No. 11-725

IN THE

Supreme Court of the United States

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, ET AL.,

Petitioners,

—v.—

MYRIAD GENETICS, INC., ET AL.,

Respondents.

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

REPLY TO BRIEF IN OPPOSITION

Daniel B. Ravicher
Sabrina Y. Hassan
Public Patent Foundation (PUBPAT)
Benjamin N. Cardozo School of Law
55 Fifth Avenue, Suite 928
New York, NY 10003

Christopher A. Hansen
Counsel of Record
Steven R. Shapiro
Sandra S. Park
Aden J. Fine
Lenora M. Lapidus
American Civil Liberties Union Foundation
125 Broad Street
New York, NY 10004
(212) 549-2500
chansen@aclu.org

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THIS CASE IS AN APPROPRIATE AND IMPORTANT VEHICLE FOR ADDRESSING THE FEDERAL CIRCUIT'S ERROR IN CONCLUDING THAT HUMAN GENES ARE PATENTABLE AND THAT STANDING DOCTRINE IN PATENT CASES IS UNIQUE.

In their Brief in Opposition, Respondents Myriad Genetics *et al.* (Myriad) offer a flurry of arguments to suggest that the Court should deny the Petition. Not only do none of those arguments have merit, many are implicitly contradicted by positions taken by Myriad and its *amici* in the lower courts.

Myriad argues that this Court will be embroiled in a cumbersome argument concerning the standing of petitioner Harry Ostrer, the plaintiff that the Federal Circuit found to have standing. BIO at 27-28. Respondents note that Dr. Ostrer recently moved from one hospital where he directed genetic research and clinical practice (NYU) to another hospital where he continues to direct genetic research and clinical practice (Montefiore). Respondents do not mention that they raised this issue in a Motion for Panel Rehearing in the Federal Circuit. The Circuit requested petitioners respond. Petitioners responded with a declaration by Dr. Ostrer that said, in part:

> 4. At the Human Genetics Program and Molecular Genetics Laboratory at NYU, "that I direct[ed], my staff and I engage[d] in both research and clinical practice relating to genetic related susceptibility to disease." A 1464. As Director of Genetics and Genomic Diagnostics at Montefiore Medical

> Center, which I direct, my staff and I engage in both research and clinical practice relating to genetically related susceptibility to disease.
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> 5. At NYU, "I ha[d] the capability and desire" to "provide patients with the results of BRCA1/2 related genetic screening for the susceptibility to breast cancer. A 1464. I have the same capability and desire at Montefiore. …
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> 8. At NYU, I had "all of the personnel, expertise, and facilities necessary to do various types of sequencing of the BRCA1 and BRCA2 genes and I [had] the strong desire for my lab to provide such sequencing services." A 1466. At Montefiore, I have all of the personnel, expertise and facilities necessary to do various types of sequencing of the BRCA1 and BRCA2 genes and I have the strong desire for my lab to provide such sequencing services.

Suppl. Decl. of Harry Ostrer, dated Sept. 12, 2011, attach. to Pls.'-Appellees' Answer to Defs.'-Appellants' Pet. for Panel Reh'g, Sept. 14, 2011, *Ass'n for Molecular Pathology v. U.S.P.T.O.*, 653 F.3d 1329 (Fed. Cir. 2011)(No. 2010-1406). Myriad argues that Dr. Ostrer nevertheless does not have standing because the letter threatening him for infringing Myriad's patents was sent to him at an NYU address, not at a Montefiore address. Dr. Ostrer's declaration also addressed this argument.

> 12. I am aware that Myriad has argued that the letter I received should be considered as directed solely at NYU and its employees and not at me. I cannot reconcile that argument with the fact that the letter was addressed to me by name. It is inconceivable to me that I could have moved to a different job, engaged in the exact same activity, and been certain that Myriad would take no action. I felt personally threatened then and I continue to feel so today.

Id. As a result of that declaration, the Federal Circuit denied Myriad's Motion for Panel Rehearing. Order, September 16, 2011. That Myriad continues to advance that argument in this Court highlights the narrow standing rules applied by the Federal Circuit, which are inconsistent with this Court's holding in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), and which led the Federal Circuit to improperly deny standing to the other plaintiffs in this case. *See* Pet. at 31-35. If anything, therefore, Myriad's standing argument simply reinforces the need for this Court to grant Question 2 presented by the Petition.

Myriad also raises a series of arguments suggesting that this case represents an inappropriate vehicle to decide the Questions Presented. Those arguments are equally without merit. In some cases, Myriad does not mention that its argument was raised and rejected by the Federal Circuit.[1] In other

[1] Compare BIO at 29 (plaintiffs cannot obtain meaningful relief because they challenged only some of Myriad's patent claims), with Pet.App. at 37-8 (plaintiffs can obtain meaningful relief

instances, Myriad does not mention the extensive evidence contradicting its assertions.[2] And in some instances, Myriad makes arguments that are unsupported by the record and that are simply wrong.[3]

Underlying all of these and similar arguments made by Myriad is the implicit assertion that the issues in this case are not very important. That

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and "Myriad has failed to direct us to any specific unchallenged claim that will" prevent meaningful relief).

[2] Compare BIO at 30 (research papers have been published on BRCA1/2), with Pet.App. at 170a-178a and Fed.Cir.App. at A7271(Myriad's patents have impeded research; the number of papers published is misleading because it simply lists papers in which the genes have been mentioned.) *See also* Brief of American Medical Association et al. as *Amici Curiae* in Support of Petitioners, Jan. 10, 2012 at 14-15; *Amici* Brief of the National Women's Health Network, et al. in Support of Petition for Writ of Certiorari, Jan. 11, 2012, at 8-10; Brief of *Amicus Curiae* Information Society Project at Yale Law School Scholars in Support of the Petition, Jan. 13, 2012 at 9-20.

[3] Compare BIO at 25 (publication of the human genome sequence renders the case unimportant for the future) with Pet. App. at 126-29 and *e.g. Amici* Brief of the National Women's Health Network et al. in Support of Petition for Writ of Certiorari, Jan. 11, 2012 at 6-20 (women are being and will continue to be harmed). *See also* M. Garber et al., "Closing Gaps in the Human Genome Using Sequencing by Synthesis," *Genome Biol.* 2009; 10(6) R60 EPub 2009 Jun 2. http://www.ncbi.nlm.nih.gov/pubmed/19490611 (gaps in genome identification remain)(viewed January 19, 2012). It also ignores that patents on genes are still being sought and granted. See *e.g.* U.S. Patent 7,928,212 (issued April 19, 2011). Finally, it ignores Myriad's own statements that gene patents remain enormously important. *E.g. Myriad Genetics Acquires Exclusive Rights to RAD51C Gene,* Myriad Genetics (January 18, 2012), http://investor.myriad.com/releasedetail.cfm?ReleaseID=640654 (Myriad press release bragging about purchase of new gene patents)(viewed January 19, 2012)

argument is strikingly contradicted by numerous assertions made by Myriad and its *amici* in the lower courts. *See e.g.* Second Corrected App. at A3440, *Ass'n for Molecular Pathology v. U.S.P.T.O.*, 653 F.3d 1329 (Fed. Cir. 2011)(No. 2010-1406)(Fed. Cir. App.) (Myriad Defendants' District Court Memorandum of Law) (a ruling for plaintiffs "would…effectively unravel the foundation of the entire biotechnology industry…"); *Id.* at A3467 (a ruling for plaintiffs would be "disastrous for an entire industry"); Brief for Appellants at 3-4, *Ass'n for Molecular Pathology, supra*, Oct. 22, 2010 ("If this judgment is not reversed… valuable future developments [in "identifying and curing genetic disorders and other diseases"] will slow or cease…"). The vast number of *amicus curiae* briefs that Myriad assembled in the Federal Circuit attest to Myriad's view of the importance of this case.[4] Pet. App. at 3a-7a.

In short, it is simply too late for Myriad to now argue that this case is unimportant. This Court should grant the petition to address the issues that (until now) both parties agree are of enormous importance.

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[4] *See e.g.* Brief of *Amicus Curiae* Boston Patent Law Association in Support of Defendants-Appellants and Reversal of Summary Judgment, Oct. 29, 2010 at 1, *Ass'n for Molecular Pathology, supra*, Oct. 22, 2010, (if plaintiffs prevail, it will "hinder the development of better diagnostics and therapies, cripple the biotechnology industry, and discourage innovation generally"); *id.*at 19 ("The BPLA views this case not just as a narrow question of whether certain isolated DNA claims are patentable but more broadly as an attack on the patent system itself.")

CONCLUSION

For the reasons stated above and in the petition, a writ of certiorari should be granted to review the judgment of the Federal Circuit in this case.

Respectfully submitted,

Christopher A. Hansen
Counsel of Record
Steven R. Shapiro
Sandra S. Park
Aden J. Fine
Lenora M. Lapidus
American Civil Liberties Union Foundation
125 Broad Street
New York, N.Y., 10004
(212) 549-2500
chansen@aclu.org

Daniel B. Ravicher
Sabrina Y. Hassan
Public Patent Foundation (PUBPAT)
Benjamin N. Cardozo School of Law
55 Fifth Avenue, Suite 928
New York, NY 10003

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