from genetic testing can be life-altering. Kathy L. Hudson et al., *Oversight of US Genetic Testing Laboratories*, 24 Nature Biotechnology 1083, 1083 (2006).

Obtaining a second opinion is critical because even the most qualified, highly skilled medical professional can make a mistake or differ in opinions. QuantialMD, *Physician Perspectives on Preventing Diagnostic Errors* 3 (2011), *available at* http://www.quantiamd.com/q-qcp/QuantiaMD_PreventingDiagnosticErrors_Whitepaper_1.pdf. A new report from QuantialMD found that almost half of 6,400 physicians surveyed said they encounter diagnostic errors—missed, late, or wrong diagnoses—at their practice at least monthly. *Id.* About two-thirds said that up to ten percent of misdiagnoses they have experienced have directly resulted in patient harm. *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." 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 (Apr. 2010) [hereinafter SACGHS 2010 Report], *available at* http://oba.od.nih.gov/oba/sacghs/ reports/SACGHS_ patents_report_2010.pdf. A sole provider of a medical service is simply not in the best interest of the public health. *See* Decl. of Debra Leonard, M.D., Ph.D., J.A. at 271–77. Since the implications of incorrect genetic test results are grave, it is imperative that patients not be prevented from seeking a second opinion.

C. Gene Patents Limit Access to Genetic Testing for Low-Income Patients Covered by Medicaid

Patents additionally create unique issues of access for low-income Medicaid recipients who need genetic tests. These problems are not limited to Myriad's BRCA1/2 test, but also arise with other genetic tests offered by patent rights holders. SACGHS 2010 Report, *supra*, at 42–44. Gaining access to genetic testing is also particularly

challenging for Medicaid patients because gene patents allow exclusive rights holders to place limits on the forms of insurance that they will accept. *Id.* at 43. 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." *Id.* 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.* (brackets in original). 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 [to them]." *Id.* at 44–45. A recent Kaiser Family Foundation State survey on preventive services for women under Medicaid, in which 48 states participated, noted that while all of the surveyed states cover mammograms, only "about half (30 states) cover BRCA testing and counseling services for women who are a higher risk for this genetic mutation associated with breast cancer." Kaiser Family Found., *State Coverage of Preventive Services for Women Under Medicaid: Findings from a State-Level Survey* 2 (2012), *available at* http://www.kff.org/womenshealth/upload/8330.pdf.

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. Unfortunately, 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.

J.A. at 121.

Access to genetic testing is also 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/mph

p439/Safety_Nets.htm (last visited Jan. 29, 2013).[2] Recent data 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 Jan. 24, 2013).[3] These tests are in excess of $3000 and for full range testing can exceed $4000. *See* Myriad Genetic Labs., Inc., *Advanced Beneficiary Notice of Non-Coverage*, *available at* http://www. myriad. com/lib/abn/Myriad-ABN.pdf. Those at risk for cancer often have no choice but to forgo potentially life-saving health care treatment because they lack either health care coverage or the resources to pay for genetic testing out-of-pocket.

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[2] *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 Population Survey* (2005), http://aspe.hhs.gov/ health/reports/05/uninsured-cps/index.htm#race.

[3] *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-enetics. html.

II. Human Genes and Isolated DNA Are Products of Nature and Not Patent Eligible.

The rationale for excluding human genes and genetic sequences rests upon the principles that:

> [L]aws of nature, natural phenomena, and abstract ideas are not patentable.

Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. __, 132 S. Ct. 1289, 1293 (2012) (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)).

The discovery of phenomena of nature, even when previously unknown, 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." (quoting Peter D. Rosenberg, Patent Law Fundamentals § 4 at 3 (1975)); *Diamond*, 450 U.S. at 185 (excluding "laws of nature, natural phenomena, and abstract ideas"). These categorical exclusions are soundly based on the idea that "[p]henomena of nature . . . mental processes, and abstract intellectual concepts are . . . the basic tools of scientific and technological work." *Gottschalk v. Benson*, 409 U.S. 63, 68 (1972); *see Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) ("manifestations of laws of nature [are] free to all men and reserved exclusively to none"); *Parker*, 437 U.S. at 593 n.15 (patentable inventions must not be "merely heretofore unknown," to avoid depriving the public of prior uses) (quoting Rosenberg, *supra*).

"In other words, natural phenomena, laws of nature, or abstract ideas, without more, are not considered to be 'useful arts.'" Edward C. Walterscheid, *"Within the Limits of the Constitutional Grant": Constitutional Limitations on the Patent Power*, 9 J. Intell. Prop. L. 291, 349 (2002).

These exclusions derive from the historic understanding that nature and science are the common heritage of mankind, free from appropriation by particular persons.

> If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea . . . . That ideas should freely spread from one to another over the globe, for the moral and mutual instruction of man, and improvement of his condition, seems to have been peculiarly and benevolently designed by nature, when she made them, like fire, expansible over all space, without lessening their density in any point . . . .

Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), *in* 13 The Writings of Thomas Jefferson 326, 333–34 (Albert Ellery Bergh ed., 1908).

In *Funk Bros.*, 333 U.S. at 132, the Court held that an inventor claiming a bacterial species that exhibited the property of mutual non-inhibition could not patent the bacteria, since it was merely a claim for a natural phenomena. *Id.* at 130. Nor was the

combining of six types of bacteria into one product—bacteria whose individual function had only been "discovered" and not "invented"— patentable. *Id.* at 132. As the Court noted:

> There is, of course, an advantage in the combination. . . . But a product must be more than new and useful to be patented; it must also satisfy the requirements of invention or discovery. The application of this newly-discovered natural principle to the problem of packaging of inoculants may well have been an important commercial advance. But once nature's secret of the non-inhibitive quality of certain strains of the species of Rhizobium was discovered, the state of the art made the production of a mixed inoculant a simple step. Even though it may have been the product of skill, it certainly was not the product of invention. There is no way in which we could call it such unless we borrowed invention from the discovery of the natural principle itself.

Id. at 131–32 (citations omitted).

Physical steps such as isolating and removing DNA cannot transform unpatentable natural phenomena into a patentable invention. Likewise in *American Wood-Paper Co. v. Fibre Disintegrating Co.*, 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." *Am. Wood-Paper*, 90 U.S. at 593–94.

In that case, American Wood-Paper sought to patent a supposedly "new" type of pulp that was better suited for the manufacture of paper than the then-existing pulp. *Id.* at 577. All pulp contains both cellulose and "intercellular matter," the latter of which must be removed to render the cellulose fit for being made into paper. *Id.* at 566. Up until this point, all pulp was removed by applying both chemical and mechanical treatment; however, American Wood-Paper managed to remove the intercellular matter using chemical means alone. *Id.* American Wood-Paper claimed that the pulp produced by mere chemical treatment alone was a "new manufacture," and thus, eligible for patent protection. *Id.* at 595.

The Court rejected the patent, holding that the new pulp was "not a new composition of matter." *Id.* at 593. The Court held as immaterial the fact that the new pulp was pure cellulose whereas the old pulp was only "approximately pure," i.e. it was still mixed with intercellular matter. *Id.* at 594.

Isolated human genes and DNA sequences are products of nature and are not patentable.

CONCLUSION

For the foregoing reasons, AARP respectfully urges the Court to grant the relief requested by petitioners and invalidate the patents.

Respectfully submitted,

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