
IN THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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,

and

LORRIS BETZ, ROGER BOYER, JACK BRITAIN, 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-Appellants.

**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.**

**BRIEF FOR AMICUS CURIAE
AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION
IN SUPPORT OF REVERSAL BUT IN SUPPORT OF NEITHER PARTY**

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June 15, 2012

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AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

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

NOT APPLICABLE

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party 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:

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Statement of Interest of *Amicus Curiae*

The American Intellectual Property Law Association (“AIPLA”) is a national bar association of approximately 15,000 members engaged in private and corporate practice, in government service, and in the academic community.

AIPLA represents a wide and diverse spectrum of individuals, companies, and institutions involved directly and indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. AIPLA members represent both owners and users of intellectual property.¹

AIPLA files this brief not to advocate for either side in this dispute, but rather to present the Association’s views as *amicus curiae* on the correct rule of law that applies to patent eligibility. No consent of the parties or leave of the Court was required for filing this brief pursuant to this Court’s April 30, 2012 Order.²

¹ After reasonable investigation, AIPLA believes that (i) no member of its Board or Amicus Committee who voted to file this brief, or any attorney in the law firm or corporation of such a member, represents a party to this litigation in this matter, (ii) no representative of any party to this litigation participated in the authorship of this brief, and (iii) no one other than AIPLA, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief.

² AIPLA participated as *amicus curiae* when this Court first addressed this appeal. Among the issues discussed in its brief, AIPLA explained the vital role that patents have played in expanding the frontiers of science and technology by, for example, sparking the biotechnology industry that has yielded Myriad’s breakthrough inventions and innumerable other discoveries. AIPLA further addressed how

I. Summary of the Argument

The Supreme Court has directed this Court to reassess its decision in this case in light of *Mayo v. Prometheus* (“*Prometheus*”).³ This Court in turn has asked for briefing on the applicability of *Prometheus* to Myriad’s isolated DNA claims and to method claim 20 of U.S. Patent No. 5,747,282. (A569-672.)

The *Prometheus* ruling does not require this Court to change its decision in this case.⁴

The *Prometheus* case addressed the patentability of process claims that harness a law of nature. In that unique situation, the Supreme Court required that the claims recite “significantly more” than simply the law of nature along with routine, implicit instructions to “apply it” where an observation required by the claim “indicates a need” to do so.⁵ However, the rationale applied in *Prometheus* to process claims does not apply to Myriad’s isolated DNA inventions. As this Court held, Myriad’s discoveries cover cutting-edge products that were produced through human ingenuity and that differ markedly from native DNA. The same pre-*Prometheus* precedents that this Court applied in upholding Myriad’s product

affirming the district court’s denial of patent protection for Myriad’s discoveries and other patents on isolated DNA inventions would devastate the biotech industry and retard innovation. AIPLA incorporates its prior brief here.

³ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, __U.S.__, 132 S. Ct. 1289 (2012).

⁴ 653 F.3d 1329 (Fed. Cir. 2011) (“*Myriad*”).

⁵ *Prometheus*, 132 S. Ct. at 1294, 1296.

claims—including *Chakrabarty*⁶ and related cases—remain the foundational precedents for evaluating Myriad’s product claims today. Indeed, *Prometheus* reaffirmed those very precedents.

Nor does the *Prometheus* decision require the panel to change its decision as to Myriad’s method claim directed to screening for cancer therapeutics. That claim does not recite a law of nature and then simply say “apply it.” Rather it recites substantial and meaningful steps for identifying new and potentially life-saving cancer drugs. To the extent *Prometheus* requires “significantly more” than a routine application of an abstract idea or natural law, the “functional and palpable” applications that this Court recognized in Myriad’s method claim satisfy that requirement.⁷

Importantly, *Prometheus* should not be read to conflate the patent eligibility determination with the separate and independent patentability standards of novelty and non-obviousness.

⁶ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

⁷ See *Myriad*, 653 F.3d at 1358 (quoting *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 868-69 (Fed. Cir. 2010)).

II. Preliminary Statement

A law of nature—namely, the relationship between certain levels of a drug metabolite and its safety and efficacy—was deemed central to the method claims in *Prometheus*. The Supreme Court therefore looked to its precedents involving methods that implicate laws of nature and abstract ideas, especially *Flook* and *Diehr*.⁸ Applying a test discerned from those cases, the Supreme Court examined *Prometheus*'s method claims to see whether they “do significantly more than simply describe [the] natural relations” at the heart of those claims.⁹

At first glance, *Prometheus* may appear ground breaking, with its focus on whether the patent claims merely recited well-understood, routine, conventional activity needed to apply a law of nature.¹⁰ *Prometheus*, however, does not depart from the Supreme Court's “law of nature” precedents. Because *Myriad*'s process claims seek no preemption of any law of nature, *Prometheus* requires no change to this Court's decision on those claims.

Nor does *Prometheus* overrule *Chakrabarty* or similar cases upon which this Court relied in finding *Myriad*'s isolated DNA products to be patent-eligible.¹¹

⁸ *Parker v. Flook*, 437 U.S. 584 (1978); *Diamond v. Diehr*, 450 U.S. 175 (1981).

⁹ *Prometheus*, 132 S. Ct. at 1297.

¹⁰ *Id.* at 1298.

¹¹ *Myriad*, 653 F.3d at 1350-51.

As with its process claims, Myriad’s DNA claims do not seek to preempt others from using any product found in nature. Rather, as this Court has already concluded, “[i]t is undisputed that Myriad’s claimed isolated DNAs exist in a distinctive chemical form—as distinctive chemical molecules—from DNAs in the human body, *i.e.*, native DNA.”¹²

III. Argument

A. Novelty and Non-obviousness Are and Should Remain Separate, Independent Standards of Patentability

In crafting a threshold patent-eligibility analysis that requires “significantly more” than “well-understood,” “routine,” “conventional,” or “obvious” steps, the Supreme Court was conscious of blurring the lines between patent-eligibility and other sections of the patent laws, such as novelty under 35 U.S.C. § 102 and obviousness under 35 U.S.C. § 103.¹³ The Court said that “overlap” may “sometimes” be required to avoid making the “law of nature” exception to § 101 a “dead letter.”¹⁴

But importantly, the Supreme Court in *Prometheus* did not announce a wholesale conflation of § 101 with §§ 102 and 103. Rather, applying *Bilski*, *Flook*, *Benson*, and *Diehr*, which all rested on § 101, the Court explained that it had

¹² *Id.* at 1351.

¹³ *Prometheus*, 132 S. Ct. at 1298.

¹⁴ *Id.* at 1303-04.

resisted any “temptation to depart from case law precedent.”¹⁵ As *Diehr*, for instance, makes clear, “[t]he ‘novelty’ of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.”¹⁶ Likewise, this Court, following Supreme Court precedent, has consistently instructed that “it is inappropriate to determine the patent-eligibility of a claim as a whole based on whether selected limitations constitute patent-eligible subject matter.”¹⁷ Considering steps or elements of a claim in isolation from the claim *as a whole* remains improper.

Consistent with Supreme Court precedent, novelty and non-obviousness are and should remain separate, independent requirements, each with its own distinct elements, proofs, and precedents. Both requirements for patentability can entail complex legal, technical, and factual inquiries regarding the state of the art, the contents of the relevant scientific literature, the inventor’s work, and the invention’s development and success. And over many decades and hundreds of decisions, this Court has developed a rich body of decisions to guide both patentability inquiries. While *Prometheus* endorses a threshold inquiry for the category of method claims that embody a law of nature or abstract idea, that

¹⁵ *Id.* at 1302.

¹⁶ *Diehr*, 450 U.S. at 188-89

¹⁷ *See In re Bilski*, 545 F.3d 943, 958 (Fed. Cir. 2008) (citing *Flook*, 437 U.S. at 594 and *Diehr*, 450 U.S. at 188).

inquiry about whether additional elements are “routine,” “conventional,” or even “obvious” should not be expanded to *all* patent claims.

Accordingly, in assessing patent eligibility under 35 U.S.C. § 101 for Myriad’s product claims, it is not germane to ask whether the skill, hard work, and ingenuity Myriad scientists used in the transformative process of making the claimed isolated DNA molecules can somehow be deemed “routine,” “conventional,” or “well-understood.” Such questions might be relevant under §§ 102 and 103 to evaluating the novelty or non-obviousness of Myriad’s product claims to a person of skill in the art. However, an analysis that imports the requirements of novelty and non-obviousness into Section 101 would risk turning determinations of patent-eligibility into unmanageable exercises dislodged from long-established and well-understood principles.

B. Patent Eligibility of Isolated DNA Molecules, Which Are Compositions of Matter, Must Be Analyzed By Applying The Applicable Precedents

The patent eligibility of Myriad’s claimed isolated DNA molecules, which are compositions of matter, must be analyzed following precedents such as *Chakrabarty* and *Funk Brothers*—precisely the approach this Court followed.¹⁸ In *Chakrabarty*, the invented bacterium in question was not nature’s handiwork, but the patentee’s own, based on the bacterium’s “markedly different characteristics

¹⁸ *Myriad*, 653 F.3d at 1348-54.

from any found in nature and one having the potential for significant utility.”¹⁹

Likewise here, Myriad’s isolated DNA is not “nature’s handiwork,” but is that of Myriad’s scientists who used skill and ingenuity to produce unique compositions of matter not found in the body. This Court thus properly considered the *Chakrabarty* inquiry of whether, through human involvement, Myriad’s claimed compositions have “markedly different” or “distinctive” characteristics when compared to compositions found in nature.²⁰

The Court took particular note of the substantial differences in size and structure between the native genome and Myriad’s claimed isolated DNA molecules. For example, in contrast to native chromosomes having at least 80 million nucleotides, the isolated BRCA1 and BRCA2 genes, with introns, each consists of about 80,000 or so nucleotides. Without introns (*i.e.*, the claimed cDNA molecules), BRCA2 shrinks to just 10,200 or so nucleotides and BRCA1 to just around 5,500 nucleotides. Furthermore, some Myriad claims cover isolated DNA molecules having as few as fifteen nucleotides. Thus, the claimed isolated DNA molecules have chemical identities that differ from those of native DNA.²¹ Indeed, “isolation of a DNA sequence is more than separating out impurities: the isolated DNA is a distinct molecule with different physical characteristics

¹⁹ 447 U.S. at 310.

²⁰ *Myriad*, 653 F.3d at 1351-52.

²¹ *Id.*; *see also id.* at 1361-63 (Moore, J., concurring-in-part).

These differences, of course, are directly related to the change in chemical bonds in the isolated DNA.”²² And those differences were wrought by significant human intervention and chemical manipulation.²³ Other Supreme Court decisions have likewise focused on the distinction between “products of nature, whether living or not, and *human-made* inventions.”²⁴

In short, *Prometheus*, which sets forth a criteria directed solely to method claims, did not change the pre-existing framework for evaluating compositions of matter. Therefore, this Court’s original ruling with respect to the claimed DNA molecules should stand.

C. The *Prometheus* Decision Synthesizes Supreme Court Precedent on the Patent Eligibility of Method Claims and Should Not Change This Court’s Decision as to Myriad’s Method Claims

Prometheus reaffirmed that the framework for analyzing patent eligible subject matter centers on the broad, but not unlimited, categories set forth in § 101 with three long-settled exceptions: laws of nature, natural phenomena, and abstract ideas.²⁵ While inventions covered by these exceptions may not be patented on

²² *Id.* at 1363 (Moore, J., concurring-in-part).

²³ *Id.* at 1352.

²⁴ *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 130 (2001) (quoting *Chakrabarty*, 447 U.S. at 313) (emphasis added).

²⁵ *Prometheus*, 132 S. Ct. at 1293.

their own, *Prometheus* confirmed that a process that “applies” one of these fundamental principles may be patentable.²⁶

Much of the *Prometheus* decision, however, explored the “significantly more” that must be included in a patent claim to transform an unpatentable principle into a patentable “application” of that principle. This requirement of “significantly more” harmonizes the various approaches taken by the Supreme Court over the years. For example, the Court has required “more” to bar process claims that would too broadly preempt the use of an underlying fundamental principle.²⁷

The Court has also eschewed claims that would circumvent the “principles underlying the prohibition against patents for ‘ideas’ or phenomena of nature.”²⁸ Likewise, the Court has rejected attempts to patent the use of a fundamental principle by simply limiting its use to a particular technological field or adding mere insignificant post-solution activity.²⁹

Consistent with Supreme Court precedent as synthesized in *Prometheus*, this Court examined Myriad’s screening method claims to determine whether the claimed steps included “more” than an abstract mental step or basic scientific

²⁶ *Id.* at 1293-94.

²⁷ *See, e.g., Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972) (rejecting claims that “would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself”); *see Prometheus*, 132 S. Ct. at 1294.

²⁸ *Flook*, 437 U.S. at 593; *see Prometheus*, 132 S. Ct. at 1294.

²⁹ *Diehr*, 450 U.S. at 191-92; *see Prometheus*, 132 S. Ct. at 1294.

principle.³⁰ Because the steps involved growing transformed cells and physically manipulating the cells to determine growth rates, this Court properly concluded that the claimed screening methods included transformative steps that were not so “manifestly abstract” as to claim only a scientific principle.”³¹ This Court further concluded that these steps of “growing,” “determining,” and “comparing,” which include the “physical manipulation of the cells,” were “central to the purpose of the claimed process.”³²

To the extent any law of nature or abstract principle might be at work here, the claimed process as a whole is exactly the well-defined, practical application that wholly integrates such law or principle to create a wholly new process using a man-made cell that further incorporates man-made sequences requiring human ingenuity. This is exactly the “significantly more” that *Prometheus* contemplates.³³

As in the Supreme Court decisions analyzed in *Prometheus*, this Court considered whether the Myriad claims would impermissibly preempt all uses of any underlying natural correlations. No threat of preemption was found, because Myriad’s method claim is “tied to specific host cells transformed with specific

³⁰ *Myriad*, 653 F.3d at 1357.

³¹ *Id.* at 1357-58 (citing *Research Corp. Techs.*, 627 F.3d at 869).

³² *Id.*

³³ *See Prometheus*, 132 S. Ct. at 1299 (“[O]ther steps apparently added to the formula something that in terms of patent law’s objectives had significance—they transformed the process into an inventive application of the formula.”).

genes[,] [is] grown in the presence or absence of a specific type of therapeutic[,] [and measures] a therapeutic effect on the cells solely by changes in the cells' growth rate.”³⁴

Because this Court correctly applied precedent to determine that Myriad's screening method claims recite “more” than an underlying fundamental principle or abstract idea, the patent eligibility of the screening method claims should be reaffirmed.

D. The Patent Eligibility of Isolated DNA Molecules Has Long Been Recognized

The PTO has granted thousands of patents claiming isolated DNA sequences and their use, and the biotechnology industry has long relied upon them. This Court should not change this interpretation of the patent statute without a “clear and certain signal from Congress.”³⁵ Both *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*³⁶ and *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*³⁷ admonished courts not to upset the settled expectations of the patent community. The U.S. biotechnology industry has led the field in the global economy in large part due to strong patent protection of DNA-based inventions. Such patent protection is critical to attracting investments and recouping the significant up front

³⁴ *Myriad*, 653 F.3d at 1358.

³⁵ *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972).

³⁶ 520 U.S. 17, 28 (1997).

³⁷ 535 U.S. 722, 739 (2002).

expenditures for the type of skill, hard work, and ingenuity required to create and develop inventions such as those claimed in this case.³⁸ A ruling that isolated DNA molecules are not worthy of patent protection would deter investment in the biotechnology industry and put hard-won competitive market positions at risk. Given the stark effect such an abrupt change in the law would have on American biotechnology ingenuity and industry,³⁹ Congress, not the courts, should initiate any dialogue about whether this settled law should be modified.⁴⁰

IV. Conclusion

The Supreme Court's holding in *Prometheus* regarding a method claim premised on a law of nature, which by definition exists independent of any human invention, should not disturb or change this Court's ruling that Myriad's isolated DNA molecules—created in the laboratory and markedly different in structure and use from native DNA—qualify for patent protection under Section 101. Nor

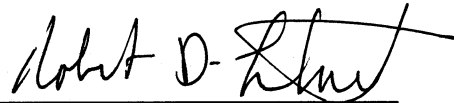
³⁸ See Melissa Wetkowski, *Unfitting: Gene Patent Limitations Too Tight For United States' Biotechnology Innovation and Growth in Light of International Patenting Policies*, 16 Sw J. Int'l L. 181, 198-99 (2010).

³⁹ Nikos C. Varsakelis, *The Impact of Patent Protection, Economy Openness and National Culture on R&D Investment: A Cross-Country Empirical Investigation*, 30 Res. Pol'y 1059, 1066 (2001).

⁴⁰ In her concurring-in-part opinion, Judge Moore properly took note of the long-standing government policy of allowing thousands of these kinds of claims and the absence of any action by Congress to reverse that policy. In view of the settled expectations that have resulted, she properly urged judicial restraint in expanding exceptions to patent eligibility where Congress has not acted. *Myriad*, 653 F.3d at 1367.

should *Prometheus* disturb this Court's holding that Myriad's method of screening for new cancer therapeutics recites a transformative, patent-eligible invention.

Respectfully submitted,



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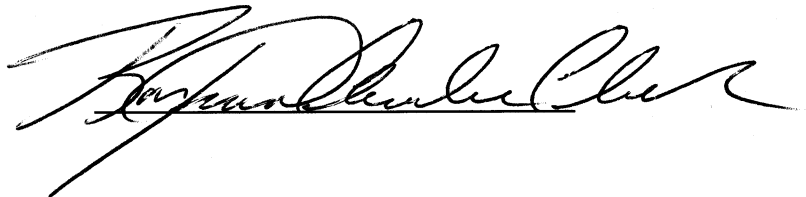
CERTIFICATE OF SERVICE

I hereby certify that June 15, 2012, one (1) original and eleven (11) true and correct copies of the BRIEF FOR *AMICUS CURIAE* AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF REVERSAL BUT IN SUPPORT OF NEITHER PARTY was filed with the clerk for the United States Court of Appeals for the Federal Circuit by hand.

I hereby certify that on June 15, 2012, two (2) true and correct copies of the BRIEF FOR *AMICUS CURIAE* AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF REVERSAL BUT IN SUPPORT OF NEITHER PARTY was served upon the following counsel of record by Overnight Courier (Federal Express):

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CERTIFICATE OF COMPLIANCE

I certify that, pursuant to Federal Rule of Appellate Procedure 29(d) and 32(a)(7)(C)(i), the foregoing brief contains 2996 words as measured by the word processing software used to prepare this brief, excluding the Corporate Disclosure Statement, Table of Contents, Table of Authorities, and this Certificate of Compliance.

Dated: June 15, 2012

