
**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 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-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 NEW YORK INTELLECTUAL
PROPERTY LAW ASSOCIATION IN SUPPORT OF NEITHER PARTY**

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June 15, 2012

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No. 2010-1406

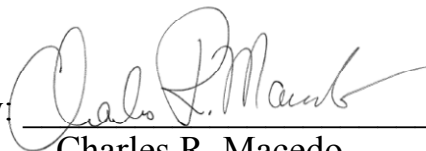
CERTIFICATE OF INTEREST

Counsel for *amicus curiae* the following:

1. The full names of every party or *amicus* represented by me are:
New York Intellectual Property Law Association
2. The name of the real party in interest (if the party named in the caption is not 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 or *amicus curiae* represented by me are:
None
4. The names of all law firms and the partners or associates that appeared for any of the parties or *amicus* now represented by me in the trial court or agency or are expected to appear in this Court are:
Anthony F. Lo Cicero and Charles R. Macedo of Amster, Rothstein & Ebenstein LLP.
and
Ronald M. Daignault and Matthew B. McFarlane of Robins, Kaplan, Miller & Ciresi L.L.P.

Dated: June 15, 2012

By:



Charles R. Macedo
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STATEMENT OF INTEREST OF *AMICUS CURIAE*

The New York Intellectual Property Law Association (“NYIPLA”) respectfully submits this *amicus curiae* brief in support of neither party. NYIPLA is a professional association of over 1,000 attorneys whose interests and practices lie in the area of patent, copyright, trademark, trade secret and other intellectual property law. NYIPLA members include a diverse group of attorneys specializing in patent law, encompassing attorneys in private practice and in-house counsel who represent businesses that own, enforce and challenge patents, as well as inventors in various proceedings before the USPTO and in Federal courts across the country. A substantial percentage of NYIPLA attorneys participate actively in patent litigation, representing both patent owners and accused infringers.¹

¹ This brief is filed pursuant to paragraph 4 of the Order vacating the court’s opinion of July 29, 2011 and reinstating the appeal (April 30, 2012), which also provided that amicus briefs may be filed without consent and leave of Court. The filing of this brief by the NYIPLA was approved by its Board on June 12, 2012 by an absolute majority of the total number of officers and members of the Board of the NYIPLA (including such officers and Board members who did not vote for any reason, including recusal), but do not necessarily reflect the views of a majority of the members of the NYIPLA or of the firms with which those members are associated. Pursuant to Federal Circuit Rule 29(c)(5), no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to its preparation or submission. After reasonable investigation, the NYIPLA believes that no member of its Board or *Amicus* Committee who voted to prepare this brief on its behalf, or any attorney in the law firm or corporation of such a Board or Committee member, or attorney who aided in preparing this brief,

ARGUMENT

NYIPLA does not offer any opinion on the ultimate validity of the claims at issue. Rather, NYIPLA submits this brief solely to provide its views regarding whether *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012) (“*Mayo*”), should be read to require modification of this Court’s prior application to those claims of the Supreme Court’s well developed patent-eligibility jurisprudence under 35 U.S.C. § 101. NYIPLA concludes that *Mayo* does not change this patent-eligibility jurisprudence, and the classes of these claims (*e.g.*, isolated DNA) are thus patent-eligible.

Mayo reversed a panel decision of this Court which had relied in part upon the machine-or-transformation test and thus further attenuated the utility of that test beyond the limitations imposed by *Bilski v. Kappos*, 130 S. Ct. 3218 (2010) (“*Bilski*”). *Mayo* nevertheless concedes that under *Bilski*, the machine-or-transformation test remains “an important and useful clue,” 132 S. Ct. at 1296, and otherwise left intact the preexisting analytical framework for determination of patent-eligibility under Section 101.

represents a party with respect to this litigation. Some Committee or Board members or attorneys in their respective law firms or corporations may represent entities, including other *amicus curiae*, which have an interest in other matters which may be affected by the outcome of this litigation.

To the extent *Mayo* does not clearly require otherwise, the members of NYIPLA hold reasonable expectations regarding the continued consistent application by this Court of its longstanding broad interpretation of patent-eligible subject matter under the Patent Act. Such a broad interpretation of patent-eligibility remains particularly important in the case of the claims of the more than 50,000 issued patents which relate to DNA which has been modified by man. *Mayo* did not disturb the current clearly-defined two-step framework governing patent-eligibility under 35 U.S.C. § 101. Accordingly, NYIPLA's members have a strong interest in ensuring that this Court likewise does not disturb the current clearly-defined analytical framework.

I. GUIDING PRINCIPLES FROM *MAYO* AND OTHER SUPREME COURT PRECEDENT

In *Mayo*, the U.S. Supreme Court set forth its latest pronouncement on patent-eligibility under 35 U.S.C. § 101. *Mayo* did not suggest that the Court intended to alter in any way its controlling analytical framework. Instead, *Mayo* reiterated the same two-step analysis confirmed by the Court in *Bilski* and held that this analysis must be applied to all patent-eligibility inquiries:

1. Does the claimed subject matter fall within one of the four statutory categories of patent-eligible subject matter: (i) process, (ii) machine, (iii) manufacture or (iv) composition of matter?

2. Is the claimed subject matter directed to one of three so-called “fundamental principles,” *i.e.*, laws of nature, natural phenomena, or abstract ideas?

See Mayo, 132 S. Ct. at 1293.

Mayo maintained that patent-eligibility should be defined under Section 101’s four categories of statutory subject matter, and importantly, did not overturn the holding in *Diamond v. Chakrabarty* that patent-eligibility be broadly construed to “include anything under the sun that is made by man,” 447 U.S. 303, 309 (1980). *Mayo*, 132 S. Ct. at 1293. *Mayo* also continued to limit the judicial exceptions of patent-eligible subject matter to the same three “fundamental principles” set forth in its prior precedent: (1) laws of nature; (2) natural phenomena; and (3) abstract ideas. *Id.*

Like this Court in *In re Bilski*, 545 F.3d 943, 960 (Fed. Cir. 2008), the Supreme Court in *Bilski v. Kappos* rejected any categorical exclusions of types of patentable subject matter from patent-eligibility. *Bilski*, 130 S. Ct. at 3227. *Mayo* is not contrary to this point of law. *Cf. Mayo*, 132 S. Ct. at 1293. *Mayo*, continues to reject shortcut analyses on patent-eligibility, and specifically rejected the machine-or-transformation test as a dispositive test of patent-eligibility. *Id.* at 1303.

As to the second step, which was the primary focus of the *Mayo* Court’s analysis, the Court again confirmed that while a claim may not preempt a

“fundamental principle,” it may nonetheless be drawn to an “application” of a fundamental principle. *Id.* at 1294.

But the difficulty, as this Court and the Supreme Court have repeatedly recognized, is to understand what “more” is necessary “to transform an unpatentable [fundamental principle] into a patent-eligible *application* of such [a fundamental principle].” *Id.* at 1294 (emphasis in original). *Mayo* recognized that the same guideposts set forth for determining if a claim is directed to an abstract principle, apply with equal force to other categories of “fundamental principles,” like “laws of nature” and “natural phenomena.” *Id.* at 1293-94.

Accordingly, consistent with its prior precedent, *Mayo* found that certain types of “more” were not enough to transform a patent-ineligible fundamental principle into a patent-eligible application of that principle:

1. Simply saying “apply it,” without more, is insufficient, *id.* at 1294;
2. While still a “useful clue,” a fundamental principle merely tied to a machine or transformed in some manner is not necessarily dispositive, *id.* at 1296;
and
3. The mere inclusion of field-of-use limitations or the addition of token extra-solutional components is inadequate, *id.* at 1301.²

² *Amicus* respectfully submits that the Court’s discussion in *Mayo*, that “purely ‘conventional or obvious’ ‘[pre]solution activity’ is normally not sufficient to

Applying these guideposts, *Mayo* found the claims at issue to be patent-ineligible because they covered a fundamental principle (*i.e.*, a law of nature), and did not add enough “more” to be a practical application of that law of nature. *See id.* at 1294.

II. APPLICATION OF THE GUIDING PRINCIPLES TO MYRIAD’S CLAIMS

This Court sought *Amici* opinion on “What is the applicability of the Supreme Court’s decision in *Mayo* to Myriad’s isolated DNA claims and to method claim 20 of the ‘282 patent?” *Ass’n for Molecular Pathology v. USPTO*, 2012 U.S. App. LEXIS 8678, at *9 (Fed. Cir. Apr. 30, 2012). While *Amicus* does not take any position on the ultimate validity of Myriad’s patent claims, *Amicus* offers the following guidance on the application of the guiding principles from *Mayo* with respect to the patent-eligibility of these claims. *See* Claims 1, 6, and 7 of U.S. Patent No. 5,837,492 (“the ‘492 patent”), claim 1 of U.S. Patent No.

transform an unpatentable law of nature into patent-eligible application of such a law,” 132 S. Ct. at 1298, should be construed as nothing more than restating that the inclusion of extra-solutional subject matter (not otherwise meaningful to the claimed invention) was not enough “more” as it did not add meaningful limitations to the claim to transform the claim into a practical application of that fundamental principle. In other words, the Court should examine whether the claim includes a significant contribution by the inventor, above and beyond the fundamental principle otherwise in the claim. *Amicus* respectfully submits this analysis should not conflate a novelty or non-obviousness analysis with a patent-eligibility analysis, as the *Mayo* Court explained there are different purposes for each of these requirements of the Patent Act. 132 S. Ct. at 1303-04.

5,693,473 (“the ‘473 patent”), and claims 1, 2, 5, 6, 7 and 20 of U.S. Patent No. 5,747,282 (“the ‘282 patent”).

A. The Myriad Claims Fall Within A Statutory Category of Patent-Eligible Subject Matter

The first step in a patent-eligibility analysis under 35 U.S.C. §101 is to inquire whether the claimed subject matter falls within one of the four statutory categories of patent-eligible subject matter: (i) process, (ii) machine, (iii) manufacture or (iv) composition of matter (or any improvement thereof). *See Mayo*, 132 S. Ct. at 1293.

This Court previously found that Myriad’s “isolated DNA” claims (Claims 1, 6, and 7 of the ‘492 patent, claim 1 of the ‘473 patent, and claims 1, 2, 5, 6, and 7 of the ‘282 patent) were directed to compositions of matter, one of the four statutory categories of patent-eligible subject matter. *See Ass’n for Molecular Pathology v. USPTO*, 653 F.3d 1329, 1350-51 (Fed. Cir. 2011) (“AMP II”). *Mayo* does not raise any contrary law on this point.

The growth rate claim, claim 20 of the ‘282 patent, is directed to a “method for screening potential cancer therapeutics.” This Court previously recognized this claim as a “process,” another one of the four statutory categories of patent-eligible subject matter. *See id.* at 1358. Here, again, this conclusion should remain unaffected by the Supreme Court’s decision in *Mayo*.

B. The Myriad Claims Do Not Preempt A Fundamental Principle

If, as in this case, the claimed subject matter falls within a statutory category of patent-eligible subject matter, the second step is to establish whether it is included in one of the three exceptions to patent-eligible subject matter by claiming a “fundamental principle”, *i.e.*, laws of nature, natural phenomena, or abstract ideas. *See, e.g., Mayo*, 132 S. Ct. at 1293; *Bilski*, 130 S. Ct. at 3225; *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

The District Court and this Court have disagreed about whether claims to isolated DNA are natural phenomena excluded from patent-eligible subject matter. The District Court interpreted Supreme Court precedent as “establish[ing] that products of nature do not constitute patentable subject matter absent a change that results in the creation of a fundamentally new product.” *Ass’n for Molecular Pathology v. USPTO*, 702 F. Supp. 2d 181, 222 (S.D.N.Y. 2010) (“*AMP I*”). This Court, however, explained Supreme Court precedent as drawing “a line between compositions that, even if combined or altered in a manner not found in nature, have similar characteristics as in nature, and compositions that human intervention has given ‘markedly different,’ or ‘distinctive,’ characteristics.” *AMP II*, 653 F.3d at 1351.

The dual nature of isolated DNA can be argued to support both conclusions. On the one hand, isolated DNA is a manufactured chemical compound, which, as a class, has long enjoyed patent protection. *See, e.g., AMP II*, 653 F.3d at 1353-54 (concluding that “isolated DNAs . . . have a markedly different chemical structure compared to native DNAs,” a fact unchanged by *Mayo*. *Cf. Mayo*, 132 S. Ct. at 1303-04). On the other hand, however, some have argued that the order of bases in an isolated DNA molecule encodes *information* that may correspond exactly to information found in nature. Irrespective of whether isolated DNA is viewed as a manufactured chemical compound or a carrier of information that is found in nature, *Amicus* respectfully submits that isolated DNA is a product of human intervention. Isolation—which involves an informed decision of what bases to include in the molecule when chemically cleaving it from other genetic materials—is a significant and consequential step reflecting the handiwork of man, and creates patent-eligible subject matter.

Congress specifically intended that patentable subject matter “include anything under the sun that is made by man.” *Chakrabarty*, 447 U.S. at 309 (quoting S. Rep. No. 82-1979, at 5 (1952); H.R. Rep. No. 82-1923, at 6 (1952)). Conversely, the Court has declared “manifestations of laws of nature” and natural phenomena are “free to all men and reserved exclusively to none.” *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948). The Supreme Court has

found that the applicable divide between patent-ineligible “natural phenomena” and patent-eligible subject matter under Section 101 lies between “products of nature . . . and human-made inventions.” *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 130 (2001). *Mayo* does not change this distinction. *Cf. Mayo*, 132 S. Ct. at 1293.

Thus, human intervention is key to this analysis. Human intervention expressly removes plants and other living subject matter from the “natural phenomenon” category. The MPEP, relying upon the legislative history of the Plant Patent Act of 1930, makes this point in its discussion of plant patents by distinguishing “a new plant found in the wild [that] is not patentable subject matter” from “the work of the plant breeder ‘in aid of nature’ [that is a] patentable invention.” MPEP § 2105 (8th ed. Rev. 8, July 2010) (referencing S. Rep. No. 71-315, at 6-8 (1930); H.R. Rep. No. 71-1129, at 7-9 (1930)). Similarly, the Supreme Court follows this distinction in that it has held that “newly developed plant breeds” fall within the ambit of Section 101 even though plant protection is also available under the Plant Patent Act and the Plant Variety Protection Act. *J.E.M.*, 534 U.S. at 143-46. In the present context, a similar divide could be drawn between DNA as it exists in nature and isolated DNA.

When the District Court previously found Myriad’s isolated DNA claims patent-ineligible subject matter as “not markedly different from native DNA as it

exists in nature,” it applied a non-existent categorical rule excluding isolated genes from patent-eligibility based on their correspondence to DNA sequences existing in nature. *AMP I*, 702 F. Supp. 2d at 232. This Court instead heeded the Supreme Court’s repeated warning against limiting the patent laws beyond the scope of Congressional intent. *AMP II*, 653 F.3d at 1353 (citing *Bilski*, 130 S. Ct. at 3226 and *Diehr*, 450 U.S. at 182). *Mayo* is consistent on this point. *Mayo*, 132 S. Ct. at 1305. The Supreme Court has also continually rejected new categorical exclusions from patent-eligible subject matter as well as rigid rules of patent-eligibility. *See Bilski*, 130 S. Ct. at 3227-28; *Chakrabarty*, 447 U.S. at 314-17. In this regard, *Mayo* rejected the machine-or-transformation test as a dispositive rule, rather than merely a “useful clue” in carrying out the patent-eligibility analysis under Section 101. *Mayo*, 132 S. Ct. at 1303.

Additionally, isolated DNA is not subject matter that can be easily discarded from patent-eligibility. There is an existing expectation of patent-eligibility resulting from the PTO’s issuance of patents directed to DNA molecules for almost thirty years. *AMP II*, 653 F.3d at 1355. As noted already by this Court, the Supreme Court has “rejected the argument that plants did not fall within the scope of § 101, relying in part on the fact that ‘the PTO has assigned utility patents for plants for at least 16 years and there has been no indication from either Congress or agencies with expertise that such coverage is inconsistent with [federal law].’” *Id.*

at 1354. The Supreme Court has also cautioned about “adopting changes that disrupt the settled expectations of the inventing community.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002). The long-standing practice of issuing patents covering isolated DNA³, as well as Examination Guidelines issued by the PTO, which reaffirmed the agency's position that isolated DNA molecules are patent-eligible, strongly favor rejecting any categorical exclusion of isolated DNA from patent-eligible subject matter. *Utility Examination Guidelines*, 66 Fed. Reg. 1092, 1092-94 (Jan. 5, 2001). *Mayo* does not change this analysis. *Cf. Mayo*, 132 S. Ct. at 1304-05.

Furthermore, just as *Bilski* recognized that business methods were not categorically excluded from patent-eligible subject matter because federal law explicitly contemplated the existence of at least some business method patents in 35 U.S.C. § 273(b)(1), patents on isolated DNA should not be categorically excluded. *Bilski*, 130 S. Ct. at 3228. In Section 27 of the Leahy-Smith America Invents Act, Congress enacted a provision which states that the PTO Director “shall conduct a study on effective ways to provide independent, confirming genetic diagnostic test activity where *gene patents . . . exist.*” Pub. L. No. 112-29,

³ Over the past thirty years, the PTO has issued more than 50,000 patents claiming nucleic acid molecules. Steven Lendaris, *AMP v USPTO and the Patent-Eligibility of Isolated Nucleic Acids*, NYIPLA Bulletin, Dec.-Jan. 2011, at 1.

125 Stat. 284-381 (2011) (emphasis added). Congress therefore continues to recognize the validity of “gene patents” as a broad genus of patent-eligible subject matter that includes inventions directed to or utilizing isolated DNA.

Even if this Court reaches the conclusion that isolated DNA represents a “natural phenomenon,” the Court must then determine whether the claims are directed to a practical application of that “natural phenomenon” as explained by *Mayo*. *Mayo* restated previous Supreme Court precedent that “an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection” as long as “the patent in practice amounts to significantly more than a patent upon the natural law itself.” *Mayo*, 132 S. Ct. at 1293-94. This Court need look no further for proof of an “application” than the fact that isolation is a necessary predicate for infringing these isolated DNA claims, and thus no native DNA (including that found within a human) with the claimed sequences would ever infringe. Since a DNA sequence could only be infringing in a non-natural form, the claim is limited to a “particular inventive application” separate from the “natural phenomenon” of the sequence itself.

As for method claim 20 of the ‘282 patent, plaintiffs argue that the claim fails the second part of the test for patent-eligible subject matter. They assert that the claim preempts the basic scientific principle that a slower rate of cell growth in

the presence of a potential therapeutic compound suggests that the compound is a cancer therapeutic.

Mayo supports the proposition that claim 20 may still fall within patent-eligible subject matter even if it includes a “fundamental principle,” in this case presumably a law of nature, as long as the claimed process is an “inventive application” of that principle. *Id.* at 1299. In order to be patent-eligible, the process must “contain other elements or a combination of elements, sometimes referred to as an ‘inventive concept,’ sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.” *Id.* at 1294.

The process of claim 20 includes more than the mere words “apply it,” token extra-solutional activity, or a simple field of use restriction. It does not preempt the use of the correlation between the use of a cancer therapeutic and a slower cell growth rate, but instead only claims the use of that principle in combination with cancer therapeutic testing on cells transformed with an altered BRCA1 gene. Finally, the claim is not so broad as to cover all uses or “both known and unknown uses” of the correlation. This Court previously concluded that claim 20 includes transformative steps, and although the machine-or-transformation test is not dispositive after *Bilski* and *Mayo*, it is still a useful clue that the claim covers a patent-eligible process.

CONCLUSION

Amicus Curiae respectfully submits that while the Myriad claims at issue may or may not run afoul of other portions of the Patent Act, they should not be found invalid under the Supreme Court interpretation of patent-eligibility under 35 U.S.C. § 101.

June 15, 2012

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

ASSOCIATION FOR MOLECULAR V PTO, 2010-1406

CERTIFICATE OF SERVICE

I, John C. Kruesi, Jr. being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by Amster, Rothstein & Ebenstein, LLP, Counsel for *Amicus Curiae NYIPLA* to print this document. I am an employee of Counsel Press.

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via Express Mail, by causing 2 true copies of each to be deposited, enclosed in a properly addressed wrapper, in an official depository of the U.S. Postal Service.

Additionally, counsel for Amici Curiae known to be appearing at the time of filing will be emailed a copy of this brief.

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June 15, 2012

