

UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK

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

Plaintiffs,

-against-

UNITED STATES PATENT AND TRADEMARK OFFICE;  
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, in their official capacity as Directors of  
the University of Utah Research Foundation,

Defendants.

No. 09 Civ. 4515 (RWS)

ECF Case

**MYRIAD DEFENDANTS' MEMORANDUM IN REPLY TO PLAINTIFFS'**  
**OPPOSITION TO MYRIAD DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

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## I. INTRODUCTION AND SUMMARY

Despite the hundreds of pages of briefs and thousands of pages of expert declarations that have been filed, the question presented by the pending cross-motions boils down, essentially, to one simple question of statutory interpretation and application: Are Myriad's patent claims within the scope of patentable subject matter defined by 35 U.S.C. § 101, which broadly makes "*any* new and useful process . . . or composition of matter" eligible for a patent? As Myriad and its co-defendants showed in their opening memorandum ("Myriad Br."), the answer to that question is plainly "yes."

*As to the "isolated DNA" claims*, summary judgment in Myriad's favor is compelled by a long and unbroken line of authority—including binding Supreme Court and C.C.P.A. precedents—starting with this Court's seminal decision in *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (S.D.N.Y. 1911), *aff'd*, 196 F. 496 (2d Cir. 1912), through the issuance of the United States Patent and Trademark Office ("USPTO") *Utility Guidelines*, 66 Fed. Reg. 1092 (Jan. 5, 2001). The "isolated DNA" claimed in Myriad's patents are "compositions of matter." Those compositions of matter are both "new"—they would never have existed in their isolated form but for the hand of the inventors, *see Diamond v. Chakrabarty*, 447 U.S. 303, 309 & n.6 (1980)—and "useful"—they have "new characteristics and new utilities" not shared by the native DNA from which they are extracted. *See* Myriad Br. 8-9. Plaintiffs' arguments against patent-eligibility, by contrast, ask this Federal District Court to overrule all of these precedents, and ignore the considered judgment of the USPTO, contrary to the Supreme Court's command in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, that Section 101 has "broad scope and applicability," and that changes to longstanding law and agency policy (such as those sought by plaintiffs here) are the province of Congress, not the courts. 534 U.S. 124, 131, 144-45 (2001).

*As to the diagnostic-method claims*, summary judgment for Myriad is also compelled by binding Supreme Court and Federal Circuit precedents, most notably *Prometheus Labs. v. Mayo*

*Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009), that holds that diagnostic methods which involve transformations of human tissue and blood samples—as Myriad’s method claims plainly do—are likewise patent-eligible under 35 U.S.C. § 101. Myriad Br. 35-41. Plaintiffs’ contrary arguments are premised on ignoring claim limitations and a misreading of the applicable precedents.

***As to plaintiffs’ First Amendment challenge***, it is meritless. The patent claims at issue are classic claims drawn to chemical compositions and methods of using those compositions; they cannot possibly impede speech or thought, as plaintiffs contend. Myriad Br. 41-42. Moreover, as to the isolated DNA claims, plaintiffs have not shown that, and it is difficult to imagine how, a composition of matter can restrict speech. As to the method claims, plaintiffs contend that “the method claims solely describe thinking”; that, too, is erroneous. *Id.* In any event, even under traditional First Amendment analysis, assuming *arguendo* that the patent claims restricted some speech, the compelling governmental interest represented by the U.S. patent system would more than justify such incidental restrictions.

***Finally, as to the plaintiffs’ Article I, Section 8, Clause 8 challenge***, that, too, fails as a matter of law. Plaintiffs do not even attempt to respond to Myriad’s showing (Myriad Br. 43-44) that this clause is only a “grant of power and a limitation on” *Congressional power* to enact patent laws, *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 5 (1966), and speaks not at all to the USPTO’s decision to issue any individual patent. That alone should sink plaintiffs’ final Constitutional claim.

All of the burdens of proof on these legal issues belong to the plaintiffs in this case, and they have not sustained those burdens. Summary judgment should be granted to Myriad.

## **II. THE CHALLENGED PATENT CLAIMS SATISFY SECTION 101**

In its opening brief, Myriad showed that its challenged patent claims satisfy 35 U.S.C. § 101 under the correct understanding of the law. Myriad Br. 20-41. Plaintiffs’ response largely

mischaracterizes the law by reading three narrow categories of patent-ineligible subject matter identified by Supreme Court cases—“[t]he laws of nature, physical phenomena, and abstract ideas,” *Chakrabarty*, 447 U.S. at 309—as sweeping exceptions to Section 101’s “broad scope and applicability.” *J.E.M. Ag Supply*, 534 U.S. at 131. Plaintiffs are wrong.

As the text of Section 101 contemplates, patent-eligibility reduces to three simple inquiries: (1) Does the subject-matter fall into one of the enumerated statutory categories (“process, machine, manufacture, or composition of matter”)? (2) Is that process, machine, manufacture, or composition of matter “new”? (3) And, is it “useful”? The reason that “laws of nature,” “physical phenomena,” and “abstract ideas” are not patent-eligible is simple: They are not “new.”

But courts must take great caution not to overread these three narrow exclusions from Section 101’s broad scope, for virtually every patentable invention is created from old, preexisting things. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 134-135 (1948) (“It only confuses the issue, however, to introduce such terms as ‘the work of nature’ and the ‘laws of nature.’ For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed ‘the work of nature,’ and any patentable composite exemplifies in its properties ‘the laws of nature.’ Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent.”) (Frankfurter, J., concurring). Courts should focus on whether something falls within Section 101’s broad scope, not on whether it fits into a “vague” category of what is excluded. *J.E.M. Ag. Supply*, 534 U.S. at 131 (“[T]his Court has already spoken clearly concerning the broad scope and applicability of § 101.”); *see also Merck & Co., Inc. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 161 (4th Cir. 1958) (“There is nothing in the language of the Act which precludes the issuance of a patent upon a ‘product of nature’ when it is a ‘new and useful composition of matter’ and there is compliance with

the specified conditions for patentability.”). That is why the Supreme Court’s three categorical limitations have been, and must be, narrowly construed.<sup>1</sup>

As set forth below, Myriad’s challenged patent claims satisfy Section 101 because (1) they are “compositions of matter” or “processes” which are (2) new and (3) useful.

**A. The Composition-of-Matter Claims Are Patent-Eligible Under Section 101**

**1. The Claimed Isolated *BRCA* DNAs Are “Compositions Of Matter,” And Plaintiffs Do Not Contend Otherwise**

It is undisputed and indisputable that the claimed isolated DNA molecules are “compositions of matter,” as that term is used in Section 101. Myriad Br. 26; Linck Decl. ¶¶ 43, 45-47, 49, 58; Doll Decl. ¶¶ 26, 34; Straus Decl. ¶¶ 29-34. The Supreme Court held in *Chakrabarty* that the “expansive” term “composition of matter” is to be “given wide scope,” and includes “all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders, or solids.” 447 U.S. at 308. Nowhere do plaintiffs contend otherwise; indeed, they refer repeatedly to Myriad’s claims as covering its “patented composition.” *E.g.*, ACLU R.Br. 19.

**2. The Claimed Isolated *BRCA* DNAs Are “New”**

The heart of the dispute in this case is whether the claimed isolated *BRCA* DNA compositions are “new” as required by Section 101. They are.

The isolated *BRCA* DNAs claimed in the patents are “new” compositions of matter that do not exist in nature. Myriad Br. 8; Kay Decl. ¶ 138; Linck Decl. ¶¶ 47, 48, 51, 54, 57, 59, 64, 77; Schlessinger Decl. ¶¶ 27, 30; Doll Decl. ¶¶ 27-29, 33. The explicit definition provided in the specifications of the Myriad patents states that an “isolated” nucleic acid (*e.g.*, DNA) is:

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<sup>1</sup> Compare *Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (holding application of mathematical formula patent-eligible) with *Gottschalk v. Benson*, 409 U.S. 63 (1972) (holding mathematical calculations patent-ineligible) and *Parker v. Flook*, 437 U.S. 584 (1978) (similar).



One which is substantially separated from *other cellular components which naturally accompany a native human sequence* ... e.g., ribosomes, polymerases, many other human genome sequences and proteins. The term embraces a nucleic acid sequence or protein *which has been removed from its naturally occurring environment*.

U.S. Patent No. 5,747,282 (“the ’282 patent”), col. 19:8-18; U.S. Patent No. 5,693,473 (“the ’473 patent”), col. 19:6-15; U.S. Patent No. 5,837,492 (“the ’492 patent”), col. 17:62-66 (emphasis added). Kay Decl. ¶¶ 16-18. Thus, by definition, “isolated” *BRCA* DNA molecules are new compositions that differ from any “naturally occurring” DNAs because naturally occurring DNA inside the cell comprises many other human genome sequences and is complexed and packaged with proteins that form integral components of chromosomes. In turn, these chromosomes are surrounded by numerous other cellular components such as ribosomes and polymerases. To obtain the “isolated DNA” compositions of the claims, first the entire genome must be extracted from the cells and separated from the chromosomal proteins and other cellular components. Then the relevant *BRCA* DNA must be excised from the genome or synthesized. Myriad Br. 30-32; Kay Decl. ¶¶ 17, 131, 133, 142-143, 173, 178.

Prior to Myriad’s invention, isolated *BRCA* DNA molecules did not exist.<sup>2</sup> Shattuck Decl. ¶¶ 6-8; Tavtigian Decl. ¶¶ 4-7. Although plaintiffs suggest otherwise (ACLU R.Br. 12), isolating *BRCA* DNAs did not simply involve plucking a previously known molecule out of a cell where it was freely floating.<sup>3</sup> Only the intense and technically complex effort of the inventors allowed the successful localization and identification of the *BRCA1* and *BRCA2* genes which are integrated in the

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<sup>2</sup> This is in contrast to the extracts of cellulose, alizarine, ultramarine, vanadium, uranium and tungsten in the cases cited by plaintiffs (ACLU R.Br. 23) where patentability was denied because the compositions were old and in common use in their respective industries. Myriad Br. 25-26.

<sup>3</sup> No evidence supports plaintiffs’ contention that isolated DNA exists in the human body. Kay Decl. ¶¶ 131-133, 143. Plaintiffs instead rely on their experts’ allegation that DNA is “free-floating” in the body because the body unwinds and separates its strands when it replicates DNA during cell division and when it transcribes the genes during protein synthesis. Nussbaum Decl. ¶ 28; Mason Supp. Decl. ¶¶ 13, 23; Klein Decl. ¶ 29. However, this evidence is irrelevant because it does not relate to “isolated” DNA, as required by each of the challenged claims. Instead, it concerns DNA that is integral with human chromosomes, attached to many other human genome sequences and not removed or isolated from their naturally occurring environment, as required by the explicit definition of “isolated” DNA provided by the patent specification. See Mason Supp. Decl. Fig. 1 showing this “unwound DNA” is tightly associated with other components.

human genome among the over 25,000 known genes and the countless number of other DNAs of unknown function. Kay Decl. ¶ 187; Shattuck Decl. ¶¶ 6-8; Tavigian Decl. ¶¶ 4-7. By identifying these particular *BRCA* DNAs and isolating them away from other genomic DNA and other cellular components, the inventors created the claimed isolated *BRCA* DNA molecules. Shattuck Decl. ¶¶ 6-8; Tavigian Decl. ¶¶ 4-7. Whether made by extraction and excision, cloning or chemical synthesis, these isolated *BRCA* DNAs were “not nature’s handiwork, but [the inventors’] own; accordingly, it is patentable subject matter under § 101.” *Chakrabarty*, 447 U.S. at 310.

This is the central holding of the line of authority stretching from Judge Learned Hand’s 1911 *Parke-Davis* opinion to the present day, as summarized and embodied in the USPTO’s guidelines. Myriad Br. 20-30. Adrenaline may be patentable if it is extracted and isolated from an animal’s suprarenal gland (*Parke-Davis*); prostaglandins extracted and isolated from human or animal prostate glands are patent-eligible (*In re Bergstrom*, 427 F.2d 1394, 1401 (C.C.P.A. 1970)); so, too, the *BRCA* DNA molecules, which have been extracted and isolated from native DNA, deserve patent-eligibility.

Plaintiffs nonetheless urge that the Supreme Court in *Chakrabarty* overruled all of these cases and installed a much higher bar for what is “new” under Section 101, such that the claimed isolated DNA compositions can only constitute patent-eligible subject matter if they are “markedly different” from “natural phenomena” (*i.e.*, DNA found in the body). ACLU R.Br. 10. To support their argument, however, plaintiffs completely mischaracterize *Parke-Davis*, when they allege a simple “extracted product without change” could not meet this test. ACLU R.Br. 28, citing 189 F. at 102-103. When the complete, *uncropped* quote from *Parke-Davis* is considered (189 F. at 103), Judge Learned Hand’s meaning is clear: patentability of compositions extracted from natural sources is not foreclosed if the composition is both new and useful.<sup>4</sup> This, of course, is completely

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<sup>4</sup> In another attempt to distinguish Myriad’s “isolated DNA” claims from the isolated adrenaline claims in *Parke-Davis*, plaintiffs either misread or misrepresent the case as requiring the rearrangement of atoms in the patented substance to create new molecules. But plaintiffs are wrong when they allege that the patented substance in *Parke-Davis* included “a

consistent with the Supreme Court’s observation in *Chakrabarty* that the applicant’s new bacterium was patent-eligible under Section 101 because it had “markedly different characteristics from any found in nature and . . . the potential for significant utility.” *Chakrabarty*, 447 U.S. at 310. Additionally, plaintiffs’ suggestion that *Chakrabarty* “clearly overruled” Judge Hand’s statement in *Parke-Davis* by proclaiming that a patent-eligible product “is a product of human ingenuity ‘having a distinctive name, character [and] use’” (ACLU R.Br. 28) is likewise without merit for the same reason. Moreover, that quotation, which originated in an 1887 Supreme Court case dealing with the tariff definition of article of manufacture (*Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)), was certainly not a proclamation of a new definition for “compositions of matter” under Section 101, and *Chakrabarty* never even mentioned *Parke-Davis*.

Moreover, plaintiffs’ new “markedly different” test seizes on the language quoted above that the Supreme Court in *Chakrabarty* used to describe how the applicant’s bacterium was “new” within the meaning of Section 101 as compared to the culture held unpatentable in *Funk Bros.*, 333 U.S. 127; *Chakrabarty*, 447 U.S. at 310. The Court was not imposing any “new” requirement for patent-eligibility beyond the “new” requirement of the statute.

Even so, the claimed isolated *BRCA* DNA compositions are, in fact, “markedly different” both in structure and function from any DNAs naturally occurring in the body. Myriad Br. 30-32; Kay Decl. ¶ 138; Linck Decl. ¶¶ 47, 48, 51, 54, 57-59, 64, 77; Schlessinger Decl. ¶¶ 27, 30; Doll Decl. ¶¶ 27-29, 33. Plaintiffs assert, and Myriad agrees, that an “isolated” nucleic acid must embrace “a nucleic acid sequence which has been removed from its naturally occurring environment”—that is the explicit definition provided by the patent specifications. ACLU R.Br. 8-9. See, e.g., ’282 patent, col. 19:8-18; ’473 patent, col. 19:6-15; ’492 patent, col. 17:62-66. But

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new and inorganic substance arising from a regrouping of atoms. . .” to create new molecules. ACLU R.Br. 27 & n.23. It does not. Judge Learned Hand, credited for his careful and thorough analysis, was instead referring to the chemical disintegration of the glandular tissue *removed* from the patented adrenaline product. Moreover, this was part of his infringement analysis (*Parke-Davis*, 189 F. at 97-98), not patentability or validity of the claims. *Parke-Davis*, 189 F. at 101-103.

isolated *BRCA* DNA molecules, by definition, do not exist in the body. Kay Decl. ¶¶ 138, 173. That alone is one “marked difference.”

Plaintiffs nonetheless argue that the critical question is whether the “sequence is different when the DNA is isolated.” ACLU R.Br. 11-12. They are wrong. The appropriate question to ask is whether the claimed *BRCA DNA compositions* are different from a composition found in nature—*i.e.*, whether they are “new” relative to those long-existing bodily products. And, based on all of the evidence of record, it is clear that those patented compositions are indeed markedly different. Kay Decl. ¶¶ 138, 173; Linck Decl. ¶¶ 47, 48, 51, 54, 57-59, 64, 77; Schlessinger Decl. ¶¶ 27, 30; Doll Decl. ¶¶ 27-29, 33. The “isolated” aspect of the claimed DNA compositions is not trivial; rather, it is *critical* to the claimed invention. It is the extraction of the native genomic DNA from the cells, removal of the surrounding cellular material, and excision of the *BRCA* DNA from native genomic DNA that allows the claimed DNA compositions to take on the properties required for their various significant uses, such as probes, primers, sequencing templates, and the like. In the presence of ribosomes, polymerases, cellular proteins and other DNA structures, native DNA molecules cannot perform these functions. Like the adrenaline of *Parke-Davis*, after isolation away from its cellular components in the animal glands, the claimed isolated *BRCA* DNAs become markedly different compositions, with markedly different functions. Kay Decl. ¶¶ 133-134, 136, 138, 173-174; Linck Decl. ¶¶ 45, 48, 51, 54, 55, 57, 64, 77; Schlessinger Decl. ¶¶ 20, 27; Doll Decl. ¶ 29.

Plaintiffs do not (indeed, could not) dispute the fact that the claimed DNA molecules possess a number of functional properties not present in native DNA. Instead, plaintiffs’ arguments focus on a single property that some of the isolated DNA molecules have in common with native DNA—its protein-coding capacity and then make the astounding quantum leap that because of this single property, what is otherwise a chemical composition somehow becomes a “phenomena of nature” similar to gravity and electricity. However, the observation that isolated DNA and native DNA share this single property is irrelevant to the critical issue of whether there are *differences* in their

properties. It is the *differences* that are legally relevant to the novelty inquiry under Section 101, not the properties held in common. Indeed, plaintiffs admit that differences may exist between isolated DNA and native DNA with respect to what humans can do with them, but assert that these differences must be itemized in the claims. ACLU R.Br. 12-13. This argument is frivolous. A patent claim need only “particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention” (35 U.S.C. § 112, ¶ 2); there is no rule of law that requires a claim to recite any of the functional properties of a novel composition,<sup>5</sup> and most certainly no rule that new functions must be recited in the claims in order to be considered in a Section 101 analysis.

The differences between isolated *BRCA* DNAs and native genes are manifest and multifold. Myriad Br. 30-32. Such isolated DNAs can be used in molecular diagnostic tests (*e.g.*, as probes,<sup>6</sup> primers, templates for sequencing reactions), in biotechnological processes (*e.g.*, production of pure *BRCA1* or *BRCA2* protein), and even in medical treatments (*e.g.*, gene therapy). Schlessinger Decl. ¶ 27; Kay Decl. ¶¶ 133-134, 136, 138, 163. By contrast, native *BRCA* genes as they exist in nature cannot be used in any of these ways or for any of these purposes. Kay Decl. ¶¶ 134, 138. As plaintiffs themselves recognize, DNA sequencing cannot be performed on DNA in the body; that “requires scientists to isolate it.” ACLU R.Br. 13.<sup>7</sup>

Indeed, in their struggle to prove otherwise, plaintiffs inadvertently prove that the isolated nucleic acids are “new” when they state that “it is only humans’ current inability to sequence DNA while it is in the body that requires scientists to isolate it.” *Id.* The fact that humans cannot

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<sup>5</sup> Plaintiffs also argue that some embodiments of the claimed compositions retain some of the functions of the naturally occurring *BRCA* gene. This argument is irrelevant. All that is required is at least one new utility (*e.g.*, serving as a template for DNA sequencing) not possessed by native DNA. Moreover, whether some embodiments might need to be further modified before being finally ready for use is also irrelevant. *Chakrabarty*, 447 U.S. at 310 (noting that *Chakrabarty*’s bacterium had “the *potential* for significant utility”) (emphasis added). The critical issue is that *BRCA* DNAs may be used in important diagnostic *BRCA* testing; native *BRCA* genes cannot. That demonstrates their novelty over naturally occurring DNA.

<sup>6</sup> Plaintiffs allege, without any evidence, that full-length *BRCA1* or *BRCA2* cannot be used as probes. This is untrue as these are routinely used, *e.g.*, in Southern blots and Northern blots. *See, e.g.*, U.S. Patent No. 6,033,857 (“the ’857 patent”), col. 38:65-39:8; ’473 patent, col. 50:46-48, 54-57.

<sup>7</sup> It is likewise irrelevant whether a *BRCA1* pseudogene appears in the body. Moreover, plaintiffs have provided no evidence that any composition comprising an **isolated** *BRCA1* pseudogene that falls within the challenged claims occurs in nature.

sequence DNA while it is in the body is a “marked difference” that demonstrates that the isolated DNA set forth in Myriad’s claims is indeed a “new” composition of matter, appropriate for patenting.

Finally, in a theme that recurs throughout their brief, plaintiffs offer “simple analogies” to try to prove that isolated DNA is not patent-eligible subject matter. In particular, they analogize isolated DNA to gold panned out of the sediment of a streambed, remarkably suggesting that “if it is redeposited into the water, it will settle and reintegrate into the streambed.” ACLU R.Br. 5. Plaintiffs’ “gold” analogy is as convenient to their theory as it is flawed. Gold has been known for thousands of years (gold, frankincense, and myrrh were presented as gifts to the Baby Jesus, *see Matthew 2:11*), and so it seems obvious that gold could not be patent-eligible (after all, it is not “new,” even in its extracted and purified form). The Court should be wary of such “simple analogies”; the facts of this case are what should guide it. And under those facts, the isolated DNA claims of Myriad’s patents are plainly “new” and patent-eligible under Section 101 of the Patent Act.

### **3. The Claimed Isolated *BRCA* DNAs Are “Useful”**

There is also no genuine dispute that the claimed isolated *BRCA* DNAs are useful, and the vehemence of plaintiffs and their *amici* in mounting this challenge essentially concedes the point. Each of the claimed compositions can be used in at least one of several important ways. For example, *BRCA* DNAs can be used in molecular diagnostic applications as sequencing templates, probes, or primers. Myriad Br. 8-9, 17-19; Kay Decl. ¶¶ 134-139, 163, 174-175, 183; Schlessinger Decl. ¶¶ 27-30; Doll Decl. ¶¶ 29, 46. In fact, the best evidence of the significant utility of isolated *BRCA* DNAs can be seen in Myriad’s BRACAnalysis<sup>®</sup> test. Critchfield Decl. ¶¶ 18, 25; Kay Decl. ¶ 188. No one disputes the importance or usefulness of *BRCA* testing, which as plaintiffs admit, cannot be done without isolated *BRCA* DNAs. ACLU R.Br. 13; ACLU Rule 56.1 Counterstatement ¶¶ 56-59. Isolated *BRCA* DNAs may also be used in biotechnological applications, such as transfer

into non-human cells or transgenic animals for mass production of *BRCA* proteins. *See, e.g.*, U.S. Patent No. 5,709,999 (“the ’999 patent”), col. 35:3-35; ’857 patent, col. 33:44-34:11; Myriad Br. 41; Kay Decl. ¶¶ 56-57, 163. Isolated *BRCA* DNAs can also be used in medicine, such as a therapeutic agent for gene therapy to treat human disease. ’999 patent, col. 32:38-35:2; ’857 patent, col. 31:15-col. 33:20; Schlessinger Decl. ¶ 27; Reilly Decl. ¶ 61.

Also, as noted *supra*, plaintiffs’ suggestion (ACLU R.Br. 9) that all isolated DNAs cannot be sequenced or used as probes without further modification is irrelevant. Plaintiffs have not demonstrated that the claimed isolated *BRCA* DNAs are not useful for any purpose, which would be required to meet their burden of proving unpatentability under Section 101. Furthermore, the allegation is also irrelevant because modification of the claimed DNA does not take it outside the scope of the claim. *See Chakrabarty*, 447 U.S. at 310 (confirming patent-eligibility of new compositions of matter having the “potential for significant utility.”)

\* \* \* \*

In sum: The claimed isolated *BRCA* DNA compositions are new and useful compositions of matter, and therefore constitute patent-eligible subject matter under Section 101.

## **B. The Diagnostic-Method Claims Are Patent-Eligible Under Section 101**

The method claims challenged in this case are all drawn to practical applications of the *BRCA1* or *BRCA2* gene and mutations in diagnosis.<sup>8</sup> All of them “transform an article into a different state or thing,” via a transformation that is “central to the purpose of the claimed process,” which renders the method claims patent eligible under Section 101. *Prometheus*, 581 F.3d at 1345.

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<sup>8</sup> All of the method claims at issue involve detecting *BRCA* mutations in a human subject except Claim 20 of the ’282 patent. Claim 20 is directed to a research tool for drug screening by contacting candidate chemical compounds with cultured cells harboring a *BRCA1* mutation to identify compounds that can inhibit cancer cell growth.

Each of the challenged method claims involves processing a human sample (*e.g.*, tumor or non-tumor) from a human subject. Kay Decl. ¶¶ 62-71. Claim 1 of the '999 patent is exemplary. It recites:

1. A **method for detecting a germline alteration in a BRCA1 gene**, said alteration selected from the group consisting of the alterations set forth in ... which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA **from a human sample** ... or analyzing a sequence of BRCA1 cDNA made from mRNA **from said human sample** ....

'999 patent, col. 161:17-23 (emphasis added).<sup>9</sup> Claim 1 of U.S. Patent No. 5,710,001 ("the '001 patent") similarly recites:

1. A **method for screening a tumor sample from a human subject** for a somatic alteration in a BRCA1 gene in said tumor which comprises comparing a first sequence selected from the group consisting of a BRCA1 gene **from said tumor sample**, BRCA1 RNA **from said tumor sample** and BRCA1 cDNA made from mRNA **from said tumor sample**

with a second sequence selected from the group consisting of BRCA1 gene **from a nontumor sample** of said subject, BRCA1 RNA **from said nontumor sample** and BRCA1 cDNA made from mRNA **from said nontumor sample**,

wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA **from said tumor sample** from the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA **from said nontumor sample** indicates a somatic alteration in the BRCA1 gene in said tumor sample.

'001 patent, col. 155:1-17 (emphasis added).

Plaintiffs ignore the claim term "from a human sample" to arrive at their preferred conclusion that the patent claims require only mental steps. But these limitations cannot be disregarded. To satisfy the claims, human tissue or blood sample must be processed to isolate and extract *BRCA1* DNA or RNA to detect mutations or alterations in the structure of the DNA or RNA (Kay Decl. ¶¶ 178, 186); under *Prometheus*, that makes the claims transformative and thus patent-eligible. This

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<sup>9</sup> Claim 1 of U.S. Patent No. 6,033,857 ("the '857 patent") does not recite a "sample" and instead recites an "allele," which is a physical nucleic acid located in the patient's chromosome that, when compared to another nucleic acid, must be transformed. This is consistent with plaintiffs' proposed definition of "allele": "one member of a pair of genes at a specific location on a chromosome. Double stranded DNA has one allele on each strand at each location. Thus, a DNA could have a wild-type allele and a mutated allele at the same location. When this occurs, one of the alleles may be dominant while the other is recessive." ACLU Br. 18.



would have been amply clear to skilled artisans in 1995 at the time the application for the '999 patent was filed. Kay Decl. ¶¶ 70, 135, 136, 184, 187; Linck Decl. ¶¶ 82-83, 90. Plaintiffs agree: “It is only humans’ inability—currently—to sequence DNA while it is in the body that requires scientists to isolate it. No technique has yet been invented to enable scientists to sequence and read DNA while it exists in the body.” ACLU R.Br. 13. Thus, the claims necessarily involve processing human samples and analyzing nucleic acid molecules—a “transformation” that is central to the purpose of the claims. Kay Decl. ¶ 186.

If the claims left any doubt on the subject, the specifications and prosecution histories of the challenged patents remove it. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1315-1317 (Fed. Cir. 2005) (en banc); *Gillette Co. v. Energizer Holdings Inc.*, 405 F.3d 1367, 1370 (Fed. Cir. 2005) (The claims, specification and prosecution history are the “most significant source” of the meaning of the claim language). The specifications of the challenged patents clearly indicate that the claimed methods all require processing samples and physically analyzing isolated nucleic acid molecules. For example, the '999 patent specification states: “[i]n order to detect the presence of a BRCA1 allele predisposing an individual to cancer, a biological sample such as blood is prepared and analyzed for the presence or absence of susceptibility alleles of BRCA1.” '999 patent, col. 28:19-24.<sup>10</sup> Thus, plaintiffs are simply incorrect in arguing that the method claims merely entail a mental process or thoughts, devoid of any transformative steps.

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<sup>10</sup> The '999 patent specification further states:

According to the diagnostic and prognostic method of the present invention, alteration of the wild-type BRCA1 locus is detected. In addition, the method can be performed by detecting the wild-type BRCA1 locus and confirming the lack of a predisposition to cancer at the BRCA1 locus.

'999 patent, col. 28:19-24. The term “BRCA1 locus” is clearly defined:

“BRCA1 Locus,” “BRCA1 Gene,” “BRCA1 DNAs” or “BRCA1 Polynucleotide” each refer to **polynucleotides**, all of which are in the BRCA1 region that are likely to be expressed in normal tissue, certain alleles of which predispose an individual to develop breast, ovarian, colorectal and prostate cancers.

'999 patent, col. 19:27-34 (emphasis added). The '999 patent specification further explains:

Useful diagnostic techniques include, but are not limited to fluorescent in situ hybridization (FISH), direct DNA sequencing, PFGE analysis, Southern blot analysis, single stranded conformation analysis (SSCA), RNase protection assay, allele-specific oligonucleotide (ASO), dot blot analysis and PCR-SSCP, as discussed in detail further below.

'999 patent, col. 12:60-65.

Plaintiffs' contention that the claims require mere comparison of a sequence of letters is equally unfounded. ACLU R.Br. 36.<sup>11</sup> The description in the patents of the claimed diagnostic screening methods makes it clear that comparison of a DNA sequence from the sample means a comparison of the DNA itself, not just letters of the alphabet as contended by plaintiffs: "... the screening method involves *amplification of the relevant BRCA sequences* . . ." using PCR or non-PCR based chemistries. '999 patent, col. 28:35-42; '001 patent, col. 28:33-40 (emphasis added). And, "[t]he most popular method used today is target amplification. Here the target *nucleic acid sequence is amplified* with polymerases." '999 patent, col. 28:43-52; '001 patent, col. 28:41-50 (emphasis added). Letters of the alphabet cannot be amplified by PCR or other chemical techniques – clearly comparison of the DNA itself is required by the claim.

Moreover, the prosecution histories of the challenged patents further clarify the meaning and scope of the method claims. See Ex. 1 at 1-42.<sup>12</sup> For example, in her statement of reasons for allowing Claim 1 of the '999 patent, the USPTO examiner explained: "[t]he claims are drawn to methods of detecting germline alterations in the BRCA1 gene *by detecting alterations in BRCA1 nucleic acids*."<sup>13</sup> Ex. 1 at 6 (emphasis added). "Nucleic acids" are chemical molecules, not a

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Predisposition to cancers, such as breast and ovarian cancer, and the other cancers identified herein, can be ascertained by *testing any tissue of a human* for mutations of the BRCA1 gene. For example, a person who has inherited a germline BRCA1 mutation would be prone to develop cancers. This can be determined by *testing DNA from any tissue* of the person's body.

'999 patent, col. 12:66-col. 13:5 (emphasis added).

<sup>11</sup> Here, plaintiffs misrepresent Myriad's position at Myriad Br. 15. The point is that DNA is not merely a sequence of letters – it is a chemical composition.

<sup>12</sup> "Ex. \_\_\_\_" refers to the exhibits to the Declaration of Laura A. Coruzzi in Support of Myriad's Memorandum in Reply to Plaintiffs' Opposition to Myriad's Motion for Summary Judgment submitted concurrently herewith.

<sup>13</sup> Similarly, in the prosecution history for Claim 1 of the '001 patent, after amending Claim 1 to the allowed form, the prosecuting attorney remarked that "Claim 1 has further been amended so that it is directed to *nucleic acid analysis*." Ex. 1 at 16 (emphasis added). In the examiner's statement of reasons for allowing Claim 1 of the '001 patent, it was stated: "The claims are drawn to methods of *screening a tumor sample* for a somatic alteration in a BRCA1 gene by detecting changes in the *structure and/or expression of the gene and its products* (transcripts and proteins expressed by said transcripts)." Ex. 1 at 22 (emphasis added).

In allowing Claim 1 of U.S. Patent No. 5,753,441 ("the '441 patent") the examiner stated that "[t]he claims are drawn to methods of detecting germline alterations in the BRCA 1 gene by detecting alterations in *BRCA1 nucleic acids* or in the *products expressed by these nucleic acids*, ...." Ex. 1 at 31 (emphasis added).

In allowing Claims 1 and 2 of the '857 patent, the examiner explained: "The claimed invention is allowable over the prior art of record because the prior art of record does not teach or fairly suggest a method of *screening for a mutation in a sample* ...." Ex. 1 at 41 (emphasis added).

sequence of letters or codes. Kay Decl. ¶¶ 125-126. Therefore, plaintiffs are simply incorrect in arguing that the method claims merely entail a mental process or thoughts, devoid of any transformative steps.

Plaintiffs' attempt to distinguish Myriad's diagnostic method claims from those upheld in the *Prometheus* case is legally flawed. At issue in *Prometheus* were several claims directed to optimizing therapeutic efficacy based on the determination of the level of the drug metabolite 6-thioguanine. Claim 1 is the only claim on which plaintiffs focus, but it was only one of the several claims examined by the Federal Circuit in that case:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) ***administering*** a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) ***determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,***

wherein the level of 6-thioguanine less than about 230 pmol per  $8 \times 10^8$  red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

*Prometheus*, 581 F.3d at 1340 (emphasis added).

Plaintiffs assert (ACLU R.Br. 43) that the “administering” step in the claim was required in the Federal Circuit’s finding of a transformation and therefore, the patentability of the claim under Section 101. ACLU R.Br. 36. Plaintiffs state that the “determining” step alone (which is analogous to the “comparing” or “analyzing” step in Myriad’s method claims), is not transformative and is insufficient to confer patentability.

Plaintiffs' interpretation of *Prometheus* is wrong. The *Prometheus* court explicitly held that its finding of patentability *did not* require the “administering” step. The court held that claim 46 of

the '623 patent, which contained only a “determining” step and not an “administering” step, was still patent-eligible under Section 101:

That omission [of an ‘administering’ step] does not diminish the patentability of the claimed methods because the determining step, which is present in each of the asserted claims, is also transformative and central to the claimed methods. Determining the levels of 6-TG or 6-MMP in a subject necessarily involves a transformation, for those levels cannot be determined by mere inspection. Some form of manipulation, such as the high pressure liquid chromatography method specified in several of the asserted dependent claims or other modification of the substances to be measured, is necessary to extract the metabolites from a bodily sample and determine their concentration.

*Prometheus*, 581 F.3d at 1347.

It is particularly notable that the “determining” step alone was found transformative even when derivation from “a sample” was not explicitly recited. Myriad’s method claims involve “comparing” or “analyzing” DNAs in a “human sample,” which clearly necessitates a transformative step central to the claimed methods. Kay Decl. ¶¶ 62-71, 186. Moreover, the dependent claims<sup>14</sup> in Myriad’s patents, as well as the specification and prosecution histories all indicate that the method claims involve physically analyzing nucleic acid chemical molecules and transformation of human samples. Kay Decl. ¶¶ 62-71, 186.

In sum: Myriad’s method claims clearly meet the “machine-or-transformation” test as set forth in *Prometheus*. They meet all the requirements of Section 101.

### **C. Myriad’s Claims Do Not Pre-Empt All Uses Of Any Fundamental Principle**

Patent claims may not be directed to fundamental principles *in the abstract* because such claims would “pre-empt” *all* uses of that principle. *In re Bilski*, 545 F.3d 943, 953 (Fed. Cir. 2008) (citing *Diehr*, 450 U.S. at 187). As stated by the Federal Circuit in *Bilski*, and as applied by that court in *Prometheus*, the requirement of a “machine or transformation” in a claim indicates that

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<sup>14</sup> The *Prometheus* court looked to dependent claims to inform its understanding of the claims. 581 F.3d at 1347. Plaintiffs here call that approach “wrong-headed” (ACLU R.Br. 37), but it is clearly permissible to look at other, dependent claims as a tool for construing an independent claim, as the Myriad Defendants do here. *Phillips*, 415 F.3d at 1314.

claim does not completely pre-empt any principle, but rather shows that a particular patent-eligible machine or transformative act is merely an application of that principle. Thus, since the method claims require a transformation as shown above, they do not run afoul of the pre-emption doctrine.

But plaintiffs confuse the question of pre-emption of fundamental principles with the very different question of whether a competitor can “design around” a patent to create a competing (but noninfringing) composition or method. Indeed, they go so far as to argue that the alleged impossibility in designing around Myriad’s patents demonstrates their patent-ineligibility under Section 101. ACLU R.Br. 40. The flaw in this analysis is that the ability of a competitor to “design around” a patent has nothing to do with patent-eligibility under Section 101 and plaintiffs cite no case to support this baseless claim. Pre-emption arises solely in cases where the patent claims are directed to “fundamental principles.” But, Myriad’s isolated DNA claims and method claims are not directed to any “fundamental principle.” Instead, they are directed to man-made compositions of matter, and transformative methods applying those compositions. *See supra* Section II A & B. Unlike Einstein’s  $E = mc^2$  and Newton’s law of gravity, the claims here have a qualitatively narrower spectrum of applicability, and thus exert no pre-emptive impact on scientific and technological research, as the thousands of research papers on the *BRCA* genes serve to demonstrate. Myriad Br. 46. The claims are certainly no more “sweeping” (ACLU R.Br. 18) than the law allows.

Even assuming *arguendo* there were some validity to their argument, plaintiffs admit that mere difficulty (as opposed to impossibility) in designing around is not a ground for patent-ineligibility. As shown below, design around is both actually and theoretically possible. Alternative methods for identifying *BRCA* –associated hereditary breast and ovarian cancer that do not require analyzing *BRCA* DNA or sequencing the DNA are possible. For example, immunohistochemistry (IHC)-based tests have already been developed for identifying *BRCA2* mutation-associated hereditary cancer. In this test, antibodies specifically binding to the C-terminus and N-terminus of normal *BRCA2* protein are used to label a patient’s tumor biopsy sample. Neither DNA isolation nor

DNA sequencing is required. *See* Patrice Watson *et al.*, *Detecting BRCA2 Protein Truncation in Tissue Biopsies to Identify Breast Cancers That Arise in BRCA2 Gene Mutation Carriers*, 27(24) J. CLIN. ONCOL., 3894 (2009) (Ex. 2).

Scientists have also successfully identified gene signatures (not utilizing *BRCA1* and *BRCA2* genes) that can be used as surrogate markers for identifying hereditary breast and ovarian cancer. For example, International Patent Application No. PCT/US2008/080358 (WO 2009/052417) (Ex. 3), which is entitled “Breast cancer profiles and methods of use thereof,” discloses the “identification and use of gene expression profiles, or patterns, suitable for the identification of breast cancer patient populations with an inherited predisposition to breast and ovarian cancer.” PCT/US2008/080358, *Abstract*. Specifically, a distinct pattern of gene expression for a panel of genes not including the *BRCA1* or *BRCA2* gene was discovered for patients with *BRCA1* mutations. This gene expression signature can be used to identify *BRCA1*-associated hereditary breast and ovarian cancer tissue. *See* PCT/US2008/080358.

Similarly, Jazaeri *et al.* have also discovered gene expression profiles (without utilizing *BRCA* genes) of *BRCA1*-linked and *BRCA2*-linked ovarian cancers. Such gene expression patterns have the potential for use in identifying hereditary breast and ovarian cancers associated with *BRCA1* or *BRCA2* mutations. *See* Amir A. Jazaeri *et al.*, *Gene Expression Profiles of BRCA1-Linked, BRCA2-Linked, and Sporadic Ovarian Cancers*, 94(13) J. NATL. CANCER INST., 990 (2002) (Ex. 4); *see also* International Patent Application No. PCT/US2003/004688 (WO 2003/068054) (Ex. 5).

Thus, while there may be some dispute as to how difficult it is to design around the Myriad patent claims at issue in this case (an abstract dispute, to be sure, in light of the posture of this case), it is certainly not impossible. Presently, isolating *BRCA1* and *BRCA2* DNA from a tissue sample and determining the sequences of the *BRCA1* and *BRCA2* genes might be the most direct and accurate approach for identifying hereditary breast and ovarian cancer. However, it does not mean

that it is impossible to design around and invent an alternative method. Plaintiffs explicitly admit this. For example, plaintiffs correctly point out that sequencing and reading DNA while it exists in the body “is theoretically possible and may very well be invented in the future.” ACLU R.Br. 13.

In reality, Myriad’s patent claims have actually stimulated innovation, created competition and spurred further spread of useful knowledge by encouraging research and design around. Critchfield Decl. ¶¶ 2-23. *See State Indus.Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985) (“One of the benefits of a patent system is its so-called ‘negative incentive’ to ‘design around’ a competitor’s products, even when they are patented, thus bringing a steady flow of innovations to the marketplace.”); Peter Lee, *Patents, Paradigm Shifts, and Progress in Biomedical Science*, 114 YALE L.J. 659, 686-688 (2004). The pre-emption concern relating to the challenged claims is clearly unwarranted.

### **III. THE CHALLENGED CLAIMS ARE CONSTITUTIONAL**

#### **A. Myriad’s Claims Conform With The First Amendment**

Myriad showed in its earlier memorandum that its patent claims do not run afoul of the First Amendment under plaintiffs’ breathtaking and unprecedented theory, because plaintiffs’ claim is entirely dependent on their incorrect notion that these patent claims cover no more than information and abstract thought processes. Myriad Br. 41-42. Plaintiffs continue to allege that Myriad’s patent claims violate the First Amendment because they restrict thought and speech, since “[t]he only novel aspect of Myriad’s patent claims is thinking ‘these are the same,’ ‘these are different,’ or ‘these differences are significant.’” ACLU R.Br. 40.

Even plaintiffs, however, now appear to surrender any notion that Myriad’s composition claims violate the First Amendment. ACLU R.Br. 40. Indeed, it is difficult to envision how a claim to a physical composition of matter could possibly restrict speech or thought. Because the

composition claims are directed to an isolated molecule, they cannot violate the First Amendment any more than any other composition claim (*e.g.*, a claim to a synthetic drug).

As to Myriad’s diagnostic-method claims, it is clear that they require far more than mere “thinking.” Myriad Br. 8-10, 17-20; Kay Decl. ¶¶ 64-67, 70, 178-187. As shown above, the patent claims, specifications, and prosecution histories all demonstrate that these claims require a physical transformation. Myriad Br. 34-42. They are not limited to mental steps (*i.e.*, “thought”).<sup>15</sup> Even if “[p]atents on thought violate the First Amendment,” as plaintiffs boldly proclaim (free of legal citation), these are not “patents on thought.” ACLU R.Br. 40. Myriad’s method claims require a physical transformation and do not restrict thought; they do not violate the First Amendment.

Finally, even if it could possibly be said, *arguendo*, that Myriad’s patent claims inhibit speech to some degree, the important (indeed, compelling) governmental interest inherent in the patent system—in particular, providing appropriate incentives for such inventions by giving inventors limited rights of exclusivity—far outweighs any possible restriction on speech caused by these patents. *See, e.g., Turner Broadcasting Sys., Inc. v. FCC*, 512 U.S. 622, 661-64 (1994). Of course, the actual restriction that these patents might work on speech is a wholly hypothetical question, because the scope, validity, and/or infringement of the Myriad patents, aside from the present case, has never been tested in court. So even assuming that they inhibit speech at all, the degree of that inhibition has not been ascertained.

In sum, these patent claims do not violate the First Amendment.

## **B. Myriad’s Claims Conform With Article I, Section 8, Clause 8**

Among other things, Myriad showed in its earlier memorandum (Myriad Br. 42) that plaintiffs’ claim under Article I, Section 8, Clause 8 of the U.S. Constitution fails because that clause

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<sup>15</sup> Plaintiffs’ declarant Matloff contradicts the plaintiffs’ own position when she states that the research that led to her publications (*i.e.*, observing BRCA-positive patients and thinking about the BRCA genes) was non-infringing. Matloff Supp. Decl. ¶ 5 (“Research and writing of papers of this kind does not require me to take any action to infringe Myriad’s patent.”).



does not impose a restriction on the USPTO's ability to issue any particular patent. Rather, the clause is both a grant of power to and a restriction on *Congress's* power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Pursuant to this power, Congress enacted the first Patent Act in 1790. In 1952 Congress again exercised this constitutional power in enacting 35 U.S.C. § 101 to broadly define the boundaries of what is patent-eligible. Plaintiffs offer no response, reiterating their argument that "these patent claims run afoul of Article I, Section 8, Clause 8 of the Constitution because they impede rather than promote the progress of science." ACLU R.Br. 40.

Any limits the Clause may impose are solely on Congress's legislative power. Yet plaintiffs concede that they challenge no enactment of Congress. ACLU R. Br. 41. ("While plaintiffs concede that deference is due to Congress here (ACLU Br. 37-38), the relevant question is not the rationality of 'composition' claims as a whole, or even an undefined category of 'gene patents.'"). Plaintiffs instead challenge specific patent claims issued by an executive agency pursuant to an enactment of Congress. ACLU R.Br. 41. ("The question is whether these claims and these policies are rationally linked to the purposes of Article I."). Since plaintiffs do not challenge any Congressional enactment made pursuant to this Clause—and it would be folly for them to challenge Section 101 as itself unconstitutional, given its 220+ year history—that should be the end of the Court's inquiry.

Even so, plaintiffs' claim that these patents "impede rather than promote the progress of science" is a fanciful one. Myriad provided an overwhelming factual showing that the patents at issue here have in fact greatly promoted science. Myriad Br. 45-50; Reilly Decl. ¶¶ 43-44; Critchfield Decl. ¶¶ 2-23. Plaintiffs' only answer is to claim that more research might have been conducted in the absence of Myriad's patents, and that it was somehow Myriad's burden to offer a "control group" to prove how much research would have been conducted in a hypothetical world where Myriad's patents never existed. ACLU R.Br. 44 ("However, this is meaningless because [Myriad] offer[s] no control group to show how many papers would have been published if the

*BRCA1/2* sequences had not been patented.”). That sort of argument just goes to show how unsuited this argument is for judicial resolution: How is a federal court supposed to make such a determination?

With widespread availability of the highest quality *BRCA* genetic testing, with the extensive research being done into the *BRCA* genes, and with people developing new technologies in an attempt to design around, the patents at issue here have clearly achieved the aims of the Constitution.

\* \* \* \*

Plaintiffs ask this Court to declare that Myriad’s patent claims do not cover patent-eligible subject matter and are otherwise unconstitutional. That relief is unprecedented enough. But the Court should not be misled by plaintiffs’ suggestion that the scope of this dispute is a modest “handful of claims.” ACLU R.Br. 2. This case is about far more than that. Certainly, the number of *amicus* briefs filed by supporters of both sides in this case demonstrates how sweeping plaintiffs’ theory is. While plaintiffs claim that “[d]rugs like Taxol, referred to by defendants (Myriad Br. 29), could still be patented” (ACLU R.Br. 2, n.6), they offer no reason why this would be the case under their analysis. Plaintiffs offer no factual or legal distinction between Taxol and isolated DNA. Taxol, a product isolated from the bark of the Pacific Yew Tree, would be a patent-ineligible “product of nature” under plaintiffs’ theory of law. But even more crucially, plaintiffs’ theories in this case threaten to knock the moorings away from the entire biotechnology industry.<sup>16</sup> And plaintiffs’ lawyers know it, too. Mr. Ravicher, President and Executive Director of the Public Patent Foundation (“PUBPAT”) told CNN, “It is absolutely our intent that upon victory this will rend [sic]

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<sup>16</sup> Over the past 29 years, the USPTO has issued some 2,645 patents claiming “isolated DNA.” Doll Decl. ¶ 35. In particular, U.S. Patent No. 4,703,008 claiming an “isolated DNA” encoding human erythropoietin has led to the successful commercialization of Epogen®. Examples of patents covering non-DNA compositions of matter isolated from natural sources include: U.S. Patent No. 2,653,899 claiming an antibiotic *isolated* from the microorganism *Saccharopolyspora erythraea*; U.S. Patent No. 5,936,063 claiming an antimicrobial peptide *isolated* from *Bufo bufo gargarizans*; U.S. Patent No. 5,212,290 claiming an “*isolated*” antibody which binds specifically to an EGFR mutant type II. Ironically, a number of relevant patents are held by plaintiffs, Drs. Haig Kazazian Jr., Stephen Warren, David Ledbetter and Wendy Chung. See, e.g., U.S. Patent No. 7,339,028 claiming an isolated human mahoganoid polypeptide; U.S. Patent No. 6,143,504 claiming isolated DNA fragments from human cells that can be used as primers; U.S. Patent No. 5,407,796 claiming a nucleic acid probe.

invalid patents on many other genes. We just had to pick one case as our case.” Posting of Heidi Ledford to Nature Blog, The Great Beyond,

[http://blogs.nature.com/news/thegreatbeyond/2009/05/patients\\_and\\_activists\\_sue\\_ove.html](http://blogs.nature.com/news/thegreatbeyond/2009/05/patients_and_activists_sue_ove.html)

(May 13, 2009). Indeed, PUBPAT’s website trumpets the broad reach of plaintiffs’ arguments:

Because the PUBPAT/ACLU lawsuit challenges the whole notion of gene patenting, its outcome could have far-reaching effects beyond the patents on the BRCA genes. Approximately 20 percent of all human genes are patented, including genes associated with Alzheimer's disease, muscular dystrophy, colon cancer, asthma and many other illnesses.

News Release, Court Upholds Right of Scientist and Patients to Challenge Gene Patents

(Nov. 2, 2009), <http://www.pubpat.org/mtdsdenied.htm>.

It is difficult to overstate the sweeping nature of plaintiffs’ arguments. Were they accepted, almost 100 years of jurisprudence would be swept away—from Learned Hand’s *Parke-Davis* opinion to the USPTO’s recent guidelines on the issuance of gene patents, which synthesized all of this law and reached the considered conclusion that patent claims such as Myriad’s claim patent-eligible subject matter. Doll Decl. ¶ 18; Linck Decl. ¶¶ 18, 30, 51-54. Following the Supreme Court’s guidance in *J.E.M. Ag Supply*, this Court should similarly uphold these claims, since there has been no “indication from either Congress or agencies with expertise that such coverage is inconsistent with [the governing statutes].” 534 U.S. at 144-45.

#### IV. CONCLUSION

For these reasons, and those set forth in Myriad's earlier memorandum, its motion for summary judgment should be granted.

Dated: New York, New York  
January 29, 2010

JONES DAY

By: /s/ Brian M. Poissant  
Brian M. Poissant  
Barry R. Satine  
Laura A. Coruzzi  
Eileen E. Falvey  
222 East 41st Street  
New York, NY 10017  
(212) 326-3939

—and—

Gregory A. Castanias (admitted pro hac vice)  
51 Louisiana Ave., N.W.  
Washington, D.C. 20001-2113  
(202) 879-3939

*Attorneys for Defendants 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*

**CERTIFICATE OF SERVICE**

This is to certify that on January 29, 2010, a true and correct copy of the foregoing document has been served on all counsel of record via the court's ECF system.

/s/ Brian M. Poissant  
\_\_\_\_\_  
Brian M. Poissant