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**United States Court of Appeals  
for the Federal Circuit**

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THE ASSOCIATION FOR MOLECULAR PATHOLOGY, THE AMERICAN COLLEGE OF MEDICAL GENETICS,  
THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY, THE COLLEGE OF AMERICAN PATHOLOGISTS,  
HAIG KAZAZIAN, MD, ARUPA GANGULY, PHD, WENDY CHUNG, MD, PHD, HARRY OSTRER, MD, DAVID  
LEDBETTER, PHD, STEPHEN WARREN, PHD, ELLEN MATLOFF, M.S., ELSA REICH, M.S., BREAST CANCER  
ACTION, BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, LISBETH CERIANI, RUNI LIMARY, GENAE  
GIRARD, PATRICE FORTUNE, VICKY THOMASON, and KATHLEEN RAKER,

*Plaintiffs-Appellees,*

v.

UNITED STATES PATENT AND TRADEMARK OFFICE,

*Defendant,*

and

MYRIAD GENETICS, INC.,

*Defendant-Appellant,*

*(caption continued on inside cover)*

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**Appeal From The United States District Court  
For The Southern District of New York  
In Case No. 09-CV-4515, Senior Judge Robert W. Sweet**

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**REPLY BRIEF FOR THE APPELLANTS**

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and

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KENDALL MORRIS, THOMAS PARKS, DAVID W. PERSHING, and MICHAEL K. YOUNG, in their official capacity as  
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*Defendants-Appellants.*

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## CERTIFICATE OF INTEREST

Counsel for the appellants, Myriad Genetics, Lorris Betz, Roger Boyer, Jack Brittain, Arnold B. Combe, Raymond Gesteland, James U. Jensen, John Kendall Morris, Thomas Parks, David W. Pershing, and Michael K. Young, certifies the following:

1. The full name of every party or amicus represented by me is:

Myriad Genetics, Lorris Betz, Roger Boyer, Jack Brittain, Arnold B. Combe, Raymond Gesteland, James U. Jensen, John Kendall Morris, Thomas Parks, David W. Pershing, and Michael K. Young

2. The name of the real party in interest represented by me is:

Myriad Genetics, Inc.; the University of Utah Research Foundation

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Jones Day (Gregory A. Castanias; Brian M. Poissant; Laura A. Coruzzi; Barry R. Satine; Eileen Falvey; Lynda Q. Nguyen; Israel Sasha Mayergoyz).

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In addition to the abbreviations set forth in Appellants' Opening Brief (at x-xi), the following abbreviations are used in this Reply Brief:

MBr. ____	Appellants' Opening Brief at page ____
ACLUBr. ____	Appellees' Brief at page ____
DOJBr. ____	Brief for the United States as Amicus Curiae in Support of Neither Party at page ____

As in Appellants' Opening Brief, all emphasis in this brief is added unless otherwise indicated.

## **INTRODUCTION**

This lawsuit is an abstract exercise, not a real case-or-controversy, over the proper interpretation of 35 U.S.C. § 101. Defendants have no concrete dispute with any plaintiff, yet plaintiffs were allowed to maintain this declaratory-judgment action. On the merits, should the Court get there, there is no basis for using § 101's coarse filter to invalidate the claims selected by plaintiffs: The claimed compositions of matter and methods are new, useful, human-made inventions that, for the first time in history, brought isolated BRCA1 and BRCA2 DNA molecules, and diagnostic methods using those molecules, into existence. They are inventions entitled to patent protection.

On jurisdictional or merits grounds, the decision should be reversed.

## **ARGUMENT**

### **I. THE DISTRICT COURT LACKED JURISDICTION**

Myriad showed (MBr. 18-30) that there is no case-or-controversy between plaintiffs and defendants, and that the district court erroneously applied a standardless "all the circumstances" test, instead of ascertaining whether those circumstances demonstrated "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). Plaintiffs' arguments for upholding jurisdiction are similarly standardless, and would allow anyone to launch a risk-free lawsuit challenging

patent validity, simply by alleging subjective fear or “chill” arising from the existence of such patents. That is not the law, nor should it be.

### 1. **Subjective Fears Do Not Justify Declaratory-Judgment**

**Jurisdiction.** Plaintiffs claim that “[i]t is fear alone that has forced them to abandon activity they fully believe they have the right to undertake.” (ACLU Br. 21.) But their subjective fears are just that—fears—not a real, live case or controversy between adverse parties. Myriad has taken no affirmative action against anyone, let alone any of the agglomeration of 20 plaintiffs, for over ten years. That should be dispositive: “*MedImmune* does not change [the] long-standing rule that existence of a patent is not sufficient to establish declaratory judgment jurisdiction. *The mere existence of a potentially adverse patent does not cause an injury nor create an imminent risk of an injury.*” *Prasco LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008). Jurisdiction “must be based on a *real and immediate* injury or threat of future injury that is *caused by the defendants.*” *Id.* at 1339 (emphasis in original). This comports with the Supreme Court’s instruction that “[i]t is the *reality* of the threat of [ ] injury that is relevant to the standing inquiry, not the plaintiff’s subjective apprehensions.” *City of Los Angeles v. Lyons*, 461 U.S. 95, 107 n.8 (1983) (original emphasis). *See also Laird v. Tatum*, 408 U.S. 1, 13-14 (1972) (“Allegations of a subjective ‘chill’ are not an

adequate substitute for a claim of specific present objective harm or a threat of specific future harm.”).

The record refutes plaintiffs’ rhetoric of “chill” in any event. Plaintiff Chung concedes that she currently conducts sequencing of BRCA genes. (A1304.) Plaintiff Matloff’s associated diagnostic laboratory, as well as “multiple” other laboratories, are also sequencing BRCA genes. (A3639-41; A3666.) Furthermore, as noted earlier (MBr. 14, 23), more than 18,000 scientists have conducted research on BRCA genes, and over 8,600 research papers have been published regarding BRCA genes, including over 45 papers by the named plaintiffs and their supporting declarants. (A3643-44.) Additionally, Myriad has facilitated research by providing free cDNA clones of BRCA genes to over 30 research institutions, including those affiliated with several plaintiffs. (A3640-41.) All of this suggests, contrary to the district court’s supposition (A35-36, A63-64), that Myriad’s decade-old actions have not dissuaded anyone from research or testing.

“[I]t is the *objective* words and actions of *the patentee* that are controlling.” *Hewlett-Packard Co. v. Acceleron LLC*, 587 F.3d 1358, 1363 (Fed. Cir. 2009) (internal citation omitted). Though plaintiffs allude to this standard (ACLUBr. 32), they disregard its substance. In fact, plaintiffs concede that “*the only reason* Plaintiffs are not undertaking these activities *is their fear* of patent infringement allegations by Myriad.” (ACLUBr. 26.)

But fear is not enough. Any “fear” must be the objectively reasonable result of the patent owner’s affirmative acts, and on that score, plaintiffs’ case falls woefully short. Put simply, while declaratory-judgment jurisdiction is determined by applying “an objective standard that cannot be met by a purely subjective or speculative fear of future harm,” *Prasco*, 537 F.3d at 1339, plaintiffs offer only subjective suspicions about future litigation. That is insufficient under the law.

**2. The Patent Owner Must Have Taken Some Affirmative Acts To Merit A Declaratory Judgment.** Myriad showed (MBr. 20-22) that, even after *MedImmune*, “declaratory judgment jurisdiction generally will not arise . . . without some affirmative act by the patentee.” *SanDisk Corp. v. STMicroelectronics, N.V.*, 480 F.3d 1372, 1380-81 (Fed. Cir. 2007). This affirmative-act requirement makes perfect sense, because no “controversy” can exist unless there are two embroiled parties—plaintiffs’ fear must be the objective result of defendants’ acts.

Plaintiffs, like the district court, deny that affirmative acts by defendants, directed towards plaintiffs, are required by law. *See* ACLUBr. 32. They nonetheless contend that “Myriad has sued or threatened every known lab to ever offer clinical BRCA testing” (ACLUBr. 29), even though several labs offer clinical BRCA testing without interference from Myriad. (A3639-40; A3666.) They also claim, without citation, that “Myriad has not ceased asserting its patents in a broad

and widely-known fashion since the day they were issued.” (ACLU Br. 33.)

Surely, were this true, plaintiffs could point to *some* act by Myriad from the last decade. “Unsupported attorney argument, presented for the first time on appeal, is an inadequate substitute for record evidence.” *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1260 (Fed. Cir. 2010).

Plaintiffs’ approach would allow a declaratory-judgment action to proceed based on one side’s speculative fears, contrary to the Declaratory Judgment Act’s purpose of “permit[ting] a threatened party to resolve its potential liability, but only when the relationship has progressed to *an actual controversy*, as required by Article III of the Constitution.” *Phillips Plastics Corp. v. Kato Hatsujou*, 57 F.3d 1051, 1053 (Fed. Cir. 1995).

**3. Stale Litigation And Licensing Activities Do Not Establish A Controversy “Of Sufficient Immediacy And Reality.”** Plaintiffs cobble together various acts by Myriad to allege that its “[a]ffirmative [a]cts [s]upport [a] [f]inding [o]f DJ [s]tanding.” (ACLU Br. 29.) But plaintiffs overlook the salient fact that the identified acts *occurred over a decade before* this action was filed.

From the past ten years, plaintiffs cannot identify any threatened action—lawsuits, suggestions of litigation, enforcement actions, attempts to license, royalty demands, barriers to regulatory approval, or otherwise—directed by Myriad toward any plaintiff. Further, plaintiffs cannot show any relevant communication from

Myriad that identified the patents-in-suit or referred to plaintiffs' products.<sup>1</sup> Thus, there is no real or immediate controversy because "not only have the defendants not taken a concrete position adverse to [plaintiffs], but they also have taken no affirmative actions at all related to [plaintiffs'] current product." *Prasco*, 537 F.3d at 1340.<sup>2</sup>

Plaintiffs try to dismiss the extensive passage of time by suggesting that *Micron Technologies, Inc. v. Mosaid Technologies, Inc.*, 518 F.3d 897, 901 (Fed. Cir. 2008), stands for the proposition that "a lapse in time does not defeat DJ standing if the patentee continued to assert its patents against others *during this period*." (ACLU Br. 33.) That is unavailing. For one, plaintiffs cannot identify

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<sup>1</sup> Even that would not be enough. *See Hewlett-Packard*, 587 F.3d at 1362 ("[A] communication from a patent owner to another party, merely identifying its patent and the other party's product line, without more, cannot establish adverse legal interests between the parties, let alone the existence of a 'definite and concrete' dispute.").

<sup>2</sup> Plaintiffs attempt to compensate for the absence of any recent affirmative acts by Myriad by instead focusing on their own alleged "meaningful preparation" to infringe. (ACLU Br. 26-29.) However, in *Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, this Court explained that "[a]lthough 'meaningful preparation' to take infringing action may suffice for declaratory [judgment] jurisdiction in some circumstances, representations to a third person about 'technological characteristics' do not establish *a justiciable controversy with the patentee*." 599 F.3d 1377, 1380 (Fed. Cir. 2010). So too here. Though others may have known of plaintiffs' products and desires, there is no evidence whatsoever that Myriad possessed such awareness. Moreover, even if Myriad knew of plaintiffs' claimed "preparation," such "knowledge of itself d[oes] not create a controversy within the contemplation of the Declaratory Judgment Act." *Id.*

any acts by Myriad against anyone “during this [ten-year] period,” and, as noted above, other laboratories were and are conducting testing, unimpeded by Myriad. For another, *Micron* is inapposite. Unlike here, the *Micron* patentee (i) sent multiple enforcement letters to plaintiff, (ii) conducted several enforcement cases and licensing campaigns during the interval between enforcement letters and the declaratory-judgment action, and (iii) stated “its intent to continue an aggressive litigation strategy.” *Id.*

**4. Plaintiffs’ Declaratory Action Would Not Afford Them The Relief They Want.** Plaintiffs acknowledge that declaratory-judgment jurisdiction cannot exist if “another patent not in the suit prevent[s] [plaintiff] from undertaking potentially infringing activities.” (ACLU Br. 29 (citing *Janssen Pharm., N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1360 (Fed. Cir. 2008).) This principle precludes jurisdiction here because the unchallenged claims of the patents-in-suit would prevent plaintiffs from engaging in the activities they purportedly desire to perform. Consequently, plaintiffs cannot satisfy the Article III requirement that a controversy “admit of specific relief through a decree of *a conclusive character.*” *MedImmune*, 549 U.S. at 127.

Plaintiffs state that “[i]f the Myriad *patents* were invalidated today, Plaintiffs could—and would—begin BRCA-related activity immediately.” (ACLU Br. 26.) That statement obscures two fundamental facts: (1) Plaintiffs do not challenge

“the Myriad patents,” but only a small group of composition and method claims that they alone selected (ACLU Br. 6, 56); and (2) plaintiffs concede that they cannot perform the necessary gene sequencing without practicing the unchallenged claims directed to DNA probes and primers. (ACLU Br. 16.) The record evidence, including plaintiffs’ own declarations, demonstrates that using DNA probes and primers is necessary to perform BRCA gene sequencing. (A2606-08; A4304-05; A4324; A4341-43.) Plaintiffs’ declarant Mason stated: “To sequence DNA, researchers *usually use* dye-terminator methods, where a single-stranded DNA template is annealed to an oligonucleotide *primer*, extended using DNA polymerase.” (A2608.) Similarly, Dr. Mark Kay explained that “analyzing BRCA1 requires a probe or primer specific to the BRCA1 gene.” (A4304-05.)

“To satisfy standing, the plaintiff must allege [] an injury-in-fact . . . redressable by a favorable decision.” *Prasco*, 537 F.3d at 1338. Here, any purported injury to plaintiffs will subsist regardless of the outcome because plaintiffs readily admit that this “Court is not being asked to rule on patentability of DNA as either primers or probes.” (ACLU Br. 16.)

\* \* \* \*

In the final analysis, this is not a real dispute. Instead, it represents plaintiffs’ attempt to shape policy based on their philosophical disagreement with patentability of genetic material. (A7387-88 (stating that plaintiffs “just had to

pick one case as [their] case”); *see also* ACLUBr. 8.) “Public policy, of course, dictates dismissal of litigation where there is neither standing nor jurisdiction.” *Indium Corp. of Am. v. Semi-Alloys, Inc.*, 781 F.2d 879, 884 (Fed. Cir. 1985).

In sum: The judgment should be reversed with an order to dismiss this case for lack of jurisdiction.

## II. THE COMPOSITION CLAIMS ARE PATENT-ELIGIBLE

Were this Court to reach the merits, it should reverse. As for Myriad’s composition claims, plaintiffs do not dispute that they are drawn to “compositions of matter” within the meaning of § 101, and they have not demonstrated that these compositions fall within one of the three narrow non-textual exceptions to patent-eligibility. Indeed, plaintiffs do not dispute Myriad’s showing (MBr. 35) that, until the inventions of the Myriad patents, isolated BRCA1 and BRCA2 DNA molecules—indisputably useful advancements—did not exist, and were not available for the benefit of the public.

1. **The Proper Legal Approach.** Myriad showed (MBr. 30-34) that the proper approach to determining whether a claimed invention is patent-eligible asks, first, whether the invention claimed falls within the specific categories of subject matter set forth in § 101—“any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”—if so, then the inquiry becomes whether plaintiffs can show that the claimed invention falls

within one of the “only three exceptions to the Patent Act’s broad patent-eligibility principles: ‘laws of nature, physical phenomena, and abstract ideas.’” *Research Corp. Techs., Inc. v. Microsoft Corp.*, No. 2010-1037, 2010 WL 4971008, at \*6 (Fed. Cir. Dec. 8, 2010) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980)). Other provisions of the Patent Act not at issue here—notably, §§ 102, 103, and 112—protect against improvidently issued patents. *Id.*; *see also Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010); MBr. 50.

*Research Corporation* confirms that Myriad’s is the correct approach. There, this Court noted that “Section 101 emphasizes that ‘any’ subject matter in the four independent categories and ‘any’ improvement in that subject matter qualify for protection.” 2010 WL 4971008, at \*6. *See also Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 2008-1403, slip op., at 11 (Fed. Cir. Dec. 17, 2010). This Court, like the Supreme Court in *Bilski*, repeatedly underscored that § 101 sets forth “broad patent-eligibility principles” (*Research Corp.*, 2010 WL 4971008, at \*7; *see also Prometheus*, slip op., at 11) and “broad statutory categories with the broadening double ‘any’ exhortation as well” (*Research Corp.*, 2010 WL 4971008, at \*6; *see also Prometheus*, slip op., at 11), creating a patent-eligibility standard that “‘Congress plainly contemplated . . . would be given wide scope.’” *Research Corp.*, 2010 WL 4971008, at \*6 (quoting *Chakrabarty*, 447 U.S. at 308); *see also Prometheus*, slip op., at 11. This Court further emphasized

that courts should not scuttle Congressional intent by reading into § 101 limitations or conditions not expressed by Congress. *Research Corp.*, 2010 WL 4971008, at \*7 (citing *Diamond v. Diehr*, 450 U.S. 175, 182 (1981)). To that end, plaintiffs must show that the applicability of one of the three nontextual exceptions is clear and indisputable—such a “disqualifying characteristic should exhibit itself so manifestly as to override the broad statutory categories of eligible subject matter and the statutory context that directs primary attention on the patentability criteria of the rest of the Patent Act.” *Id.* at \*7.

The approach required by *Bilski*, *Research Corporation*, and *Prometheus* compels reversal here: Myriad’s isolated DNA claims are drawn to one of the specific categories of patent-eligible subject matter: “any new and useful . . . composition of matter, or any new and useful improvement thereof.” And, contrary to plaintiffs’ claim that “the [Supreme] Court has described ‘products of nature’ as an exception” to § 101 (ACLU Br. 39), it is crystal-clear that “products of nature” is not one of the “*only three exceptions* to the Patent Act’s broad patent-eligibility principles.” *Research Corp.*, 2010 WL 4971008, at \*6. It necessarily follows that plaintiffs cannot sustain their burden of showing that it is “manifestly” clear that isolated DNA molecules fall within one of the exceptions as a “product of nature.”

**2. There Is No Sweeping “Products of Nature” Exception To § 101.**

As *Myriad* showed (MBr. 41-46), plaintiffs and the district court misread Supreme Court precedent as supporting a sweeping “products of nature” exception from the scope of § 101; plaintiffs repeat the same mistake in their brief before this Court. (ACLU Br. 37-45.)

In *Diamond v. Diehr*, the Court observed that terms like “principles of nature” are uniquely unhelpful because, “carried to its extreme,” application of such terms would “make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious.” 450 U.S. at 189 n.12. Similarly, over 60 years ago, Justice Frankfurter presciently noted that terms such as “the work of nature” are

vague and malleable terms infected with too much ambiguity and equivocation [since] [e]verything that happens may be deemed ‘the work of nature’ . . . . Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent.

*Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 134-35 (1948)

(Frankfurter, J., concurring).

When Justice Frankfurter wrote those words, requirements of patent-eligibility and patentability were combined in a single prolix section of the *Revised*

*Statutes*:

Any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvements thereof, or who has invented or discovered and asexually

reproduced any distinct and new variety of plant, other than a tuber-propagated plant, not known or used by others in this country, before his invention or discovery thereof, and not patented or described in any printed publication in this or any foreign country, before his invention or discovery thereof, or more than one year prior to his application, and not in public use or on sale in this country for more than one year prior to his application, unless the same is proved to have been abandoned, may, upon payment of the fees required by law, and other due proceeding had, obtain a patent therefor.

R.S. 4886, then codified at 35 U.S.C. § 31. In 1952, when the modern Patent Act was passed, these requirements were divided into current 35 U.S.C. §§ 101, 102, and 103. (The plant-patent provisions were separately re-codified.)

As Myriad showed (MBr. 43-46), early cases seeming to address a “products of nature” doctrine are best understood under the modern Patent Act as specific applications of § 102’s novelty requirement or § 103’s nonobviousness requirement, because unpatentable “products of nature” are, by definition, old and do not involve human “invention.” *Funk Brothers* itself was decided under the requirement then called “invention” (rooted in the “invention” and novelty requirements of R.S. 4886) and now called “nonobviousness.” (See MBr. 43-45.) Using these well-established principles avoids the “vague,” “malleable,” “ambigu[ous],” and “equivoca[l]” approach decried by Justice Frankfurter, and imposes appropriate discipline upon the decisional process: The challenger of a patent claim must identify the “old” product or products of nature, and demonstrate why, when viewed through the lenses of the state of the art at the time of the

claimed invention, and the level of ordinary skill in that art, the claimed invention is the same as the old matter, or merely an obvious, noninventive variation over what was already known.

3. **No Case Since 1952 Has Found That A Composition-Of-Matter Claim Failed Section 101.** Significantly, since the passage of the 1952 Act, up until the 2010 district-court decision here, no composition-of-matter claim had been caught in § 101's "coarse eligibility filter." This is for good reason: Compositions of matter are squarely within the text of the statute, and none of the three atextual exceptions—"laws of nature, physical phenomena, and abstract ideas"—embraces compositions of matter. Thus, numerous decisions have upheld the patent-eligibility of compositions of matter isolated from natural sources. MBr. 36, citing *In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979), *In re Kratz*, 592 F.2d 1169 (C.C.P.A. 1979), and *In re Bergstrom*, 427 F.2d 1394 (C.C.P.A. 1970); *see also Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156 (4th Cir. 1958).

Plaintiffs nonetheless argue (ACLUBr. 39) that claims to isolated DNA molecules "do not survive section 101 because they cover natural phenomena and products of nature." As noted, "products of nature" is not one of the three atextual exceptions, and "natural phenomena"—which *Diehr* used as a synonym for "physical phenomena," *see* 450 U.S. at 185—would not embrace isolated DNA molecules. The word "phenomenon" means "an observable fact or event."

*Webster's Third New Int'l Dictionary* 1696 (1976). The Supreme Court's use of the term is consistent with that dictionary definition—it refers not to a composition of matter, but, rather, to a scientific principle or inherent property. *See, e.g., O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 116 (1853) (“the discovery of a principle in natural philosophy or physical science, is not patentable”); *LeRoy v. Tatham*, 55 U.S. (14 How.) 156, 174-75 (1852) (“It is admitted, that a principle is not patentable. A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.”); *cf. Patton v. Yount*, 467 U.S. 1025, 1034 (1984) (“That time soothes and erases is a perfectly natural phenomenon, familiar to all.”).

Plaintiffs similarly claim (ACLU Br. 39), quoting *Parker v. Flook*, 437 U.S. 584, 593 (1978), that isolated DNA molecules “are not the kind of ‘discoveries’ the statute was enacted to protect,” yet they leave out the explanatory footnote that immediately follows in the *Flook* opinion, which confirms that the “natural phenomenon” exception is limited to old “scientific principle[s]” or relationships that have “always existed,” not new compositions of matter: “Such ‘mere’ recognition of a theretofore existing phenomenon or relationship carries with it no rights to exclude others from its enjoyment. . . . There is a very compelling reason for this rule. The reason is founded upon the proposition that in granting patent rights, the public must not be deprived of any rights that it theretofore freely

enjoyed.” 437 U.S. at 593 n.15 (quoting P. Rosenberg, *Patent Law Fundamentals* § 4, p. 13 (1975)). Here, as Myriad has shown, and as plaintiffs have never disputed, “the public” never “freely enjoyed” any “rights” attendant to isolated BRCA1 and BRCA 2 DNA molecules until those molecules were isolated by the inventors, and Myriad’s patents disclosed these new, useful and valuable inventions to the public. (MBr. 35-36, 47-48.) In exchange for disclosing these human-made inventions, Myriad is properly allowed, by statute, a limited exclusionary right.

**4. The Proper Legal Standard Is Not “Markedly Different.”**

Plaintiffs now try to avoid the fight they started in the district court, namely, whether the legal standard set forth by *Chakrabarty* is “markedly different characteristics from any found in nature,” or, as Myriad urged, whether the law simply requires that the challenged compositions be “a product of human ingenuity ‘having a distinctive name, character, and use.’” 447 U.S. at 309-10. *See* ACLUBr. 40 & n.14. As Myriad showed (MBr. 41-43), and plaintiffs do not dispute, “markedly different characteristics” was not meant to be a rule of law, nor is it a workable legal standard. But, whatever verbal formulation the legal standard might take, it is clear that Myriad’s isolated BRCA1 and BRCA2 DNA molecules are patent-eligible because they are the product of human ingenuity, and possess a

distinctive name, character, and utilities when compared to native DNA. MBr. 35-36, 47-48, 50-52.

Plaintiffs nonetheless make the same mistake the district court did in evaluating the distinctions between “native DNA” and “isolated DNA”—they ignore the differences entirely, preferring to focus on their similarities. *See* ACLUBr. 42-43. But it is the differences that make the difference: Unlike native DNA, isolated DNA molecules are “nonnaturally occurring”; they are “products of human ingenuity” in creating them; they have a “distinctive name” (“isolated BRCA1 and BRCA2 DNA molecules”), a “distinctive . . . character” (isolated DNA molecules have broken covalent bonds, free ends, are chemically inert, incapable of transmitting information, stripped of modifications and other cellular components such as proteins and other nucleic acid molecules); and “distinctive . . . use[s]” as probes, primers, sequencing templates, and inserts for sub-cloning into gene therapy vectors, all of which are valuable for diagnosis and treatment of cancers. (A4335-39; *see* MBr. 47-48.) These *differences* between the human-isolated BRCA1 and BRCA2 DNAs and their native counterparts render these compounds patent-eligible, giving them practical, meaningful, real-world utilities. Indeed, in *Chakrabarty* itself, the Court focused solely on the *differences* between the manmade bacterium and naturally occurring bacteria, not the similarities, which would have been plentiful. *See* 447 U.S. at 305, 306 & n.3, 310.

By contrast, the approach utilized by the district court, plaintiffs, and the United States suffers from the same standardlessness that concerned Justice Frankfurter. That approach, which allows decisionmakers to ignore these differences, is not sensitive to whether the claimed invention, at the time of its invention, represented a new or nonobvious human-made advancement over what existed in unaltered nature. Around 1995, at the time of the Myriad inventions, the identification, isolation, excision, and purification of the claimed isolated DNA molecules represented an unpredictable, unanticipated breakthrough. (A259-361; A569-672; A775-869.) Hypothetically speaking, however, had the Myriad compositions been made in 2011, the state of the art—and the level of ordinary skill—might tell a different story with respect to their novelty and nonobviousness. In both cases, though, the claimed compositions would be exactly the same “products of human ingenuity,” and should pass through § 101’s “coarse eligibility filter” in the same way, allowing the more “powerful tools” of other provisions of the Patent Act to act as better-calibrated patentability filters. *Research Corp.*, 2010 WL 4971008, at \*8; *see also* MBr. 50; DOJBr. 17.

5. **Myriad’s Patents Are Not Impermissibly Preemptive.** Plaintiffs claim that Myriad’s patents “have a preemptive effect.” ACLUBr. 43. All patents—exclusionary instruments by definition—have some “preemptive effect”;

the question is whether Myriad's patents preempt laws of nature, physical phenomena, or abstract ideas. As shown above, they do not.

In arguing otherwise, plaintiffs say that "Myriad has not denied that its patents allow it to exclude anyone from working with the BRCA1/2 molecules." ACLUBr. 44. This argument unintentionally points up the improper nature of this declaratory-judgment action (Myriad has never asserted that "its patents allow it to exclude anyone from working with the BRCA1/2 molecules," so plaintiffs have to rely on the absence of a denial—a dog that did not bark). *See* Section I, above. Beyond that, the claim that Myriad's patents have had a "preemptive effect" or somehow impeded "research or clinical" work on *BRCA1* and *BRCA2* is demonstrably false. Many test methods have been developed for determining BRCA predisposition to cancer (*see* A7382-84; A7454-7662), and those methods are not impeded by the claims plaintiffs opted to challenge. Additionally, over 18,000 researchers have conducted studies on BRCA molecules, and over 8,000 relevant papers have been published—all since these inventors disclosed their inventions to the public by patenting them. MBr. 14 (citing A3439-40, A3444, and A3484-87). That is not impermissible pre-emption; that is the patent system working as it should.

**6. The PTO's Judgment That Isolated DNA Molecules Are Patentable Subject Matter Is Unaffected By The United States' Brief. Myriad**

showed (MBr. 37-39) that, under the Supreme Court’s approach in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124 (2001), the Court should follow the PTO’s views and longstanding practices regarding § 101’s coverage in the absence of any “indication from either Congress or agencies with expertise that such coverage is inconsistent with [the governing statutes].” *Id.* at 144-45. Indeed, Congress, by enacting amendments to § 103(b) which presume that patents on “nucleotide sequences” were appropriate,<sup>3</sup> as well as by enacting §§ 271(e)(1) & (g), *see Genetic Alliance Amicus Br.* 19-20, has indicated that such coverage is *consistent with* the Patent Act. If plaintiffs have a complaint about the scope of patent-eligible material, it is properly directed at Congress, not the courts.

The United States has nonetheless filed a brief urging that isolated genomic DNA molecules should not be patent-eligible subject matter, but that other similar molecules (*e.g.*, isolated cDNA molecules) reflecting “human ingenuity” should be patent-eligible. That brief does not represent the views of the relevant “agenc[y]

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<sup>3</sup> Plaintiffs wrongly contend that § 103(b) does not show Congress’s understanding and intent that isolated DNA is patentable. (ACLU Br. 48 n.16.) The legislative history demonstrates that the patentability of isolated nucleotide sequences or genes was viewed as a “given,” but Congress recognized that such patent protection, by itself, did not afford sufficient rights to the biotechnology industry. Using Amgen’s patent estate as the “poster child” for this legislation, Senator Hatch explained—and Amgen’s counsel Steven M. Odre confirmed in his testimony—that Amgen was able to obtain a patent that included claims to the gene encoding erythropoietin. 141 Cong. Rec. S11201-03, 11207 (Aug. 2, 1995). Indeed, Amgen’s patent, U.S. Patent No. 4,703,008, claims “a purified and isolated DNA sequence” encoding erythropoietin, and includes dependent claims specifying genomic DNA as well as cDNAs.

with expertise,” namely, the PTO: For one, the PTO did not sign the United States’ brief, even though, according to the United States’ brief, “[t]his appeal . . . implicates the expertise and responsibilities of” the PTO. (DOJBr. 1.) The PTO’s absence from that brief is truly extraordinary.<sup>4</sup> For another, the Director has taken the even more extraordinary step of announcing that the PTO will not follow the position set out in the Department of Justice’s filing, but instead will continue to follow the *Utility Examination Guidelines*. Peter Loftus, *US Patent Office Keeps Status Quo Amid Gene-Patent Fight*, Dow Jones News Service, Nov. 2, 2010, available at <http://online.wsj.com/article/BT-CO-20101102-706673.html>. In short, the United States’ brief is nothing but a litigating position determined by one of the political branches; standing by itself in this way, the Department of Justice has no claim to the sort of expertise that merits deference. *See, e.g., Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990) (holding that no deference is due to an agency not charged by Congress with administering the statute); *American Signature, Inc. v. United States*, 598 F.3d 816, 827 (Fed. Cir. 2010) (“Where the agency’s

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<sup>4</sup> It is unheard of for the PTO not to join in a United States *amicus curiae* filing before this Court in a patent case. *See, e.g.,* Brief for the United States as *Amicus Curiae* on Rehearing *En Banc* in Support of Neither Party, *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. 2008-1511 *et al.* (Fed. Cir. Aug. 2, 2010); *Ortho-McNeil Pharm. v. Lupin Pharms.*, 603 F.3d 1377, 1377 (Fed. Cir. 2010); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1338 (Fed. Cir. 2010) (*en banc*); *Voda v. Cordis Corp.*, 476 F.3d 887, 889 (Fed. Cir. 2007); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1306 (Fed. Cir. 2005) (*en banc*).

interpretation seeks to advance its litigating position, deference is typically not afforded to the agency’s position announced in a brief.”).

While there is much to recommend in the Department of Justice’s brief, its contradiction of longstanding PTO practice and the *Utility Examination Guidelines* with respect to the patent-eligibility of isolated genomic DNA molecules (*see* DOJBr. 18) is wrong and indefensible. Certainly, the Department was correct to chastize the district court for “erroneously cast[ing] doubt on the patent-eligibility of a broad range of manmade compositions of matter whose value derives from the information encoding capacity of DNA,” particularly “cDNAs, vectors, recombinant plasmids, and chimeric proteins, as well as countless industrial products, such as vaccines and genetically modified crops, created with the aid of such molecules—[they] are in every meaningful sense the fruits of human ingenuity and thus qualify as ‘human-made inventions’ eligible for patent protection under section 101.”<sup>5</sup> (DOJBr. 9-10, citing *J.E.M. Ag Supply*, 534 U.S. at 130 (in turn quoting *Chakrabarty*, 447 U.S. at 313).)

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<sup>5</sup> The Department of Justice correctly concluded that the claimed cDNA molecules are patent-eligible. The claimed cDNA molecules have a distinctive name, “BRCA1 and BRCA2 cDNA molecules,” and a distinctive character—BRCA1 and BRCA2 cDNAs are synthetic molecules that exclude certain regulatory and other non-protein-coding sequences found in naturally occurring DNA. BRCA1 and BRCA2 cDNAs have distinctive uses as well—these molecules can be used to make synthetic and recombinant proteins, as well as to serve as primers and probes for detecting cancer-predisposing mutations. Yet the district court found both the claims to isolated genomic DNA molecules and the

But the Department of Justice missed the mark by asserting that “the district court correctly held . . . that genomic DNA that has merely been isolated from the human body, without further alteration or manipulation, is not patent-eligible.” (DOJBr. 10.) Attaching adverbs like “merely” to the critical “isolated” aspect of the claims—as well as offering inapposite analogies to other products (“coal, cotton, and saffron”) that have been isolated by humans for thousands of years (DOJBr. 21)—does not provide a principled distinction for deciding this case, or future cases, under § 101. The isolated DNA molecules of Myriad’s claims qualify as “human-made inventions” in the same way as do the admittedly patent-eligible “broad range of manmade compositions of matter whose value derives from the information encoding capacity of DNA.” The Department of Justice may assert that “[c]rossing the threshold of section 101 requires something more than identifying and isolating what has always existed in nature” (DOJBr. 35), but “merely” saying so—without defining that “something more”—does not make it so.

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claims to cDNA molecules to be patent-ineligible on the same grounds—that their value derives from the information-encoding capacity of DNA. (A221-22.) As pointed out by the Department of Justice, this is not an appropriate ground for ineligibility. Plaintiffs’ similar argument (ACLUBr. 50-51) that cDNAs appear naturally in the body as pseudogenes is factually incorrect, because those substances are not “isolated” but are integral with human chromosomes and attached to other genomic sequences. (A4320-22.)

The bottom line is this: Human inventors isolated the BRCA1 and BRCA2 DNA molecules, and by so doing brought the challenged compositions of matter into existence. They are “the fruits of human ingenuity.” That satisfies § 101.

### **III. THE METHOD CLAIMS ARE PATENT-ELIGIBLE**

Myriad showed (MBr. 53-61) that the district court erred by concluding that the claims involving “analyzing” or “comparing” gene sequences were not patent-eligible as “abstract mental processes.” (A234.) Plaintiffs’ arguments to the contrary are unavailing.

1. **The Proper Legal Approach.** Since Myriad’s opening brief, this Court has issued its decisions in *Research Corporation*, holding that certain claimed methods for rendering a digital halftone image in computerized printing were patent-eligible under § 101, and in *Prometheus*, again holding that certain medical diagnostic methods were likewise patent-eligible.

In *Research Corporation*, the Court observed that the Supreme Court “has ‘never provide[d] a satisfying account of what constitutes an unpatentable abstract idea,’” 2010 WL 4971008, at \*7 (quoting *Bilski*, 130 S. Ct. at 3236 (Stevens, J., concurring)), and went on to conclude that a “disqualifying characteristic” such as abstractness, if it is to invalidate an otherwise patent-eligible method or process, “should exhibit itself so manifestly as to override the broad statutory categories of

eligible subject matter and the statutory context that directs primary attention on the patentability criteria of the rest of the Patent Act.” *Id.*

And in *Prometheus*, this Court again upheld the patent-eligibility of Prometheus’s method claims, holding that they “recite a patent-eligible application of naturally occurring correlations between metabolite levels and efficacy or toxicity, and thus do not wholly preempt all uses of the recited correlations.” *Prometheus*, slip op., at 15. The Court also “reaffirm[ed] that the treatment methods in Prometheus’s patents in suit satisfy the transformation prong of the machine-or-transformation test, as they ‘transform an article into a different state or thing,’ and this transformation is ‘central to the purpose of the claimed process.’” *Id.*, slip op., at 16 (quoting *In re Bilski*, 545 F.3d 943, 962 (Fed. Cir. 2008) (*en banc*)).

Under the approach endorsed by the Supreme Court and this Court, the method claims are plainly patent-eligible. Section 101 makes “process[es],” or improvements thereon, patent-eligible; under 35 U.S.C. § 100, “[t]he term ‘process’ means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.” Each claimed method has “functional and palpable applications in the field of [diagnostic medicine],” *see Research Corp.*, 2010 WL 4971008, at \*7—in particular, the specific applications of “detecting a germline alteration in a BRCA1 gene”

(A463:17-18), “screening a tumor sample from a human subject for a somatic alteration in a BRCA1 gene in said tumor” (A566:155:2-4), “screening potential cancer therapeutics” (A665:156:15), “screening germline of a human subject for an alteration of a BRCA1 gene” (A771:155:17-18), “identifying a mutant BRCA2 nucleotide sequence in a suspected mutant BRCA2 allele” (A965:169:41-42), and “diagnosing a predisposition for breast cancer in a human subject.” (A965:169:47-48.) These “specific applications or improvements to technologies in the marketplace are not likely to be so abstract that they override the statutory language and framework of the Patent Act.” *Research Corp.*, 2010 WL 4971008, at \*7.

These are not abstract ideas at all—they are specific, functional, and palpable ways of detecting cancer-predisposing abnormalities in a human being, or identifying cancer therapeutics useful to that particular individual. They do not preempt a natural phenomenon, but, rather, utilize a natural phenomenon as one of a series of particular, specific steps that limit the application of this principle. *See Diehr*, 450 U.S. at 187 (“Their process admittedly employs a well-known mathematical equation, but they do not seek to pre-empt the use of that equation. Rather, they seek only to foreclose from others the use of that equation in conjunction with all the other steps in their claimed process.”); *Prometheus*, slip op., at 15-16 (similar).

## 2. The Method Claims All Require Transformations Of A Human

**Sample.** Under the machine-or-transformation inquiry, which is no longer mandated but remains “useful” under § 101, *see Bilski*, 130 S. Ct. at 3227; *Prometheus*, slip op., at 10, 16-23, these claims require transformations—the physical manipulation of human tissue or blood in order to isolate the patient’s DNA, and a second, separate physical manipulation of the isolated DNA itself in sequencing. Myriad showed (MBr. 57-60) that the district court erred by viewing the claims’ use of the term “sequence” as referring merely to the alphabetical information of a DNA sequence, when the patent instruments show that a “sequence” is a molecule, not just information. Plaintiffs do not urge that the method claims are patent-ineligible under this construction; rather, they accuse Myriad of improperly “import[ing]” terms into the claims. (ACLUBr. 56.) However, Myriad’s construction and methodology are true to this Court’s precedents, to the patent documents themselves, and to their prosecution history, all of which demonstrate that “sequences” are molecules, not letters or mere information. (A7377-81; A7409-52.)

Plaintiffs indirectly concede the court’s claim-construction error (ACLUBr. 56-57) by arguing that the dependent claims “require hybridizing, amplifying, electrophoresing, and/or cloning” of those sequences. But these dependent claims would make no sense if what was being hybridized, amplified, etc. was mere

information. The claims require the use of an extracted human sample, which in and of itself requires a transformation. Then, DNA sequences (molecules) in the extracted human sample are themselves transformed by further analysis. (A4339-43.) *See Prometheus*, slip op., at 18.

*Prometheus* similarly confirms that the transformations required by Myriad's claims for determining a sequence from a human sample render those claims patent-eligible. In *Prometheus*, the Court concluded that “[d]etermining the levels of 6-TG or 6-MMP in a subject necessarily involves a transformation.” Slip op., at 18. So it is with Myriad's method claims as well. *See* MBr. 59-60.

With respect to claim 20 of the '282 patent, plaintiffs repeat the district court's erroneous, myopic focus on “the essence of the claim.” (A241.) Plaintiffs contend that claim 20 “preempts a basic scientific principle *extended to the BRCA1 gene context*,” *i.e.*, that a slower rate of cell growth when compound X is present may indicate that compound X is a cancer therapeutic. (ACLUBr. 59.) While the claim may include and utilize that principle, it is scarcely preemptive of all uses of that principle. Rather, this specific method limits its application, as plaintiffs recognize, “to the BRCA1 gene context” by requiring, *inter alia*, “growing a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer.” (A665:156:16-17.) That is a classic transformation, which even the district court recognized (A241)—it simply ignored it as not part of the claim's

“essence.” That was erroneous under Supreme Court precedent, which commands that the entire claim be evaluated. *Diehr*, 450 U.S. at 188; *Flook*, 437 U.S. at 594; *Prometheus*, slip op., at 12, 15-16; MBr. 55-56.

*Prometheus* also answers plaintiffs’ arguments based on *In re Grams*, 888 F.2d 835 (Fed. Cir. 1989), which contend that the step of “growing a transformed . . . cell” is “merely a preparatory, data-gathering step.” ACLUBr. 59. In *Prometheus*, the Court concluded that “the administering and determining steps in Prometheus’s claimed methods are not ‘merely’ data-gathering steps or ‘insignificant extra-solution activity’” but instead were “part of treatment regimes for various diseases.” Slip op., at 21. Here, what plaintiffs call “mere” data-gathering is core to the claimed methods, whose purposes are, *e.g.*, “screening germline of a human subject for an alteration of a BRCA1 gene” (A771:155:17-18), and involve steps of analyzing a human sample to ascertain *that particular human’s* proclivity to cancer.

In sum: The method claims are patent-eligible.

#### **IV. JUDGMENT FOR MYRIAD IS APPROPRIATE**

Because the undisputed facts demonstrate that Myriad’s claims satisfy § 101 and *Bilski*, the only remaining issue is whether plaintiffs’ constitutional arguments, not reached by the district court under the constitutional-avoidance principle, impede outright reversal. They do not.

To start, plaintiffs have abandoned their argument that Myriad's patent claims are invalid under Article I, Section 8, clause 8 of the Constitution. *See* ACLUBr. 60-63. As Myriad showed (MBr. 61-62), that argument was frivolous.

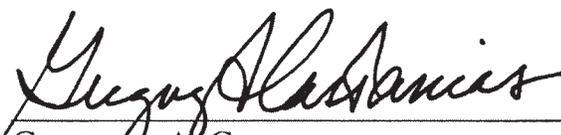
Plaintiffs nonetheless maintain their similarly frivolous First Amendment challenge to Myriad's patent claims. However, this challenge is premised on plaintiffs' erroneous assertions (i) that the method claims cover only "abstract ideas" (*see* ACLUBr. 60), and (ii) that the composition-of-matter claims violate "the doctrine that prevents the patenting of natural phenomena, abstract ideas, and products and laws of nature." *See* ACLUBr. 62. Plaintiffs' First Amendment claim is therefore coextensive with and dependent upon their erroneous arguments regarding patent-eligibility; it provides no alternative ground for affirmance if the district court's § 101 conclusions are reversed.

## CONCLUSION

The judgment of the district court should be reversed.

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Respectfully submitted,



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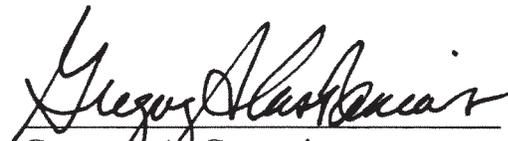
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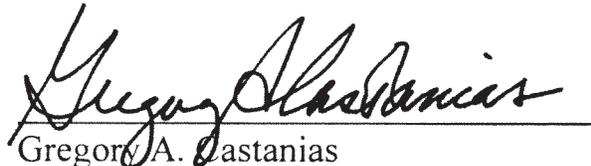
  
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## CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B), because it contains 6,959 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6), because it has been prepared in a proportionally spaced typeface using Microsoft Word 2003 in Times New Roman 14 point font.

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