

No. 2010-1406

In The United States Court of Appeals for the Federal Circuit

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, THE AMERICAN COLLEGE OF
MEDICAL GENETICS, THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY,
THE COLLEGE OF AMERICAN PATHOLOGISTS, HAIG KAZAZIAN, MD,
ARUPA GANGULY, PhD, WENDY CHUNG, MD, PhD, HARRY OSTRER, MD,
DAVID LEDBETTER, PhD, STEPHEN WARREN, PhD, ELLEN MATLOFF, M.S.,
ELSA REICH, M.S., BREAST CANCER ACTION, BOSTON WOMEN'S HEALTH BOOK
COLLECTIVE, LISBETH CERIANI, RUNI LIMARY, GENAE GIRARD, PATRICE
FORTUNE, VICKY THOMASON, and KATHLEEN RAKER,

Plaintiffs-Appellees,

v.

UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendant,

and

MYRIAD GENETICS, INC.,

Defendant-Appellant,

and

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

Defendants-Appellants.

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

**APPELLEES' RESPONSE TO APPELLANTS' SUGGESTION OF MOOTNESS,
OR, IN THE ALTERNATIVE, MOTION TO REMAND**

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INTRODUCTION

Defendants-appellants Myriad Genetics *et al.* (Myriad) have filed Appellant's Suggestion of Mootness, or, In the Alternative, Motion to Remand. This Suggestion amounts to little more than a repeat of their prior Petition for Panel Reconsideration dated Aug. 29, 2011 (Dkt. Entry (D.E.) 264). Plaintiffs-appellees AMP *et al.* (plaintiffs) replied to that petition on September 15, 2011. This Court denied Myriad's petition on September 16, 2011 (D.E. 268). Because Myriad raises no new arguments, this response largely tracks (and in some cases is identical to) plaintiffs' prior response, adding only where necessary to respond to a few minor assertions in the current submission.

At the time this case was briefed and argued before this Court, plaintiff Dr. Harry Ostrer was employed at New York University (NYU). A1462-1504. On the basis of his professional capabilities and intentions and his contacts with defendant Myriad, this Court found that Dr. Ostrer had standing. *Ass'n for Molecular Pathology v. PTO*, 653 F.3d 1329, 1344 (Fed. Cir. 2011), *vacated*, 132 S. Ct. 1794 (2012). The Court essentially relied on two facts: First, Dr. Ostrer is ready, willing and able to engage in infringing testing. Dr. Ostrer "seeks to undertake specific *BRCA*-related activities---*BRCA* diagnostic testing" and he "not only has the resources and expertise to immediately undertake clinical *BRCA* testing, but also states unequivocally that he will immediately begin such testing." *Ass'n*

for Molecular Pathology, 653 F.3d at 1345-46. Second, Dr. Ostrer alleges “an injury traceable to Myriad” both because he received a letter from Myriad threatening him (*id.* at 1344-45; A1494) and because he was aware that “Myriad was asserting its patent rights against other similarly situated parties.” (*Ass’n for Molecular Pathology*, 653 F.3d at 1345).

Dr. Ostrer left his position at NYU effective August 29, 2011. He assumed a new position as Director of Genetic and Genomic Diagnostics at Montefiore Medical Center in New York. He is also a Professor of Pathology and Genetics at the Albert Einstein College of Medicine. In his new position, Dr. Ostrer continues to “seek[] to undertake BRCA diagnostic testing.” Ostrer Supplemental Decl. ¶¶ 3-8, 10, Sept. 12, 2011 (attached to Appellees’ Answer to Appellants’ Pet. for Panel Reh’g, Sept. 14, 2011). In addition, in his new position, he has “the resources and expertise to immediately undertake clinical BRCA testing.” *Id.* ¶ 10. Finally, he “will immediately begin such testing” if the patents in this case are invalidated. *Id.*

Dr. Ostrer will not begin such testing in his new position (as he did not at NYU) because he was personally threatened by Myriad’s letter. A1494. As a result of that letter, Dr. Ostrer remains convinced that if he were to engage in BRCA clinical testing, Myriad would sue him for infringement. Ostrer Supplemental Decl. ¶¶ 11-12. Dr. Ostrer also will not begin such testing because

he remains aware that Myriad has asserted its patent rights against similarly situated parties. *Id.*

ARGUMENT

I. THIS COURT HAS ALREADY TWICE DENIED MYRIAD'S LEGAL ARGUMENT AND THE LACK OF ANY NEW ARGUMENT OR FACT DICTATES A THIRD DENIAL.

Because Dr. Ostrer continues to have the intention and ability to infringe, the only legal question raised by the Suggestion is whether he no longer has an “injury traceable to Myriad” because the threatening letter he received was addressed to him personally at the time he was an NYU employee.

If Myriad is correct that the only threat made in Myriad's letter was to NYU as an entity, not Dr. Ostrer, then Dr. Ostrer never had individual standing.

However, this Court's holding precludes that interpretation; because NYU has not been a plaintiff, the Court's holding was that Myriad's letter to Dr. Ostrer was sufficient to give him standing. Moreover, the Court indicated that Drs. Kazazian and Ganguly would have had standing but for their uncertain commitment to conduct testing, even though Myriad treated them similarly to Dr. Ostrer.

Myriad's threatening letters were directed at Dr. Kazazian and his and Dr. Ganguly's employer, the University of Pennsylvania, and its lawsuit was filed against their employer. *Ass'n for Molecular Pathology*, 653 F.3d at 1339-40, 1346; A1378-1459. Once again, the implication of the Court's decision is that the

distinction Myriad is now attempting to draw between the plaintiffs and their employers is without merit.

In addition, this Court denied Myriad's Petition for Panel Rehearing. Because the standing/mootness issues raised by Myriad are jurisdictional, the Court could not have denied the Petition if it had had merit. That denial represents the second time this Court rejected Myriad's argument.

Myriad offers no new facts in its Suggestion. It does cite the Montefiore website apparently to cast doubt on Dr. Ostrer's declaration. Appellants' Suggestion of Mootness, or in the Alternative, Mot. to Remand at 19, May 30, 2012, D.E. 283. The version of the website cited was outdated and the current website reinforces the accuracy of Dr. Ostrer's supplemental declaration, which was submitted after he had begun working at Montefiore. *See Laboratory Services*, Montefiore Medical Center, <http://www.montefiore.org/pathology-services-clinical-laboratory> (last visited June 4, 2012). Myriad also asks for the opportunity to do discovery in the district court on the facts contained in Dr. Ostrer's declaration, but does not provide one single fact or piece of evidence to suggest that Dr. Ostrer's declaration is inaccurate. Absent such a proffer, discovery would not be warranted.¹ "The 'heavy burden of persua[ding]' the

¹ Myriad's hint that it wants to re-argue redressability based on the existence of other patent claims should also be rejected. *See* Suggestion at 19-20. It was persuasively rejected by this Court the last time it was made. *Ass'n for Molecular*

court” that a case is moot “lies with the party asserting mootness.” *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000) (quoting *United States v. Concentrated Phosphate Exp. Ass'n*, 393 U.S. 199, 203 (1968)). See also *Dey Pharma, LP v. Sunovion Pharms. Inc.*, 677 F.3d 1158, 1165-66 (Fed. Cir. 2012). Myriad has not met that burden.

II. UNDER THE PANEL’S DECISION, PLAINTIFFS HAVE STANDING.

A. Dr. Ostrer

The standard articulated by the panel in this case appears to be that a plaintiff cannot have declaratory judgment standing unless the patent holder “directed any letters or other communications . . . at them.” *Ass’n for Molecular Pathology*, 653 F.3d at 1340. Myriad argues that it did not direct a letter to Dr. Ostrer, but only to NYU. The letter, of course, is addressed to Dr. Ostrer. A1494. The notion that he was free to infringe so long as he went elsewhere, but NYU as an entity and its employees were not free to infringe, strains credulity.²

Pathology, 653 F.3d at 1347-48. Myriad still has not identified any patent claims that would block the activities the plaintiffs seek to undertake, and plaintiffs do not concede that any claims would. *Teva Pharm. USA, Inc. v. Eisai Co.*, 620 F.3d 1341, 1347-48 (Fed. Cir. 2010), *vacated on other grounds*, 131 S. Ct. 2991 (2011). In addition, Myriad’s argument reinforces plaintiffs’ standing. The not-so-hidden assertion is that “if the Court declares the challenged claims invalid, we’ll sue the plaintiffs on other claims.”

² Myriad’s assertion that its subjective intent was based on NYU as “the true intended recipient of Myriad’s license offer” (Suggestion at 13) not only rings hollow, but is contrary to this Court’s holdings that the relevant question is an

The Court's rationale for its "directed any ...communications at them" standard is not entirely clear. If it is based on the view that such communication demonstrates that the patent holder is aware of the plaintiffs' actions and considers them infringing, then that rationale applies to Dr. Ostrer today. Although Myriad professes not to know what actions Dr. Ostrer is taking, his declarations while he was still at NYU and after he went to Montefiore establish that he has the ability to and would engage in precisely the actions that led to Myriad's threatening letter. If the court's rationale is based on the view that Dr. Ostrer's unwillingness to infringe is motivated by a threat of suit, rather than some other factor, that rationale also applies to Dr. Ostrer today. Regardless of the rationale for the Court's standard, there is nothing in the Court's earlier decision that suggests that an individual's standing is conclusively dependent on his employment status, particularly when a change in employment status represents no change in intent or ability to infringe.

Myriad also repeats its hint that it might not sue to enforce its patents, citing a webpage that purports to identify labs that, according to Myriad, "are conducting BRCA clinical diagnostic testing today without a license agreement from Myriad." Suggestion at 17 n.4. It is not surprising that Myriad relegates this hint to a

objective one, not a subjective one. "The test [for declaratory judgment jurisdiction in patent cases], however stated, is objective" *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988). "Indeed, it is the objective words and actions of the patentee that are controlling." *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 979 (Fed. Cir. 1993).

footnote and refuses to be more specific about any infringement. Even the most casual reading of the webpage provides no evidence of lack of a license and many of the labs listed do have licenses or other agreements with Myriad. *E.g.*, A2466. None of the labs even purports to be doing the full sequencing of the BRCA1/2 genes that is the core of this case. Moreover, plaintiffs twice sought a covenant not to sue, but Myriad refused to provide it. A1256-58; A3364; Pls.-Appellees' Opp. to Defs.-Appellants' Mot. for a 60-Day Extension at 2, D.E. 34.

B. Ms. Reich

Even if Myriad is correct that only NYU and its employees have standing, then plaintiff Elsa Reich has standing. She was and is an NYU employee. A1564-1583. To the extent NYU has been threatened, as Myriad asserts, she has been threatened. She has “the immediate capability and desire to” induce infringement and would do so were it not for the patents. A1570. *See, e.g., Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1365 (Fed. Cir. 2004).

C. Ms. Matloff

The panel also asserted that “[n]one of the plaintiffs besides Drs. Kazazian, Ganguly, and Ostrer, allege that Myriad directed any letters or other communications regarding its patents at them.” *Ass’n for Molecular Pathology*, 653 F.3d at 1340. That is simply incorrect and contrary to the factual findings of the district court. Plaintiff Ellen Matloff’s declaration makes clear that she

personally had conversations with Myriad in which she was told by Myriad that she and geneticists at Yale would violate Myriad's patents if they performed tests that were not being offered by Myriad, and which she wanted to perform. A7721-22; A1552-53. This panel held that a plaintiff had standing if Myriad directed "any ... communications regarding its patents at them." Even under that standard, Ms. Matloff has standing.

III. THE COURT SHOULD REVIEW AND REVERSE ITS CONCLUSION THAT THE OTHER PLAINTIFFS DO NOT HAVE STANDING.

A. ACMG

Although the panel found that plaintiff Dr. Ostrer had standing, the court did not address the standing of the organizational plaintiff American College of Medical Genetics and Genomics (ACMG),³ of which Dr. Ostrer is a member. A7697. The undisputed record reflects that gene patenting is germane to ACMG's purpose. A7693-94. Pursuant to well-established Supreme Court law, ACMG therefore has organizational standing. *Warth v. Seldin*, 422 U.S. 490, 511 (1975).

B. The Other Plaintiffs

In *MedImmune, Inc. v. Genentech, Inc.*, the Supreme Court declared that the correct standing analysis in patent cases, as in all other Article III cases, "is

³ As plaintiffs note in their letter to the Clerk also filed today, the formal name of ACMG has changed from American College of Medical Genetics to American College of Medical Genetics and Genomics. The acronym has not changed and nothing in the corporate structure of the organization has changed.

whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” 549 U.S. 118, 127 (2007) (citation and internal quotation marks omitted); *see also Holder v. Humanitarian Law Project*, 130 S. Ct. 2705, 2717 (2010) (citing *MedImmune* in a non-patent case for the proposition that plaintiffs need not await actual enforcement before bringing a lawsuit or to have a credible fear of enforcement). *MedImmune* instructs that bright line rules and steadfast requirements are inappropriate when analyzing a plaintiff’s standing in a declaratory judgment action. 549 U.S. at 127. Yet, this Court imposed just such a rule in concluding that plaintiffs lacked standing unless they were personally threatened by Myriad. The Court found:

Myriad’s active enforcement of its patent rights forced Dr. Ostrer, *as well as every other similarly situated researcher and institution*, to cease performing the challenged *BRCA* testing services Myriad’s enforcement efforts *eliminated all competition* [N]othing in the record suggests that *any* researcher or institution has successfully attempted to compete with Myriad, or that Myriad has in any way changed its position with regard to its patent rights.

Ass’n for Molecular Pathology, 653 F.3d at 1346 (emphasis added). The court then inexplicably held that these facts did not amount to an “injury traceable to Myriad” and amounted to “suffering an attenuated, nonproximate, effect from the existence of a patent,” for all of the plaintiffs other than Dr. Ostrer. *Id.* at 1345-48.

It is difficult to reconcile a holding that all of the plaintiffs have been “forced to cease” their activity as a result of Myriad’s actions and that the effect of Myriad’s actions was to “eliminate all competition” with a holding that the effect of Myriad’s actions was “attenuated, non-proximate,” and insufficient to create standing. Furthermore, the idea that a plaintiff cannot have standing unless a patent holder “directed any letters or other communications regarding its patents at them,” *id.* at 1340, is contrary to numerous decisions of the Supreme Court that parties may bring challenges even if they have not been personally threatened by those who enforce the requirement they seek to challenge.

In *MedImmune*, the Supreme Court held that this Court’s prior standing rules were contrary to precedent including *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239 (1937), “where jurisdiction obtained even though the very reason the insurer sought declaratory relief was that the insured had given no indication that he would file suit.” 549 U.S. at 132 n.11. This holding was consistent with many other decisions from that Court. *Doe v. Bolton*, 410 U.S. 179, 188 (1973) (finding that physicians have standing “despite the fact that the record does not disclose that any one of them has been prosecuted, or threatened with prosecution, for violation of the State's abortion statutes”); *Virginia v. Am. Booksellers Ass’n, Inc.*, 484 U.S. 383, 393 (1988) (“We are not troubled by the pre-enforcement nature of this suit. The State has not suggested that the newly enacted law will not be enforced, and

we see no reason to assume otherwise. We conclude that plaintiffs have alleged an actual and well-founded fear that the law will be enforced against them.”). Indeed, as *American Booksellers* suggests, the burden is on the enforcers to say that they will not enforce, a burden Myriad in this case has studiously refused to meet. *See also Vt. Right to Life Comm., Inc. v. Sorrell*, 221 F.3d 376, 382 (2d Cir. 2000).

This Court has upheld standing for pre-enforcement challenges to a statute. *Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1370 (Fed. Cir. 2007).

In that case, this Court said:

The injury need not have been already manifested. “A plaintiff who challenges a statute must demonstrate a realistic danger of sustaining a direct injury as a result of the statute's operation or enforcement. But one does not have to await the consummation of threatened injury to obtain preventive relief. If the injury is certainly impending that is enough.” *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979) (internal citations and quotations omitted).

Id. Although plaintiffs here are challenging the validity of a privately held patent, not the validity of a publicly passed statute, that is a difference without a distinction. The elements required for Article III standing do not differ based on the public or private nature of the potential enforcer. A party can show a substantial controversy based on impending injury resulting from an invalid law or patent. A requirement that the law or patent be enforced against a party before they can seek judicial alleviation of that injury is contrary to the law.

The panel’s rule that a party does not have declaratory judgment standing unless he or she has been personally threatened by a patent holder is even more restrictive than this Court’s prior “reasonable apprehension” test, rejected by the Supreme Court in *MedImmune*. A person or entity can have a “reasonable apprehension” based on actions taken against others. If everyone who engaged in an infringing activity was sued, it would be irresponsible for others contemplating infringement not to feel a “reasonable apprehension.” It is error for the Court to adopt a new test that is more restrictive than the one rejected by the Supreme Court as too narrow. If the proper test is applied, based on the findings that all of the plaintiffs have been “forced to cease” activities as a result of Myriad’s actions that “eliminated all competition” and that “nothing has changed,” each of the plaintiffs has standing.

CONCLUSION

Because Plaintiffs have standing, the Court should reject Myriad's Suggestion and deny its motion.

Dated: June 7, 2012



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CERTIFICATE OF INTEREST

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

Association for Molecular Pathology; American College of Medical Genetics and Genomics; American Society for Clinical Pathology; College of American Pathologists; Haig Kazazian, MD; Arupa Ganguly, PhD; Wendy Chung, MD, PhD; Harry Ostrer, MD; David Ledbetter, PhD; Stephen Warren, PhD; Ellen Matloff, M.S.; Elsa Reich M.S.; Breast Cancer Action; Boston Women's Health Book Collective; Lisbeth Ceriani; Runi Limary; Genae Girard; Patrice Fortune; Vicky Thomason; and Kathleen Raker.

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

Same as above.

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

None.

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

American Civil Liberties Union Foundation (Christopher A. Hansen; Sandra S. Park; Lenora M. Lapidus; Aden Fine); Public Patent Foundation (PUBPAT), Benjamin N. Cardozo School of Law (Daniel B. Ravicher; Sabrina Y. Hassan).



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CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of June, 2012, I caused the original and three true and correct copies of the foregoing Appellees' Response to Appellants' Suggestion of Mootness, or, in the Alternative, Motion to Remand to be mailed to the Court via UPS overnight; two copies to be served upon counsel for Appellants via UPS overnight; and one true and correct copy of the Response to be served upon the counsel of record listed below via first-class United States mail.

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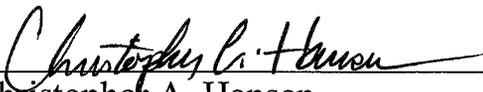
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