No. 12-398

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

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QUESTIONS PRESENTED

1. The challenged composition claims are directed to particular isolated molecules of deoxyribonucleic acid that were identified and defined by human inventors. Did the Federal Circuit correctly apply *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), to conclude that these molecules, defined and isolated by human inventors, are "product[s] of human ingenuity 'having a distinctive name, character [and] use,'" particularly (i) where those isolated molecules were created by humans, do not occur in nature, and have new and significant utilities not found in nature, (ii) where the U.S. Patent and Trademark Office ("PTO") has issued similar patents since at least 1984, and issued *Utility Guidelines* in 2001 confirming that such isolated molecules are patent-eligible as human-made inventions under § 101, (iii) where investors and technology companies have placed significant reliance interests in these settled property rights over the last 30 years, (iv) 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), and (v) where the challenged claims do not preempt or preclude the use of alternative technologies to identify a patient's cancer predisposition?

2. Did the Court of Appeals correctly apply *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), when it held that one of the challenged method claims (claim 20) was patent-eligible under § 101 because, unlike the method

claims held invalid in *Mayo*, claim 20 is based not on a law of nature but on a man-made, non-naturally-occurring transformed cell that is the product of human invention?

3. Did the Court of Appeals correctly conclude that 19 of the 20 plaintiffs recruited to join this suit lacked standing because they either had no injury traceable to Myriad, or 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 (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.

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BRIEF IN OPPOSITION

Petitioners present three unrelated questions—are Myriad's patent claims covering certain defined and isolated molecules patent-eligible compositions of matter under 35 U.S.C. § 101; was claim 20 of Myriad's U.S. Patent No. 5,747,282, covering a diagnostic method utilizing a new and never-before-known substance, properly upheld as patent-eligible; and did 19 of the 20 recruited plaintiffs lack a case or controversy with Myriad? Each was correctly answered in the affirmative by the Federal Circuit, which applied established and undisputed rules of law to the particular factual record in this case to reach these conclusions. Because these three disparate questions involve nothing more than the application of settled law to particular facts, and because this case is otherwise an exceedingly poor vehicle for this Court's review, certiorari should be denied.

BACKGROUND

A. The Longstanding Issuance Of Composition-Of-Matter Claims Drawn To Isolated DNA Molecules

The challenged composition claims are not drawn to cover "human genes" or any human being's DNA. Rather, they are limited to "isolated" BRCA molecules. Thus, to be covered by the composition claims, BRCA DNA must be "substantially separated from other cellular components which naturally accompany a native human sequence or protein," *e.g.*, it must be synthesized in a laboratory or otherwise "removed from its naturally occurring environment." C.A. App. A597.

The PTO has long recognized the human ingenuity required to create isolated DNA molecules. Applying its "specific expertise in issues of patent law," *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 145 (2001), the PTO long ago determined that claims to "isolated" molecules of DNA reflect human-made, patent-eligible inventions. Thus, over the last 30 years it has issued thousands of patents directed to isolated DNA molecules—indeed, the challenged patents themselves began issuing 15 years ago. *See, e.g.*, Pet. App. 61a-62a; *id.* at 87a-88a (Moore, J., concurring-in-part); C.A. App. 3710. And the PTO has issued over 40,000 patents drawn to DNA-related subject matter. *See*, *e.g.*, Eric J. Rogers, *Can You Patent Genes? Yes and No*, 93 J. PAT. & TRADEMARK OFF. SOC'Y 19, 19, 40 (2010).

Moreover, in 2001, consistent with its longstanding practice, the PTO promulgated—after an extensive notice-and-comment process—*Utility Guidelines* formally establishing that molecules that could be derived from genetic material "can be the basis for a patent" where the particular gene (a molecule) is "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).

Over these 30-some years of consistent practice, and based on the PTO's *Guidelines* on patenting isolated DNA molecules, the investing and inventing communities have relied on the certainty of that patent protection to develop significant advancements in human, agricultural, and industrial products. This "outpouring of scientific creativity," reflecting "substantial investment of time and money,"

was "spurred by the patent system" and the decades-long understanding that isolated DNA molecules are deserving of patent rights. Pet. 88a (Moore, J., concurring-in-part).

B. Myriad's Critical Contribution To Genetic Testing And Commensurate Patent Protection

To improve individualized patient care, doctors and scientists have long devised various ways to identify a patient's hereditary predisposition to diseases. In the field of hereditary breast and ovarian cancer research, for decades preceding Myriad's specification of the BRCA genes, clinicians worked to develop methods of evaluating a patient's family history to estimate her breast cancer risk ("pedigree analysis"). While occasionally inexact, such analysis enabled a scientific estimation of risk. Still used today, pedigree analysis falls outside the patents-in-suit.

With the subsequent advent of molecular sequencing techniques, researchers sought to improve risk determination by characterizing the genes, if any, responsible for breast and ovarian cancer. In the mid-1990s respondents (collectively, "Myriad") successfully isolated the "BRCA" molecules and disclosed their creation to the world. This momentous advancement required significant skill, insight, and invention on the part of Myriad's inventors. After first devising a technique to define a particular genetic region within the genome, Myriad sought ways to assess cancer risk based on genetic mutations correlating with a predisposition to breast and ovarian cancer. C.A. App. A4802-03. Although it was believed by 1990 that there was at least one genomic region where these mutations occurred, no

one had identified or defined any such region. *Id.* at A4803-04, A4771-72. Myriad did that by applying its genetic mapping technology to define the precise genetic material that its inventors called the "BRCA1 molecules," and thereafter the "BRCA2 molecules."

Once defined and specified by these human inventors, Myriad isolated those molecules from the cells in which they are found in nature and from other genomic material. *Id.* at 4804. This stage of the inventive process itself depended on an enormous amount of human judgment, including how to define the beginning and end of what came to be called the BRCA1 and BRCA2 genes, and then creating isolated DNA molecules corresponding to those particular defined genes. *Id.* at A4772-80, A4801-03, A5193-96. Myriad then used these isolated molecules to develop and launch a molecular test for targeted isolation and sequencing of a patient's BRCA DNA, which drastically improved accuracy in determining the patient's breast and ovarian cancer risk.

Myriad's inventions were universally hailed. The European Patent Office, for example, called Myriad's achievements "a major breakthrough which was not obvious to the skilled person." Board of Appeal of the European Patent Office, No. T 1213/05 at 69-70 (2007), www.epo.org/law-practice/case-law-appeals/pdf/t051213eu1.pdf ("EPO"); *see also* C.A. App. A4780 (Myriad's invention was "a scientific accomplishment that required many inventive steps, not the least of which was to contradict the scientific dogma of the time"); *accord id.* at A4769-79, A279-80, A588-89, A785-86. But these inventions did not come cheaply—they required monumental private investment. *See* Letter from Eric Y. Drogin & Robert

A. Armitage to David J. Kappos re: Genetic Diagnostic Testing (Apr. 16, 2012) 5, *available at* www.uspto.gov/aia_implementation/gene-comment-aba.pdf. Consistent with reliance on the PTO's longstanding interpretation of § 101, "[m]uch of that investment was made on a sound expectation that the risks being taken to commercialize new technology hold the promise of producing financial returns commensurate with the magnitude of the inherent risks." *Id.* With these incentives to develop the new technologies, and Myriad's public disclosures in return, the patent system worked exactly as intended.

Myriad's patent protection is commensurate with its contributions and has not inhibited others from developing additional technologies in this field. For example, gene expression profiles, inspired by Myriad's inventions but outside the scope of Myriad's patents, have been devised to test breast and ovarian cancer risk. Int'l Patent Application No. PCT/US2008/080358, Publication No. WO/2009/052417 (published Apr. 23, 2009) (Wendy S. Rubinstein, applicant). In addition, with recent advancements in sequencing techniques, random ("shotgun") sequencing and other technologies can likewise test predisposition without practicing Myriad's patents. Indeed, in 2001, seven years after Myriad's inventions, the human genome project used random sequencing to determine and publish the entire human genome sequence. In 2007, the entire genetic makeup of Dr. James Watson himself, whom petitioners invoke, Pet. 20 n.10, was characterized using whole-genome sequencing (he was found to possess a BRCA1 mutation). *See* BIO-IT WORLD, *Project Jim: Watson's Personal Genome Goes Public*,

www.bio-itworld.com/newsitems/2007/may/05-31-07-watson-genome (last visited Oct. 30, 2012). Such sequencing, which does not require isolation of a BRCA-specific DNA molecule but instead randomly selects genetic material to sequence a patient's entire genetic makeup, is not covered by the challenged claims. *See* Christopher M. Holman, *Will Gene Patents Derail the Next Generation of Genetic Technologies?: A Reassessment of the Evidence Suggests Not*, 80 UMKC L. REV. 563, 579 (2012) ("[N]o U.S. court has ever interpreted a claim to an isolated or purified DNA molecule so broadly that it would be inevitably infringed by DNA sequencing.").

Other technologies that can identify genetic mutations without infringing the challenged claims are untargeted single-molecule testing and protein-truncation testing. *See, e.g.*, *DNA Sequencing: Applications*, OXFORD NANOPORE TECHNOLOGIES, http://www.nanoporetech.com/technology/analytes-and-applications-dna-rna-proteins/dna-sequencing-applications (last visited Oct. 30, 2012); *DNA: An Introduction to Nanopore Sequencing*, OXFORD NANOPORE TECHNOLOGIES, http://www.nanoporetech.com/technology/analytes-and-applications-dna-rna-proteins/dna-an-introduction-to-nanopore-sequencing (last visited Oct. 30, 2012); PACIFIC BIOSCIENCES, http://pacificbiosciences.com (last visited Oct. 30, 2012); Holman, *supra*, 80 UMKC L. REV. at 579 (Pacific Biosciences' gene-sequencing technology "relies on the observation of DNA synthesis as it occurs on an immobilized DNA polymerase, and in my view does not entail isolation of defined DNA molecules"); J.T. den Dunnen & G.J. van Ommen, *The Protein Truncation Test: A Review*, NAT'L CENTER FOR BIOTECHNOLOGY INFO., http://www.ncbi.

nlm.nih.gov/pubmed/10425032 (last visited Oct. 30, 2012); D. Pushkarev et al., *Single-Molecule Sequencing of an Individual Human Genome*, NAT'L CENTER FOR BIOTECHNOLOGY INFO., http://www.ncbi.nlm.nih.gov/pubmed/19668243 (last visited Oct. 30, 2012).

C. District Court Proceedings

On May 12, 2009, close to 15 years after Myriad's patents issued, the American Civil Liberties Union Foundation ("ACLU") and the Public Patent Foundation ("PPF") filed a declaratory-judgment action on behalf of 20 recruited plaintiffs. Their complaint alleged, *inter alia*, that a few selected claims of Myriad's patents are patent-ineligible under § 101. Pet. App. 361a. Plaintiffs' counsel hand-selected the challenged claims, as part of a strategy of "pick[ing] one case" for a broad assault on all patents covering similar subject matter. C.A. App. A7387-88.

The district-court proceedings focused on: (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.

On the jurisdictional issue, Myriad argued that seventeen plaintiffs lacked any justiciable controversy because Myriad never had any communications with them regarding the patents-in-suit. *See* Pet. App. 24a. For the remaining three (all individuals, Drs. Ostrer, Ganguly, and Kazazian), Myriad showed that any communications with them or their organizations had occurred over a decade earlier, and therefore were too stale to demonstrate a real and immediate controversy. *See id.* at 21a-23a.

Petitioners responded with declarations from various plaintiffs, including Dr. Ostrer. As the Director of NYU's Molecular Genetics Laboratory, Dr. Ostrer averred that after Myriad offered a license to NYU's laboratory in 1998 (addressed to Dr. Ostrer as the laboratory director), which NYU declined, C.A. App. A2964-74, NYU had not provided clinical sequencing for fear that Myriad would assert the challenged patents, *id.* at A2935 ¶ 7, A2934 ¶ 4. He also stated that NYU's laboratory "has all of the personnel, expertise, and facilities necessary to do various types of [BRCA1/2] sequencing," and it "could, and would . . . do full sequencing." *Id.* at A2936 ¶ 9. In their declarations, Drs. Ganguly and Kazazian averred that if the challenged claims were invalidated, they would *consider* performing BRCA1/2 testing. *Id.* at A2852 ¶ 11.

The district court sustained jurisdiction, reasoning that *MedImmune*'s "all circumstances" test does not require a patentee to have taken any action toward any specific plaintiff. Pet. App. 402a. Instead, the court stated that only "some affirmative act by the [patentee] relating to enforcement of its patent rights," regardless to whom such enforcement is directed, creates a case or controversy for any potential plaintiff. *Id.* at 399a. The court concluded that based on Myriad's activities in the late 1990s 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 406a. This conclusion contradicted the evidence of widespread testing by numerous laboratories and scientists (including various named plaintiffs), without lawsuits.

The parties then cross-moved for summary judgment on the patent-eligibility of the challenged method and composition claims under § 101 as well as the First Amendment and the Patent and Copyright Clause (Article I, Section 8, Clause 8) of the U.S. Constitution.

The district court held that none of the composition claims were patent-eligible. The court identified the question presented as "whether the isolated DNA claimed by Myriad possesses 'markedly different characteristics' from a product of nature" (not, as petitioners assert here, "Are human genes patentable?"). Pet. App. 333a. It concluded that all such claims were invalid because "none of the structural and functional differences cited by Myriad" constitute a marked difference between native DNA and the claimed isolated DNA molecules. *Id.* at 336a.

Regarding method claim 20 (the only method claim at issue here), the court concluded that it was not patent-eligible because it sought "to patent a basic scientific principle." *Id.* at 355a.

D. Federal Circuit Proceedings And Petitioners' First Petition

The Federal Circuit upheld the district court's finding of declaratory-judgment jurisdiction, but only as to Dr. Ostrer. *Id.* at 153a-54a. On the merits, it concluded that the composition claims and method claim 20 were patent-eligible. *Id.* at 179a.

Petitioners did not pursue *en banc* review, instead seeking certiorari. Their questions presented were only the first and third questions presented here. Cert. Pet. at i, 132 S. Ct. 1794 (2011) (No. 11-275). Petitioners made clear that "[n]one of the method claims" was at issue. *Id.* at 7 n.2.

While their petition was pending, this Court decided *Mayo*, which involved § 101 as applied to method claims. *See* 132 S. Ct. at 1294. This Court then granted the petition in this case, vacated the Federal Circuit's judgment, and remanded for further consideration in light of *Mayo*. Pet. App. 1a.[1]

E. Proceedings On Remand

On remand, even though the petition had disclaimed a challenge to method claim 20, the Federal Circuit requested supplemental briefing on the applicability of *Mayo* to the challenged isolated DNA claims *and* claim 20. Apr. 30, 2012 C.A. Order.

First, however, Myriad filed a suggestion of mootness based on events subsequent to the Federal Circuit's now-vacated opinion: Effective August 29, 2011, Dr. Ostrer had left NYU. *See* Pls.' Answer to Defs.' Pet. for Reh'g at 2. He is instead employed by the Albert Einstein College of Medicine and Montefiore Medical Center (collectively, "Montefiore"). *Id.* There is no colorable claim of a Myriad-Montefiore controversy concerning the challenged claims. *See* Aplts.' Suggestion of Mootness at 10-13. Accordingly, Myriad suggested that the appeal was moot because whatever claim Dr. Ostrer once had to standing depended entirely on Myriad's 1998 license offer to NYU, where he no longer worked. The Federal Circuit declined Myriad's suggestion without opinion. June 11, 2012 C.A. Order. In its subsequent

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[1] Two months later, this Court granted, vacated, and remanded another case in light of *Mayo*. *See WildTangent, Inc. v. Ultramercial, LLC*, 132 S. Ct. 2431 (2012). *WildTangent* remains pending before the Federal Circuit.

opinion, the court adhered to its earlier jurisdictional analysis, holding that Dr. Ostrer had standing based on Myriad's decade-old license offer to NYU because: (1) "the relevant circumstances surrounding Myriad's assertion of its patent rights have not changed"; and (2) Dr. Ostrer, through his NYU employment, "remains in the same position with respect to his ability and his desire to provide BRCA testing as in the late 1990s." Pet. App. 25a, 36a-37a. The court also adhered to its ruling that Drs. Ganguly and Kazazian had not demonstrated any controversy with Myriad, because their "some day intentions are insufficient to support an actual or imminent injury for standing," and held that the remaining plaintiffs had not shown a case or controversy either. *Id.* at 32a, 36a (internal quotations omitted).

On the merits, the court reexamined Myriad's claims to isolated DNA molecules and again held them patent-eligible, noting that the particular inquiry for composition claims remained the *Chakrabarty* test viewed, of course, in light of the fundamental principles reiterated in *Mayo*.

Judge Lourie's lead opinion for the court observed that "[w]hile *Mayo* and earlier decisions concerning method claim patentability provide valuable insights and illuminate broad, foundational principles, the Supreme Court's decisions in *Chakrabarty* and *Funk Brothers [Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948),] set out the primary framework for deciding the patent eligibility of compositions of matter, including isolated DNA molecules." Pet. App. 48a. Summarizing *Chakrabarty*'s test as whether human invention produced compositions with a "distinctive name, character and use" from what

exists in nature, Judge Lourie applied that test by cataloging a variety of differences between the claimed compositions and native DNA caused by human intervention, including 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 49a, 51a (internal quotations and brackets omitted). These differences, Judge Lourie explained, "result[ed] from human intervention to cleave or synthesize a discrete portion of a native chromosomal DNA, imparting on that isolated DNA a distinctive chemical identity as compared to native DNA." *Id.* at 52a. 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 48a.

Concurring, Judge Moore likewise relied on "the framework of *Funk Brothers* and *Chakrabarty* in conjunction with the direction of [*Mayo*]" to analyze whether the isolated DNA claims, which she agreed are not "human genes," "have markedly different characteristics with the potential for significant utility." *Id.* at 79a. Analyzing the composition claims in three categories, she first determined that claims drawn to cDNA molecules 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 80a. Regarding claims covering isolated DNA molecules with short nucleotide sequences, Judge Moore reasoned that such claims are also patent-eligible given their different structural characteristics (*e.g.*, different chemical

bonds and nucleotide sequences) as compared to native DNA, and 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 82a. Lastly, considering 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 85a-86a. She further explained that the patent-eligibility of these claims is confirmed by the PTO's decades-long policy of granting patents on isolated DNA molecules, and the investing and inventing communities' settled expectations of patent-eligibility for such claims. *Id.* at 87a-94a.

Even Judge Bryson, dissenting in part, looked to "the test employed by the Supreme Court in *Chakrabarty*" when addressing the composition claims. *Id.* at 110a. He agreed that one category of the challenged claims (claims drawn to cDNA molecules) are patent-eligible under that test. *Id.* at 98a. For the other composition claims, he also concurred that isolating DNA molecules results in a "material change made to those genes from their natural state." *Id.* at 102a. 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.* Accordingly, like the district court, he determined, based on his own evaluation of the similarities (and not the distinctive properties engendered by isolation), that the non-cDNA composition claims were not "markedly different" from native DNA, and thus in his view not patent-eligible. *Id.* at 110a-13a.

As for claim 20, which claims "a method for screening potential cancer therapeutics via changes in cell growth rates," *id.* at 67a, the Federal Circuit applied *Mayo* and again unanimously held the claim patent-eligible. The court pointed to "transformed" cells as a key element and starting point of that claim, demonstrating its human ingenuity and distinguishing it from the claims in *Mayo*. *See id.* at 68a. Because claim 20 "is tied to specific host cells" that "are derived by altering a cell to include a foreign gene, resulting in a man-made, transformed cell with enhanced function and utility," the court rejected petitioners' argument that the claim concerned merely an abstract scientific idea about the cause of a slower growth rate, and held the claim patent-eligible. *Id.* at 68a, 70a.

F. Corrections Of Petitioners' Misstatements

Pursuant to this Court's Rule 15.2, Myriad provides the following corrections to misstatements in petitioners' recitation of fact and law.

1. The first question presented bears no relation to the uncontroverted facts of this case. Petitioners seek to present this case as asking whether "human genes" are patent-eligible. Of course, the genetic material naturally existing in every human being is not an "invention," *i.e.*, it is not the product of human ingenuity. But this case does not involve claims to such "native" human genes. The challenged composition claims are instead narrowly drawn to specific, defined DNA molecules, isolated by human scientists in laboratories, that do not naturally occur. As Judges Lourie and Moore explained, molecules of isolated BRCA1 and BRCA2 DNA are chemical "composition[s] of matter" that are just as deserving

of patent eligibility as any other human-made molecule. Indeed, numerous pharmaceutical and biotechnical inventions are claimed as specified molecules. This perhaps explains petitioners' insistence on framing their first question as "Are human genes patentable?", instead of addressing the question actually presented to and answered by the lower courts regarding the patent-eligibility of molecules defined, cultivated, and isolated by men and women through the application of human ingenuity.

2. Petitioners also contend that "[s]tandard isolation results in random DNA fragments that are identical to those that exist naturally in the body." Pet. 4. By definition, however, an "isolated" DNA molecule *has been removed from its naturally occurring environment*. *See, e.g.*, C.A. App. A597; *see supra* at 1-2, 4. A molecule cannot simultaneously be "removed from its naturally occurring environment" and "exist naturally in the human body"—its naturally occurring environment. 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 of "human intervention to cleave or synthesize a discrete portion of a native chromosomal DNA, imparting on that isolated DNA a distinctive chemical identity as compared to native DNA." Pet. App. 51a-52a.

Petitioners' belated factual claim that covalent bonds of DNA molecules may be broken in the body, Pet. 12, is irrelevant. This assertion omits critical elements of the definition of "isolated" DNA. Isolated DNA is not merely DNA that has had bonds broken;

the breaking of covalent bonds, while important, is but one part. Isolation further requires separation of the specific DNA of interest from the rest of the DNA in the body and even the rest of the fragmented DNA that may be present in a test tube outside the body. Even setting aside the human-engineered initial fragmentation breaking the covalent bonds, such *specific, precisely defined* (*i.e.*, targeted) separation does not naturally occur in the body. Thus, it is a contradiction in terms to say that "isolated" DNA exists within the body. C.A. App. A4291 ¶ 17, A4322 ¶ 133, A4324 ¶ 137, A4325 ¶ 143, A4412 ¶¶ 47-48, A4413-14 ¶¶ 51-53, A4723 ¶ 11. Even the petition elsewhere acknowledges this fact. *See* Pet. 4.

3. Contrary to petitioners' cursory and unsupported assertions, Pet. 2, 25, neither Myriad nor its patents hinder research of BRCA genes. One named plaintiff concedes that she "could sequence the BRCA1 and BRCA2 genes for purely research purposes," and has been doing so without impediment. C.A. App. A1305 ¶ 15, A1304 ¶ 11. The undisputed 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 commenced since Myriad publicly disclosed its inventions. *Id.* at A3643 ¶ 13, A4540-41 ¶ 41-45. Moreover, multiple laboratories provide "second opinions" regarding BRCA1/2 test results. *Id.* at A3666. In short, Myriad's patents do not hinder research. *See, e.g.*, Christopher M. Holman, *Debunking the Myth That Whole Genome Sequencing Infringes Thousands of Gene Patents*, 30 NATURE BIOTECHNOLOGY 240 (2012); John P. Walsh et al., *View from the Bench: Patents*

and Material Transfers, 309 SCIENCE 2002, 2003 (2005).

4. Petitioners allege that Myriad has "stopped other laboratories from creating and offering new and improved testing procedures" and has "the right to exclude the rest of the scientific community from examining the naturally-occurring genes of every person in the United States." Pet. 2-3. These statements are false. The challenged claims do not preempt, preclude, or prohibit others from creating and offering new and improved testing services.

To the contrary, Myriad's composition claims are limited to the precise isolated molecules it created and that are recited in the patents. These claims do not preempt or preclude other technologies that have been developed and are currently being used to study the human genome and identify genetic mutations to assess a patient's cancer predisposition—*e.g.*, gene expression profiles, whole-genome sequencing, untargeted single-molecule sequencing, and protein-truncation testing. *See supra* at 5-7. These technologies "sequence" DNA without the need for "isolation."

In fact, earlier in this case (January 2010), petitioners stated: "It is only humans' inability—currently—to sequence DNA while it is in the body that requires scientists to isolate it." Pls.' Mem. of Law at 13 (S.D.N.Y. 2010) (No. 09-4515), ECF No. 219. This falsely suggests there are only two options: sequence in the body or sequence "isolated" DNA. While DNA still cannot be sequenced in the body, DNA extracted from the body but not "isolated" can be, and has been, sequenced. For example, random sequencing and protein-truncation testing have been

used for years to identify genomic variations, including BRCA mutations. More recently, multiple companies, *e.g.*, Oxford Nanopore and Pacific Biosciences, have developed single-molecule technologies that can perform untargeted sequencing of DNA, which may include BRCA genes, without infringing the challenged claims. *See supra* at 5-7.

5. Petitioners contend that the challenged composition claims "define[] the gene according to how it functions in the body—*i.e.*, that it codes for and produces a polypeptide or protein." Pet. 6. That is untrue. Each claim is a specific, defined molecule isolated from the body; none is claimed in terms of its "function." Terms such as "encoding" or "coding for" are commonly used in DNA patent claims to recite physical structure, not function—they are "structural terms" that define Myriad's human-made molecules. *See In re Deuel*, 51 F.3d 1552, 1557-58 (Fed. Cir. 1995). Petitioners' contentions to the contrary, like their insistence upon redefining the question presented as "Are human genes patentable?", reflect a misunderstanding of basic scientific principles, well-established case law, and the nature of the composition claims at issue; at a minimum, they demonstrate that the petition is grounded on disputed antecedent facts.

REASONS FOR DENYING THE WRIT

This case is unworthy of certiorari because it concerns the application of settled law to particular facts. The Federal Circuit has twice correctly applied § 101 and this Court's decisions in *Chakrabarty*, *Mayo*, and *MedImmune*. The court's decision is also consistent with the policy goal of the Patent Act, the considered judgment of the PTO, and longstanding

practice. Further, the issues presented are unique and fact-bound, and in order to even reach the § 101 issues, the Court would have to take up antecedent jurisdictional questions and preempt percolation in the Federal Circuit, the appellate court statutorily vested with unifying and clarifying U.S. patent law. The Court should deny the petition.

I. THE COURT OF APPEALS CORRECTLY APPLIED THIS COURT'S PRECEDENTS TO DETERMINE THAT THE COMPOSITION CLAIMS ARE PATENT-ELIGIBLE

The Court of Appeals correctly applied § 101 and this Court's precedents to conclude that the claimed isolated molecules are human-made "compositions of matter." Section 101 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)).

When determining the patent-eligibility of composition-of-matter claims, all agree that the proper distinction is "between products of nature" and "human-made inventions." *Chakrabarty*, 447 U.S. at 313; *see* Pet. 21. At its most basic, *Chakrabarty* asks whether a purported "invention" is in fact the result of human ingenuity. *Chakrabarty*, 447 U.S. at 312-13 (something "created wholly by nature unassisted by man" is patent-ineligible, whereas something produced by man "in aid of nature [is] a patentable invention" (internal quotations omitted)). As *Chakrabarty* held, a composition created with "human ingenuity" and

having a "distinctive name, character [and] use" from what exists in nature is what separates "a hitherto unknown natural phenomenon," ineligible for patent protection, from "a nonnaturally occurring manufacture or composition of matter," which is patent-eligible. *Id.* at 309-10 (internal quotation omitted).

Mayo did not disturb *Chakrabarty*, and petitioners do not argue otherwise. Rather than address the eligibility of composition claims, *Mayo* applied § 101 to the method claims in that case. Nonetheless, in the course of that analysis, *Mayo* fundamentally asked the same question that *Chakrabarty* asks: Has there been a human-made invention? *See Mayo*, 132 S. Ct. at 1293-94; 1 WILLIAM C. ROBINSON, THE LAW OF PATENTS 115 (1890) ("Every invention has its origin in man. It is his addition to the agencies already existing in nature" that creates an invention). Since all agree that *Chakrabarty* states the proper rule, petitioners' first question is not worthy of certiorari because an allegation of "misapplication of a properly stated rule of law" is rarely a legitimate basis for certiorari review. Sup. Ct. R. 10.

In any event, faithfully applying *Chakrabarty* in light of *Mayo*, the Federal Circuit correctly held that Myriad's composition claims were indeed products of human ingenuity and were thus patent-eligible. The claimed molecules squarely constitute statutory "compositions of matter"—nucleotides linked to each other by a phosphodiester backbone. *See Bilski*, 130 S. Ct. at 3226 (the term "composition of matter" is to be "understood with common usage," and citing *Chakrabarty*). Further, the record reflects that they are products of human ingenuity, not of nature. Pet.

App. 14a, 52a; C.A. App. A3493, A3709, A4290, A4317-20, A4723-24.

Petitioners themselves have repeatedly admitted that isolated DNA molecules are "compositions" of matter under § 101, and they do not argue otherwise here. Pet. App. 48a; C.A. App. A6911. Their dispute is with the Federal Circuit's application of *Chakrabarty*, based on petitioners' dismissive view that the claims' "only 'inventive concept'" "is disclosure of the law of nature." Pet. 25. Not only is this factual assertion unworthy of certiorari, but it is wholly unsupported: As Judge Lourie put it, human ingenuity, *i.e.*, invention, takes place when "human intervention has given" the claimed invention "'markedly different,' or 'distinctive,' characteristics." Pet. App. 50a (quoting *Chakrabarty*, 447 U.S. at 310); *see also Chakrabarty*, 447 U.S. at 310 (because the claims were directed to a new bacterium with markedly different characteristics from any found in nature and having the potential for significant utility, the composition "[wa]s not nature's handiwork" and the claims were patent-eligible). Judge Lourie emphasized the "inventive concept" involved in defining the structure of the claimed molecules and thus creating a new chemical entity that had never existed before. Judge Moore similarly recognized that the claimed isolated molecules "are not naturally produced without the intervention of man." Pet. App. 82a.

The Myriad inventors' numerous inventive choices—which ultimately, though far from inevitably, proved successful—yielded human-made molecules with structures and utilities different from any material existing in nature. As the European

Patent Office has observed, "[t]he positional cloning of the BRCA1 gene was very complex and involved many uncertainties," and Myriad "had to take a multitude of decisions" in defining what became known as the BRCA molecules. EPO at 12. Acknowledging that such human ingenuity produced the challenged isolated molecules, the Federal Circuit properly held the claims patent-eligible.

The Federal Circuit's holding is also consistent with the overall goal of the Patent Act to incentivize, with a limited right to exclude, those who bring new, useful inventions forward to the public. The utility of Myriad's inventions is unquestionable, and the record reflects that these never-before-isolated DNA molecules provide substantial new utilities, most notably their use as molecular tools 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 tools, a patient can now more accurately learn of her genetic predisposition to, *e.g.*, breast cancer, and in turn receive personalized medical treatment. The patent laws appropriately rewarded the women and men responsible for these inventions.

The Federal Circuit's decision is also correct in view of the PTO's longstanding practice of issuing such patents, as illustrated by its 2001 *Utility Guidelines.* These guidelines reflect the PTO's considered judgment that the definition and isolation by humans of a particular DNA molecule results from human ingenuity. In trivializing the key claim term "isolated," *e.g.*, Pet. 4, petitioners contradict the PTO's rigorous analysis underlying its *Guidelines*.

J.E.M.'s approach is on all fours with this case. There, this Court reiterated that § 101 has "broad scope and applicability," and refused to deny patent protection to sexually reproduced plants where the "PTO ha[d] assigned utility patents for plants for at least 16 years and there ha[d] been no indication from either Congress or agencies with expertise that such coverage is inconsistent with [the governing statutes]." 534 U.S. at 131, 144-45. The present case for patent eligibility is even stronger, with nearly 30 years of uninterrupted agency interpretation and practice in this area (versus 16 years in *J.E.M.*), over 40,000 DNA-related patents (versus 1,800 plant patents in *J.E.M.*), and a substantial portion of the American biotechnology sector and investing community that has relied on such settled 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" covering isolated DNA. Pet. App. 89a (Moore, J., concurring-in-part) (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002)). Moving the goalposts of patent eligibility for these patents now would also undermine the interests of the investing community: Clear and certain patent protection is critical to honor the interests of past investors, such as those who funded the research behind these inventions, but it is even more essential to economic growth that future investors—not only in biotechnology, but in all industries—know that § 101 is not subject to judicial reinterpretation just because 30 years have passed since *Chakrabarty*. *See* Pet. 16.

In short, petitioners do not dispute that *Chakrabarty* supplies the rule of decision here; they merely question its application to the facts. That is, of course, not ordinarily an appropriate reason for certiorari. And, in any event, the Federal Circuit's decision was correct. Patent-eligibility under § 101 and this Court's precedents, most significantly *Chakrabarty*, follows when human intervention brings about a new and useful composition of matter for the public good. Myriad's composition claims plainly did so here.

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

The Federal Circuit's decision is not in conflict with any other federal appellate decision or decisions of this Court. Nor do petitioners genuinely allege a conflict. Although they contend that "the Federal Circuit departed dramatically from *Mayo*, *Chakrabarty*, *Funk Brothers*, and *American Fruit Growers*," *id.* at 22, there is no departure from precedent here, let alone a "dramatic" one.

Mayo, by its terms, concerned only the particular *method* claims before it. 132 S. Ct. at 1294. Its fundamental guidance, however, only supports the Federal Circuit's decision on the challenged composition claims. As *Mayo* explained, to be patent-eligible, claims must produce something inventive, beyond a natural law itself. *Id.* at 1293-94. Myriad's inventors applied human ingenuity to nature to create something new and useful—human-made molecules that can be used as diagnostic tools.

Petitioners themselves do not seriously contend that *Mayo* altered the relevant analysis. Indeed,

they state that *Mayo* "did not settle" the patent-eligibility of the challenged composition claims. Pet. 17. That question is settled, in Myriad's favor, by this Court's longstanding precedent regarding composition claims.

Nonetheless attempting to stake their petition on *Mayo*, petitioners argue that the Federal Circuit erred in giving weight to the biotechnology community's settled expectations, in contravention of *Mayo*'s supposed "reject[ion]" of such reliance "when it invalidated certain medical patents that the PTO had approved for many years." *Id.* at 30. Not so. *Mayo* determined that the reliance interest in that case was not particularly strong, and it did so only after concluding that the method claims at issue, directed merely to laws of nature, were patent-ineligible, as precedent has long proscribed. *See* 132 S. Ct. at 1304-05. But where, as here, the precedent does not "lead[] inexorably to the conclusion that isolated DNA molecules are not patentable subject matter," Pet. App. 93a-94a (Moore, J., concurring-in-part), it is proper not to upset settled expectations. Indeed, as relevant here, *Mayo* expressly directed that courts "must hesitate before departing from established general legal rules," preferring instead that courts rely on "the role of Congress in crafting more finely tailored rules where necessary." 132 S. Ct. at 1305. Thus, far from supporting petitioners' argument, *Mayo* confirms that the Federal Circuit reached the correct result.

Petitioners also cite *Mayo* for the proposition that the § 101 inquiry "turns on whether the patent preempts use of the laws and products of nature." Pet. 22. There is no conflict here, either. The proper

interpretation or application of § 101 does not "turn on" preemption. By their nature, all patent claims are preemptive. *See Mayo*, 132 S. Ct. at 1305. The vast preemptive scope of the claims in *Mayo* served only as confirmation that the Court's conclusion of patent ineligibility was correct. *See id.* at 1302 ("The presence here of the basic underlying concern that these patents tie up too much future use of laws of nature *simply reinforces* our conclusion" that the claims are patent-ineligible (emphasis added)). As the Court explained, preemption concerns arise with claims "that too broadly preempt the use of a natural law." *Id.* at 1294.

Here, by contrast, Myriad's inventions do not preempt, much less "too broadly preempt," natural law. Numerous alternatives are available for determining a patient's predisposition to breast and ovarian cancer without using isolated BRCA molecules. *See supra* at 5-7. Moreover, the patent protection Myriad received covers its human-made contributions and no more. *See Mayo*, 132 S. Ct. at 1303 (the concern is "how much future innovation is foreclosed relative to the contribution of the inventor"). No law of nature is tied up by patenting a new, specific, defined, and useful molecule, as Myriad has done here. The existence of multiple other technologies currently used to determine cancer predisposition is dispositive evidence of the lack of any improper preemption. *See supra* at 5-7.

As for the other three precedents petitioners cite, there is likewise no conflict. They merely show that a legal rule applied to different facts may yield different results. In *Chakrabarty*, this Court upheld the patent-eligibility of a bacterium 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 v. Wiegmann*, 121 U.S. 609, 615 (1887)). Here too, the particular claimed molecules are "a product of human ingenuity" that, because of their definition and isolation by human inventors, have been given new characteristics from the "native" gene embedded in the genome, and substantial new utilities as diagnostic tools. Pet. App. 59a ("isolating genes to provide useful diagnostic tools and medicines is surely what the patent laws are intended to encourage and protect").

The Federal Circuit's decision is also in perfect harmony with *Funk Brothers* and *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931), cases that anticipated *Chakrabarty*'s test but, on their particular facts, reached different results. In *Funk Brothers*, the combination of preexisting, commercially available strains of bacteria "d[id] not disclose invention or discovery" (under the pre-1952 Patent Act, which equated "invention" with "nonobviousness" under current § 103). 333 U.S. at 132. In *American Fruit Growers*, the small amount of borax added to the rind of a fresh orange did not constitute a "manufacture" because there was no "change in the name, appearance, or general character of the fruit." 283 U.S. at 11-12. Unlike those claims, the isolated DNA molecules here take on different properties and utilities upon their isolation from native DNA, and those differences are the direct consequence of human intervention. Pet.

App. 51a; *id.* at 82a, 89a-90a (Moore, J., concurring-in-part).

In arguing that the results in *Funk Brothers* and *American Fruit Growers* should govern, petitioners mischaracterize the claims here as merely a "blueprint" for "coding for" the genetic material in the body; under this view, petitioners say, the patents claim only a natural function. Pet. 24. This is factually incorrect and mischaracterizes the claim language. The patents do not claim the compositions with reference to their functions; and the "coding for" language is a structural, not a functional, limitation in the claims. *See In re Deuel*, 51 F.3d at 1557-58. The composition claims are limited to claims for a specific, precisely defined composition with a specific, non-naturally occurring structure—a particular, human-defined, isolated DNA molecule. *See supra* at 14-16, 18. As the Federal Circuit ruled, the claims are directed to a specific and new chemical entity that does not exist in nature and that has uses unrelated to how the "code" operates in the body. Pet. App. 44a-46a, 50a-51a (unlike natural DNA "exist[ing] in the body as one of forty-six large, contiguous DNA molecules," the claims are drawn to "a free-standing portion"); *accord id.* at 81a-82a (the claims "are truncations" that "are not naturally produced without the intervention of man").

Meanwhile, since the PTO first began issuing patents drawn to isolated DNA molecules over 30 years ago, "claims similar to the ones at issue in this case have been the focal point of important litigation." *Id.* at 88a (Moore, J., concurring-in-part) (citing *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200 (Fed. Cir. 1991)). Yet no appellate court has ruled

them ineligible. In *Amgen*, although § 101 ineligibility was apparently pled as an affirmative defense, *see* 927 F.2d at 1204, it was not the subject of any appellate decision. Indeed, no appellate court has ruled any composition claim ineligible since § 101's current formulation was included in the 1952 Patent Act. Without any conflict, this Court's review is unwarranted.

III. THE COURT OF APPEALS CORRECTLY DETERMINED THAT CLAIM 20 IS PATENT-ELIGIBLE

Petitioners' challenge to the patent-eligibility of method claim 20 does not warrant review. Indeed, petitioners had already abandoned their challenge to this claim when they failed to seek its review in their prior petition. This vehicular problem stands as a threshold obstacle to petitioners' challenge here. Further, the patent-eligibility of claim 20 is a fact-bound question that need not detain this Court. *See* Sup. Ct. R. 10.

In any event, the Federal Circuit correctly applied *Mayo* to hold that claim 20, which claims a method for screening cancer therapeutics, is patent-eligible. Under *Mayo*, a method claim is patent-eligible if it "do[es] significantly more" than describe natural laws. 132 S. Ct. at 1297. The *Mayo* claims "simply t[old] doctors to gather data from which they may draw an inference in light of the correlations" and provided no "practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself." *Id.* at 1297-98. Accordingly, the claims had not done significantly more than describe a natural law and thus were patent-ineligible. *Id.*

Claim 20, by contrast, "does significantly more" than simply describe natural laws. Indeed, the claim starts not with a "natural law" (as in *Mayo*), but with a new and useful product of human ingenuity—"a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer"—and applies additional steps to that transformed cell so that a new, useful, and inventive method of determining the efficacy of a cancer therapeutic was made available to the public. Pet. App. 427a. Each transformed cell, central to the claim, is a non-naturally-occurring, human-made creation that is plainly more than what exists in nature. Thus, the claim "includes more than the abstract mental step of looking at two numbers and 'comparing' two host cells' growth rates," *id.* at 68a, and "recites patent-eligible subject matter under § 101," *id.* at 70a.

Petitioners argue that the Federal Circuit misapplied *Mayo* by putting too much emphasis on the transformed cell, Pet. 31-32, and they proclaim—without record support—that "transformed cells containing altered DNA are conventional products widely available for purchase." *Id.* at 32. Nothing in the record even suggests that such "transformed cells" were available at the time of the invention, much less now. Moreover, petitioners fail to explain why these considerations, even were they true, overcome the fact that each transformed cell is non-naturally-occurring. Lastly, contrary to petitioners' overstatement that the method claim "[p]revent[s] any researcher from engaging in this science to find a cancer treatment," *id.*, the claim "is tied to specific host cells *transformed* with specific genes and grown in the presence or absence of a specific type of therapeutic," Pet. App. 70a. Properly characterized,

claim 20 is patent-eligible, and the Federal Circuit's correct decision presents no basis for this Court's review.

IV. JURISDICTIONAL PROBLEMS OVERWHELM THE PETITION

Petitioners' third question presented seeks to overturn the Federal Circuit's jurisdictional ruling against 19 of the 20 plaintiff-petitioners. In raising this threshold question last, petitioners seek to elide the jurisdictional deficiency inherent in their petition. Because the Federal Circuit properly rejected the asserted standing of those 19 plaintiffs, the justiciability of this case rests entirely on one individual, Dr. Ostrer. His standing would have to be addressed before reviewing the § 101 questions, because the "case-or-controversy requirement subsists through all stages of federal judicial proceedings, trial and appellate." *Lewis v. Continental Bank Corp.*, 494 U.S. 472, 477-78 (1990).

According to the Federal Circuit, Dr. Ostrer had standing based on his affiliation with an NYU laboratory that had once received and declined a license offer from Myriad to practice the patents-at-issue. Although Dr. Ostrer, not NYU, is the named plaintiff, NYU is plainly the real party in interest. Otherwise, whoever is the personal addressee of a letter like Myriad's letter to NYU would have personal standing, regardless whether the organizational affiliation remained, contrary to fundamental principles underlying standing to bring a lawsuit. Pet. App. 34a (noting that Dr. Ostrer's standing stemmed from Myriad's 1998 license offer to NYU, which would "require[] NYU to make a

payment to Myriad" for certain BRCA1/2 testing performed by that laboratory).

But Dr. Ostrer no longer works at NYU, and his new employer, Montefiore, has never had any controversy with Myriad. Indeed, Myriad and Montefiore have never communicated about the patents-in-suit. *See* Aplts.' Suggestion of Mootness, Decl. of R. Marsh. Whether or not the 1998 Myriad-NYU correspondence created a controversy between Dr. Ostrer and Myriad at the time suit was filed in 2009, and Myriad maintains that none existed then, any such controversy certainly evaporated by 2011; it did not follow him to Montefiore.

On these facts, although the Federal Circuit denied Myriad's suggestion of mootness, a substantial question remains regarding Dr. Ostrer's continued standing. This Court would have to consider this issue to assure itself of Article III jurisdiction before reaching any of the § 101 issues.

Although petitioners seek to overcome this obstacle by arguing for the standing of the other plaintiffs, petitioners themselves apparently do not have confidence in those arguments, raising those threshold jurisdictional arguments only as their final question presented. Indeed, petitioners' arguments allege no decisional conflict; they merely, and incorrectly, state that the Federal Circuit adopted a "new and inflexible rule" regarding declaratory-judgment jurisdiction. Pet. i. That court, however, plainly analyzed standing according to this Court's precedent, looking properly to the existence of a bilateral controversy, and not the subjective feelings or perceived inhibitions of the plaintiffs alone. Pet. App. 28a-42a. Thus, even setting aside Dr. Ostrer's

lack of standing, petitioners' final question presented, asking whether the Federal Circuit correctly applied settled law to the other plaintiffs, is not worthy of certiorari.

V. THIS CASE IS A POOR VEHICLE FOR REVIEW

Additional vehicular problems render this case a poor candidate for the Court's review.

First, this case represents an abstract challenge to Myriad's patents. Petitioners alone selected the particular claims to challenge, leaving unchallenged several claims that they concede will continue to impede BRCA 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." Pls.' 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 the petition. *See, e.g.*, *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992).

Second, Myriad was unable to assert counterclaims of infringement because no plaintiff was actually conducting any BRCA-related testing services; accordingly, this Court's review would be inhibited because the exact scope of the challenged claims has not been defined. The district court performed only limited claim construction, and without infringement assertions the courts had no reason to determine the precise scope of the claims' exclusionary rights. Yet petitioners themselves argue that this Court will have to address questions of claim construction to properly analyze patent-eligibility. *See* Pet. 28 (asserting that Judge Lourie's conclusion "contradicts

both the patent claim language . . . and this Court's repeated admonition that patents should be evaluated according to the actual claim language"). Moreover, much of petitioners' effort to obtain this Court's review is premised on their unsubstantiated speculation that Myriad's claims will inhibit those "who want to undertake testing and research involving the patented genes in order to improve diagnosis and treatment for patients" and will "exclude the rest of the scientific community from examining the naturally-occurring genes of every person in the United States." *Id.* at 2-3, 20, 27 n.12. Such assertions have never been tested in any adversary proceeding. And had they been tested, they would have been exposed as false, for several non-infringing technologies for determining a patient's cancer predisposition are currently available. *See supra* at 5-7. Likewise, with no review of the form of testing petitioners might utilize, to determine whether such testing would infringe, there has been no analysis of what the claims do *not* cover, *e.g.*, whole-genome sequencing. These obstacles are additional antecedent problems, neither mentioned nor fairly included within the questions presented, that make this case a poor vehicle.

Third, as to the patent-eligibility of the challenged composition claims, there is not a single opinion for the panel. Petitioners seek to make this a reason for review. Pet. 16-17. But, had there been a true need to reconcile divergent judicial viewpoints, it would have been appropriate for petitioners to first seek *en banc* review from that court. *See, e.g.*, *Bilski*, 130 S. Ct. at 3224-25, 3231 (noting the Federal Circuit's statutory task of unifying patent law); *Festo*, 535 U.S. at 729-30; *Warner-Jenkinson Co. v. Hilton Davis*

Chem. Co., 520 U.S. 17, 23-24 (1997). For whatever reasons, they did not. Meanwhile, in a case that petitioners contend demonstrates those judges' "divergent views" on patent-eligibility under § 101, Pet. 18, the Federal Circuit has granted *en banc* review to consider the patent-eligibility of certain method claims in light of *Mayo*. *See CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, Order, No. 2011-1301 (Fed. Cir. Oct. 9, 2012). It is thus apparent that, if the patent-eligibility of composition claims like these did present an important and recurring issue, the Federal Circuit stands ready to consider such a question *en banc*.[2]

Fourth, the relevance of patenting isolated human DNA is ever diminishing in light of the publication of the entire human genome in 2001 (several years after the 1994 and 1995 filing dates of the patents-in-suit), thus presenting arguable bars to patentability under other provisions of the Patent Act (such as obviousness under § 103) for any claims to isolated human DNA molecules sought after that date. Further, such patents issued before the 2001 publication of the entire human genome will soon expire—Myriad's patents-in-suit all expire by 2015. Thus, the unique facts of this case, presenting issues unlikely to recur, make it an inappropriate candidate for certiorari.

Fifth and finally, despite over 30 years of isolated DNA patents, this case is the first and still only appellate decision to address the patent-eligibility of such compositions. In nonetheless challenging these

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[2] Also pending before a Federal Circuit panel is another § 101 case. *See WildTangent*, 132 S. Ct. 2431; n.1, *supra*.

claims, it is clear that petitioners seek, via judicial ruling, a change in the settled understanding of § 101 that allows patents on isolated genetic molecules. *See* Pet. 19-20. Such efforts, particularly with the deeply settled reliance interests of the technology and investing communities at stake, should be addressed to Congress, not the courts. *See Mayo*, 132 S. Ct. at 1305. As Judge Moore recounted, Congress is "[f]ar from oblivious to the patenting of genes [citing several bills regarding gene patents]" and "is obviously aware of the issues presented in this case"; "'any recalibration of the standard of patentability remains in its hands.'" Pet. App. 92a-93a (quoting *Microsoft Corp. v. i4i Ltd.*, 131 S. Ct. 2238, 2252 (2011); brackets omitted).

Moreover, any consideration of the settled expectations that isolated molecules are patent-eligible should take into account the consequences of a legal rule that would apply far beyond the realm of human DNA. Many biotechnology companies' intellectual-property endeavors, and the investors on which those companies rely, depend on patents covering isolated DNA corresponding to non-human genes. Advancements in these other areas allow, *e.g.*, beverages to be clarified, food starches broken down, paper recycled, clothes cleaned and softened, and agricultural waste reduced to fuel. Altering the expectations that these useful developments will be patent-protected is the role of policymaking, not adjudication. *See Chakrabarty*, 447 U.S. at 317.

For any or all of these reasons, this case lacks the "important" and "compelling" attributes required for this Court's review.

CONCLUSION

The petition should be denied.

Respectfully submitted,

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October 31, 2012