No. _____

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

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, known as BRCA1 and BRCA2. These patents claim every naturally-occurring version of those genes, including mutations, on the theory that Myriad invented something patent-eligible simply by removing ("isolating") the genes from the body. Petitioners are primarily medical professionals who regularly use routine, conventional 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 upholding a method claim by Myriad that is irreconcilable with this Court's ruling in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)?

3. 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 threatened with an infringement action?

PARTIES TO THE PROCEEDINGS

The petitioners are the 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. 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 here.

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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This Court's order granting certiorari, vacating, and remanding in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* is reported at 132 S. Ct. 1794 (2012) (App. at 1a). The opinion of the United States Court of Appeals for the Federal Circuit following remand from this Court is reported at 2012 WL 3518509 (Fed. Cir. Aug. 16, 2012) (App. at 2a-119a). The Federal Circuit's original decision is reported at 653 F.3d 1329 (Fed. Cir. 2011) (App. at 120a-231a). The district court opinion granting summary judgment to petitioners and denying summary judgment to respondents is reported at 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (App. at 232a-357a). An earlier opinion of the district court denying the motion to dismiss based, in part, on standing is reported at 669 F. Supp. 2d 365 (S.D.N.Y. 2009) (App. at 358a-425a).

JURISDICTIONAL STATEMENT

The Federal Circuit's decision in this case following remand was issued on August 16, 2012. This petition is thus timely. Jurisdiction is conferred by 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

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."

STATEMENT

1. This is the second petition filed in this case. The prior petition was granted, and the case vacated and remanded for further proceedings in light of this Court's decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012). Upon remand, a divided panel of the Federal Circuit reaffirmed its earlier ruling upholding the challenged composition claims and one of the method claims, after concluding that *Mayo* was largely irrelevant to the issues presented here.

2. The central issue in this case is whether human genes may be patented. More specifically, this case challenges patents awarded to Myriad Genetics 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 20a-21a. Myriad claims exclusive control over the genes once they have been "isolated" – that is, removed from the body and other cellular material. The patent claims include every single natural variation of the genes, including those that have not yet been isolated. *See* App. at 297a-300a.

Myriad has exercised its authority as a patent holder to prohibit standard clinical testing of the BRCA1/2 genes, to inhibit scientific research involving the genes, and to prevent patients from accessing their own genetic information. Myriad's patents have allowed it to dictate the cost of genetic testing, stopped other laboratories from creating and offering new and improved testing procedures, and made it impossible to obtain second opinions that could better inform patients of their cancer risk. Myriad and other gene patent holders have gained

the right to exclude the rest of the scientific community from examining the naturally-occurring genes of every person in the United States.

3. Every human body contains DNA. Genes are fragments of DNA that uniquely embody laws of nature that determine, in part, the structure and functions of the body. App. at 257a-63a. They do so by coding for and producing proteins (or polypeptides) that do the work of the body and define many of our characteristics. *Id.* Genes are created naturally and can vary from one individual to another. App. at 260a-61a. Genetic alterations or variations, which also occur naturally, can be inherited or can occur after birth. App. at 378a. Variants can appear to be unimportant, correlate with an increased risk of disease or disorder ("mutations"), or have unknown significance ("variant of unknown significance"). App. at 261a. The significance of the variant is purely a function of nature. App. at 270a.

Certain BRCA1/2 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 278a, 20a. Thus, for many patients, knowing whether their genes contain the harmful mutations is essential to making informed medical decisions. App. at 278a-79a, 20a.

In order to provide effective treatment to patients and to research a wide range of diseases,

including cancer, medical professionals conduct genetic testing for clinically significant alterations. App. at 270a-72a. There are a variety of methods by which medical professionals can examine genes. *Id.* Basic methods involve "isolating" the DNA, which removes the DNA from the cell and associated material and randomly fragments it. Fed. Cir. Second Corrected App. Vol. VI at A7036-39.[1] Myriad did not develop the methods by which geneticists "isolate" the BRCA1/2 genes, App. at 270-72a, and those methods, which are routinely used by geneticists to sequence thousands of other human genes on a daily basis, *id.*, are not the subject of this lawsuit.

Standard isolation results in random DNA fragments that are identical to those that exist naturally in the body. Pls.-Appellees' Pet. for Panel Reh'g at 6-8, *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011). Isolation simply makes a person's genetic information more accessible for sequencing by medical professionals. App. at 270a. After sequencing, 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 257a, 260a-61a. 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 260a-61a. The patents on the DNA give Myriad the exclusive right to look for

[1] Citations to the appendix filed below with the Federal Circuit are denoted Fed. Cir. App. Vol. ___ at ___.

variants of BRCA1 and BRCA2, even when using routine, conventional methods for isolating and sequencing.

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. Yet, 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 270a-72a, 279a. Further, 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 them to provide genetic information to patients.

4. 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.[2] 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

[2] The University of Utah Research Foundation is an owner or co-owner of each of the challenged patents, App. at 248a, and has acted jointly with Myriad throughout the litigation.

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 240a-48a.

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 effect of the challenged patents is to preempt scientific inquiry and medical care to the detriment of patients' health and 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 297a-303a. Nine of the challenged claims cover the BRCA1/2 genes.[3] Each of those claims defines the gene according to how it functions in the body – *i.e.*, that it codes for and produces a polypeptide or protein. App. at 297a-300a. 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.

[3] The complaint also challenged method claims on comparing the "wild-type" or non-mutated genetic sequence to the genetic sequence of a sample obtained from a patient. App. at 301a-302a. All but one of the method claims were declared invalid by both the district court and the Federal Circuit. App. at 63a-67a, 344a-53a. The five method claims declared invalid are not the subject of this petition.

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 297a-99a. The patent specifications define "isolated" DNA as having been removed from the cell and separated from other genetic material. App. at 307a-08a. 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 10a-11a. Other claims cover all variations and mutations in the BRCA1/2 genes, both known and unknown. App. at 296a-300a.[4]

Some of Myriad's claims, such as claim 5 of patent '282, explicitly cover any isolated DNA having 15 nucleotides or more. Because DNA with as few as 15 nucleotides of the BRCA1 gene appear throughout the genome, these claims extend to segments of other genes. App. at 115a-16a, 299a; Fed. Cir. App. Second Corrected App. Vol. VI at A7017. Moreover, according to the patent specifications, each of the claims covers virtually every short fragment of the BRCA1/2 genes and the full-length genes. *E.g.*, '282 patent at 6:26-30, 25:36-37. Also according to the specifications, all of the claims cover cDNA, a form of DNA that is complementary to naturally-occurring RNA in which some of the non-protein-coding nucleotides known as introns have been removed.

[4] The other claims at issue in this petition are set forth in the Appendix. App. at 426-28a.

App. at 266a-68a, 336a-39a; *but see* App. at 47a, n.9. Myriad has never argued that any of its claims is limited to one form of DNA, including cDNA. Through its combined patents, Myriad claims ownership of the BRCA1/2 genes of every person in the United States.

In addition, this petition involves one method claim. Claim 20 of the '282 patent is on "a method for screening potential cancer therapeutics," which involves "growing a transformed eukaryotic [human or animal] cell containing an altered BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic" and then comparing the growth rate with the growth rate of the cell in the absence of the compound. App. at 12a-13a, 426a. Claim 20 patents the basic scientific process of observing the naturally-occurring growth rate of a cell with a BRCA1 mutation grown in the presence of any compound, and comparing it to the cell's growth rate without the compound; the claim does not specify any inventive steps or tools or limit the compound that is used.[5]

5. The defendants moved to dismiss in the district court largely on the grounds that plaintiffs lacked standing. App. at 392a. The court denied that motion. App. at 412a. Both plaintiffs and Myriad subsequently moved for summary judgment, and the PTO moved for judgment on the pleadings. App. at 237a. The district court granted the plaintiffs' motion for summary judgment and denied

[5] Claim 20 is no different from a method of administering any substance to a person and observing whether the person's temperature went up or down, except that it occurs outside the body.

Myriad's motion. *Id.* The constitutional claims against the PTO were dismissed based on the doctrine of constitutional avoidance. *Id.* at 357a.

The district court's finding that each of the plaintiffs had standing was based on 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 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 25a-26a. 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 BRCA1/2 genes if possible, and were prevented from doing so solely as a result of fear of suit by Myriad.[6] App. at 407a-10a. The district court found that the remaining plaintiffs (genetic counselors and women's health groups who referred patients 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 patent enforcement. App. at 410a-12a.

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[6] Drs. Kazazian and Ganguly had been sequencing BRCA1/2 genes until they were forced to stop as a result of letters and lawsuits by Myriad. App. at 21a-25a. Their declarations indicated they would consider resuming that activity if the patents were invalidated. App. at 36a.

The district court granted plaintiffs' motion for summary judgment in a 153-page, comprehensive opinion. App. at 232a-357a. 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 so that it is no longer a law or product of nature. App. at 320a-23a (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. Brogdex 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 333a-44a. In holding that patents on isolated DNA claim a law and 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 335a (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 342a. The court also invalidated the patents on cDNA for largely the same reason. App. at 339a.

6. Myriad appealed to the Federal Circuit. Plaintiffs did not appeal the dismissal of the PTO, which is no longer a party here, although plaintiffs continued to raise their First Amendment claims against the University of Utah defendants. The United States did, however, participate in the proceedings on the initial appeal and remand as *amicus curiae*, largely supporting plaintiffs.

A divided panel of the Federal Circuit reversed. The court was unanimous in rejecting Myriad's contention that none of the plaintiffs had standing. 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 and because Myriad's active patent enforcement had stopped Dr. Ostrer, and every other researcher and clinician, from performing testing. App. at 37a. The court further noted that Dr. Ostrer has "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 35a-36a. While accurate, that statement did not distinguish Dr. Ostrer from 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 407a-12a. Nonetheless, the court

denied the standing of other plaintiffs because, unlike Dr. Ostrer, they had not been individually contacted by Myriad, even though the court did find that Myriad had caused all similarly situated researchers to stop performing genetic testing. App. at 37a, 41a. The Federal Circuit dismissed the plaintiffs whose standing was based on contributory or inducing infringement essentially without comment. App. at 32a-33a, 41a.

Each member of the panel wrote a separate opinion discussing the patentability of human genes. Judge Lourie held that in analyzing whether an "isolated" gene has "markedly different characteristics" from what is found in nature, the functionality of the gene was irrelevant. App. at 55a. Thus, even if "isolated" genes were functionally identical to genes in the body, they would still be patentable. *Id.* He held that "isolated" DNA is 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 51a-57a, even though fragments of DNA with broken covalent bonds are created both in the body and in the "isolation" process. Pls.-Appellees' Pet. for Panel Reh'g at 4, *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011); *see* Fed. Cir. Second Corrected App. Vol. VI at A7036-38.

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 85a. She found that a full-length "isolated" gene "does not clearly have a new

utility and appears to simply serve the same ends devised by nature." App. at 85a-86a. 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." App. at 86a. She nevertheless found full-length genes to be patentable because of the "historical background" of the PTO's practice of granting gene patents and industry reliance on that practice. *Id.* Although conceding that none of the claims is limited to small fragments of genes, she nevertheless opined on their patentability. *See* App. at 82a.

In his dissenting opinion, Judge Bryson held the genes were not patentable. App. at 102a. He reasoned:

> 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 110a.

7. Upon remand following *Mayo*, each panel member adhered to his or her previous views and the court again upheld the validity of Myriad's patents on DNA by the same 2-1 vote.[7]

Judge Lourie's consideration of *Mayo* was limited to two short paragraphs, which purported to distinguish *Mayo* on the ground that its reference to the preemptive effect of the invalidated patent in that case was applicable only to "laws of nature," not "products of nature." Rejecting the findings of the district court that DNA is a unique composition in its embodiment of natural laws, Judge Lourie ruled that the patents in this case do not claim a law of nature. App. at 56a. Indeed, despite *Mayo*'s explicit discussion of preemption, Judge Lourie seemingly rejected the relevance of preemption in *any* patent case by emphasizing that patents are supposed to be preemptive. App. at 58a-59a.

Judge Moore, unlike Judge Lourie, thought that *Mayo* "clearly ought to apply equally to manifestations of nature (composition claims)." App. at 79a. Even so, she did not alter her conclusion or analysis in any material way to reflect this Court's holding. Neither she nor Judge Lourie even referred

[7] The court also adhered to its prior views on standing with one alteration. It found that the organizational plaintiffs did not have standing because they had not been threatened by Myriad. App. at 41a. The Federal Circuit continued to find Dr. Ostrer has standing, despite Myriad's argument that he lost standing when he moved from NYU to Montefiore Medical Center, where he is Director of Genetics and Genomic Diagnostics, App. at 25a. Dr. Ostrer submitted a declaration stating that he continues to have the desire and ability to test the BRCA1/2 genes and continues to feel threatened. *Id.*

to this Court's apparent rejection of her "reliance" argument in *Mayo*. 132 S. Ct. at 1305.

Judge Bryson's dissenting opinion on remand applied this Court's reasoning in *Mayo*.

> Has the applicant made an 'inventive' contribution to the product of nature? Does the claimed invention involve more than "well-understood, routine, conventional" elements. Here, the answer to those questions is no.

App. at 112a. He also rejected the deference that Judge Lourie and Judge Moore had given to prior PTO practice, noting that it "give[s] the PTO lawmaking authority that Congress has not accorded it." App. at 119a.

The court's ruling on two other points was unanimous, both before and after remand. First, it held that cDNA was patentable subject matter, *e.g.*, App. at 47a-48a, 80a-81a, 98a, ignoring the district court's finding that none of the claims is limited to cDNA, that cDNA result from natural phenomena, and that cDNA sequences are found in the human genome. App. at 268a, 339a. Second, it upheld method claim 20 of patent '282,[8] stating: "By definition . . . performing operations, even known types of steps on . . . transformed subject matter" is patentable even if Myriad did not transform the subject matter and even if the "transformations" are undefined and can be routine and conventional. App. at 67a-70a.

[8] *See* description of claim 20, p.8, *supra*.

Finally, the Federal Circuit did not address petitioners' constitutional claims, either in its original decision or on remand.

REASONS FOR GRANTING THE WRIT

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

In recent years, this Court has granted certiorari on several cases concerning the patentability of methods. *Mayo*, 132 S. Ct. 1289; *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). *See also Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., cert. dismissed*, 548 U.S. 124 (2006). Yet the Court has not addressed the patent eligibility of compositions of matter for over thirty years. It is crucial for the Court now to address that question. The results of the remand order illuminate the problem. Directed to reconsider its prior holding in light of *Mayo,* each panel member in the Federal Circuit had a different view on how, if at all, *Mayo* applied to this case.

The scientific, medical, and legal communities need 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 DNA that makes up genes function the same whether they are inside or outside the body. App. at 337a-44a. Circuit Judge Lourie, by contrast, held that the function of genes inside and outside the body is always irrelevant. App. at 55a. In his view, isolated DNA is patentable because removing a gene from the body necessarily alters its chemical structure. App. at 53a-58a. Judge Moore thought that the court must examine both function and structure. App. at 81a-82a. 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 based on patentees' reliance on PTO past practice. App. at 85a-94a. Finally, Judge Bryson found genes unpatentable because any structural changes were incidental to the isolation process and "only a consequence of possession." App. at 110a.

In reaching these various conclusions, 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. App. at 341a, 110a. Judges Lourie and Moore found that fact irrelevant and did not address the preemptive effect of these patents on clinical practice and research.

The Court's recent *Bilski* and *Mayo* decisions did not settle any of these disputes. The opinions of the panel members after remand each relied on the same, divided reasoning as before *Mayo*, with minimal change. Moreover, other Federal Circuit

judges continue to adopt divergent views in cases raising fundamental Section 101 questions, even as to method patents. Three months after *Mayo* was issued, the Federal Circuit upheld patents on a method for exchanging financial obligations. *CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, 685 F.3d 1341 (Fed. Cir. 2012). The majority ruled that Section 101 eligibility need not be decided first, as the threshold inquiry, and that unpatentability must be "manifestly evident." *See id.* at 1348, 1352. A dissent objected to the failure to identify an "inventive concept," as *Mayo* instructs. *Id.* at 1357. Federal Circuit judges have themselves recognized that "we continue to disagree vigorously over what is or is not patentable subject matter," citing to this case among others. *Compare MySpace, Inc. v. GraphOn Corp.*, 672 F.3d 1250, 1261 (Fed. Cir. 2012), *with id.* at 1269 (Mayer, J., dissenting) (stating that a "robust application of section 101 is required to ensure that the patent laws comport with their constitutionally-defined objective."). *See also Ultramercial, LLC v. Hulu, LLC*, 657 F.3d 1323, 1330 (Fed. Cir. 2011) (finding that claimed invention must be "manifestly abstract" to fall outside of Section 101), *vacated and remanded*, *WildTangent, Inc. v. Ultramerical, LLC*, 132 S. Ct. 2431 (2012); *Intervet v. Merial Ltd.*, 617 F.3d 1282, 1295 (Fed. Cir. 2010) (Dyk, J., concurring-in-part and dissenting-in-part) (voicing doubts about the Section 101 eligibility of isolated DNA).

The executive branch, too, has expressed different opinions in this litigation. The PTO granted these patents and has published guidelines authorizing patents on isolated DNA. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5,

2001).[9] However, 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 in this case 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). *See also* Br. for the United States as Amicus Curiae in Supp. of Neither Party, *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 2012 WL 3518509 (Fed. Cir. Aug. 16, 2012). The PTO did not sign either brief submitted by the United States.

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, this is the first to present and thoroughly litigate the issue of whether isolated DNA is patentable subject matter. 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 254a-85a.

Until the patent eligibility of isolated genes is clarified, important stakeholders will be forced to act – or will be chilled from acting – without clear legal guidance. These include the clinicians and scientists

[9] These Guidelines are not entitled to any deference. *Arnold P'ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004).

who want to undertake testing and research involving the patented genes in order to improve diagnosis and treatment for patients. Section 101 plays an important role in invalidating patents on laws and products of nature that impede innovation, avoiding the high litigation costs and intensive resources needed to resolve, for example, novelty or obviousness inquiries. *See Mayo*, 132 S. Ct. at 1304. Thus, determining Section 101 eligibility avoids "creating significantly greater legal uncertainty," *id.*

There were 64 amicus briefs filed previously in the Federal Circuit and this Court, signed by 102 organizations, corporations, or individuals, all highlighting the importance of resolving this case. Among those who signed briefs supporting plaintiffs were numerous major medical associations, health care providers, and organizations committed to patient advocacy.[10] These amici weighed in because of the significant impact of gene patents on scientific advancement and health care. *See* App. at 4a-7a, 122a-26a. As the Department of Justice said in its brief to the Federal Circuit: "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*

[10] Other amici in support of plaintiffs included the Southern Baptist Convention. A notable brief opposing gene patents was also filed by Dr. James Watson, who co-discovered DNA's double helix. Myriad's amici included associations of biotechnology corporations and patent attorneys. They too recognized that the issues raised by this petition are critical.

Pathology v. U.S. Patent and Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011).[11]

Given the unresolved legal issues, the conflicting views of the PTO and the Department of Justice, and the importance of clarity for the medical and scientific communities, this case plainly merits plenary review.

II. PATENTS ON "ISOLATED" DNA ARE INVALID UNDER THIS COURT'S SECTION 101 JURISPRUDENCE AND THE U.S. CONSTITUTION.

1. 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. *Chakrabarty*, 447 U.S. at 309. "'[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, 957 (C.C.P.A. 1931). In *Mayo*, the Court affirmed that subject matter eligibility remains a threshold question, separate and distinct from considerations of utility or novelty. 132 S. Ct. at 1304.

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[11] This question will continue to impact personalized medicine, despite the achievement of the Human Genome Project, given the large number of issued patents, the ongoing approval of DNA patents, and remaining gaps in genome identification.

In upholding these patents, the Federal Circuit departed dramatically from *Mayo*, *Chakrabarty*, *Funk Brothers*, and *American Fruit Growers* – this Court's seminal cases on the law and product of nature doctrine. The Court has held that a claimed composition must have "a distinctive name, character [and] use" and "markedly different characteristics from any found in nature," *Chakrabarty*, 447 U.S. at 309-10 (alteration in original) (citation omitted); or, as *Mayo* described, what is patented must be based on an "inventive concept" and "add enough" to the natural phenomena to warrant patenting. 132 S. Ct. at 1294, 1297.

As *Mayo* makes clear, a key aspect of the Section 101 analysis turns on whether the patent preempts use of the laws and products of nature. Does the patent "risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries . . . " "relative to the contribution of the inventor?" 132 S. Ct. at 1294, 1303; *see also Funk Bros.*, 333 U.S. at 130-31 (invalidating patents that cover the "handiwork of nature" or "qualities [that] are the work of nature"). 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. Unless the composition is rooted in an inventive concept, thus having markedly different characteristics from any found in nature, and does not tie up future innovation, the patent will

encumber "the storehouse of knowledge of all men." *Id.* at 130.

The Court has examined the key characteristics of a claimed composition, including function, to determine 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." *Chakrabarty*, 447 U.S. at 310 (quoting *Funk Bros.*, 333 U.S. at 131). The *Chakrabarty* bacterium was both structurally and functionally different from its natural state, containing new genetic material and becoming capable of degrading oil in its new form. By contrast, the challenged patent in *Funk Brothers* was based on a naturally-occurring phenomenon; namely, the ability of certain "isolated" bacteria to efficiently fix nitrogen without inhibiting each other. 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, the Court invalidated the patent because the patent holder did "not create [a] state of inhibition or of non-inhibition in the bacteria." 333 U.S. at 130-31.

Similarly, in *American 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). And in *Mayo*, the Court concluded that the patents covered a

law of nature – the relationship between certain metabolite levels and drug efficacy in a patient. 132 S. Ct. at 1297. Although the claims involved human intervention in administering a drug and determining metabolite levels, they monopolized this naturally-occurring relationship and thus were invalid. *Id.*

Under this precedent, the patents on isolated DNA improperly claim products and laws of nature. The claims themselves define "isolated DNA" according to a naturally-occurring functional characteristic – namely, "coding for" a naturally-occurring polypeptide. *See, e.g.*, claim 1, '282 patent, at App. 426a. 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 does not have markedly different characteristics from any found in nature. 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.

Moreover, the naturally-occurring coding relationship between DNA and proteins is a law of nature, unchanged by "isolating" the DNA. Other chemicals in the human body remain the same, albeit in different quantities, from person to person; DNA, on the other hand, codes for and transmits distinctive biological information. As the district court held, "DNA, and in particular the ordering of its

nucleotides, therefore serves as the physical embodiment of laws of nature – those that define the construction of the human body." App. at 335a. Isolation of DNA was a well-known technique at the time these patents were sought, and continues to be a routine preparatory step for using human genes in research and clinical practice. Fed. Cir. Second Corrected App. Vol. VI at A6963, A7037. The only "inventive concept" contained within these patents is disclosure of the law of nature; *i.e.*, the fact that this DNA codes for the BRCA protein and embodies information regarding a person's heredity and susceptibility to disease.

The broad preemptive effect of these patents is further evidence that they claim laws and products of nature. The patents cover all isolated forms of the naturally-occurring genes, whether previously identified or not. The patents grant Myriad the authority to prevent all research and clinical testing of the genes, raising the same concerns about patenting a "building-block" that has troubled the Court. *See Mayo*, 132 S. Ct. at 1303. These patents tie up basic uses of the genes, "foreclose[ing] more future innovation than the underlying discovery could reasonably justify." *Id.* at 1292. Unlike patents on drugs which can be invented around by developing another drug that treats the same condition, patents on isolated DNA bar access to every person's genetic information.

Myriad has vigorously enforced its patents, impeding medical practice and innovation in numerous ways. App. at 22a-25a, 37a, 281a-95a. It has prevented clinical testing by other labs, 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 279a, 285a-86a. Many women, upon obtaining results from Myriad, wish to get a second opinion before they make life-changing medical decisions, such as obtaining or refraining from prophylactic surgery, but cannot obtain confirmatory testing through other labs. App. at 288a-89a. Myriad also prevents others from providing testing at a lower price, or for free, and only 130 million of America's 308 million people can currently receive insurance coverage for their testing. Fed. Cir. Second Corrected App. Vol. VI at A4703.

The patents also interfere with deepening our knowledge about these genes and breast and ovarian cancer. Currently, Myriad collects a huge amount of data on the nature and significance of variants in the BRCA1/2 genes, but refuses to share that data with the scientific community and has no obligation to collaborate with others. App. at 289a-293a. The patents impede new advances in genetic testing that can efficiently sequence the many genes now associated with breast and ovarian cancer, or indeed the entire human genome. *See, e.g.*, Hilmi Ozcelik et al., *Long-Range PCR and Next-Generation Sequencing of BRCA1 and BRCA2 in Breast Cancer*, 14 J. Molecular Diagnostics 419, 467 (2012); Tom Walsh et al., *Mutations in 12 Genes for Inherited Ovarian, Fallopian Tube, and Peritoneal Carcinoma Identified by Massively Parallel Sequencing*, 108 Proc. Nat'l Acad. Sci. U.S. 17857, 18032 (2011).

The rationale for granting a patent – the need to create economic incentives to advance science – did not apply in this case. Other researchers were

also looking for the BRCA genes and had indicated that they would share their results with the scientific community. App. at 273a-77a, 289a-94a. 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 BRCA1/2 would have been made available to the public even without the patent incentive. *See* App. at 293a-95a; Sec'y's Advisory Comm. on Genetics, Health, & Soc'y, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (2010).

Finally, it is of critical importance to patient health that knowledge about these genes increase so as to advance diagnosis and treatment of breast and ovarian cancer, as well as the many other diseases associated with these genes. Because Myriad has authority to prevent research on a part of the human body[12] and to prevent development of new or better clinical tests, the consequences for women's health are enormous. This case does not question the patentability of new instruments, drugs, or methods of diagnosis or treatments. Instead, it concerns perhaps the most basic elements of biology, human genes. As the district court found: "The widespread use of gene sequence information as the foundation for biomedical research means that resolution of

[12] In opposing the first petition to this Court, Myriad claimed that it has generously permitted research. This assertion is contradicted by evidence provided by researchers. *See* Fed. Cir. Second Corrected App. Vol. III at A2673-74, A2888-93, A3022-23. And more importantly, the question in this case is not whether Myriad has been a generous corporate citizen but whether patent exclusivity permits it to prevent further research on human genes.

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 362a.

2. The Federal Circuit in this case reached the wrong result because it asked the wrong questions. It focused on trivial changes to DNA incidental to isolation that fall far short of "markedly different characteristics from any found in nature." It failed to identify what is inventive about these claims. And, it failed to consider their preemptive effects while giving undue weight to patentees' interests.

The opinion of the court by Judge Lourie focused only on the chemical structure of DNA, disregarding its biological characteristics. App. at 55a. ("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."). His conclusion contradicts both the patent claim language – which claims isolated DNA coding for a specified protein, rather than DNA with defined chemical ends – 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.

Under Judge Lourie's approach, any cleavage of chemical bonds would render the resulting

molecule patentable even though BRCA1/2 fragments, with covalent bonds broken, naturally exist in the body. *Compare* App. at 53a *with* Pls.-Appellees' Pet. for Panel Reh'g at 4, *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011). Such a rule has never been endorsed by this Court, or to the best of our knowledge by any court, and runs counter to this Court's pragmatic approach to applying Section 101. *Bilski*, 130 S. Ct. at 3226-27 (rejecting a rigid "machine-or-transformation" test for method claims). As in *Bilski*, the Federal Circuit again imposed an inflexible test unrooted 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. *See Chakrabarty*, 447 U.S. at 309-10; *Funk Bros.*, 333 U.S. at 130. Instead, it turned to past practice of the PTO and industry reliance to uphold claims she thought "on a blank canvas" might be invalid. App. at 86a-96a.

Despite *Mayo*'s concerns about the impact of patents on innovation, the majority refused to consider how the patents preempt use of laws and products of nature, impeding clinical and scientific work. App. at 43a-44a, 58a-59a (stating that effects of the patents, such as monopolizing genetic testing and prohibiting confirmatory testing, are not relevant to the legal question and that "limited preemption is inherent in every patent"). It is true that every valid patent excludes others from using the invention. However, the central question under Section 101 is whether the patent preempts use of a

law or product of nature, as these patents do. For example, a claim that includes small segments of DNA that are not limited to the patented genes, like claim 5 of patent '282, preempts researchers from working with that segment wherever it appears in the genome, foreclosing scientific inquiry far beyond what Myriad's discovery of two genes could ever justify. *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. *See also Lab. Corp. of Am. Holdings,* 548 U.S. at 126-27 (Breyer, J., dissenting) ("[S]ometimes *too much* patent protection can impede rather than 'promote the Progress of Science and useful Arts.'").

The Federal Circuit further departed from precedent by concluding that Section 101 questions should be resolved in favor of patentees based on their reliance interests. App. at 61a-62a and 87a-96a. This Court unequivocally rejected that proposition in *Mayo* when it invalidated certain medical patents that the PTO had approved for many years. 132 S. Ct. at 1304-05.

Lastly, the entire panel ignored the district court's factual finding that cDNA results from natural phenomena and can appear in the body. Ignoring the fact that nature dictates the composition and order of nucleotides that make up cDNA, the Federal Circuit held that cDNA was patentable because it is more often created in a lab. App. at 54a.

3. Patents on isolated DNA also violate the First Amendment because they block scientific inquiry into the patented DNA. These patents prevent access to each person's genetic information

and deprive others from examining the BRCA1/2 genes and engaging in fundamental scientific work. It is not possible to "invent around" human genes, as one can 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. THE METHOD CLAIM UPHELD BELOW IS INCONSISTENT WITH *MAYO* AND SHOULD HAVE BEEN REJECTED.

The Federal Circuit properly rejected all but one of Myriad's method claims. The one it upheld should have been rejected as well. The court's failure to do so reflects a misunderstanding or misapplication of *Mayo* and warrants review given the Federal Circuit's critical role in interpreting patent law.

In *Mayo*, this Court invalidated a patent on examining a human's natural reaction to a single drug. Here, claim 20 of patent '282 similarly involves examining a human (or animal) cell's natural reaction to any potential drug.[13] The Federal Circuit found *Mayo* irrelevant to the claim's validity because instead of measuring how the drug affects the body, the scientist is measuring how the drug affects a "transformed" cell. *See* App. at 68a-69a. Yet, the patent does not require that the cell be

[13] *See* description of claim 20, p. 8, *supra*.

transformed by the patent holder, just as the drug in *Mayo* was not patented by Prometheus; indeed, transformed cells containing altered DNA are conventional products widely available for purchase. Nor does the claim specify the nature of the transformation. It simply assumes that such a cell is used.

Testing the effectiveness of a potential therapeutic by comparing its effect on cell growth with the cell growth occurring without the compound is routine, conventional science. Preventing any researcher from engaging in this science to find a cancer treatment is precisely the preemptive effect that led this Court to invalidate the claim in *Mayo* and should invalidate this claim as well.

IV. 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 face a credible threat of enforcement need not await actual enforcement before bringing a lawsuit). Exalting form over substance, the Federal Circuit improperly ruled that petitioners lacked standing unless they were personally threatened by Myriad.

Even applying its erroneous standard, the Federal Circuit held that Dr. Ostrer had standing, allowing this case to proceed. App. at 32a, 40a-42a. But, inexplicably, the court held that only Dr. Ostrer has standing despite its finding that:

> 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 37a (emphasis added). According to the Federal Circuit, these facts did not establish an "injury traceable to Myriad" for anyone other than Dr. Ostrer. Instead, it characterized the injury suffered by every similarly situated researcher and institution as an "attenuated, non-proximate, effect from the existence of [Myriad's] patent." App. at 41a.

It is difficult to reconcile findings that all of the plaintiffs have been "forced to cease" their actions as a result of Myriad's patent enforcement 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 24a, 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 this Court's precedent. *See Doe v. Bolton*, 410 U.S. 179, 188 (1973); *Virginia v. Am. Booksellers Ass'n, Inc.,* 484 U.S. 383, 393 (1988). *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); App. at 286a-87a.

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 erroneous. It is even more restrictive than that court's prior "reasonable

apprehension" test, rejected by this Court in *MedImmune*.[14] The medical organizational plaintiffs and most of the physician plaintiffs are 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. *See 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 providers was sufficient to trigger liability for inducing infringement).

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[14] This was not the circuit's only clear error. Although the panel found that Dr. Ostrer had standing, the court denied the standing of the organizational plaintiff American College of Medical Genetics and Genomics (ACMG), of which Dr. Ostrer is a member. App at 41a; Fed. Cir. Second Corrected App. Vol. III at A2933. The undisputed record reflects that gene patenting is germane to ACMG's purpose. App. at 241a. Pursuant to well-established law, 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 24a. That is simply incorrect and contrary to the factual findings of the district court. Plaintiff Ellen Matloff's declaration makes clear that she personally 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 383a. 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.

CONCLUSION

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

Respectfully submitted,

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APPENDIX