No. 11-725

IN THE

Supreme Court of the United States

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 KALI N. MURRAY AND ERIKA R. GEORGE AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

Erika R. George
Of Counsel
University of Utah
S.J. Quinney College of Law
332 S. 1400 E., Rm. 101
Salt Lake City, UT 84112
(801) 581-7358

Kali N. Murray
Counsel of Record
Marquette University
Law School
1215 W. Michigan St.
Milwaukee, WI 53233
(414) 288-5486
kali.murray@mu.edu

Andrew F. Spillane
Of Counsel
3748 S. Austin St.
Milwaukee, WI 53207
(414) 769-9721

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INTEREST OF *AMICI CURIAE*

Kali N. Murray is an assistant professor of law at Marquette University Law School.[1] Before teaching at Marquette, she practiced law at Venable, LLP, where she focused on patent litigation. Drawing upon her experience as a litigator, she teaches courses in patent law, international intellectual property, and property law. She has concentrated her academic research agenda on the varied players enforcing, governing, and participating in patent law, whether citizens, businesses, or the USPTO as an administrative agency.

Erika R. George is a professor of law at the University of Utah S.J. Quinney College of Law. She has devoted her career to human rights advocacy, beginning as Articles Editor of the Harvard Civil Rights-Civil Liberties Law Review and including her service on the board of the American Civil Liberties Union of Utah. Before entering the academy, she practiced law at Jenner & Block in Chicago. She teaches constitutional law and civil procedure and has written extensively on

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[1] Counsel of record for all parties received notice at least 10 days prior to the due date of these *amici curiae*'s brief. Petitioners gave their blanket consent for *amici* to file briefs on December 15, 2011. Respondents have consented to the filing of this brief on December 29, 2011. No counsel representing any party to the case authored this brief in whole or in part, and no counsel or party made any monetary contribution to the preparation or submission of the brief.

civil rights issues, particularly their effects on women.

SUMMARY OF THE ARGUMENT

Petitioners suffer and will continue to suffer, injury from the overbreadth of Myriad's patent claims, creating an actual controversy sufficient for them to bring suit under the Declaratory Judgment Act. If this Court does not allow such petitioners to bring suit, gaps and thickets in patent law will remain, undermining inventors' ability to protect their ingenuity.

The United States Court of Appeals for the Federal Circuit's ("Federal Circuit") central failure below was to minimize the Petitioners' claimed injury under Section 101 of the Patent Act. In particular, the Federal Circuit failed to appreciate the significant threshold injury suffered by the Petitioners in their communication related to scientific, medical, and public health concerns. At its core, subject matter that is not patentable is aimed to keep information within a common storehouse of man, available to all, to be both accessed and exchanged freely. Thus, intellectual property principles are tethered to the First Amendment's right to give and receive information. Myriad's claims are directed at information so fundamental to medical science and research, that granting them a monopoly would freeze the free flow of basic information and violate First Amendment values.

We respectfully urge the Court to grant certiorari to clarify proper standing analysis for declaratory judgment patent suits, with particular

attention to the threshold injury under Section 101 of the Patent Act.

ARGUMENT

I. THE DECLARATORY JUDGMENT ACT SHOULD BE CONSTRUED TO PERMIT DIVERSE STAKEHOLDERS TO CHALLENGE INVALID PATENTS.

The Declaratory Judgment Act permits "any interested party" to seek a court's declaration of "rights and other legal relations" involved "[i]n a case of actual controversy." 28 U.S.C. § 2201(a) (2006). The Declaratory Judgment Act's remedial purposes are well understood. *See, e.g.*, *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007); 10B Charles Alan Wright, Arthur R. Miller, & Mary Kay Kane, *Federal Practice and Procedure* § 2751 (3d ed. 2011).

Less understood, however, is the Declaratory Judgment Act's specific relevance to patent law. The passage of the Declaratory Judgment Act ameliorated significant procedural deficiencies in patent litigation. The Patent Act of 1952 and its predecessors granted patentees' the power of initiative: that is, the power to bring suit for infringement. *See* 35 U.S.C. § 281 (2006). If a patentee declined to bring suit, the threat of a so-called "scarecrow" patent would linger, chilling innovation and competition alike. *See Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83, 96 (1993) ("Merely the desire to avoid the threat of a 'scarecrow' patent, in Learned Hand's phrase, may therefore be sufficient to establish jurisdiction under the Declaratory Judgment Act.")

(footnote omitted) (*quoting Bresnick v. United States Vitamin Corp.*, 139 F.2d 239, 242 (2d Cir. 1943)). Given the breadth and severity of these consequences, "[i]t is quite possible that in no other branch of the law has the Declaratory Judgment Act assumed such significance and magnitude as in the litigation of patent causes." Sidney W. Russell, *Some Patent Aspects of Declaratory Procedure*, 32 J. Pat. Off. Soc'y 504, 504 (1950) (footnote omitted).

Nevertheless, the Federal Circuit's decision below has once again failed to fulfill the remedial purposes of the Declaratory Judgment Act within patent law. This Court itself has admonished the Federal Circuit's declaratory judgment standing doctrines as recently as *MedImmune v. Genentech*, 549 U.S. 118 (2007). In that case, this Court required "all the circumstances" to be considered when determining whether a live controversy existed between the parties, an actual conflict that could be conclusively resolved through declaratory relief, as opposed to a merely advisory opinion. *MedImmune*, 549 U.S. at 127 (*quoting Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)); *cf. Muskrat v. United States*, 219 U.S. 346 (1911). In doing so, *MedImmune* rejected the Federal Circuit's test requiring a "reasonable apprehension" of a patent infringement suit to establish standing. *Id.* at 132-33 n.11.[2] Despite

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[2] The "reasonable apprehension" test at one time had two elements: "There must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity

this Court's express admonishment and the Federal Circuit's facial recognition of *MedImmune*, *e.g. Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 653 F.3d 1329, 1343 (Fed. Cir. 2011), the Federal Circuit's current declaratory judgment standing test reintroduces one element of the now-defunct "reasonable apprehension" test and refashioning another in a similar form. Megan M. La Belle, *Standing to Sue in the Myriad Genetics Case*, 2 Cal. L. Rev. Cir. 68, 83 (2011). In doing so, the Federal Circuit's decision below violated the letter of *MedImmune*—by refusing to consider "all the circumstances" attending justiciability—and the spirit of this Court's tradition of providing greater opportunities to challenge invalid patents. *See* cases discussed *infra* p. 8.

But the Federal Circuit has done more than return to a disfavored approach. The Federal Circuit has denied standing to persons harmed by the patents challenged in this case. As such, researchers will have their scientific inquiry limited, (Fed. Cir. App'x at A1038-A1041) physicians will not be able to discuss preventative medical testing with their patients, (*id.* at A1039) and patients will have less choice and control over

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which could constitute infringement or concrete steps taken with the intent to conduct such activity." *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1380 (Fed. Cir. 2004). Less than a year later, the Federal Circuit restricted standing all the more, recasting the "reasonable apprehension of suit" test into the "reasonable apprehension of *imminent* suit" test. *MedImmune*, 549 U.S. at 132 n.11 (*citing Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005).

their own health care outcomes (id. at A1043-A1046). More broadly speaking, the Federal Circuit's position will have a ripple effect on others wishing to challenge invalid patents. Invalid patents' deleterious effects on innovation and access to technology will persist, unchallenged and thus unchecked.

For these reasons, the Supreme Court should grant certiorari to reemphasize its long line of precedent against the Federal Circuit's persistent restrictions and address the society-wide public interest in a robust system for enforcing patent law's limits.

A. The Federal Circuit Persists in Failing to Recognize that Deleterious Patents Injure a Broader Set of the Patent System's Stakeholders.

Those interested in a properly functioning patent system are many and varied: scientists, researchers, and engineers creating advances in technology; manufacturers and designers implementing and vending these advances in the marketplace; and the consumers putting these inventions and discoveries to their own use. Just as these stakeholders benefit from patent policy functioning properly, they can suffer injury from invalid patents. And injury calls upon the courts to make the injured whole. *E.g. Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 163 (1803).

But the Federal Circuit's standing jurisprudence has fixated on competitive injury, at

the expense of the concrete and particularized harms diverse stakeholders that have "broader concerns" in invalid patents. Kali N. Murray, *Rules for Radicals: A Politics of Patent Law*, 14 J. Intell. Prop. L. 63, 77, 79 (2006) (*citing* Steven L. Winter, *The Metaphor of Standing and the Problem of Self-Governance*, 40 Stan. L. Rev. 1371, 1461 (1988)). Indeed, the Federal Circuit's refusal to grant standing to diverse stakeholders is pervasive. In the past, the Federal Circuit denied various plaintiffs' claims under the Administrative Procedure Act (APA) against the Commissioner of the USPTO, deciding that associations and individuals suing in one case had not alleged injuries within the "zone of interests" contemplated by the Patent Act. *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 937-38 (Fed. Cir. 1991). Post-grant reexamination proceedings were also closed to a third party requester in *Syntex (U.S.A.) Inc. v. USPTO*, 882 F.2d 1570, 1571 (Fed. Cir. 1989). These positions stem from numerous principles, whether patent law as a private law model or understanding that the main type of injury inflicted by patent law is competitor injury. *See* Murray, *supra*, at 77, 79 (*citing* Winter, *supra*, at 1410-11). In all events, the Federal Circuit's jurisprudential choices have, as a result, tightly bound third parties' rights to recourse for injuries caused by patents.

Contrary to the Federal Circuit's longstanding limitative approach to standing, this Court has moved in the opposite direction, favoring "authoritative testing of patent validity" and the

"removal of restrictions on those who would challenge the validity of patents." *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 344-45 (1971). For example, in *Altvater v. Freeman*, 319 U.S. 359, 363, 365 (1943), this Court held that "a decision of non-infringement . . . does not dispose of the counterclaim which raises the question of validity" in a case where a patent licensee acquiesced in paying royalties, though it did so "under protest." Likewise, in *Cardinal Chemical Co. v. Morton International*, 503 U.S. 83, 100 (1993), this Court held that an adjudication of patent noninfringement does not moot questions surrounding the noninfringed patent's validity. Among other reasons for reversing the Federal Circuit's decision to the contrary, this Court reiterated the "strong public interest in the finality of judgments in patent litigation." *Id.* To be sure, patent validity questions are inflected with "greater public importance" than infringement charges. *Id.* (*quoting Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327 (1945)).

Despite this Court's repeated calls to allow parties to challenge invalid patents—including the long-standing justiciability rule of considering "all the circumstances" when deciding whether a controversy exists, *id.* at 127 (*quoting Maryland Casualty Co.*, 312 U.S. at 273)—the Federal Circuit's decision below continues to impose limits on the circumstances that court deems relevant to declaratory judgment standing. From the infringement perspective, the Federal Circuit's

opinion below reaffirmed that standing cannot be had when a patentee has not engaged in affirmative acts related to its patents. *Myriad*, Case No. 10-1406, at 28 (*quoting Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1339 (Fed. Cir. 2008); *citing SanDisk Corp. v. Stmicroelectronics, Inc.*, 480 F.3d 1372, 1380-81 (Fed. Cir. 2007)). Under this rule, even parties apprehensive about infringement liability would be denied standing if the patent's owner lacked an enforcement history, allowing a patentee by its own conduct to engender the fears the Declaratory Judgment Act aimed to calm simply by keeping their right to sue "sheathed." *Arrowhead Industrial Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735 (Fed. Cir. 1988).

Reaching even further is the Federal Circuit decision's dismissive rejection of the patients' claims of injury. That court could not "see how the inability to afford a patented invention could establish an invasion of a legally protected interest for purposes of standing." *Myriad*, 653 F.3d at 1375 n.3. In that footnote, the Federal Circuit brushed aside an entire category of injury, denying parties like the patients here the chance to challenge patents restricting their access to new technology. Moreover, it constrains their ability to receive important information pertaining to health care determinations and compromises full and open communication between the parties and their health care providers.

Binding the Declaratory Judgment Act's remedial purpose removes yet another avenue for

interested parties to challenge invalid patents. In addition to the Federal Circuit's jurisprudence discussed above, the post-grant opposition proceedings set forth in the Leahy-Smith American Invents Act not only provide a limited time-frame in which to challenge patents, but they also have no bearing on patents currently in force. La Belle, *supra*, at 71 n.15 (*citing* Pub. L. No. 112-029, §§ 6, 35 125 Stat. 284, 299-313, 341 (2011)). As such, for some injured by invalid patents, the Declaratory Judgment is among their last chances for a remedy.

B. The Existence of Invalid Patents Stymies Innovation and Restricts Access to New Technology.

Declarations of invalidity do not find normative justification only by reason of a patent's invalidity in the abstract. These declarations carry practical significance. Invalid patents bring widespread harm by chilling otherwise legitimate activity in the scientific community and in the market.

The sheer number of patents currently in force can constrict further research and thus stymie innovation. Sometimes, the grant of inconsistent patents over similar subject matter can lead to conflicting rights to exclude, leading to an "anticommons." Michael A. Carrier, *Innovation for the 21st Century* 255-56 (2009) (*quoting* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Sci. 698, 699 (1998)). For example, some inventors may devise an improvement upon

an earlier invention, but a broader patent predating it may mean practicing the later-issued patent infringes the earlier one. *Rolls-Royce Ltd. v. GTE Valeron Corp.*, 800 F.2d 1101, 1110 n.9 (Fed. Cir. 1986); 5 Donald S. Chisum, *Chisum on Patents*, § 16.02[1][a] (Rev. Ed. 2010) (discussing "blocking patents"). Along the same lines, in fields such as the biotechnology and software development, industry participants must contend with research bottlenecks and patent thickets from too many patents, stifling further development. Robin Feldman & Kris Nelson, *Open Source, Open Access, and Open Transfer: Market Approaches to Research Bottlenecks*, 7 Nw. J. Tech. & Intell. Prop. 14 (2008); Robert Hunt & James Bessen, *The Software Patent Experiment*, Fed. Reserve Bank of Phil. Bus. Rev. 30 (Q3 2004).

Exacerbating patents' chilling effects are the broadly defined actions constituting infringement. With the exceedingly broad and amorphous definition of infringing use under 35 U.S.C. § 271 (2006), *see Bauer & Cie v. O'Donnell*, 229 U.S. 1, 10-11 (1913); *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282 (Fed. Cir. 2005); 5 Chisum, *supra*, § 16.02[4], nearly anyone can qualify as an infringer due to unauthorized use, even a competitor's customers, *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 484 (1964).

Simultaneously, the Federal Circuit has nearly nullified the experimental use defense, an out for researchers to test a patented invention as part of scientific inquiry without the impending threat of infringement liability. Carrier, *supra*, at 257-60.

Indeed, the Federal Circuit itself has expressly interpreted the experimental use defense "very narrowly." *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343 (Fed. Cir. 2000) (*citing Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984)). While Justice Story refused to punish researchers for engaging in scientific inquiry without the expectation of profit, *Whitemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813); *Sawin v. Guild*, 21 F. Cas. 554 (C.C.D. Mass. 1813), the Federal Circuit now will sanction scientific research conducted by a non-profit research university. *Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

In this case, numerous researchers stand ready to engage in testing to improve upon current *BRCA*2 and *BRCA*1 gene testing, but cannot do so with threats leveled at them by Myriad in cease-and-desist letters. (Fed. Cir. App'x at A1038-A1039.) Others researchers could evaluate gene testing results in a more cost-effective and time-efficient manner, but Myriad's patents currently prevent them from realizing this potential. (*Id.* at A1039-A1040.) And one genetic counselor, Elsa W. Reich, claims that "[h]aving only one laboratory prevents independent confirmation of test results and interpretation of the meaning of variants of uncertain significance." (*Id.* at A1041.)

Beyond stifling innovation, threats of infringement suits chilling manufacturing, distribution, and sale in the market restrict the abilities of consumers to obtain meaningful access to patented inventions. *See O'Reilly v. Morse*, 56

(15 How.) 62, 113 (1853) (fearing that a patent covering the use of a certain energy would deny "the public . . . the benefit of" future technological improvements on patented technology "without the permission of this patentee"). Two of the patient-plaintiffs here, Lisbeth Ceriani and Patrice Fortune, have felt this harm firsthand. (Fed. Cir. App'x at A1043, A1045.) Despite their health coverage under a low-income Medicaid insurance program, Myriad denied their request for testing by refusing their insurance. (*Id.*) Both Ms. Ceriani and Ms. Fortune lack the financial resources to pay for this testing out of pocket. (*Id.*)

To stem the widespread harms that invalid patents cause, rigorous enforcement of patent validity becomes necessary. But at this point, patent law's primary enforcers are businesses practicing patented inventions, their competitors, and non-practicing entities. For them, enforcing patents to maintain the system's overall integrity and further the public policy favoring innovation may carry secondary significance, with their balance sheets and other business concerns influencing their choices to litigate patents' validity. *Cf.* Eric C. Wrzesinski, Comment, *Breaking the Law to Break into the Black: Patent Infringement as a Business Strategy*, 11 Marq. Intell. Prop. L. Rev. 193 (2007). As such, large gaps in patent enforcement may emerge. Such gaps may leave otherwise invalid patents—and the chilling effects that accompany them—unchecked.

This Court has an opportunity in this case to clarify the need for reliable legal mechanisms to

challenge invalid patents currently in force.

II. THE COMMON LAW EXCEPTIONS TO PATENTABLE SUBJECT MATTER EXPRESS FIRST AMENDMENT VALUES THAT REQUIRE RIGOROUS ENFORCEMENT TO PROTECT THE FLOW OF TECHNOLOGICAL INFORMATION.

Declaratory relief to deem certain patents invalid finds special justification when the underlying reason for invalidity is the lack of patentable subject matter under 35 U.S.C. § 101. These exceptions for the basic building blocks of nature and scientific inquiry are effected with First Amendment values in the free flow of information, both a speaker's right to communicate technical information and the listener's right to receive and benefit from that information. *See, e.g.*, *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976).

As such, this Court should recognize that section 101's exceptions for patentable subject matter is tethered to the First Amendment's right to receive information. Accordingly, this Court should grant certiorari to give meaning to these First Amendment values—values with public consequences reverberating throughout the scientific community and affecting consumer choice—and their proper role within patent law's governance structure.

A. Exceptions to Patentable Subject Matter Aim to Facilitate Further Innovation and Broaden the Public's Access to the Fruits of Research and Development.

Axiomatic in patent law is that nearly "anything under the sun" can be eligible for patent protection. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (*quoting* S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952)). Excepted from this expansive definition of patentable subject matter are the "laws of nature, physical phenomena, and abstract ideas." *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (*quoting Chakrabarty*, 447 U.S. at 309) (quotation marks omitted). These exceptions date back to English patent cases, including *Nielson v. Harford*, 151 Eng. Rep. 1266 (1841). This Court likewise recognized these exceptions in two cases from the 1850s, *Le Roy v. Tatham*, 55 U.S. (14 How.) 156 (1852), and *O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1853).

This Court has continued to apply these exceptions even with the passage of new patent statutes. *See, e.g.*, *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) (following cases predating the Patent Act of 1952). *Gottschalk* provides one example of a meaningful way in which courts can augment the innovation policies advanced by the Patent Act of 1952.

Aside from the common law exceptions' historical role alongside various patent statutes,

these exceptions serve vital theoretical practical purposes. One such purpose speaks to the patent laws' internal consistency: patents grant inventors property rights for their endeavors, and numerous federal court decisions before the Patent Act of 1952 suggested that no one truly "invents" natural occurrences or scientific principles. *E.g. In re Norris*, 179 F.2d 970 (C.C.P.A. 1950); *Reynolds v. Emaus*, 87 F. Supp. 451 (W.D. Mich. 1949).

In like sense, the common law exceptions to patentable subject matter reflect another principle running deep in intellectual property law: that one cannot claim property in ideas and nature. *See, e.g.*, *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. (20 Wall.) 498, 507 (1877) ("[a]n idea of itself is not patentable."); *Le Roy*, 55 U.S. at 175 ("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."); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) ("[T]he heat of the sun, electricity, or the qualities of metals[] are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none."); *International News Service v. Associated Press*, 248 U.S. 215, 234 (1918) ("[T]he information respecting current events contained in the literary production[] is not the creation of the writer, but is a report of matters that ordinarily are *publici juris*.").

Failing to recognize or enforce section 101's exceptions would also bring about widespread public injury. These injuries may manifest in two

ways. First, this Court recognized how patents covering laws of nature and abstract ideas can slow down technological development in *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852), and *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 113 (1853). In *O'Reilly*, one of the claims in a patent on electrical telegraphs included the use of electromagnetic energy itself. *Id.* at 112. Such a claim, this Court noted, swept too broadly. *Id.* at 113. Patenting the telegraph's energy "shuts the door against inventions of other persons." *Id.* In like sense, this Court in *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 174-75 (1852), expressed concern that, should a patent claim cover a process's result or effect, that claim "would prohibit all other persons from making the same thing by any means whatsoever. This, by creating monopolies, would discourage arts and manufactures, against the avowed policy of the patent laws." *Id.* at 175.

Second, this Court feared restrictions on the public's use of the stuff of nature and abstract ideas. In *O'Reilly*, this Court noted that a patent on the energy giving a device its power would effectively block others from using improvements upon that technology. 56 U.S. at 113. In this Court's words, the improvement's "inventor could not use it, nor the public have the benefit of it, without the permission of this patentee." *Id.*

In summary, these exclusions ensure that patents do not create a property right to exclude others from technological use and development's most basic building blocks. *See Gottschalk*, 409 U.S. at 67.

B. First Amendment Values Inform Exceptions to Patentable Subject Matter and Instruct that a Vibrant Marketplace of Ideas Requires Open Access to the Storehouse of Knowledge.

Exceptions to patent eligibility for "laws of nature, physical phenomena, and abstract ideas," *Bilski*, 130 S. Ct. at 3225, are consistent with the core First Amendment values that aim to protect access to information and ideas in order to promote the exchange of information and ideas. Thus, the common law exceptions to patentable subject matter are analogous to the idea-expression dichotomy, 17 U.S.C. § 102(b) (2006), and the fair-use exception within patent law, § 107, that provide similar protection within copyright law of First Amendment values.

As this Court explained in *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 390 (1967), "It is the purpose of the First Amendment to preserve an uninhibited marketplace of ideas in which truth will ultimately prevail, rather than to countenance monopolization of that market, whether it be by the Government itself or a private licensee." *Id.* The persistence of a patent granted on ineligible subject matter works to undermine the purpose of the First Amendment because it serves to create a monopoly that in effect removes essential information from the marketplace of ideas. It is inconsistent with "the spirit of the First

Amendment [to] contract the spectrum of available knowledge." *Griswold v. Connecticut*, 381 US 479, 482 (1965).

The matters covered by this Court's exceptions to patentability are "part of the storehouse of knowledge of all men." *Funk Bros.*, 333 U.S. at 130. The storehouse is a protected space for information that belongs in the public sphere necessary to facilitate the proper functioning of the marketplace to which the First Amendment ensures access. It is therefore appropriate that the storehouse remain stocked with basic staples. This Court has instructed that Congress cannot authorize the issuance of patents "whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available," *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 5-6 (1966), and has cautioned against enlarging the patent monopoly "without regard to the innovation, advancement or social benefit gained thereby," *id.*

In *Gottschalk v. Benson*, 409 U.S. 63, 67-68 (1972), this Court explained that "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." These basic tools of scientific and technological work are storehouse staples. They are properly excluded from patent protection. Granting patent protection to such ineligible subjects would potentially impede rather than promote scientific progress. *See Laboratory Corp. of America Holdings v. Metabolite*

Laboratories, Inc., 548 U.S. 124 (Breyer, J. dissenting). Essentially, it is contended by Petioners here that the challenged patents are invalid because they grant Myriad a monopoly over currency in the marketplace of ideas.

Storehouse staples are "free to all men and reserved exclusively to none." *Funk Bros.*, 333 at 130, reflecting an appreciation for the importance of ensuring access to information in the creation and dissemination of knowledge protected by the First Amendment.

The First Amendment presupposes that freedom of expression is "not only an aspect of individual liberty—and thus a good unto itself—but also is essential to the common quest for truth and the vitality of society as a whole." *Bose Corp. v. Consumers Union of United States, Inc.*, 466 U.S. 485, 503-04 (1984). The patent system may grant a private monopoly but does so "conditioned by a public purpose." *Blonder-Tongue*, 402 U.S. at 344. The public interest in maintaining a storehouse to facilitate fair trade in scientific inquiry implicates First Amendment concerns.

Improvidently issued patents on the basic tools of scientific and technological work impede progress and work against the public interest and values protected by this Court's First Amendment jurisprudence. The enterprise of engaging in scientific expression merits First Amendment protection as this Court and others have acknowledged the value of scientific injury. *Cf. Miller v. California*, 413 U.S. 15, 24 (1973) (holding works should be evaluated in their entirety for

"literary, artistic, political or *scientific* value") (emphasis added); *see also Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 446-47 (2d Cir. 2001) ("[T]he First Amendment protects scientific expression and debate just as it protects political and artistic expression."). Raiding the storehouse risks the result of reducing the quality and quantity of scientific inquiry.

> "In science, the relation between experiment and free thought is familial. Although the pursuit of knowledge is not the summum bonum but only one good among many, one hesitates to impede it or to set a precedent that might be used to inhibit other socially controversial precedent."

Stephen Breyer and Richard Stephen Breyer and Richard Zeckhauser, *The Regulation of Genetic Engineering*, 1 MAN AND MEDICINE 1-12 (1975).

C. The Federal Circuit Failed to Appreciate the Totality of the Circumstances Which Includes the Collective Plaintiffs' Claims Under the First Amendment and the Implications of Patent Eligibility Exceptions.

The extent to which the challenged patents serve to limit the high value protected First Amendment communicative conduct engaged in by the Plaintiffs merits this Court's consideration. The ability of the physician and research organization plaintiffs to engage in scientific inquiry, information exchange, and innovation was

has been restricted. The ability of patients to obtain information about their health has been similarly circumscribed. The challenged patents have operated as a restraint on protected activities that raises cognizable First Amendment issues that support standing.

Because the challenged patents are so broad and sweeping as to potentially include the basic tools of scientific inquiry more properly left in the storehouse of human knowledge, research efforts of the plaintiffs have been stymied. It is appropriate within the context of a Section 101 "threshold" inquiry of eligibility to ensure that the governmental grant of a patent does not unduly limit the expressive claims of others. This Court has expanded the availability of standing where restraints exist that risk "chilling" the exercise of First Amendment rights. *Virginia v. American Booksellers, Ass'n, Inc.*, 484 US 383,384 (1988) (granting pre-enforcement standing and exception to "injury in fact" requirement where booksellers allege an infringement of the First Amendment rights of book buyers). This Court has also altered the traditional rules governing standing in the First Amendment context where plaintiffs challenge overly broad restrictions on expressive conduct because "it has long been recognized that the First Amendment needs breathing space." *Broadrick v. Oklahoma*, 413 U.S. 601, 612 (1973). Where a statute is overbroad litigants are permitted to challenge it, whether or not their own rights are violated, because the existence of an overbroad statute may prevent others from

engaging in constitutionally protected speech. *Id.* A patent granted on ineligible subject matter presents similar challenges.

The record demonstrates that plaintiffs have refrained from certain activities fearing infringement action by Myriad. (Fed. Cir. App'x at A1284, A2773-A2774, A2979-A2980). Courts have even recognized injury sufficient to sustain standing in the First Amendment context where plaintiffs claim that they have forgone expression so as to avoid the consequences of enforcement. *Pittman v. Cole*, 267 F.3d 1269, 1283 (11th Cir. 2001) ("Plaintiffs do not have to expose themselves to enforcement in order to challenge a law. Rather, an actual injury can exist when the plaintiff is chilled from exercising her right to free expression or forgoes expression in order to avoid enforcement consequences. In such an instance, which is what is alleged here, the injury is self-censorship." *Id.* Great weight is given to the danger of self-censorship because of the potential 'chilling' effect a measure may have on protected activity. *LSO, Ltd. v. Stroh*, 205 F.3d 1146, 1156 (9th Cir. 2000) ("We have noted that the tendency to find standing absent actual, impending enforcement against the plaintiff is stronger "in First Amendment cases, '[f]or free expression-of transcendent value to all society, and not merely to those exercising their rights-might be the loser." (citations omitted.)

Courts have emphasized the importance of the free flow of truthful, non-misleading information within the doctor-patient relationship. *See Trammel v. United States*, 445 U.S. 40, 51 (1980)

("[T]he physician must know all that a patient can articulate in order to identify and to treat disease; barriers to full disclosure would impair diagnosis and treatment."); *Conant v. Walters*, 309 F.3d 629, 636 (9th Cir.2002) ("An integral component of the practice of medicine is the communication between a doctor and a patient. Physicians must be able to speak frankly and openly to patients."); *see also Sorrell v. IMS Health Inc.*, 131 S.Ct. 2653, 2664 (2011) ("A consumer's concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue.... That reality has great relevance in the fields of medicine and public health, where information can save lives.").

The Supreme Court has rejected restraints on freedom of expression that would place physicians in an "undesired and uncomfortable straightjacket." *Planned Parenthood of Missouri v. Danforth*, 428 U.S. 52, 67 (1976). Because it remains the responsibility of physician to ensure that appropriate information is conveyed to their patients based on the condition of the patient, *City of Akron v. Akron Center for Reproductive Health*, 462 U.S. 416, 443 (1983) the Supreme Court has consistently cleared "obstacles in the path of the doctor" upon whom patients are entitle to rely for advice in connection with health care decisions. Id. (citing *Whalen v. Roe*, 429 U.S. 589, 604 n. 33 (1977)). In the physician-patient relationship, patients expect that physicians will not without relevant information regarding care options and consequences. *Rust v. Sullivan*, 500 U.S. 173, 218

(Blackmun, J., dissenting) ("[I]n our society, the doctor-patient dialogue embodies a unique relationship of trust . . . each of us attaches profound importance and authority to the words of advice spoken by the physician."). These cases are instructive because the plaintiffs seeking to share information about the predisposition to breast or ovarian cancer allege they have been constrained by an improvidently granted federal patent that permits Myriad to enforce its legal interests that are adverse to those of the plaintiffs. (*See, e.g.*, Fed. Cir. App'x at A1284.) While researchers and physicians would like to offer gene testing, they are ultimately constrained by patent restrictions. (*See, e.g.*, *id.* at A149; A151; A1284.) Patients are left to make decisions on their own from a position of uncertainty without the benefit of full information because of various barriers to accessing the genetic testing offered exclusively through Myriad. (*See, e.g.*, *id.* at A20-A25; A1594-A1595; A1598-1599; A1602-1603; A1606-1607; A1610-1611; A1614-1617; A160; A2652; A2937-2938; A3065; A3072-3073; A3077; A2851).

While potential cancer suffers may seek information from sources other than their physicians, any such sources would be "poor substitutes for a medical doctor; information from chat rooms and tabloids cannot make up for the loss of individualized advice from a physician with many years of training and experience." *Conant,* 309 F.3d at 644. For researchers there likely is no substitute for the natural phenomenon removed from the storehouse of knowledge by the challenged

patents. A patent invalid by reason of ineligibility cannot effectively be "invented around."

These limits placed on the Plaintiffs' freedom of expression presented by continued validity of Myriad's patents establish a substantial controversy between the adverse legal interests between the parties of sufficient immediacy and reality to warrant judgment satisfying the standard set forth by this Court in *MedImmune*, 549 U.S. 118. The Federal Circuit failed to consider the totality of the circumstance. In this case there are fundamental First Amendment values under threat as well as important public issues at stake. Litigation is the primary means by which patent quality is monitored. Therefore, the declaratory judgment action is an importance device in ensuring patent validity. La Belle, *supra*, at 71. Appropriately, *MedImmune* provides a legal standard that facilitates standing for this challenge. *Id.* By failing to apply the proper standard the Federal Circuit leaves few in position to protect the storehouse of knowledge.

CONCLUSION

Patent policy depends on its caretakers. When invalid patents stifle the patent system's goals, it falls on patent law's enforcers to police its boundaries. This Court's generalized review is therefore warranted and necessary.

Respectfully submitted,

Kali N. Murray
Counsel of Record
Marquette University Law School
1215 W. Michigan St.
Milwaukee, WI 53233
(414) 288-5486
kali.murray@mu.edu

Erika R. George
Of Counsel
University of Utah
S.J. Quinney College of Law
332 S. 1400 E., Rm. 101
Salt Lake City, UT 84112
(801) 581-7358

Andrew F. Spillane
Counsel for Amici Curiae
3748 S. Austin St.
Milwaukee, WI 53207
(414) 769-9721