No. 11-725

IN THE

Supreme Court of the United States

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

v.

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

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF IN OPPOSITION

GREGORY A. CASTANIAS
Counsel of Record
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
(202) 879-3939
gcastanias@jonesday.com

Counsel for Respondents

QUESTIONS PRESENTED

1. Are the challenged patent claims, which claim particular isolated molecules of deoxyribonucleic acid ("DNA"), eligible for patenting under 35 U.S.C. § 101, (i) where those isolated molecules are undisputedly "compositions of matter" which do not naturally occur, (ii) where those isolated molecules have new and significant utilities not found in nature, (iii) where the U.S. Patent and Trademark Office ("PTO") has issued similar patents since at least 1984, (iv) where the PTO in 2001 issued Utility Guidelines after extensive notice and comment proceedings confirming that such isolated molecules are patent-eligible as human-made inventions under § 101, (v) where significant investment and property rights have been created in biotechnology companies and products over the last 30 years based on the patent-eligibility of such isolated molecules, and (vi) where no similar challenge to the patent-eligibility of such isolated molecules has been mounted in the United States, before or since this lawsuit (and thus no conflict is alleged or could exist)?

2. Did the Court of Appeals correctly conclude that 19 of the 20 plaintiffs recruited to join this suit lacked standing because they either lacked any injury traceable to Myriad, or had failed to show any "controversy, between parties having adverse legal interests, of sufficient immediacy and reality" because certain plaintiffs' speculative intentions to practice the challenged patents at some unspecified time in the future did not "warrant the issuance of a declaratory judgment" under *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)?

CORPORATE DISCLOSURE STATEMENT

No parent or publicly held company owns 10% or more of the stock of respondent Myriad Genetics, Inc. or of the University of Utah Research Foundation.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

TABLE OF AUTHORITIES
(continued)

Page(s)

CONSTITUTIONAL AND STATUTORY AUTHORITIES AND RULES

OTHER AUTHORITIES

TABLE OF AUTHORITIES
(continued)

Page(s)

BRIEF IN OPPOSITION

The petition should be denied, as neither question presented by petitioners merits this Court's review. As to the first, "Are human genes patentable?", that is not the question that was raised in or decided by the lower courts. Rather, the question correctly answered by the Federal Circuit was whether particular isolated molecules of DNA, which were never available to the public until humans invented them, and whose utility is clear and unquestioned, were eligible for patenting as "compositions of matter" under 35 U.S.C. § 101. The Federal Circuit's affirmative answer to the question that *was* presented to it squared with almost 30 years of PTO practice, with 30 years of substantial investment and reliance by the biotechnology sector, with the PTO's 2001 *Utility Guidelines*, and with the overarching purpose of U.S. patent law, which is to make new and useful inventions available to the public in exchange for a limited period of exclusivity.

The second question, a jurisdictional one, is not worthy of certiorari, either, and its presence only confirms that this case is a poor vehicle for addressing either question. Petitioners are 20 individuals and organizations recruited as plaintiffs by two public-interest law firms to challenge a few selected patent claims. The Federal Circuit concluded that only one of the 20 plaintiffs had a sufficiently real and immediate dispute with the patentee Myriad Genetics, Inc. ("Myriad") to satisfy the case-or-controversy requirement. The Federal Circuit's conclusion as to that one plaintiff is itself incorrect, and presents an antecedent jurisdictional

issue that would need to be resolved by this Court, thereby making this petition a poor vehicle for review.

Despite the PTO's long and consistent practice of allowing claims to isolated DNA molecules as patent-eligible subject matter, and the establishment of a thriving biotechnology industry with human, agricultural, and industrial products and companies, this case is the first—and still only one—to challenge the patent-eligibility of such isolated molecules in the appellate courts. Indeed, the entire human genome was published in 2001 (several years after the 1994 and 1995 filing dates of the relevant patents), and in that light, claims to isolated human DNA molecules sought after that date face bars to patentability under other provisions of the Patent Act, including 35 U.S.C. § 103 (non-obviousness). Thus, the relevancy of this § 101 issue is ever diminishing with the expiration of existing patent terms, and will soon vanish. Importantly, Myriad did not assert counterclaims of infringement against any of the plaintiff-petitioners. Consequently, the petitioners' speculations about the precise exclusionary scope of Myriad's patent claims are just that; they have never been tested in any adversary proceeding. Finally, petitioners did not ask the Federal Circuit to rehear this case *en banc*. Thus, even if this case did present the sort of important and recurring question meriting this Court's consideration—and it does not—then it would better await a case unencumbered by substantial antecedent jurisdictional problems, where the exclusionary scope of the patent claims is tested rather than purely speculated, and where the full Federal Circuit is asked to consider the question in the first instance.

BACKGROUND

A. Patents Directed To Isolated DNA Molecules As Compositions Of Matter Have Been Issued For Almost 30 Years

Patent claims directed to isolated DNA molecules are not a new development; indeed, the challenged patents here were filed over sixteen years ago. Rather, the PTO has been issuing patents directed to isolated DNA molecules since the early 1980s. *See, e.g.*, Pet. App. 53a; *id.* at 80-81a (Moore, J., concurring-in-part). One investigation calculated that during the past thirty years, the PTO has issued 2,645 patents with claims directed to "isolated DNA." C.A. App. 3710 (declaration of former Acting Director of the PTO and Acting Under Secretary of Commerce for Intellectual Property). Another recent article concluded that the PTO has granted over 40,000 patents to DNA-related subject matter. *See* Eric J. Rogers, *Can You Patent Genes? Yes and No*, 93 J. PAT. & TRADEMARK OFF. SOC'Y 19, 19, 40 (2010).

Nor does this case present the first judicial challenge to DNA-related patent claims. Indeed, the Federal Circuit addressed invalidity challenges under §§ 102, 103, and 112 (though not a patent-eligibility challenge under § 101) to DNA-related claims over twenty years ago in *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991). *See* Pet. App. 81a (Moore, J., concurring-in-part).

Moreover, in 2001, consistent with its long-standing practice, the PTO promulgated *Utility Guidelines*—after an extensive notice-and-comment process—setting forth its formal policy that "an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its

natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it." 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001). The guidelines further provide:

> A patent claim directed to an isolated and purified DNA molecule could cover, *e.g.*, a gene excised from a natural chromosome or a synthesized DNA molecule. An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter … because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound.

Id.

Over these 30-some years, the biotechnology industry has proven to be "among our most innovative," Pet. App. 90a (Moore, J., concurring-in-part), and the companies which have relied upon the steady understanding that isolated DNA molecules are patent-eligible have "made the reasonable decision to invest large amounts of time and money into the identification, isolation, and characterization of genes," and in turn have developed a rich portfolio of advancements in human, agricultural, and industrial products. *Id.*

Accordingly, the patent-eligibility of isolated DNA molecules has been well established for decades.

B. The History Of This Case

1. On May 12, 2009, the American Civil Liberties Union Foundation ("ACLU") and the Public Patent Foundation ("PPF") filed a declaratory-judgment action on behalf of twenty recruited plaintiffs, alleging, among other things, that a few selected claims of the challenged patents are invalid under § 101 for claiming subject matter ineligible for patent protection. Pet. App. 242a. The specifically challenged claims were hand-picked by plaintiffs' counsel, who made clear that this suit was fueled by PPF's desire to "just pick one case as our case" to make a generalized challenge against all patents covering similar subject matter. C.A. App. A7387-88.

The district-court proceedings focused on two principal issues: (1) Myriad's motion to dismiss the declaratory-judgment suit for lack of a real and immediate case or controversy; and (2) the parties' cross-motions for summary judgment on the merits.

2. Myriad moved to dismiss this suit, arguing that seventeen of the plaintiffs lacked a justiciable controversy because Myriad never had any communications with them regarding the challenged patents. *See* Pet. App. 22a. As for the three remaining plaintiffs—Drs. Ostrer, Kazazian, and Ganguly—Myriad showed that any communications with them or their organizations occurred more than a decade before plaintiffs filed this action, and therefore were too stale to demonstrate a real and immediate controversy under the Declaratory Judgment Act. *See id.* at 20a-22a. Myriad also showed that two prior cases concerning the challenged patents concluded more than ten years before commencement of this suit and did not involve

any named plaintiff, and so did not demonstrate a real and immediate controversy, either. *See id.* at 22a.

Petitioners responded by submitting a collection of declarations from various plaintiffs. Among them was a declaration from Dr. Ostrer, who at that time was the Director of NYU's Molecular Genetics Laboratory. *See* C.A. App. A2932. Dr. Ostrer averred that his NYU laboratory "has all of the personnel, expertise, and facilities necessary to do various types of [BRCA1/2] sequencing," and that his laboratory at NYU "could, and would . . . do full sequencing." *Id.* at A2936 ¶ 9. Dr. Ostrer also stated that because of a collaborative-license offer that Myriad made to NYU in 1998 (*id.* at A2964-74), his laboratory has not provided clinical sequencing for fear that Myriad would assert the challenged patents. *Id.* at A2935 ¶ 7; A2934 ¶4. Drs. Ganguly and Kazazian also submitted declarations in which they stated that if the challenged claims were invalidated, they would then consider whether to perform BRCA1/2 testing. *Id.* at A2852 ¶ 11.

The district court denied the motion to dismiss based on its view that *MedImmune's* "all circumstances" test does not require a patentee to have taken any action toward any specific plaintiff. Pet. App. 283a. Instead, the district court stated that only "some affirmative act by the [patentee] relating to enforcement of its patent rights," regardless of to whom such enforcement is directed, suffices to establish a controversy for declaratory-judgment jurisdiction. *Id.* at 280a. The district court then concluded that based on Myriad's activities occurring in the late 1990s (various licensing letters and two

lawsuits) there "is the widespread understanding that one may engage in [BRCA1/2] testing at the risk of being sued for infringement liability by Myriad." *Id.* at 287a. This conclusion was contrary to a record that showed widespread testing activities by numerous laboratories and scientists (including various named plaintiffs), without lawsuits.

3. With Article III jurisdiction upheld by the district court, the parties presented cross-motions for summary judgment on the merits. Plaintiffs sought summary judgment that certain method claims (not at issue in the petition) and composition-of-matter claims in the challenged patents were invalid under § 101, and violated both the First Amendment and the Patent and Copyright Clause (Article I, Section 8, Clause 8) of the U.S. Constitution. Defendants asked the court to grant summary judgment that the claims were drawn to patent-eligible subject matter and not in violation of any constitutional provision. Following briefing and submission of numerous expert declarations by each party, the district court held that none of the composition claims covered patent-eligible subject matter.

The district court's opinion began by noting that the question presented by plaintiffs' challenge to the composition claims was not "are human genes patentable," but "whether the isolated DNA claimed by Myriad possesses 'markedly different characteristics' from a product of nature." Pet. App. 214a. The district court did not distinguish between the various categories of composition claims. Instead, the court concluded that all such claims were invalid because "none of the structural and functional differences cited by Myriad" constitute a marked

difference between the native DNA and the claimed isolated DNA molecules. *Id.* at 216a. The district court focused heavily on the similarities (rather than differences) between native and isolated DNA, and gave dispositive weight to a DNA molecule's nucleotide sequence: "The preservation of this defining characteristic of DNA in its native and isolated forms mandates the conclusion that the challenged composition claims are directed to unpatentable products of nature." *Id.* (Even this conclusion was scientifically incorrect, as the claimed isolated molecules have a different sequence after isolation, due to the breaking of covalent bonds. *See* Pet. App. 45a-47a.)

4. The Federal Circuit upheld the district court's finding of declaratory-judgment jurisdiction, but only as to one of the 20 plaintiffs, Dr. Ostrer. On the merits, the Federal Circuit reversed the district court's holding that the composition-of-matter claims did not claim patent-eligible subject matter. (The Court of Appeals also reversed the district court's determination that one of Myriad's method claims was not patent-eligible; because the method claims are not at issue in the petition, we do not mention them further.)

a. As to jurisdiction, the three-judge panel unanimously held that only "one Plaintiff, Dr. Ostrer, has established standing." Pet. App. 30a. Based on Dr. Ostrer's district-court declaration, which was not supplemented with live testimony or cross-examination, the Federal Circuit noted that, by virtue of his employment at NYU, "Ostrer [] indicates that his lab has all the personnel, facilities, and expertise necessary to undertake clinical BRCA

testing." *Id.* at 23a. The Federal Circuit also noted that Dr. Ostrer "seeks to undertake specific BRCA-related activities," *id.* at 33a, for which Myriad sought a "collaborative license requir[ing] NYU to make a payment to Myriad," *id.* at 32a. The Federal Circuit then held that Myriad's decade-old offer to NYU of a collaborative license sufficed to establish a case or controversy with Dr. Ostrer, because: (1) "the relevant circumstances surrounding Myriad's assertion of its patent rights have not changed," *id.* at 34a; and (2) Dr. Ostrer "remains in the same position with respect to his ability and his desire to provide BRCA testing as in the late 1990s," *id.* at 35a.

The Federal Circuit held that Drs. Ganguly and Kazazian had not demonstrated a case or controversy with Myriad, because their declarations amounted to "'some day intentions' [that] are insufficient to support an 'actual or imminent' injury for standing." *Id.* at 34a. The court then held that the remaining plaintiffs also had not shown a case or controversy with Myriad given the absence of any "affirmative acts by the patentee directed at specific Plaintiffs." *Id.* at 38a-39a. As the Federal Circuit explained: "Simply disagreeing with the existence of a patent or even suffering an attenuated, non-proximate, effect from the existence of a patent" does not suffice under this Court's declaratory-judgment precedents. *Id.* at 39a.

b. On the merits, the panel concluded that the composition-of-matter claims were indeed patent-eligible under § 101. In the lead opinion, Judge Lourie began with the observation that "Plaintiffs' challenge under § 101 [to] Myriad's composition claims [is] directed to 'isolated' DNA molecules." *Id.*

at 40a. Judge Lourie began by observing that "the parties … appear to agree that isolated DNAs are compositions of matter," *id.* at 43a, and noted that "[i]t is undisputed that Myriad's claimed isolated DNAs exist in a distinctive chemical form—as distinctive chemical molecules—from DNAs in the human body." *Id.* at 45a-46a. Judge Lourie proceeded to catalogue a variety of differences between the claimed compositions and native DNA, including the facts that isolated DNA molecules: (1) are "free standing"; (2) are "synthesized" or have "chemically severed" backbones; and (3) have significantly fewer nucleotides than native DNA. *Id.* at 46a. In view of such differences, Judge Lourie explained that "human intervention in cleaving or synthesizing a portion of a native chromosomal DNA imparts on that isolated DNA a distinctive chemical identity from that possessed by native DNA." *Id.* Thus, "we conclude that the challenged claims to isolated DNAs, whether limited to cDNAs or not, are directed to patent-eligible subject matter." *Id.* at 43a.

Judge Moore, concurring in the judgment, noted the lead opinion's "thoughtful analysis of the scientific principles associated with the claims at issue," *id.* at 67a, and, like Judge Lourie, recognized that "isolated DNA sequences [are] at issue in this case," *id.* at 70a, not "human genes." Nonetheless, she offered a separate opinion on the issue.

Judge Moore analyzed the composition claims according to three different categories. First, addressing claims drawn to cDNA molecules, Judge Moore determined that such claims are patent eligible because, among other reasons, "cDNA sequences do not exist in nature," cDNA molecules

"only contain[] the coding nucleotides," and such molecules "can be used to express a protein in a cell which does not normally produce it." *Id.* at 73a. Turning next to claims covering isolated DNA molecules with short nucleotide sequences, Judge Moore reasoned that such claims are also patent-eligible given their (1) different structural characteristics (*e.g.*, different chemical bonds and nucleotide sequences) as compared to native DNA, *id.* at 74a-75a, and (2) different functional characteristics, such as the ability to be "used as primers in a diagnostic screening process" and "as the basis for probes." *Id.* at 76a. Lastly, considering composition claims covering isolated DNA with longer nucleotide sequences, Judge Moore determined that these claims, too, are patent-eligible, given their structural differences from native DNA. *Id.* at 78a. Judge Moore further explained that the patent-eligibility of these claims is confirmed by the PTO's decade-long policy of granting patents on isolated DNA molecules, and the public's settled expectations of patent-eligibility for such subject matter. *Id.* at 80a-82a.

Judge Bryson wrote a separate opinion, in which he agreed with the majority that the challenged claims drawn to cDNA molecules are patent-eligible. *Id.* at 94a. Like the majority, Judge Bryson also viewed the specific dispute as whether "the process of isolating genetic material from a human DNA molecule makes the isolated genetic material a patentable invention." *Id.* Also, like the majority, Judge Bryson noted that isolating DNA molecules results in a "material change made to those genes from their natural state." *Id.* at 98a. Judge Bryson, however, placed significantly less weight on this

change than did the majority because, in his view, the change "is necessarily incidental to the extraction of the genes from the environment in which they are found." *Id.* Judge Bryson also disagreed with the majority as to the factual import of severing covalent bonds. *Id.* at 99a. Accordingly, like the district court, he determined, based on his own evaluation of the similarities, that the non-cDNA composition claims were not "markedly different" from native DNA, and thus in his view not patent-eligible. *Id.* at 100a-104a.

c. After the Federal Circuit issued its opinion, both parties sought panel rehearing; neither side requested rehearing *en banc*. Petitioners sought a rehearing concerning standing for plaintiffs other than Dr. Ostrer, and concerning the patent eligibility of the challenged composition claims. The Federal Circuit denied the petition.

Myriad sought rehearing based on events occurring after issuance of the Federal Circuit's opinion. In particular, Myriad learned, and petitioners confirmed, that Dr. Ostrer ceased his employment at NYU, effective August 29, 2011. *See* Pltfs' Answer to Dfts' Pet. for Reh'g at 2. Since that time, Dr. Ostrer has been employed by Montefiore Medical Center ("Montefiore"). *Id.* Accordingly, Myriad requested a rehearing to declare this action moot because whatever claim Dr. Ostrer had to standing depended upon the Myriad-NYU correspondence in 1998, and because there is no colorable claim (or evidence) of a Myriad-Montefiore controversy concerning the challenged patents. The Federal Circuit denied Myriad's petition.

C. Corrections of Petitioners' Misstatements of Fact and Law

Pursuant to this Court's Rule 15.2, and in view of the factual background provided above, Myriad provides the following specific corrections to address petitioners' misstatements of fact and law.

1. The first question posed by the petition bears no relation to the uncontroverted facts of this case. This case does not involve the question of whether "human genes" are patent-eligible. Yet petitioners seek this Court's review by making inflammatory, incorrect statements such as "[t]hrough its combined patents, Myriad claims ownership of the BRCA1 and BRCA2 genes of every American." Pet. 8. These types of assertions have no foundation in the record, nor in scientific fact, yet they are replete throughout the petition. The challenged patent claims do not cover "human genes," contrary to petitioners' attempts to recast the nature of this case. *See, e.g.*, Pet. i, 2-3, 6-7, 16-18. Rather, the challenged claims are specifically drawn to compositions of matter covering isolated DNA molecules that do not naturally exist. In fact, every judge to consider the challenged claims has made clear that the claims cover "'isolated' DNA molecules," not human genes. Pet. App. 40a (majority opinion); *id.* at 62a (concurring opinion); *id.* at 94a (dissenting opinion); *id.* at 179a (district-court opinion).

2. The claimed isolated DNA molecules are not "products of nature," nor do they "exist naturally in the body." Pet. 5. The specifications of the challenged patents teach that isolated DNA molecules are not naturally occurring; rather, they are "substantially separated from other cellular

components which naturally accompany a native human sequence or protein, *e.g.*, ribosomes, polymerases, many other human genome sequences and proteins." *See, e.g.*, C.A. App. A597 at col. 19, ll. 8-18. Thus, isolated DNA molecules "embrace[] a nucleic acid sequence or protein which has been removed from its naturally occurring environment, and include[] recombinant or cloned DNA isolates and chemically synthesized analogs or analogs biologically synthesized by heterologous systems." *Id.* As Judge Lourie explained in his lead opinion: "It is undisputed that Myriad's claimed isolated DNAs exist in a distinctive chemical form—as distinctive chemical molecules—from DNAs in the human body," because "human intervention in cleaving or synthesizing a portion of a native chromosomal DNA imparts on that isolated DNA a distinctive chemical identity from that possessed by native DNA." Pet. App. 45a-46a. Further, contrary to petitioners' belated factual claim that covalent bonds of DNA molecules may be "formed and broken in the body" (Pet. 13), DNA cannot, in fact, be *isolated* in the body. By definition, isolated DNA is that which is excised and separated from its native environment; such a process does not naturally occur. This scientific principle is well-supported in the record, as shown in the declarations of Drs. Mark Kay, Joseph Schlessinger, and Nancy Linck, among others. C.A. App. A4291 ¶ 17, A4322 ¶ 133, A4324 ¶ 137, A4325 ¶ 143, A4412 ¶¶ 47-48, A4413-14 ¶¶ 51-53; A4723 ¶ 11. Even the petition ultimately acknowledges this fact. *See* Pet. 4.

3. Contrary to petitioner's claims (*e.g.*, Pet. 3, 5), significant structural and functional differences exist between naturally-occurring DNA and the isolated

DNA molecules covered by the challenged claims. Judge Lourie's majority opinion surveyed the structural differences between natural DNA and the claimed isolated DNA molecules, identifying differences such as chemically-severed backbones, significantly fewer nucleotides, and the free-standing nature of isolated DNA molecules as compared to natural DNA. In the concurring opinion, Judge Moore likewise canvassed various structural and functional differences between natural DNA and isolated DNA molecules, including "change[s] in chemical bonds," "substantially smaller molecule[s]," "distinctly different sequence of nucleotides," and ability of isolated DNA molecules to be "used as primers in diagnostic screening procedures" and "as the basis for probes." Pet. App. 71a-72a, 76a. Indeed, even the dissenting opinion, though assigning less legal weight to such differences, noted that there is a "material change" between natural DNA and the claimed isolated DNA molecules. *Id.* at 98a. And, the record reflects a number of submissions by experts detailing the differences in structure, function, and utility between isolated DNA molecules and native, or genomic DNA in the body. *See, e.g.*, C.A. App. A4320-35, A4335-39 (declaration of Stanford University School of Medicine Professor Dr. Kay); A4410-12 ¶¶ 44-48 (declaration of Dr. Linck); A4723 & A4728-29 (declaration of Chairman of Pharmacology Department at Yale University School of Medicine Dr. Schlessinger).

4. Petitioners wrongly accuse the lead and concurring opinions of "depart[ing]" from this Court's precedent in assessing patent eligibility. Pet. 25-30. To the contrary, both Judges Lourie and Moore applied the same test petitioners urged on the lower

courts, *i.e.*, whether a claimed invention is "markedly different" or "distinctive" from what exists in nature unaltered by the human inventive hand. *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980). *See* Pet. App. 45a; *id.* at 74a-77a. Similarly, petitioners incorrectly state that the Federal Circuit adopted a "new and inflexible rule" regarding declaratory-judgment jurisdiction. Pet. i. Rather, the Federal Circuit plainly analyzed the standing issues according to this Court's declaratory-judgment precedent, looking properly to the existence of a bilateral controversy, and not the subjective feelings or perceived inhibitions of the plaintiffs alone. Pet. App. 26a-39a.

5. In challenging the Federal Circuit's holding that 19 of 20 plaintiffs lacked standing to bring this action, petitioners omit any mention of the dispositive change in circumstances concerning Dr. Ostrer—the lone plaintiff that the Federal Circuit held to have standing. The Federal Circuit's determination that Dr. Ostrer had standing was entirely predicated on his employment at NYU. The court found that Myriad's offer "to [Dr. Ostrer's] institution, NYU Medical Center, [of] a limited collaborative license . . . requir[ing] NYU to make a payment to Myriad" served as the basis for a justiciable controversy. Pet. App. 32a. The court reasoned that such controversy persisted for over a decade because "the relevant circumstances remain unchanged." *Id.* at 35a However, after the Federal Circuit issued its opinion, Dr. Ostrer himself unilaterally changed those "circumstances" by ending his employment at NYU. *See* Pltfs' Answer to Dfts' Pet. for Reh'g at 2. Instead, Dr. Ostrer is now employed at Montefiore, *id.*, an institution with which Myriad has never had a controversy, and

where petitioners lack even an arguable claim to a controversy. Accordingly, since the Federal Circuit issued its opinion, the relevant circumstances have materially changed such that even Dr. Ostrer no longer has a colorable claim to standing to maintain this action.

6. Contrary to petitioners' cursory assertions (Pet. 2, 19-22) unsupported by record citation, neither Myriad nor the existence of the challenged patents hinder research of BRCA1/2 genes or preclude all sequencing of such genes. The record evidence demonstrates otherwise. In fact, one of the named plaintiffs concedes that she "could sequence the BRCA1 and BRCA2 genes for purely research purposes," C.A. App. A1305 ¶ 15, and has been doing so without impediment, *id.* at A1304 ¶ 11. The unchallenged facts further demonstrate that 18,000 researchers have conducted studies on BRCA1/2 genes, over 8,000 relevant papers have been published on BRCA1/2 genes, and over 130 clinical trials regarding BRCA1/2 genes have been commenced since the inventors disclosed their inventions to the public. *Id.* at A3643 ¶ 13; A4540-41 ¶ 41-45. Moreover, the record shows that there are multiple laboratories that provide "second opinions" regarding BRCA1/2 test results for deleterious mutations. *Id.* at A3666. All of these facts accord with scholarly articles concluding that the existence of such patents does not hinder research. *See, e.g.*, Christopher M. Holman, *Trends in Human Gene Patent Litigation*, 322 SCIENCE 198, 199 (2008); John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002, 2003 (2005).

REASONS FOR DENYING THE WRIT

There is a panoply of reasons for this Court to deny the petition—the correctness of the judgment below, the absence of any conflict, 30 years of acceptance and reliance by the biotechnology sector, the uniqueness of this case, the abstractness of the challenge, and the inevitable antecedent jurisdictional issues that this Court would have to take up in order to reach the merits of the § 101 issue, which itself is misrepresented by petitioners as "[a]re human genes patentable?"

I. THE COURT OF APPEALS' DECISION WAS CORRECT

In this case, the Federal Circuit, the appellate court vested with the statutory mission of unifying and clarifying U.S. patent law, issued a judgment that was not only correct, but also consistent with the text of the Patent Act, with this Court's decisions, with the considered judgment of the PTO, with industry practice, and with every discernible policy goal of the Patent Act.

First, the challenged isolated DNA molecules are unquestionably and undisputedly "compositions of matter" within the text of § 101. That section provides that "[w]hoever invents or discovers any new and useful . . . composition of matter, or any new and useful improvement thereof, may obtain a patent therefor . . . ." This language is purposely "expansive" and "comprehensive," *Chakrabarty*, 447 U.S. at 308, to "ensure that 'ingenuity should receive a liberal encouragement.'" *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (quoting, through *Chakrabarty*, 5

Writings of Thomas Jefferson 75-76 (H. Washington ed. 1871)).

The claimed isolated DNA molecules satisfy the statute because they are nucleotides linked to each other by a phosphodiester backbone. Pet. App. 13a, 45a-46a, 70a-71a; C.A. App. A3493, A3709, A4290, A4317-20, A4723-24. Petitioners have never disputed—indeed, they have repeatedly admitted—that isolated molecules of deoxyribonucleic acid are "compositions" of matter under this definition, and they do not argue otherwise here. Pet. App. 43a; C.A. App. A6911. As such, the claimed isolated DNA molecules falls squarely within the statutory term "composition of matter." *See Bilski*, 130 S. Ct. at 3226 (explaining that the term "composition of matter" is to be "understood with common usage" and citing *Chakrabarty*).

Second, the Court of Appeals correctly concluded that the claimed isolated molecules are human-made "invent[ions]" under § 101. As Judge Lourie put it, human invention takes place when "human intervention has given" the claimed invention "'markedly different,' or 'distinctive,' characteristics." Pet. App. 45a (quoting *Chakrabarty*, 447 U.S. at 310 and *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)). Judge Moore similarly recognized that the claimed isolated molecules "are not naturally produced without the intervention of man." Pet. App. 75a (Moore, J., concurring-in-part).

Third, the Federal Circuit correctly upheld the composition-of-matter claims in view of the PTO's longstanding practice of issuing such patents, as illustrated by its 2001 *Utility Guidelines.* As noted above, these guidelines reflect the PTO's considered

judgment that the human identification and isolation of a particular DNA molecule represents human intervention that constitutes a human invention of a composition of matter under § 101. As Judges Lourie and Moore each recognized, this Court "has repeatedly stated that changes to longstanding practice should come from Congress, not the courts." Pet. App. 52a; *see also id.* at 87a-93a.

In *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124 (2001), this Court reiterated that § 101 has "broad scope and applicability," and refused to deny patent protection to sexually reproduced plants in view of the fact that the "PTO has assigned utility patents for plants for at least 16 years and there has been no indication from either Congress or agencies with expertise that such coverage is inconsistent with [the governing statutes]." *Id.* at 144-45. In *J.E.M.*, 16 years of agency practice and "some 1,800 utility patents for plants" led to this conclusion. *Id.* at 127. The present case is even stronger, for there has been over 30 years of uninterrupted agency practice, over 40,000 DNA-related patents (Pet. App. 53a), and a substantial portion of the biotechnology sector of the American economy was built in reliance on that patent protection. ""To change so substantially the rules of the game now,' after more than a century of practice, 'could very well subvert the various balances the PTO sought to strike when issuing the numerous patents which have not yet expired and which would be affected by our decision.'" Pet. App. 82a-83a (Moore, J., concurring-in-part) (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002)).

Finally, the Federal Circuit's holding of patent-eligibility is consistent with the overall goals of the Patent Act, which is to incentivize those who bring new, useful inventions forward to the public with a limited right to exclude. The utility of Myriad's inventions has never been questioned, and the record reflects that these never-before-isolated DNA molecules brought with them substantial new utilities, most notably their use as molecular tools (*e.g.*, probes or primers) because of their ability to target and form stable chemical structures with a BRCA DNA sequence from a patient's tissue samples. *See, e.g.*, C.A. App. A3455-57; A3468-72; A4324; A4338-43. By using these newly-created molecular tools, a patient can now more accurately learn of her genetic predisposition to, *e.g.*, breast cancer, and in turn receive a personalized course of medical treatment. Patients no longer have to rely on the past and less precise method of determining predisposition risk based on family history. The patent laws appropriately rewarded the inventors.

II. THE COURT OF APPEALS' DECISION IS NOT IN CONFLICT WITH THE DECISIONS OF ANY OTHER APPELLATE COURT OR OF THIS COURT

The Court of Appeals' decision is not in conflict with any other federal appellate decision, including from the Federal Circuit itself, or with any decision of this Court. Nor is any such conflict alleged by petitioners. Indeed, the word "conflict" appears nowhere in the petition.

What petitioners do claim, however, is that the Federal Circuit's decision "violates long-established Supreme Court precedent that prohibits the

patenting of laws of nature, natural phenomena, products of nature, and abstract ideas." Pet. 25. In particular, petitioners allege that "the Federal Circuit departed dramatically from *Chakrabarty*, *Funk Brothers*, and *American Fruit Growers*." *Id.* There is no departure from precedent here, let alone a "dramati[c]" one, and petitioners overstate the Federal Circuit's holding when they say that "the opinion of Judge Lourie concluded" that "a claimed composition" "become[s] patentable simply because there has been a change in its structure." Pet. 25-26.

In the case of each of these three precedents, the dispute between the parties is not as to the rule of law that emerges from each, but simply in the application of that rule to the particular facts of this case. In *Chakrabarty*, this Court upheld the patent-eligibility of a bacterium under § 101, because the claim was "not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character and use.'" 447 U.S. at 309-10 (quoting *Hartranft*, 121 U. S. at 615). The Federal Circuit's decision is in perfect harmony with *Chakrabarty*, because here, too, the isolated molecules claimed by the Myriad patents are "a product of human ingenuity," and because of their isolation by human inventors, the molecules have been given new characteristics from the "native" gene embedded in the genome, and substantial new utilities as diagnostic tools. Pet. App. 52a ("isolating genes to provide useful diagnostic tools and medicines is surely what the patent laws are intended to encourage and protect").

Chakrabarty quoted language from *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), which was a "case decided on obviousness." Pet. App. 44a. In *Funk Brothers*, the patent claimed "[a]n inoculant for leguminous plants" made up of "a plurality of selected . . . strains of different species of bacteria of the genus Rhizobium." 333 U.S. at 128 n.1. The Court concluded that this claim, which called simply for mixing two or more known strains of bacteria, created no new invention (in the words of the present-day 1952 Patent Act, the combination was "obvious") because the bacteria mixed together worked the same way as when administered to plants separately. *Id.* at 131; *see also Chakrabarty*, 447 U.S. at 310 (contrasting Chakrabarty's new, human-made bacterium with Funk's mixtures of old, known bacteria). Here, isolated DNA molecules present a different case than in *Funk Brothers*, not only because no obviousness claim is asserted, but also because the claimed isolated DNA molecules *do* take on different properties and utilities upon their isolation from the chromosome, and those differences are directly dependent upon the intervention of human inventors. Pet. App. 45a-49a; Pet. App. 70a-73a (Moore, J., concurring-in-part).

Finally, in *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931), this Court concluded that the addition of a small amount of borax to the rind of a fresh orange did not meet the statutory definition of a "manufacture"—a question not presented here—because the dictionary definition of that term required the creation of "an article for use which possesses a new or distinctive form, quality, or property," *id.* at 11, and the orange in question was, in the Court's view, unchanged by the addition of

borax as a preservative: "It remains a fresh orange, fit only for the same beneficial uses as theretofore." *Id.* at 12. Here, by contrast, there is no dispute that these isolated molecules satisfy the statutory definition of "composition of matter," Pet. App. 43a, and the inventors of these isolated molecules of DNA—unlike the person who coated a fresh orange with borax—created a previously unknown and unavailable resource for doctors and scientists, with great diagnostic utility for patients.

In sum, the Federal Circuit's decision was a faithful application of this Court's precedents, all of which recognize that where human intervention brings about a new and useful composition of matter for the public good, that meets § 101's "broad," "expansive," and "comprehensive" standard of patent eligibility.

III. THE QUESTIONS PRESENTED ARE UNIQUE TO THIS CASE, FACTBOUND, AND UNLIKELY TO RECUR

Since the PTO first issued a patent drawn to an isolated DNA molecule in 1984, no appellate case—until this one—challenged the patent-eligibility of such claims under § 101. The absence of such challenges is not for want of opportunities, however: "[C]laims similar to the ones at issue in this case have been the focal point of important litigation." Pet. App. 81a (Moore, J., concurring-in-part) (citing *Amgen*, 927 F.2d 1200). In *Amgen*, for example, the isolated-DNA-molecule claims at issue were challenged principally on grounds of prior invention (*see* 35 U.S.C. § 102(g)), obviousness (*id.* § 103), failure to set forth the best mode (*id.* § 112), non-enablement (*id.*), and inequitable conduct. *See*

Amgen, 927 F.2d at 1205-15. While ineligibility under § 101 was apparently pled as an affirmative defense, *see id.* at 1204, it was not the subject of any appellate decision. Nor has any other appellate decision since the enactment of the 1952 Patent Act struck down any kind of composition-of-matter claim as ineligible for patenting under § 101. And it is doubtful that § 101 will ever need to be litigated in this area in the future, because the complete human genome was published in 2001. This development will make it exceedingly unlikely that new claims to such isolated human DNA molecules will arise. *See* Robert S. Schwartz, *Genes for Free: The Effect of Publication of the Human Genome on the Patentability of Genes and Gene-Based Inventions*, 23 PACE L. REV. 731, 745 (2003); Holman, 322 SCIENCE at 198-99 (noting in 2008 that "the number of human gene patent litigations pending at any given point in time has fallen off in recent years," that "[t]his decline corresponds to reports of a similar marked decline in the filing and issuance of DNA patents in the United States since 2001", and concluding that "fears expressed concerning human gene patents have not been manifested overtly in litigation"). Further, most gene-related patents filed before the 2001 publication of the human genome will soon expire. Thus, the unique nature of this case makes it a singularly inappropriate candidate for certiorari.

Moreover, as the Court of Appeals' opinions implicitly recognize, proper resolution of this case requires consideration of an extensive welter of underlying scientific facts. While all parties agreed that petitioners' § 101 challenge presented a question of law, the summary-judgment record created at the

district court demonstrates that this question of law is informed by important underlying scientific facts, and in this record, prominent scientists and other experts have viewed the human inventive contribution to the claimed inventions quite differently than petitioners now suggest. *See, e.g.*, C.A. App. A4320-33 ¶¶ 131-54 (detailing inventive contributions provided by inventors and the challenged claims); *id.* at A4410-12 ¶¶ 44-48 (explaining same). Moreover, the record reflects declarations from experts regarding the benefit of such patents to the public. *Id.* at A4543-44, A4546 ¶¶ 50-56, 60-62 (declaration of Dr. Philip Reilly explaining how challenged patents have accelerated further innovation and research); A4729 ¶ 31 (declaration of Dr. Schlessinger explaining importance of patents to medical innovation). The factbound nature of this inquiry presents an additional reason to deny certiorari. *See, e.g.*, *United States v. Johnson*, 268 U.S. 220, 227 (1925) ("We do not grant a certiorari to review evidence and discuss specific facts.").

IV. THIS CASE PRESENTS A POOR VEHICLE FOR THIS COURT'S REVIEW

In addition to all of these other reasons for denying certiorari, a series of vehicular problems with this case counsels against this Court's review.

First, as noted above, the petition is encumbered by a set of antecedent jurisdictional problems. Petitioners themselves have highlighted one of these problems—affecting 19 of the 20 plaintiff-petitioners—by asking for review of the Federal Circuit's jurisdictional ruling as to these 19 petitioners. Of course, their request for review

alleges no conflict with respect to this jurisdictional issue, and offers no explanation why this Court should take up that issue, when one of the 20 petitioners was held to have a sufficient dispute with Myriad to sustain this declaratory-judgment action.

The apparent reason that petitioners seek review on this jurisdictional issue, however, is because even the one petitioner held by the Federal Circuit to have standing—Dr. Ostrer—in fact has no sufficiently live case-or-controversy with Myriad to sustain jurisdiction under Article III. The "case-or-controversy requirement subsists through all stages of federal judicial proceedings, trial and appellate. To sustain our jurisdiction … it is not enough that a dispute was very much alive when suit was filed, or when review was obtained in the Court of Appeals." *Lewis v. Continental Bank Corp.*, 494 U.S. 472, 477-78 (1990). Here, substantial questions regarding Dr. Ostrer's stake (if any) in this case would also have to be resolved at the outset, before the Court could reach the merits of the § 101 issue.

Consistent with this Court's precedent that a justiciable controversy must be real and immediate—rather than imagined—and must be between adverse parties—rather than one-sided—the Federal Circuit unanimously and correctly held that seventeen named plaintiffs lacked standing given the absence of any "affirmative acts by [Myriad] directed at specific Plaintiffs." Pet. App. 38a-39a. Two additional plaintiffs (Drs. Kazazian and Ganguly) lacked standing because they had no active commitment to engaging in any testing even if the claims were invalidated. Pet. App. 30a-32a.

Applying the same principle to the present circumstances demonstrates that this case is now moot because of Dr. Ostrer's change in employment. Importantly, the Federal Circuit rooted its finding that Dr. Ostrer had standing based on a controversy stemming from a collaborative license offer that Myriad made to NYU in 1998 that would "require[] NYU to make a payment to Myriad" for certain BRCA1/2 testing performed by an NYU laboratory at which Dr. Ostrer was formerly employed. *Id.* at 32a-34a. Myriad, however, has never had any controversy with Montefiore, Dr. Ostrer's current employer; indeed, the record reflects no Myriad communication with Montefiore, no actions directed to Montefiore by Myriad, and no awareness by Myriad of any actions being taken by Montefiore. And, any controversy created by Myriad's 1998 offer of a collaborative license to NYU cannot follow Dr. Ostrer to his employment at an entirely different institution, Montefiore. Indeed, assuming NYU had signed the offered collaborative license with Myriad in 1998, *see* Pet. App. 31a-32a, those license rights would not have followed Dr. Ostrer to Montefiore; rather, such rights would have remained with NYU. These jurisdictional deficiencies thus render this case a poor vehicle for resolving the questions presented.

Second, even aside from the correctness *vel non* of the Federal Circuit's jurisdictional decision, the posture of this case—a declaratory-judgment action mounted by 20 recruited plaintiffs—makes this case a poor vehicle. This case is an abstract challenge seeking an advisory opinion. The particular patent claims put at issue were selected for a § 101 challenge by petitioners alone. Yet petitioners did not contest all of the claims of Myriad's challenged

patents. Specifically, petitioners left unchallenged several claims (*e.g.*, to primers and probes) which petitioners concede will continue to impede sequencing and other conduct in which they seek to engage: "Myriad has obtained patents on DNA as probes. Claim 6 of '473 is one example and not challenged here." Plfs' C.A. Br. at 16; *see also* C.A. App. A432-23; A6973 ¶ 40; A7021. Accordingly, there exist significant issues of redressability, yet another antecedent jurisdictional problem with this petition. *See, e.g.*, *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (explaining that standing requires that "it must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision'").

Moreover, Myriad did not assert counterclaims of infringement against any of these plaintiff-petitioners, because Myriad had no basis to believe that any of them were engaged in, or likely to engage in, infringing behavior. This is particularly important, because much of petitioners' effort to obtain this Court's review is premised upon such disputable speculation as "patents on genes . . . preven[t] advances in science and medicine that could result in better diagnosis and treatment" (Pet. 20), "[t]he patents give Myriad the authority to prevent all research and clinical testing of the BRCA1 and BRCA2 genes" (Pet. 21), "claims like 5 and 6 of patent '282 preempt researchers from working with that segment of DNA, wherever it may appear in the genome" (Pet. 29-30), and "[p]atents on isolated DNA . . . block scientific inquiry into the patented DNA." Pet. 30. These assertions are just that—assertions—but they have not been tested in the crucible of litigation, let alone demonstrated to be

true in this case, because Myriad did not assert its patents against any petitioner, and so the lower courts had no reason to determine the precise scope of the patents' exclusionary rights. Indeed, after analyzing this issue, one commentator concluded that "properly interpreted these claims likely would not have the broad preclusive effect attributed to them by the critics." Christopher M. Holman, *Gene Patents Under Fire: Weighing the Costs and Benefits, in* BIOTECHNOLOGY AND SOFTWARE PATENT LAW 260, 287 (Emanuela Arezzo & Gustavo Ghidini eds., 2011).

In any event, the record belies petitioners' sweeping claims, showing that over 18,000 researchers have conducted studies on the BRCA1 and BRCA2 molecules, resulting in the publication of over 8,000 scientific papers. C.A. App. at A3439-40; A3444; A3484-87; *see also* Holman, *supra*, 322 SCIENCE at 199. That is hardly a "block[age of] scientific inquiry." If this case did present an important and recurring issue—which it does not—it would be better for this Court to await another such case, where the patent owner has actually asserted the exclusionary force of its patents, so that this Court can properly evaluate the "preemptive" force of those patent claims instead of relying on bald and dubious assertions such as those put forth by the petitioners here.

Third, petitioners themselves suggest that this Court will have to address questions of patent claim construction in order to properly analyze the patent-eligibility issues. *See* Pet. 28 (asserting that the "mode of analysis" set forth in Judge Lourie's opinion "contradicts both the patent claim language . . . and this Court's repeated admonition that patents should

be evaluated according to the actual claim language"). This is yet another antecedent problem, neither mentioned nor even fairly included within the questions presented, that makes this case a poor vehicle for this Court's review.

Fourth, while petitioners claim that "[t]his case is an ideal vehicle to analyze the Section 101 question" because their "sole claim under the Patent Act" was brought under § 101 (Pet. 20), in truth this fact renders this case a poor vehicle, not an ideal one. Any consideration of the proper role of § 101 necessarily requires a proper understanding of whether, or how, other provisions of the Patent Act might apply to those claims. Section 101, in fact, concludes with the proviso that its broad, inclusive categories of patent-eligible subject matter are "subject to the conditions and requirements of this title." As this Court and the Federal Circuit have repeatedly held, § 101 is an overly blunt tool for sifting inventions that should be allowed patents from those that should not be patented. *See, e.g.*, *Research Corp. Techs. v. Microsoft Corp.*, 627 F.3d 859, 869 (Fed. Cir. 2010) ("[T]he Patent Act provides powerful tools to weed out claims that may present a vague or indefinite disclosure of the invention. Thus, a patent that presents a process sufficient to pass the coarse eligibility filter may nonetheless be invalid."); *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1066-68 (Fed. Cir. 2011) (same); *see generally Bilski*, 130 S. Ct. at 3225 (same).

The much finer and better-calibrated filters provided by § 102's novelty requirement and § 103's non-obviousness requirement, to name just two, take into account such important, case-and-technology-

specific factors as the level of ordinary skill in the particular art, the knowledge of the ordinary artisan at the time of invention, the expectations of others in the art, and so on. *See, e.g.*, *Graham v. John Deere & Co.*, 383 U.S. 1 (1966); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). By contrast, without the presence of claims or defenses under §§ 102 and 103, the courts in this case have been asked to make largely abstract, policy-based pronouncements, untethered to statutory text, about what sorts of inventions should be allowed to pass through the first, "coarse" filter of § 101. If there were a serious and recurring issue worthy of this Court's consideration buried here, it would be better considered in a case that also allows for consideration of these other "conditions and requirements of this title," and their interplay with § 101.

Fifth, it bears repeating that, as to the Federal Circuit's holding with respect to the composition-of-matter claims being challenged here, there is only a judgment, not a single opinion for the court. Pet. 16-18; *see* Pet. App. 62a, 67a (Moore, J., concurring-in-part). Petitioners seek to make this a reason for this Court's review. Pet. 16-19. But, had there been a true need to reconcile these divergent judicial viewpoints, it would have been appropriate for petitioners to first seek *en banc* review from the Federal Circuit before approaching this Court. For whatever reasons, though, they did not. This is particularly important for cases coming from the Federal Circuit, because that court's statutory mission is to unify national law with respect to patents (and other subjects within its jurisdiction), as this Court has long recognized. *See, e.g.*, *Bilski*, 130 S. Ct. at 3231 (encouraging "the Federal Circuit's

development of other limiting criteria that further the purposes of the Patent Act and are not inconsistent with its text"); *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996) ("It was just for the sake of such desirable uniformity that Congress created the Court of Appeals for the Federal Circuit as an exclusive appellate court for patent cases, H.R. Rep. No. 97-312, pp. 20-23 (1981), observing that increased uniformity would 'strengthen the United States patent system in such a way as to foster technological growth and industrial innovation.'"). Again, were there a serious and recurring issue worthy of this Court's consideration, it would be better addressed in a case where the Federal Circuit has had, or has taken, the opportunity to exercise its statutory mission by considering the issues *en banc*. *See, e.g.*, *Bilski*, 130 S. Ct. at 3224-25; *Festo*, 535 U.S. at 729-30; *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 23-24 (1997); *Markman*, 517 U.S. at 376.

Finally, it is clear that petitioners seek, via judicial ruling, a policy change from the longstanding practice of allowing patents on isolated genetic molecules. *See* Pet. 20. Such efforts at changing national policy, particularly policy that has engendered such reliance and investment over the past 30 years, should be addressed to Congress, not to the courts. Pet. App. 53a; *id.* at 88a-93a (Moore, J., concurring-in-part). As this Court has long admonished, courts "should not read into the patent laws limitations and conditions which the legislature has not expressed." *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933).

Only Congress is equipped with the ability to make judgments about whether the benefits of such patents outweigh any claimed detrimental impact on society. Yet petitioners ask this Court to undertake exactly that sort of exercise, on a judicial record where Myriad's experts have refuted each and every one of the petitioners' allegations on the subject. *See* Pet. 2, 5, 19-22. As noted above, for example, Myriad's patents have not impeded over 8,000 research articles by over 18,000 authors (including 35 articles authored by four of the petitioners). C.A. App. A3643-44. Myriad's patented work has made genetic testing widely available to patients in all 50 states at an affordable cost to patients where 90% of Myriad's testing is covered insurance with a weighted average out-of-pocket expense for such tests at under $100. Decl. of Dr. Gregory C. Critchfield at 6-7, Dec. 18, 2009, ECF No. 158. More than 40,000 healthcare providers have used Myriad's testing and more than 2,600 insurance payors have reimbursed for testing under more than 80,000 insurance plans. *Id.* at 12, 15-16. Contrary to petitioners' insinuation (Pet. 22), second-opinion testing to confirm deleterious mutations is available at multiple laboratories. C.A. App. A3666. Even the district court recognized that resolution of "these disputes of fact and policy are not possible within the context of these motions." Pet. App. 170a, 178a.

Moreover, any consideration of these issues will need to take into account the consequences of a legal rule far beyond the realm of human DNA. Many biotechnology companies' intellectual-property protection depends on patents covering isolated DNA corresponding to non-human genes, such as in the food, pulp and paper, detergents, and biofuels

industries. Advancements in these areas allow beverages to be clarified, food starches to be broken down, paper to be recycled, clothes to be cleaner and softer, and agricultural waste to be reduced to fuel. This is the role of policymaking, not adjudication, and this Court is "without competence to entertain these arguments—either to brush them aside as fantasies generated by fear of the unknown, or to act on them. [They are] matter[s] of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives." *Chakrabarty*, 447 U.S. at 317.

CONCLUSION

The petition should be denied.

Respectfully submitted,

GREGORY A. CASTANIAS
Counsel of Record
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
(202) 879-3939
gcastanias@jonesday.com

January 13, 2012

Counsel for Respondents