

No. \_\_\_\_\_

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IN THE  
**Supreme Court of the United States**

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THE ASSOCIATION FOR MOLECULAR PATHOLOGY, ET AL.,  
*Petitioners,*

—v.—

MYRIAD GENETICS, INC., ET AL.,  
*Respondents.*

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

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**PETITION FOR A WRIT OF CERTIORARI**

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## QUESTIONS PRESENTED

Many patients seek genetic testing to see if they have mutations in their genes that are associated with a significantly increased risk of breast or ovarian cancer. Respondent Myriad Genetics obtained patents on two human genes that correlate to this risk, including any naturally occurring mutations of those genes, on the theory that simply by removing (“isolating”) the genes from the body, they have invented something patentable. Petitioners are primarily medical professionals who routinely use standard genetic testing methods to examine genes, but are prohibited from examining the human genes that Myriad claims to own. This case therefore presents the following questions:

1. Are human genes patentable?
2. Did the court of appeals err in adopting a new and inflexible rule, contrary to normal standing rules and this Court’s decision in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), that petitioners who have been indisputably deterred by Myriad’s “active enforcement” of its patent rights nonetheless lack standing to challenge those patents absent evidence that they have been personally and directly threatened with an infringement action?

## **PARTIES TO THE PROCEEDINGS**

The petitioners are the Association for Molecular Pathology, American College of Medical Genetics, 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. The respondents are Myriad Genetics, Inc., and in their official capacity as directors of the University of Utah Research Foundation, 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. The United States Patent and Trademark Office (PTO) was dismissed as a defendant by the district court and that ruling was not appealed. Accordingly, the PTO is not a respondent in this Court.

## **RULE 29.6 CORPORATE DISCLOSURE STATEMENT**

Petitioners do not have any parent corporations, and no publicly held company owns 10 percent or more of the stock of any petitioner.

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## OPINIONS BELOW

The opinion of the United States Court of Appeals for the Federal Circuit, App. at 1-112a, is reported at 653 F.3d 1329 (Fed. Cir. 2011). The district court opinion granting summary judgment to plaintiffs/petitioners and denying summary judgment to defendants/respondents, App. at 113-238a, is reported at 702 F. Supp. 2d 181 (S.D.N.Y. 2010). An earlier opinion of the district court, App. at 239-306a, denying the motion to dismiss based, in part, on standing is reported at 669 F. Supp. 2d 365 (S.D.N.Y. 2009).

## JURISDICTIONAL STATEMENT

The Court of Appeals decision in this case was issued on July 29, 2011. Both parties filed petitions for panel rehearing. The court denied the petition by plaintiffs Association for Molecular Pathology *et al.* on September 13, 2011, and the petition of defendants Myriad *et al.* on September 16, 2011. This petition is thus timely. Jurisdiction is conferred by 28 U.S.C. § 1254(1).

## STATUTORY AND CONSTITUTIONAL PROVISIONS

35 U.S.C. § 101 provides: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

The First Amendment of the United States Constitution provides that:

“Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.”

### STATEMENT OF THE CASE

1. This case challenges the patenting of human genes. More specifically, it challenges patents awarded to Myriad Genetics<sup>1</sup> on two genes, known as BRCA1 and BRCA2 because mutations of those genes correlate with an increased risk of hereditary breast and ovarian cancer. App. at 19a. Myriad claims exclusive control over the genes once they have been “isolated” – that is, removed from the body and other cellular material. Myriad and other gene patent holders have gained the right to exclude the rest of the scientific community from examining thousands of naturally-occurring human genes and to prevent patients’ access to their own genetic information. The practical consequence of these patents is that Myriad has the authority to stop standard clinical testing of and research on its genes. For those at risk of hereditary cancer, the effect is to prevent second opinions and to block access to alternative and potentially more comprehensive tests and lower cost options.

The BRCA1 and BRCA2 genes exist in the body of every single person. *See* App. at 119a. For

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<sup>1</sup> Myriad obtained the patents at issue with others, including the University of Utah Research Foundation, which is an owner or co-owner of each of the challenged patents. App. at 129a. They have acted jointly throughout this litigation.

many patients, knowing whether their genes contain the harmful mutations is essential to making informed medical decisions. App. at 159-60a. Myriad did not develop the methods by which geneticists look at or “isolate” the BRCA1 and BRCA2 genes. App. at 151-53a. Those methods, which were well-known and are used by geneticists to sequence thousands of other human genes on a daily basis, *id.*, are not the subject of this lawsuit. Myriad’s patents on the genes, however, prevent clinicians from using those methods to examine anyone’s BRCA1 and BRCA2 genes.

Myriad defends its patents on the grounds that those patents cover only “isolated” genes, and that “isolated” genes are distinguishable from genes in the body. Three of the four judges who have issued opinions in this case (the District Court judge and three Court of Appeals judges each writing separate opinions) found that “isolated” genes were functionally identical to genes in the body (the fourth judge did not express an opinion, asserting that this fact was irrelevant). Three of the four judges also found that “isolated” genes were virtually identical structurally to genes in the body (the fourth asserted that an insignificant chemical change was transformative). Notwithstanding these findings, and notwithstanding this Court’s repeated holdings that products and laws of nature are not patentable, a split Federal Circuit ruled that Myriad’s gene patents were valid, reversing the district court.

2. Every human body contains DNA. Genes are segments or fragments of DNA that determine, in part, the structure and functions of the body. App. at 138-44a. They are created naturally. App. at 139-

42a. Through naturally-occurring processes in the body, genes produce proteins (or polypeptides) and those proteins do the work of the body. *Id.* Genes vary from one individual to another. Genetic alterations or variations can be inherited or can occur after birth, but in both instances they come about naturally. App. at 141-42a. Variants can appear to be unimportant, correlate with an increased risk of disease or disorder (“mutations”), or have unknown significance (“variant of unknown significance”). *Id.* The significance of the variant is purely a function of nature. App. at 151a.

In the context of BRCA1 and BRCA2, certain genetic mutations have been correlated with a much higher risk of cancer. “Women with BRCA1 and BRCA2 mutations face up to an 85% cumulative risk of breast cancer as well as an up to 50% cumulative risk of ovarian cancer...The existence of BRCA1 and BRCA2 mutations is therefore an important consideration in the provision of clinical care for breast and/or ovarian cancer.” App. at 159a.

In order to provide effective treatment to patients and to research a wide range of diseases and conditions, including cancer, pathologists, clinical laboratory scientists, and other medical professionals conduct genetic testing for clinically significant alterations. App. at 151-53a. There are a variety of methods by which medical professionals can examine genes. *Id.* Basic methods involve extracting or “isolating” the DNA, which removes the DNA from the cell and associated proteins and randomly fragments it. Second Corrected App. Vol. VI at A7036-39, *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed.

Cir. 2011) (No. 2010-1406). The standard process of isolation does not result in DNA fragments that do not exist naturally in the body. *Id.* It simply makes a person's genetic information more accessible for sequencing by medical professionals. *Id.* Thousands of medical professionals, including many of the plaintiffs, isolate and sequence genes daily, and the processes by which isolation and sequencing are done are not at issue here. App. at 151-53a.

At the end of the process, the medical professional has a long string of four letters (A, C, T, and G) that correspond to the four nucleotides that make up DNA and genes. App. at 138a, 141-42a. The structure, function, and sequence of the nucleotides are created entirely by nature. *Id.* The medical professional looks to see if there are variants, *e.g.*, whether natural processes have caused there to be a C where a T would normally be. App. at 141-42a.

This is what Myriad does when it examines patients' BRCA1 and BRCA2 genes looking for variants. Its process is not unique. What is unique is its exclusive control over people's genetic information as a result of the patents it has been granted for BRCA1 and BRCA2, preventing other clinicians from accessing these genes for testing.

After completing its genetic tests, Myriad issues a report that essentially says: We have examined the genes obtained (or "isolated") from your blood sample. Because they are identical to the genes in your body, we can say with assurance that you do (or do not) have a variant. App. at 151-53a, 160a. The report then informs the patient: Based on the medical literature, this variant does (or does not)

mean you have an increased risk of breast or ovarian cancer (or we do not know what the significance of the variant is). *Id.* If the “isolated” genes patented by Myriad were not identical to the genes in the body, Myriad could not use the “isolated” genes to provide genetic information to patients.

3. This lawsuit began in 2009 with the filing of a complaint in the United States District Court for the Southern District of New York against the United States Patent and Trademark Office (PTO), as well as the patent holders, Myriad Genetics and the directors of the University of Utah Research Foundation. Plaintiffs include four national organizations of physicians, geneticists, researchers, clinicians, and other health professionals with a combined total of over 150,000 members, as well as six of the nation’s leading geneticists, two genetic counselors, two women’s health and breast cancer organizations, and six patients who have been diagnosed with or are at risk of hereditary breast or ovarian cancer. App. at 121-29a.

Plaintiffs alleged in their complaint that the patents are invalid under Section 101 of the Patent Act because they cover products and laws of nature and abstract ideas. They also alleged that the effects of the challenged patents is to preempt scientific inquiry and medical care to the detriment of patients’ health and to scientific advancement, in violation of both Article I, Section 8, Clause 8 and the First Amendment of the U.S. Constitution.

The complaint challenged fifteen claims from seven different patents. App. at 178-84a. The claims relevant to this Petition cover the BRCA1 and

BRCA2 genes.<sup>2</sup> Each of those claims defines the gene according to how it functions in the body. App. at 179-81a. For example, claims in the patent 5,747,282 ('282) include:

1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.
2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.
5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.

App. at 179-80a. The patent specifications define "isolated" DNA as having been removed from the cell and separated from other genetic material. App. at 189-90a. The referenced sequences (*e.g.*, SEQ ID NO.\_\_\_\_) identify the lengthy nucleotide sequences found in a "wild-type" (non-mutated or normal) BRCA1 gene and the amino acid sequence found in a protein created by a wild-type BRCA1 gene. App. at 179a. Other claims<sup>3</sup> cover all variations and mutations in the BRCA1 and BRCA2 genes, both known and unknown. App. at 178-81a.

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<sup>2</sup> The complaint also challenged methods of comparing the "wild-type" or non-mutated genetic sequence to the genetic sequence of a sample obtained from a patient. App. at 181-84a. All but one of the method claims were declared invalid by both the district court and the Court of Appeals. App. at 54-61a, 224-36a. None of the method claims is the subject of this petition.

<sup>3</sup> The other claims at issue in this petition are contained in the Appendix. App. at 307-08a.

According to the patent specifications, each of the claims covers virtually every short fragment of the BRCA1 and BRCA2 genes as well as the full-length genes. *E.g.*, '282 patent at 6:26-30, 25:36-37. Thus, the patents claim any fragments as short as 15 nucleotides (comprised of the A, C, G, and T component bases) of the gene, which consists of many thousands of nucleotides. *Id.*; App. at 179-80a. Additionally, the patents cover cDNA, a form of DNA that can also be found in the body, albeit less frequently, in which some of the inessential (non-coding) nucleotides known as introns have been removed. App. at 148-50a, 218-20a. Myriad has never argued that any of its claims is limited to any one form of DNA, including cDNA. Through its combined patents, Myriad claims ownership of the BRCA1 and BRCA2 genes of every American.

4. In the district court, the defendants moved to dismiss largely on the grounds that the plaintiffs did not have standing. App. at 273a *et seq.* The court denied that motion. App. at 293a. Both plaintiffs and Myriad subsequently moved for summary judgment, and the PTO moved for judgment on the pleadings. App. at 118a. The district court granted the plaintiffs' motion for summary judgment and denied Myriad's motion. *Id.* The court dismissed the constitutional claims against the PTO based on the doctrine of constitutional avoidance. *Id.*; App. at 236-37a.

The district court's finding that each of the plaintiffs had standing was based on an application of this Court's opinion in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), which held that standing in patent cases should be analyzed in the

same manner as standing in non-patent cases. The district court found that Myriad had taken affirmative acts to enforce its patents “through personal communications, cease-and-desist letters, licensing offers, and litigation.” App. at 287a. The court also found that each plaintiff had the capacity, ability, and desire to engage in infringing activity (or activity to contribute to or induce infringement) but was prevented from doing so by the patents. App. at 288-93a. More specifically, each of the physician plaintiffs and at least one physician member of each of the medical association plaintiffs submitted declarations indicating they sequenced genes on a regular basis, would immediately utilize their standard sequencing methods to sequence the BRCA1 and BRCA2 genes if possible, and were prevented from doing so solely as a result of fear of suit by Myriad.<sup>4</sup> App. at 290-91a. The district court found that the remaining plaintiffs (genetic counselors and breast cancer advocacy groups who referred women for testing, and patients who sought to be tested) had standing based on their stated desire to contribute to infringement by referring patients (or themselves) to physicians for testing, a desire frustrated solely by Myriad’s active enforcement of its patents. App. at 291-93a.

The district court granted plaintiffs’ motion for summary judgment in a 153-page, comprehensive opinion that relied heavily on facts presented by both

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<sup>4</sup> Drs. Kazazian and Ganguly had been sequencing BRCA1 and BRCA2 genes until they were forced to stop as a result of letters and lawsuits by Myriad. App. at 20-23a. Their declaration indicated they would consider resuming that activity if the patents were invalidated. App. at 34a.

parties and carefully analyzed the decisions of this Court holding that patents cannot be issued on laws of nature, products of nature, or abstract ideas. App. at 113-238a. The district court began by discussing the standard set by this Court for determining if a patented composition of matter – like the DNA at issue here – has been sufficiently changed such that it is no longer a product of nature. App. at 201-04a (citing *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948); and *American Fruit Growers Inc. v. Brodges Co.*, 283 U.S. 1 (1931)).

The district court considered Myriad’s arguments regarding both structural and functional differences between “isolated” DNA and the DNA inside the human body, ultimately concluding that none caused “isolated” genes to be “markedly different,” *Chakrabarty*, 447 U.S. at 310, from genes in the body. App. at 214-24a. In holding that isolated DNA remains a product of nature, the district court emphasized the unique properties of genes as

[I]nformation ... [that] reflects its primary biological function; directing the synthesis of *other* molecules in the body – namely, proteins, “biological molecules of enormous importance” which “catalyze biochemical reactions” and constitute the “major structural materials of the animal body.”

App. at 216a (emphasis in original; citations omitted). The district court found that in isolating the genes, Myriad did not “alter its essential characteristic – its nucleotide sequence that is

defined by nature and central to both its biological function within the cell and its utility as a research tool in the lab.” App. at 222a. The court also invalidated the patents on cDNA for largely the same reason. App. at 218-20a.

5. Myriad appealed to the Federal Circuit. Plaintiffs did not appeal the dismissal of the PTO, which is therefore no longer a party to the case, although plaintiffs continued to raise their First Amendment claims against the University of Utah defendants. The United States did, however, participate in the appellate proceedings as *amicus curiae*. It was personally represented by the Solicitor General and, as more fully described below, largely supported plaintiffs’ position.

A divided panel of the court of appeals reversed. The court was unanimous, however, in rejecting Myriad’s contention that none of the plaintiffs had standing. Specifically, all three judges agreed that plaintiff Dr. Harry Ostrer had standing to sue because he had received a letter from Myriad proposing a BRCA licensing agreement for which a royalty would need to be paid. The court found:

Myriad’s active enforcement of its patent rights forced [plaintiff] Dr. Ostrer, *as well as every other similarly situated researcher and institution*, to cease performing the challenged BRCA testing services, leaving Myriad as the sole provider of BRCA clinical testing in the United States ... Myriad’s enforcement efforts eliminated all competition...”

App. at 35a (emphasis added). The court further noted that Dr. Ostrer had “not only the resources and expertise to immediately undertake clinical BRCA testing, but also states unequivocally that he will immediately begin such testing.” App. at 34a. While accurate, that statement did not distinguish Dr. Ostrer from the most of the other physician plaintiffs and members of the medical association plaintiffs who submitted similar or identical evidence of their resources, expertise, capability, and desire to begin testing. App. at 288-92a. The court denied the standing of other plaintiffs because, unlike Dr. Ostrer, they had not been individually contacted by Myriad. App. at 39-40a. The court found that although Myriad’s “active enforcement” of its patents had “forced...every other...researcher and institution” to cease testing, Dr. Ostrer alone had standing because there had not been “affirmative acts by the patentee directed at specific Plaintiffs.” App. at 35-39a. The court of appeals discarded the plaintiffs whose standing was based on contributory or inducing infringement essentially without comment.

On the merits, each member of the panel wrote a separate opinion discussing the patentability of human genes, and each opinion analyzed the issue differently. Judge Lourie purported to apply the standard in *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980), that a court must analyze whether an “isolated” gene is “markedly different” from what is found in nature.<sup>5</sup> He held that in performing this

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<sup>5</sup> Myriad had argued that the “markedly different” standard had not been established by the Court and should not be applied.

analysis, the functionality of the gene was irrelevant. App. at 49a. Thus, even if “isolated” genes were functionally identical to genes in the body, they would still be patentable. *Id.* He held that “isolated” DNA was structurally different from DNA on the sole basis that in the process of being removed from the body and its surrounding chemicals and tissues, a covalent (electron) bond has been broken. App. at 46-49a. Covalent bonds are naturally-occurring bonds that hold together DNA. Plaintiffs-Appellees’ Petition for Panel Rehearing at 4, *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 10-01406). They are constantly formed and broken in the body. *Id.*; see Second Corrected App. Vol. VI at A7036-38, *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406).

Judge Moore, by contrast, found that both structure and function were relevant in determining if a composition is “markedly different” from what is found in nature. App. at 77-79a. She found that a full-length “isolated” gene “does not clearly have a new utility and appear to simply serve the same ends devised by nature.” App. at 79a. She said: “If I were deciding this case on a blank canvas, I might conclude that an isolated DNA sequence that includes most or all of a gene is not patentable subject matter.” *Id.* She nevertheless found full-length genes to be patentable because of the “historical background” of the PTO’s past practice of granting gene patents. *Id.* She also held that small fragments of genes were patentable subject matter because removal caused the fragments to have different chemical elements at each end. App. at 75-

77a. Moreover, she noted that small fragments can be used as probes and primers – segments of DNA that are used by laboratories in the process of genetic testing. *Id.*

In his dissenting opinion, Judge Bryson held the genes were not patentable.

Myriad is claiming the genes themselves, which appear in nature on the chromosomes of living human beings. The only material change made to those genes from their natural state is the change that is necessarily incidental to the extraction of the genes.

App. at 98a. Judge Bryson noted that Federal Circuit Judge Dyk had expressed the same view in a separate case, reasoning that “prematurely plucking the leaf [off a tree] would not turn it into a human-made invention. That would remain true if there were minor differences between the plucked leaf and the fallen autumn leaf...” *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1295 (Fed. Cir. 2010) (Dyk, J., concurring in part). Judge Bryson concluded:

The structural differences between the claimed “isolated” genes and the corresponding portion of the native genes are irrelevant to the claim limitations, to the functioning of the genes, and to their utility in their isolated form. The use to which the genetic material can be put, *i.e.*, determining its sequence in a clinical setting is not a new use; it is only a consequence of possession. In order to

sequence an isolated gene, each gene must function in the same manner in the laboratory as it does in the human body.

App. at 105-06a. He further concluded that the PTO's past practice was not entitled to significant weight because the courts, not the PTO, have ultimate authority to determine what is patentable under the laws enacted by Congress. App. at 110-12a. All three members of the court held that cDNA was patentable subject matter. *E.g.*, App. at 42-43a, 73-74a, 94a. The court ignored the district court's construction of the claims, App. at 189-90a, and found that cDNA did not appear in the body and is simply "inspired by nature." App. at 73a. The majority of the court did not identify which claims in the patents were limited to cDNA. *See* App. at 43a. The court also did not address the constitutional claims raised by plaintiffs.

Plaintiffs petitioned for rehearing by the panel, arguing that certain facts relied on in the opinions of Judge Lourie and Judge Moore were not in the record and were flawed. Specifically, plaintiffs argued that Judge Lourie's reliance on the breaking of covalent bonds that occurs when DNA is "isolated" in concluding that isolated DNA is markedly different from DNA was erroneous. Covalent bonds are indeed broken in the process of "isolation" as the DNA is fragmented. But covalent bonds are also broken inside the body as part of natural processes. Fragments of genes identical to the fragments found after "isolation," with broken covalent bonds and different ends, exist naturally in the body. Plaintiffs-Appellees' Petition for Panel Rehearing at 4, *Ass'n for*

*Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 10-01406); Fed. Cir. App. at A7036-40. Broken covalent bonds simply do not distinguish an “isolated” gene from a product of nature. *Id.* Defendants also petitioned for rehearing on the holding that Dr. Ostrer had standing to challenge the BRCA1 and BRCA2 patents. Both rehearing motions were denied without opinion.

## REASONS FOR GRANTING THE WRIT

### I. THE QUESTION OF WHETHER HUMAN GENES AND THE INFORMATION THEY CONVEY ARE PATENTABLE IS OF PARAMOUNT IMPORTANCE TO THE FUTURE OF PATENT LAW, THE ADVANCEMENT OF MEDICAL SCIENCE, AND PATIENTS’ HEALTH.

In recent years, this Court has granted certiorari on several cases concerning the patentability of methods. *Bilski v. Kappos*, 130 S. Ct. 3218 (2010); *Prometheus v. Mayo Collaborative Services*, granting, vacating and remanding 130 S. Ct. 3543 (2010), and cert. granted, 131 S. Ct. 3027 (June 20, 2011). *See also Metabolite v. Laboratory Corp.*, cert. disp. 548 U.S. 124 (2006). For over thirty years, the Court has not addressed the patentability of compositions of matter under Section 101. There can be little doubt that it is crucial for the Court to address this subject.

The legal community needs guidance from this Court regarding the scope of Section 101 as it applies to compositions of matter and DNA. Four federal judges in this case have written opinions on the

patentability of human genes. Each has adopted a different method of analyzing the issues. The district court judge held that neither DNA nor cDNA is patentable subject matter because the genes that make up DNA function the same whether they are inside or outside the body. App. at 214-24a. He thus rejected the notion that isolated DNA is markedly different than the DNA that exists in nature. Federal Circuit Judge Lourie, by contrast, held that the function of genes inside and outside the body is always irrelevant. App. at 49-50a. In his view, isolated DNA is patentable because removing a gene from the body necessarily alters its chemical structure. App. at 46-47a. Judge Moore thought that the court must examine both function and structure. App. at 75-77a. Although she found that full-length genes were functionally and to a significant degree structurally identical whether isolated or not, she nevertheless found them patentable by deferring to the PTO's past practice. App. at 79a. With respect to small fragments of genes, she found that they could be used outside the body as probes or primers, unlike small identical fragments found inside the body, and were therefore patentable. App. at 75-78a. Finally, Judge Bryson found genes unpatentable because any structural changes were incidental to the isolation process and any functional use was "only a consequence of possession."<sup>6</sup> App. at 105-06a. All three court of appeals judges ignored the district court's factual

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<sup>6</sup> Judge Bryson's analysis was foreshadowed by Federal Circuit Judge Dyk's opinion in an earlier case. *See Intervet v. Merial Ltd.*, 617 F.3d 1282, 1295 (Fed. Cir. 2010) (Dyk, J. concurring in part and dissenting in part).

finding that cDNA appears in the body and found it patentable because it is more often created in a lab. That cDNA and DNA are functionally identical was, they apparently thought, irrelevant. None identified which of the claims, if any, is limited to cDNA.

All of the judges purported to apply this Court's standard in *Chakrabarty* that a patentable composition must be "markedly different" from a product of nature, but each differed in how to apply that standard to full-length genes, gene fragments, and cDNA. Each had divergent views on the relevance of the existence of genes or gene fragments that are identical inside and outside of the body. Each also disagreed on the degree to which minor structural alterations incident to removal render a composition patentable and the relevance of function in assessing patentability. The district court and Judge Bryson found it highly relevant that Myriad's entire business is based on the fact that "isolated" genes have the identical nucleotide sequence as genes in the body – because otherwise any diagnostic conclusions drawn from the "isolated" gene would be impossible. Judges Lourie and Moore found that fact irrelevant.

The executive branch, too, has expressed different opinions in this litigation. The PTO granted the patents at issue in this case and has published guidelines authorizing the patenting of isolated DNA. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).<sup>7</sup> However, when this case reached the Federal Circuit, the United

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<sup>7</sup> These Guidelines are not entitled to any deference. *Arnold P'ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004).

States adopted a different position. After consulting with the “Patent and Trademark Office (PTO), the National Institutes of Health (NIH), the Antitrust Division of the Department of Justice, the Centers for Disease Control and Prevention, the Office of Science and Technology Policy, and the National Economic Council, among others,” the United States concluded that DNA and human genes are not patentable, but that cDNA is. Br. for the United States as Amicus Curiae in Supp. of Neither Party at 1, *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406). Contrary to the usual practice, the PTO did not sign the brief that was submitted by the United States. Arguing personally on behalf of the United States, the Solicitor General proposed a new method of analyzing the degree to which a part of the human body is patentable: the “magic microscope.” Because the same DNA molecule could be seen if a magic microscope were to be invented allowing one to zoom in and view the DNA inside a human body, isolated DNA is a product of nature.<sup>8</sup> App. at 83a.

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<sup>8</sup> The Department of Health and Human Services has also weighed in on the question of gene patents. Last year, its Secretary’s Advisory Committee on Genetics, Health, and Society issued a report concluding that gene patents were unnecessary to incentivize research or the development of clinical testing and impeded patient access to genetic testing and quality assurance in testing. Dep’t of Health & Human Serv., Sec’y’s Advisory Comm. on Genetics, Health, and Soc’y, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (April 2010), available at [http://oba.od.nih.gov/oba/sacghs/reports/SACGHS\\_patents\\_report\\_2010.pdf](http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf).

This case is an ideal vehicle to analyze the Section 101 question. Plaintiffs' sole claim under the Patent Act was brought pursuant to Section 101. Unlike other Federal Circuit cases dealing with isolated DNA patents, *see, e.g., Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1293 (Fed. Cir. 2010) (Dyk, J., concurring in part and dissenting in part), this is the first to present and thoroughly litigate the issue of whether isolated DNA falls within the Section 101 exceptions. At the district court, all parties agreed on the fundamental characteristics of isolated DNA and disputed only the application of the law to the facts. App. at 135-60a.

This case is not, however, solely about the pressing need to clarify the legal doctrine governing the patentability of compositions of matter and the scope of the product of nature exception. At its core, it presents a critical question of great concern to this country, especially patients affected by hereditary breast and ovarian cancer and the medical and scientific communities: are patents on genes valid, thus preventing advances in science and medicine that could result in better diagnosis and treatment? There were thirty amicus briefs filed in the court of appeals signed by sixty-seven organizations, corporations, associations, or individuals. Among those who signed briefs supporting plaintiffs were (1) major medical associations (beyond the four associations who are plaintiffs themselves), including the American Medical Association (AMA), the American Society of Human Genetics, the American College of Embryology, and the American College of Obstetricians and Gynecologists, and (2) organizations committed to advocacy on behalf of patients, including the March of Dimes, AARP, the

Canavan Foundation, the Claire Altman Heine Foundation, the National Organization for Rare Disorders, National Tay-Sachs and Allied Diseases Association, Ovarian Cancer National Alliance, and Facing Our Risk of Cancer Empowered, which advocates on behalf of patients and families affected by hereditary breast and ovarian cancer.<sup>9</sup> All of these amici weighed in because of the significant impact of gene patents on patient care. App. at 3-7a, 129-32a. As the Department of Justice said in its brief: “The extent to which basic discoveries in genetics may be patented is a question of great importance to the national economy, to medical science, and to the public health.” Br. for the United States as Amicus Curiae in Supp. of Neither Party at 1, *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406). *See also* Br. for Amicus Curiae Intellectual Prop. Law Ass’n in Supp. of Reversal, but in Supp. of Neither Party at 2, *Ass’n for Molecular Pathology*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406) (“Anything but simple, however, are the legal issues raised by those questions and the ramifications of the District Court's decision. At stake are significant medical and economic interests of individuals and industries alike.”).

The patents give Myriad the authority to prevent all research and clinical testing of the BRCA1 and BRCA2 genes. Myriad has vigorously enforced its patents to stop clinical testing by any

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<sup>9</sup> Other amici in support of plaintiffs included the Southern Baptist Convention. Myriad’s amici included associations of biotechnology corporations. They too recognized that this issue is critical.

other lab. App. at 163-66a, 262-65a. Myriad did so even during a period of several years when it failed to look for all known mutations and was thus providing false negative results to some women. App. at 160a. Other labs, which were willing to do more comprehensive and therefore more accurate testing, were barred by Myriad from doing so. App. at 166-67a. Currently, Myriad collects a huge amount of data on the nature and significance of variants in the BRCA1 and BRCA2 genes, but refuses to share that data with the scientific community and has no obligation to fully develop scientific knowledge about the genes. App. at 174a. Many women, upon obtaining results from Myriad, wish to get a second opinion before they submit to life-altering, prophylactic surgery. Myriad refuses to allow any lab to confirm the results through sequencing the genes. App. at 169-70a. The patents preclude others from providing testing, even where they could do so for a lower price or for free. Myriad has contracts with only half of the state Medicaid insurance programs. Only 130 million of America's 308 million people can receive insurance coverage for their testing. Second Corrected App. Vol. VI at A4703, *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406).

The usual rationale for granting a patent – the need to create economic incentives to advance science – did not apply in this case and does not apply to products of nature. Researchers besides Myriad's were also looking for the BRCA1 and BRCA2 genes and had indicated that they would share their results with the scientific community. The widespread clinical testing of other, unpatented genes and the

extraordinary importance of breast and ovarian cancers make it clear that diagnostic tests resulting from the discoveries of BRCA1 and BRCA2 would have been made available to the public even without the patent incentive. *See* App. at 175-76a.

Indeed, as this Court has suggested, patenting basic elements of nature has the opposite effect, stifling research and scientific advancement. Where the claimed composition's "qualities are the work of nature," those qualities are not patentable, for "[t]hey are manifestations of laws of nature, free to all men and reserved exclusively to none." *Funk Bros.*, 333 U.S. at 130. To otherwise hold would be "allowing a patent to issue on one of the ancient secrets of nature now disclosed." *Id.* at 132. Accordingly, "[p]atent law seeks to avoid the dangers of overprotection just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten," by bringing certain types of invention and discovery within the scope of patentability while excluding others. *Lab. Corp. of Am. Holdings v. Metabolite Labs.*, 548 U.S. 124, 127 (U.S. 2006) (Breyer, J., dissenting); *Cf. Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 155 (U.S. 1950) (Douglas, J., concurring) ("Every patent is the grant of a privilege of exacting tolls from the public. The Framers plainly did not want those monopolies freely granted. The invention, to justify a patent, had to serve the ends of science-to push back the frontiers of chemistry, physics, and the like").

Finally, it is of critical importance to women's health that knowledge about breast and ovarian cancer increase in order to advance diagnosis and

treatment. This case does not question the patentability of new methods of diagnosis or methods of treatment. It does not deal with new drugs or new instruments. Instead, it concerns perhaps the most basic elements of biology, human genes:

Genes are basic units of heredity found in all living organisms and are responsible for the inheritance of a discrete trait . . . . Together, the approximately 25,000 genes in the human body make up the human genome. The genome, and the genes within it, are contained within almost every cell in the human body and define physical traits such as skin tone, eye color, and sex, in addition to influencing the development of conditions such as obesity, diabetes, Alzheimer's disease, and bipolar disorder.

App. at 139-40a. As the district court found, "The widespread use of gene sequence information as the foundation for biomedical research means that resolution of these issues will have far-reaching implications, not only for gene-based health care and the health of millions of women facing the specter of breast cancer, but also for the future course of biomedical research." App. at 243a.

The extraordinary importance of the issues presented by this case combined with the lack of clarity concerning the legal issues it presents merit review by this Court.

## II. PATENTS ON “ISOLATED” DNA ARE INVALID UNDER THIS COURT’S SECTION 101 JURISPRUDENCE AND THE U.S. CONSTITUTION.

The patenting of isolated DNA violates long-established Supreme Court precedent that prohibits the patenting of laws of nature, natural phenomena, products of nature, and abstract ideas. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). “[T]he relevant distinction’ for purposes of § 101 is . . . ‘between products of nature, whether living or not, and human-made inventions.’” *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 130, 134 (2001) (quoting *Chakrabarty*, 447 U.S. at 313). See also *Gen. Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641, 643 (3d Cir. 1928); *In re Marden (Marden II)*, 47 F.2d 958, 959 (C.C.P.A. 1931); *In re Marden (Marden I)*, 47 F.2d 957 (C.C.P.A. 1931). In *Bilski*, the Court affirmed that subject matter eligibility remains a threshold question, separate and distinct from considerations of utility or novelty. 130 S. Ct. at 3225; see also *Parker v. Flook*, 437 U.S. 584, 593 (1978); *Diamond v. Diehr*, 450 U.S. 175, 189-90 (1981).

In deciding that the patents at issue survive Section 101, the Federal Circuit departed dramatically from *Chakrabarty*, *Funk Brothers*, and *American Fruit Growers*, this Court’s seminal cases on the product of nature doctrine. Those cases held that a claimed composition does not become patentable simply because there has been a change in its structure, as the opinion of Judge Lourie

concluded below. Instead, the Section 101 inquiry involves more: whether the claimed composition has “a distinctive name, character [and] use” and “markedly different characteristics from any found in nature,” *Chakrabarty*, 447 U.S. at 309-10 (citation omitted), and does not cover “nature’s handiwork” or “qualities that are the work of nature.” *Id.*; *Funk Bros.*, 333 U.S. at 130. Unless what is claimed meets these criteria, the patent will encumber “the storehouse of knowledge of all men.” *Funk Bros.*, 333 U.S. at 130.

Thus, the Court has examined the key characteristics, including function, of a claimed composition and determined whether they are the work of nature. Comparing the unpatentable combination of bacteria in *Funk Brothers* with the genetically-engineered and patentable *Chakrabarty* bacterium, the Court in *Chakrabarty* concluded that the latter has “markedly different characteristics from any found in nature,” while the former’s discovery is “nature’s handiwork.”

‘The combination of species [in *Funk Brothers*] produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.’

Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101.

*Chakrabarty*, 447 U.S. at 310 (quoting *Funk Bros.*, 333 U.S. at 131). Because the patent holder of the "isolated" *Funk Brothers* bacteria did "not create [a] state of inhibition or of non-inhibition in the bacteria," he could not patent the product, even though the bacteria did not exist together naturally, and even though their aggregate nitrogen-fixing capability had been newly identified and had commercial utility. 333 U.S. at 130-31. Similarly, in *Am. Fruit Growers, Inc. v. Brogdex Co.*, the Court rejected the patenting of a fruit that had been treated with mold-resistant borax, although the "complete article is not found in nature" and despite its "treatment, labor and manipulation." 283 U.S. 1, 11-12 (1931). The Court held that it did not become an "article of manufacture" unless it "possesses a new or distinctive form, quality, or property" distinct from nature. *Id.*

Just as the fruit and the aggregation of bacteria strains were products of nature, so too are the isolated DNA at issue here. The patent claims themselves define "isolated DNA" according to a naturally-occurring functional characteristic – namely, "coding for" a naturally-occurring polypeptide. Thus, the claims explicitly recognize that DNA stores and conveys specific information –

as dictated by the natural order of nucleotides – that serves as the blueprint for proteins, and ultimately the cells and organs, that make up the human body. Because this blueprint is the essential characteristic of DNA and remains the same before and after isolation, “isolated” DNA has neither a distinctive name, character, or use from naturally-occurring DNA, nor markedly different characteristics. Both are DNA, their structures are not markedly different, the protein coded for by each is the same, and their use in storing and transmitting information about a person’s heredity is identical.

The Federal Circuit failed to properly analyze DNA’s characteristics in light of this Court’s precedents. The opinion of the court by Judge Lourie focused only on the chemical structure of DNA, disregarding its biological characteristics. App. at 50a (“We recognize that biologists may think of molecules in terms of their uses, but genes are in fact materials having a chemical nature and, as such, are best described in patents by their structures rather than their functions.”). That mode of analysis contradicts both the patent claim language – claiming isolated DNA as coding for a specified protein – and this Court’s repeated admonition that patents should be evaluated according to the actual claim language, *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996); *White v. Dunbar*, 119 U.S. 47, 52 (1886). It also ignores the Court’s decisions establishing that function is a critical factor for determining whether something is patentable under Section 101. *Chakrabarty*, 447 U.S. at 310. Otherwise, the fruit of *American Fruit Growers* would surely have been patentable, for its structure was quite different from the naturally occurring

fruit, even though its use for human consumption remained the same. *See* 283 U.S. at 11-12. Furthermore, Judge Lourie elevated the importance of chemical bonds such that any cleavage of a covalent bond would render the resulting molecule patentable. App. at 49a. Such a rule has never been endorsed by this Court, or to the best of our knowledge, by any court, and runs counter to the pragmatic approach this Court has taken in applying Section 101. *Bilski*, 130 S. Ct. at 3226-27 (rejecting a rigid “machine-or-transformation” test for method claims). As in *Bilski*, the court of appeals again imposed an inflexible test not rooted in precedent.

Though the concurring opinion by Judge Moore discussed the structure and function of isolated DNA, it failed to take into account whether its qualities are the work of nature. *Chakrabarty*, 447 U.S. at 309-10; *Funk Bros.*, 333 U.S. at 130. In her view, an isolated DNA sequence that includes most or all of a gene might not be patentable because it would not have a clearly new utility or function compared to a naturally-occurring gene; however, a 15 nucleotide segment, as claimed in patent `282 cl. 5, would be patentable, because it could potentially be used as a primer or probe. App. at 75-79a. This holding flatly contradicts the Section 101 case law barring patents on a phenomenon of nature. *Funk Bros.*, 333 U.S. at 130. Because small sequences of DNA are repeated throughout the human genome, a claim on small segments of DNA, like claims 5 or 6 of `282, covers portions of the DNA of nearly all human genes, not just BRCA1. App. at 107-08a. None of the claims at issue here are limited to new uses of DNA fragments as primers or probes. Accordingly, claims like 5 and 6 of patent `282

preempt researchers from working with that segment of DNA, wherever it may appear in the genome, and poses a serious threat to scientific freedom and advancement. See *Bilski*, 130 S. Ct. at 3230-31; *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972); *Funk Bros.*, 333 U.S. at 130 (“The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men . . . . He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes.”). See also *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126-27 (2006) (Breyer, J., dissenting) (“[S]ometimes *too much* patent protection can impede rather than ‘promote the Progress of Science and useful Arts.’”).

Patents on isolated DNA, whether small segments or whole genes, also violate the First Amendment because they block scientific inquiry into the patented DNA. These patents prevent access to each person’s individual genetic information and deprive others from examining the BRCA1 and BRCA2 genes and engaging in fundamental scientific work. It is not possible to “invent around” human genes, as it is with a true invention, like a carburetor. Because the patents grant control over a body of knowledge and over pure information, they violate the First Amendment. *Ashcroft v. Free Speech Coal.*, 535 U.S. 234, 253 (2002) (“First Amendment freedoms are most in danger when the government seeks to control thought or to justify its laws for that impermissible end. The right to think is the beginning of freedom . . .”).

**III. BY HOLDING THAT PETITIONERS LACKED STANDING UNLESS THEY WERE PERSONALLY THREATENED BY MYRIAD, THE FEDERAL CIRCUIT IMPOSED A RIGID STANDING REQUIREMENT CONTRARY TO THIS COURT'S APPROACH IN *MEDIMMUNE*.**

In *MedImmune, Inc. v. Genentech, Inc.*, this Court declared that the correct standing analysis in patent cases, as in all other Article III cases, “is 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 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, the Federal Circuit imposed just such a rule in concluding that plaintiffs lacked standing unless they were personally threatened by Myriad.

The court of appeals 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.

App. at 34-35a (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, non-proximate, effect from the existence of a patent," for all of the plaintiffs other than Dr. Ostrer. App. at 34-39a.

It is difficult to reconcile a holding that all of the plaintiffs have been "forced to cease" their actions 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," App. at 23a, is contrary to numerous decisions of this 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*, this Court held that the Federal Circuit'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 this 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. App. at 286-87a. See also *Vt. Right to Life Comm., Inc. v. Sorrell*, 221 F.3d 376, 382 (2d Cir. 2000) (civil cases); *Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1370 (Fed. Cir. 2007).

The Federal Circuit’s newly minted 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 that court’s prior “reasonable apprehension” test, rejected by this Court in *MedImmune*. 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.<sup>10</sup>

For the reasons stated above, the Federal Circuit’s new rule is erroneous. The medical organizational plaintiffs and most of the physician plaintiffs would be identical for standing purposes to Dr. Ostrer, because they have the equipment, expertise and desire to engage in testing but have refrained solely as a result of Myriad’s repeated suits and threats. In addition, the Federal Circuit’s inflexible standing requirement led it to wrongly dismiss the plaintiffs whose standing is based on contributory or inducing infringement. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1365 (Fed. Cir. 2004) (disseminating medical information and a directory of medical service

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<sup>10</sup> This was not the circuit’s only clear error. 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 (ACMG), of which Dr. Ostrer is a member. App. at 249a. The undisputed record reflects that gene patenting is germane to ACMG’s purpose. App. at 244-45a. Pursuant to well-established law in this Court, ACMG therefore has organizational standing. *Warth v. Seldin*, 422 U.S. 490, 511 (1975). 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.” App. at 23a. 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. App. at 264a. The court of appeals held that a plaintiff had standing if Myriad directed “any ... communications regarding its patents at them.” Even under that standard, Ms. Matloff has standing.

providers was sufficient to trigger liability for inducing infringement).

## CONCLUSION

For the reasons stated above, the petition for certiorari should be granted.

Respectfully submitted,

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December 6, 2011