

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

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INTEREST OF *AMICI CURIAE*

Kali N. Murray is an assistant professor of law at Marquette University Law School¹ 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, intellectual property, 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 United States Patent and Trademark Office (“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

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 October 12, 2012. Respondents consented to the filing of this brief on October 26, 2012. 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.

teaches constitutional law and civil procedure and has written extensively on gender equality.

SUMMARY OF THE ARGUMENT

The public's interest in the constitutional patent system is varied. An individual patent, like an invalid statute, can impose significant harm on a range of social interests. Among these social harms may be the communicative barriers imposed on the physician-patient relationship, the communicative barriers placed on researchers who seek to use the relevant information contained within a patent, and the communicative barriers placed on advocates who seek to ensure public health by disseminating information to impacted communities. Individual and organizational petitioners suffer and will continue to suffer, immediately significant injury from the wide scope of Myriad's patent claims, creating an actual controversy sufficient for them to bring suit under the Declaratory Judgment Act ("DJA").

The United States Court of Appeals for the Federal Circuit ("Federal Circuit"), therefore, erred below in two key respects. First, the Federal Circuit ignored this Court's clear and direct guidance in *MedImmune v. Genentech*, 549 U.S. 118 (2007), that a claim of patent invalidity must be examined under "all the circumstances" relevant to determining whether a live controversy exists under the Declaratory Judgment Act. *MedImmune*, 549 U.S. at 127

(citing *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941); cf. *Muskrat v. United States*, 219 U.S. 346 (1911)). Second, the Federal Circuit has failed to recognize the significant threshold injuries suffered by the individual and organizational plaintiffs engaged in scientific, medical and public health pursuits when the ability to communicate crucial information and engage in inquiry is compromised. These specific injuries arise because Myriad's patents have received protection where none should exist. An authoritative testing of the validity of these patents under the common law exceptions to Section 101 of the Patent Act of 1952 ("Patent Act") is necessary to end the injury imposed upon individual and organizational plaintiffs who find that their ability to give and receive information under the First Amendment has been improperly impeded.

We respectfully urge the Court to grant certiorari to clarify proper standing analysis for declaratory judgment patent suits, with particular attention to the individual and organizational standing afforded to plaintiffs under Section 101 of the Patent Act.

ARGUMENT

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

Those interested in a properly functioning patent system are many and varied: researchers engaging in cutting-edge scientific inquiry; manufacturers and designers implementing and selling these advances in the marketplace; and consumers putting these inventions and discoveries to use. While these diverse stakeholders benefit from the existence of disclosed valid patents, they can also be harmed by the existence of invalid patents.

The Federal Circuit's decision below erroneously constrains the needs of these diverse stakeholders. Its announced test imposes an improperly restrictive threshold injury on individual and organizational plaintiffs. Specifically, the Federal Circuit requires a declaratory judgment plaintiff to establish "injury in fact" by alleging both "(1) an affirmative act by the patentee related to the enforcement of his patent rights, *SanDisk Corp. v. STMicrolabs, Inc.*, 480 F.3d 1372, 1380-81 (Fed. Cir. 2007), and (2) meaningful preparation to conduct potentially infringing activity," *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 880 (Fed. Cir. 2008).

The effects of the Federal Circuit's "affirmative act" test are far-reaching and profound. First, the "affirmative act" test appears to permit standing for

only one category of impacted declaratory judgment plaintiffs, those individual plaintiffs impacted by the patentee's aggressive affirmative enforcement of his or her patent. Such a narrow test for standing undermines the remedial purposes of the Declaratory Judgment Act, which suggests that a flexible inquiry into "totality of circumstances" in order to determine whether or not declaratory relief is appropriate. Second, the "affirmative act" test appears to entirely preclude organizational standing within patent infringement context, by requiring that a declaratory judgment assessment be tied to the actions of an individual patentee, rather than the organization's goals or mission. Therefore, this Court's review is warranted.

A. The Declaratory Judgment Act Mandates a Flexible Case-Specific Inquiry As To Whether a Controversy Exists Between Relevant Parties.

The Declaratory Judgment Act permits "any interested party" to seek a court's declaration of "rights and other legal relations" whether or not "further relief is or could be sought" "[i]n a case of actual controversy." 28 U.S.C. § 2201(a) (2006). This Court requires that such a determination under the Declaratory Judgment Act requires "all the circumstances" to be considered when determining whether a live controversy exists between the parties, so to ensure an actual conflict exists that can be conclusively resolved through declaratory relief as opposed

to a merely advisory opinion. *MedImmune*, 549 U.S. at 127 (quoting *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). This determination under the Declaratory Judgment Act must meet the constitutional requirements of Article III of the U.S. Constitution. Therefore, a declaratory judgment plaintiff must prove that standing to bring the claim, among other constitutional requirements, such as ripeness and mootness. See generally *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992).

The requirement that a declaratory judgment plaintiff must demonstrate an “affirmative act” of enforcement on the patent by the patent holder in order to show an “injury in fact” has been incurred is erroneous both under this Court’s relevant precedent and under the remedial structure of the Declaratory Judgment Act. The Court’s precedent in *MedImmune* mandates a full review of the relevant factual circumstances of each case, *on its own terms*. This flexible inquiry is the appropriate approach in determining whether or not a declaratory judgment plaintiff has constitutional standing. The Federal Circuit’s substitution, of an inflexible test that curtails inquiry into all the circumstances of a case directly contradicts this Court’s determination in *MedImmune*. 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. The “affirmative act” test is not only incompatible with this

Court’s precedent; it is also incompatible with the role of the Declaratory Judgment Act in preserving a role in patent litigation for diverse patent stakeholders.

Our previous brief, Br. of Kali N. Murray and Erika R. George, 2012 WL 166994 (January 13, 2012), emphasized that the Declaratory Judgment Act serves to balance out a significant procedural advantage granted to a patent owner under § 281 of the Patent Act, 35 U.S.C. § 281 (2006), which allows the patentee to initiate an infringement claim. Consequently, under § 281 only the patentee has the power to initiate suit against potential infringers.

The Declaratory Judgment Act therefore exists as an integral alternative vehicle within the context of patent infringement because it permits diverse kinds of injury-in-fact to be alleged by diverse categories of declaratory judgment plaintiffs. The remedial structure of the Declaratory Judgment implies an inquiry into the standing of a respective plaintiff is not necessarily dependent on equivalent standing under the Patent Act.² For instance, in *United Food & Commercial Workers Local Union Number 137, et al. v. Food Employers Council Inc.*, 827 F.2d 519, 522 (9th Cir. 1987), the Court of Appeals for the Ninth Circuit (“Ninth Circuit”) noted that standing for a declaratory judgment plaintiff can exist independently of the

² An inquiry into appropriate subject-matter jurisdiction, however, is linked to the related statute. *Shelby Oil v. Phillips Petroleum*, 339 U.S. 667, 672 (1950).

“antitrust injury” required under Section 4 of the Clayton Act. The Court suggested that reading was possible as the textual commitments of the Declaratory Judgment Act create a declaratory remedy, which is available “whether or not further relief . . . could be sought.” *Id.* at 523 (*citing* 28 U.S.C. § 2201(a)).

If, as the Federal Circuit desires, the “affirmative act” test is adopted as the sole test for establishing standing for declaratory judgment plaintiffs, a plaintiff would have to wait for the patentee to act in order to trigger a sufficient injury-in-fact under the Declaratory Judgment Act. This will force diverse declaratory judgment plaintiffs into a singular procedural posture, by always requiring them to allege that the patentee has acted in some way to harm the declaratory judgment plaintiff. This development would undermine the safety valve served by the Declaratory Judgment Act within the patent infringement. A singular test for standing based on the affirmative acts of declaratory judgment plaintiffs should not be the only test for standing of the declaratory judgment plaintiffs.³ Rather such a test, ideally, would be

³ This is not to suggest, however, that the “affirmative act” test is without its own infirmities. For instance, its requirement of a narrow requirement that the patentee has undertaken an affirmative action may unnecessarily restrict standing where “a patent in a particular field creates a present risk to the ongoing economic activities of participants in that field.” Br. of Intellectual Property Professors as Amici Curiae, 2012 WL 3643738, *3 (August 23, 2012).

one among many, undertaken with a precise eye on any given set of circumstances.

A flexible inquiry into constitutional standing is especially appropriate within the context of patent law. Because of patent law’s diversity of legal sources, including statutory, common law, and constitutional law, a range of patent disputes can be heard under the Declaratory Judgment Act. The typical declaratory judgment plaintiff does not want to be considered an infringer of a given patent and in a patent dispute will often allege that declaratory relief is needed since its potentially infringing acts will prompt the patentee to sue under § 281. The typical declaratory judgment plaintiff, therefore, suffers from a “mirror injury” insofar as the plaintiff’s injury reflects the same type of injury suffered by patentee under § 281 – the harm caused by the existence of a potentially infringing act.

This is not to say that a typical declaratory judgment plaintiff is the *only* party that might be injured by the existence of an invalid or improperly granted patent. The remedial structure of the Declaratory Judgment Act permits a declaratory judgment plaintiff to allege harm that differs from a mirror injury that is raised by a potential infringer. In fact, this Court has recognized another type of injury suffered by a declaratory judgment plaintiff: those instances where there needs to be an “authoritative testing of patent validity” and with its accompanying “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). In those cases, it is evident that a patent can be invalid even where it is not infringed. This Court has suggested that a claim of validity can exist independently even after an infringement claim has been dismissed. 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 non-infringement does not moot questions surrounding the non-infringed patent’s validity.

This Court’s precedent is illustrative of why the Declaratory Judgment Act may serve as an important vehicle to undertake an independent inquiry into the validity of a patent. Thus, it seems likely that a declaratory judgment plaintiff may challenge existence of an invalid patent under the Declaratory Judgment Act even where a claim for infringement does not exist under § 271 of the Patent Act. An inquiry into the validity of patent offers a way to examine issues of “greater public importance” in a way not afforded to a mere infringement claim, which seeks to adjudicate claims between two private parties. *Cardinal Chemical Co. v. Morton International*, 503 U.S. 83 at 100 (quoting *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327 (1945)).

A required demonstration of mirror injury, therefore, is not appropriate in every circumstance. Rather, in those cases where authoritative testing of a patent’s validity is required, it might be helpful to see the injury-in-fact suffered by a declaratory judgment plaintiff is equivalent to one harmed by an invalid statute: the mere existence of such patent can potentially threaten the legal interests of the harmed individual. See George W. Pugh, *The Federal Declaratory Remedy: Justiciability, Jurisdiction and Related Problems*, 6 Vand. L. Rev. 87, 88 (1952) (“It is suggested that the cases dealing with the interest requirement in fact break down into two broad groups: (1) those actions in which the decision will be of little if any immediate significance beyond the parties to the action and those in privity with them, and (2) those actions in which the decision will be of immediate significance beyond the immediate parties, as for example, actions involving the constitutionality of statutes or the validity of patents.”).

Such claims, of course, are not without limit. A standing inquiry into a patent may turn on the same issues that confront a court that addresses whether a declaratory judgment plaintiff has been harmed by an invalid statute: “the appropriateness of the issues for decisions by courts and the hardship of denying judicial relief.” See *Joint Anti-Fascist Committee v. McGrath*, 341 U.S. 123, 154 (1951) (Frankfurter, J., concurring). Indeed, not every patent will have an immediate significance beyond the particular concerns of the respective parties. However, some

patents – like the patents at issue here, which claim in part, genetic materials that are the basic subject matter of human existence – will have immediate significance to a range of social interests. A patent may have immediate significance when, as with those patents at stake here, such patents cause harm by limiting access to the basic building blocks of nature and scientific inquiry, or by blocking 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).

The injuries at stake in this declaratory judgment action are not abstract. In particular, in our previous brief, we noted that the existence of Myriad’s invalid patents impose significant social costs on communications embodied within their respective patents. Some individual plaintiffs suffered immediately significant harm in their ability to access health care and services. For instance, 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.*)

Other individual plaintiffs suffer from the inability to discuss relevant medical information. Individual physicians and plaintiffs are 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-A1599; A1602-A1603; A1606-A1607; A1610-A1611; A1614-A1617; A160; A2652; A2937-A2938; A3065; A3072-A3073; A3077; A2851).

These harms, of course, impact the individual plaintiffs, but they also cause harms that are of immediate significance to others that are not involved in this case. The grant of the Myriad patents has imposed a collective social tax in excess of their individual usefulness, and therefore, provides an important example of why “harm” in patent law in all of its statutory, constitutional, and common-law forms, must be served by a flexible inquiry under the Declaratory Judgment Act.

B. The Declaratory Judgment Act Flexible Inquiry Should Afford Standing to Individual and Organizational Plaintiffs.

The law on organizational standing is well established and affords organizations two types of standing. “An association has standing to bring suit on behalf of its members when its members would otherwise have standing to sue in their own right, the interests at stake are germane to the organization’s purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.” *Friends of the Earth, Inc. v. Laidlaw Environmental Services*, 528 U.S. 167, 181 (2000). Further, “an organization has standing on its own behalf if it meets the same standing test that applies to individuals. The organization must show actual or threatened injury in fact that is fairly traceable to the alleged illegal action and likely to be redressed by a favorable court decision.” *Spann v. Colonial Village, Inc.*, 899 F.2d 24, 27 (D.C. Cir. 1990).

The Federal Circuit’s reliance on the “affirmative acts” test is, therefore, in error because it essentially precludes a claim of organizational standing under the Declaratory Judgment Act in two key respects. First, the Federal Circuit’s “affirmative acts” test mandates that declaratory judgment plaintiffs can claim standing only in those instances where the patentee has undertaken steps that suggest they are likely to sue for potential infringement. As discussed, *supra*, this precludes a claim of relief for

those individuals harmed by the existence of an invalid patent. It follows, then, that any organization representing one of these individual members, would not have standing under this restrictive test. Second, in the same respect, this restrictive test would preclude independent organizational standing insofar as such organizations would not be able to claim that their organizational mission was harmed by the existence of an invalid patent. For example, the claims of an entity like Breast Cancer Action, a national education and activist organization that exercises its First Amendment rights when it seeks to “transform breast cancer from a private medical crisis to a public health emergency” could not be brought. (A1402) Similarly, the Boston Women’s Health Book Collective engages in education and advocacy and publishes information about public health and genetic analysis. (A1042-A1043).

Central to the missions of both these organizations is communicating information that pertains to the health and welfare of the public. Genetic counselors within these organizations would serve as the messengers of crucial health information, were their First Amendment rights not curtailed by the existence of an invalid patent. See, e.g., Alexandra Minna Stern, *Telling Genes: The Story of Genetic Counseling in America* (2012) (assessing the role of genetic counseling in public health communications). The Federal Circuit offers no independent reason for why public

interest organizations within patent law should be constrained in so crippling a manner.

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. It is, therefore, appropriate in those circumstances that a court examine whether the declaratory judgment plaintiff has been impacted by the existence of the invalid patent. Maintaining the existence of this possibility under the Declaratory Judgment Act is vital since the Federal Circuit has denied various plaintiffs' claims under the Administrative Procedure Act 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), and closed access to a third-party requester in *Syntex (U.S.A.) Inc. v. USPTO*, 882 F.2d 1570, 1571 (Fed. Cir. 1989). For third parties to have any recourse against the injuries caused to their rights by invalid patents, the Declaratory Judgment Act must

be allowed to operate as the crucial safety valve that this Court has indicated it is.

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