
**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,
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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 OF INTELLECTUAL PROPERTY OWNERS ASSOCIATION
IN SUPPORT OF APPELLANTS**

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JUNE 15, 2012

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

The Association for Molecular Pathology v. USPTO

2010-1406

CERTIFICATE OF INTEREST

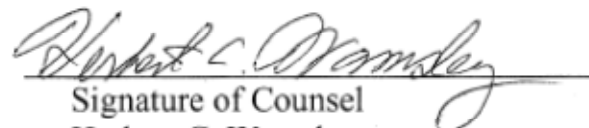
Counsel for the *Amicus Curiae* Intellectual Property Owners Association certifies the following:

1. The full names of every party or amicus represented by me is:
Intellectual Property Owners 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: **NONE**
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of *amicus curiae* represented by me are: **NONE**
4. The names of all law firms and the partners or associates that appeared for the *amicus curiae* now represented by me in the trial court or agency or that are expected to appear in this Court are:

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INTEREST OF THE AMICUS CURIAE¹

The Intellectual Property Owners Association (IPO) is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in intellectual property rights. IPO's membership includes more than 200 companies and over 12,000 individuals who are involved in the association either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO regularly represents the interests of its members before Congress and the USPTO and has filed amicus curiae briefs in this Court and other courts on significant issues of intellectual property law. This brief was approved by the IPO Board of Directors. A list of the IPO board members can be found in the Appendix.²

SUMMARY OF ARGUMENT

IPO believes that Myriad's isolated DNA claims are patent eligible under 35 U.S.C. § 101 because they claim manufactures or compositions of matter that are the product of human ingenuity, as opposed to laws of nature, natural phenomena

¹ No party's counsel authored this brief in whole or part; no party or party's counsel contributed money intended to fund preparing or submitting the brief; and no person other than amici, their members, or counsel contributed money intended to fund preparing or submitting the brief. IPO submits this brief in response to this Court's order of April 30, 2012, which provides that amicus briefs may be filed without leave of the Court.

² IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting.

or abstract ideas. IPO also believes that method claim 20 of Myriad's '282 patent is patent eligible under § 101 because claim 20 does not preempt other uses of the naturally occurring form of the BRCA1 gene and is not directed to use of the BRCA1 gene in the abstract. Finally, any ban on patenting isolated human DNA or gene-based diagnostic methods would negatively impact investment in research, technology and innovation, contrary to the policy motivations enunciated in *Mayo* and the settled expectations of the biotechnology and pharmaceutical industries.³

ARGUMENT

I. Claims to Isolated DNA Molecules Are Patent Eligible Under § 101

1. Controlling Supreme Court Precedent Supports the Patent Eligibility of Isolated Human DNA.

The Patent Act defines four classes of patent-eligible inventions: machines, processes, manufactures, and compositions of matter. Isolated human DNA can be considered either a “manufacture” or a “composition of matter.”

The Supreme Court defined the scope of the “manufacture” class under § 101:

in accordance with its dictionary definition to mean “the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.”

Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980) (quoting *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931)). The Court gave an equally

³ IPO expressly declines to take any position regarding whether the patent claims at issue in this case satisfy any conditions for patentability beyond § 101.

expansive reading to the class of “composition of matter”:

“[C]omposition of matter” has been construed consistent with its common usage to include “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.”

Id. (quoting *Shell v. Watson*, 149 F. Supp. 279, 280 (D.D.C. 1957)).

The Supreme Court in *Chakrabarty* found no constitutional, philosophical, or jurisprudential infirmities in the choice by Congress to define patent eligible subject matter broadly. Indeed, the Court cited Thomas Jefferson for the proposition that the patent laws *should* be broadly construed with regard to what is patent eligible, referencing the first Patent Act of 1793 and Jefferson’s exhortation that “ingenuity should receive a liberal encouragement.” *Id.* (quoting 5 Writings of Thomas Jefferson 75-76 (Washington ed. 1871)) (citing Act of Feb. 21, 1793, § 1, 1 Stat. 319). The Court noted that this liberality had been a steadfast characteristic of every Patent Act since the first, including the 1952 Act. In this context, the Court noted Congress’s intent to stay true to Jefferson’s vision by defining statutory subject matter to “include anything under the sun that is made by man.” *Id.* at 309 (quoting S. Rep. No. 82-1979 (1952); H.R. Rep. No. 82-1923 (1952)).

The Court recognized that the scope of patent-eligible subject matter was not infinite. But the Court was parsimonious in setting forth what was not patent eligible: “laws of nature, physical phenomena, and abstract ideas,” which the Court

exemplified as “a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter.” *Id.* Similarly, the Court said “[I]ikewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity.” *Id.*

The Court fashioned a straightforward test of whether a manufacture or composition of matter was patent eligible: it must demonstrate the “hand of man,” something that is “a product of human ingenuity ‘having a distinctive name, character [and] use.’” *Id.* at 309–10 (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)). The Court distinguished *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948) in this regard, where the patentee had discovered only “some handiwork of nature” and thus had not invented something that was patent eligible. *Chakrabarty*, 447 U.S. 310 (quoting *Funk Bros.*, 333 U.S. at 131). IPO believes that any manufacture or composition of matter evincing the “hand of man” should be patent eligible.

2. Isolated Human DNA Is Patent Eligible Because It Evinces the Hand of Man.

Isolated human cDNA is a manufacture under the Patent Act because it is made by enzymatically-generating copies of cellular messenger RNA (mRNA). In manufacturing isolated DNA, an inventor must identify a cell that expresses a gene, isolate the mRNA and enzymatically convert the mRNA into DNA. The enzymatic conversion is performed by a viral enzyme called reverse transcriptase

that is absent from cells that have not been intentionally infected by a virus that produces the enzyme. Significantly, cDNA copies of mRNAs encoding isolated human DNA do not exist without human intervention.

Claims to isolated human DNA do not encompass the naturally occurring genes that are present in cells. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092-02 (Jan. 5, 2001). Thus, a patent claim on isolated human DNA does not implicate an individual's right to her own genes, since the individual's genes clearly fall outside the scope of the patent claims.

As a consequence of the intervention of the "hand of man" in isolating the claimed DNA, the manufactured DNA has uses not shared with naturally occurring DNA (for example, as genetic probes and for producing useful quantities of proteins encoded by the DNA). The various manipulations and alterations required to manufacture isolated human DNA impart these new properties and characteristics to the claimed DNA so that it becomes "a product of human ingenuity 'having a distinctive name, character [and] use.'" *Chakrabarty*, 447 U.S. at 309-10. This transformation distinguishes the claimed isolated DNA from DNA as it occurs in nature, and makes the claimed DNA patent eligible under § 101.

Claims to isolated human DNA satisfy the *Chakrabarty* requirement to show "the hand of man" because isolated DNA is a "non-naturally occurring manufacture or composition of matter -- a product of human ingenuity," *id.* at 309, and thus should be eligible for patenting under Supreme Court precedent.

3. *Mayo v. Prometheus* Did Not Overrule *Chakrabarty*.

The Supreme Court cited *Chakrabarty* with approval. *Mayo*, 132 S. Ct. at 1293. While the Court in *Mayo* cautioned against permitting claims that merely recite a law of nature combined with the words “apply it,” *id.* at 1294 (citing *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972)), (an admonition that may be necessary for claims that broadly recite fundamental laws in ways where the natural law is preempted), this is not the case for Myriad’s DNA claims. These claims are narrowly drawn to specific chemical compounds having a particular sequence recited as an affirmative limitation in the claims. These claims are not drafted in broad functional terms and do not cover all DNA encoding human BRCA genes. These claims are limited to a particular amino acid sequence for the protein encoded by the DNA molecule. The chemical structure of the isolated DNA molecules set forth in these claims limits claim scope in a way that avoids the preemption concerns identified in *Mayo*.

This self-limiting property of Myriad’s DNA claims also avoids another concern raised by the Court in *Mayo*, i.e., that the patent statute not be interpreted “in ways that make patent eligibility ‘depend simply on the draftsman’s art’ without reference to the ‘principles underlying the prohibition against patents for [natural laws].’” *Id.* This concern was based on the danger that upholding such overbroad patents would permit the patentee to “preempt the use of a natural law.”

Here, the draftsman's art is limited by the nature of the subject matter: a composition of matter or manufacture having a certain chemical structure that must be set forth with sufficient particularity to distinguish it from the prior art. The chemical structure of the claimed isolated DNA molecules, not the draftsman's art, cabins such claims and safeguards against the dangers identified in *Mayo*.

The Court also found the claims in *Mayo* to be patent ineligible because, except for the natural law, the steps in the claims involved only "well-understood, routine, conventional activity previously engaged in by researchers in the field." *Id.* Here, Myriad's claims are directed towards something entirely new: specific, isolated DNA molecules that were unknown in the art prior to their isolation, and that have been transformed by the hand of man into fundamentally new manufactures or compositions of matter having their own "distinctive name, character [and] use." *Chakrabarty*, 447 U.S. at 309-10.

Additionally, the Court in its *Mayo* decision was concerned lest the claims inhibit future innovation. The Court characterized patents as:

a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention, by, for example, raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements.

Mayo, 132 S. Ct. at 1305. These concerns do not apply to Myriad's DNA claims

because the information content of DNA is not patented. Myriad's claims are limited to chemical compounds, the isolated DNA molecules themselves. The genetic information contained within naturally occurring DNA -- the sequence of the A, T, C, and G nucleotides -- does not fall within the scope of these claims. Moreover, the naturally occurring DNA molecules in their native state are outside the scope of Myriad's claims and can be freely utilized without fear of patent infringement. Finally, even the isolated DNA molecules fall outside the scope of Myriad's patent claims once they are reintroduced into a cell (e.g., to produce useful quantities of the encoded protein), because the DNA molecules are then no longer "isolated." Thus, the Supreme Court's concern about claims monopolizing "the basic tools of scientific technological work" is not implicated by recognizing Myriad's isolated DNA claims as patent eligible.

Finally, Myriad's DNA claims have not had any negative effects on technological development, another concern of the Supreme Court in *Mayo*. For example, a cursory scan of the medical and scientific literature reveals more than eight thousand articles and reports regarding human BRCA 1 and BRCA 2 genes since the patents-in-suit were granted. Coupled with the limited scope of Myriad's isolated DNA claims and the limited possibility that isolated DNA claims could be broadly interpreted (or enforced) to "inhibit future innovation," there is no policy basis for excluding isolated DNA claims from patent eligibility.

II. Method Claim 20 Is Patent Eligible Under § 101 Because the Claim Does Not Preempt Other Uses of the BRCA1 Gene.

A method claim incorporating or using a natural law is patent eligible under § 101 if the claim, when considered as a whole, is drawn to a specific process that implements or applies the natural law without preempting other uses of the natural law. *Diamond v. Diehr*, 450 U.S. 175 (1981); *cf. Mayo*, 132 S. Ct. at 1298-99.

In *Diehr*, the Supreme Court held claims directed to a manufacturing process based on a natural law (the Arrhenius equation) patent eligible because the claims were drawn to a specific process that used the Arrhenius equation and did not preempt other uses of the equation. On that basis, the Supreme Court concluded that the claims were not impermissibly foreclosing use of the Arrhenius equation in the abstract. 450 U.S. at 192-93. The claimed method in *Diehr* included:

installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time.

Id. at 187. The Supreme Court noted that the “claims involve[d] the transformation of an article, in this case raw, uncured synthetic rubber, into a different state or thing,” and that the claims “describe[d] in detail a step-by-step method for accomplishing such, beginning with the loading of a mold with raw, uncured rubber and ending with the eventual opening of the press at the conclusion of the cure.” *Id.* at 184. Although the patented process recited the use of the Arrhenius

equation, the Supreme Court held that the claims were patent eligible because the “claims [were not] an attempt to patent a mathematical formula, but rather [were] drawn to an industrial process.” *Id.* at 192-93. Additionally, rather than seeking to preempt others from using the Arrhenius equation, Diehr instead “[sought] only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process.” *Id.* at 187.

In contrast, the Supreme Court in *Mayo* held claims for a method of calibrating drug dosages based on a natural law (i.e., a metabolite-toxicity/inefficacy correlation) to be patent ineligible because “the patent claims at issue . . . effectively claim[ed] the underlying laws of nature themselves.” 132 S. Ct. at 1305. The claimed method in *Mayo* included:

measur[ing] (somehow) the current level of the relevant metabolite, . . . us[ing] particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and . . . reconsider[ing] the drug dosage in light of the law.

Id. at 1299. In concluding that the claims were patent ineligible under § 101, the Supreme Court reasoned that the steps set forth in the claimed method “add[ed] nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field.” *Id.* at 1289. As a result, even though the claim recited the metabolite-toxicity/inefficacy correlation in combination with nonspecific, routine steps, the Supreme Court held that the claim effectively preempted all uses of the correlation. *Id.* at 1305.

IPO believes that claim 20 is directly analogous to the method claim upheld in *Diehr*. When considered as a whole, claim 20 should be patent eligible because it is directed to a specific drug screening process that employs an *altered* form of the BRCA1 gene and does not preempt other uses of the naturally occurring BRCA1 gene. In particular, claim 20 recites a multi-step method for identifying potential cancer therapeutics comprising:

growing a *transformed* eukaryotic host cell containing an *altered* BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic, growing said *transformed* eukaryotic host cell in the absence of said compound, determining the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells, wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.

Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 653 F.3d 1329, 1335 (Fed. Cir. 2011) (emphasis added).

The method steps of claim 20, when taken as a whole, are not a mere drafting effort designed to monopolize a natural law. Instead, like the patent eligible claim in *Diehr*, claim 20 seeks only to prevent others from using a specific metric (growth rates) with specific types of host cells (eukaryotic host cells) transformed with specific genes (altered BRCA1 genes) that are grown in the presence or absence of specific types of therapeutics (cancer therapeutics). *Id.* at 1358. Moreover, claim 20 does not encompass the use of naturally occurring

BRCA1 genes. Instead, claim 20 requires the use of altered BRCA1 genes. As such, claim 20 does not preempt uses of the unmodified, naturally occurring BRCA1 gene. Therefore, IPO believes that method claim 20 is not claiming the use of BRCA1 genes in the abstract and should be patent eligible under § 101.

III. A Ban on Patenting Isolated Human DNA and Gene-based Diagnostic Screening Methods Would Negatively Impact Research, Technology and Innovation

Over the prior decades, inventors have obtained thousands of U.S. patents claiming isolated DNA and/or diagnostic screening methods using genetic information. It is no coincidence that during this same time period, investment in U.S.-based research in these fields has been sizeable and robust. In addition to breast cancer, gene-based research is currently being funded looking for improved treatments and screening methods for diabetes, cardiovascular disease, autism, Parkinson's disease, Alzheimer's disease, immunological disorders, asthma and most forms of cancer. Banning patents on isolated human DNA or diagnostic uses of genetic information, however, will necessarily force these researchers (and those who fund them) to find alternative ways to protect their technology, such as through trade secret protection.

If the possibility of patent protection is removed, innovation in genetic-based diagnostics would be harmed. There would be no incentive (indeed, there would be strong *disincentives*) to disclose the genetic basis of complex diagnostic assays.

This would inevitably reduce progress in genetic diagnostic research, since there would be much less disclosure of proprietary research of the type that now routinely appears in published patent applications.

Similarly, one of the most promising benefits of elucidating human genetic sequence information is the development of personalized medicine, the use of genetic information to diagnose disease propensity and make improved therapeutic choices. But continued investment in and development of this technology will depend on the incentive provided by patent protection, an incentive that is threatened by the district court's decision holding Myriad's patents to be unpatentable under § 101.

The expectation of the biotechnology and pharmaceutical industries in the patentability of isolated human DNA and gene-based screening methods has been settled for decades. Any fundamental reversal of this settled expectation "risk[s] destroying the legitimate expectations of inventors in their property." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002). No such upheaval is required by Supreme Court precedent, including *Mayo*.

Finally, the impact of affirming the district court's decision is not limited to isolated human DNA or medical and pharmaceutical applications thereof. Many other fields, including industrial biotechnologies involving alternative fuels, industrial biochemicals, and genetically modified foods, would be harmed because

these industries have depended for decades on patent protection for isolated DNA inventions from non-human organisms. Eliminating patent protection on these embodiments of isolated DNA inventions would do more than upset the settled expectations of the industry; it would inhibit innovation and retard if not prevent development of new and useful compositions of matter that are isolated from natural sources.

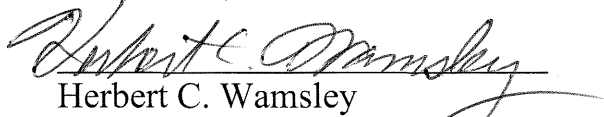
As but one example, patents protecting a gene for the enzyme phytase from the bacteria *E. coli* have facilitated the development of an animal feed supplement that reduced the environmental impact of fecal phosphate from livestock. See, e.g., U.S. Pat. No. 6,190,897. The biofuels industry is based in part on enzymes that break down plant carbohydrates. This is particularly important in efforts to adopt “green” renewable technologies, which generally require enzymatic or other biological solutions to convert biological products (such as cellulosic materials) that are resistant to conventional chemical degradation methods. Many of the most useful enzymes for these purposes come from wood-rotting fungi such as *T. reesei*, *A. niger* and *F. verticilloides*, and recombinant DNA technologies can and have been applied to produce industrial-scale quantities of these enzymes. For example, significant progress in the development of this technology has been achieved using a glucoamylase enzyme isolated from the fungus *T. reesei*, permitting improved production of biofuels like ethanol. See U.S. Pat. No. 7,413,887. Continued growth

of the biofuels industry depends critically on the ability to patent the fruits of the highly resource-intensive research and development required to isolate naturally occurring DNA and use it to produce economically important enzymes. Barring patent protection for such DNA-based inventions will have negative, far-reaching consequences for many research-based industries throughout the United States.

CONCLUSION

IPO urges this Court to find that Myriad's isolated DNA claims represent patentable subject matter because they claim manufactures or compositions of matter that are the product of human ingenuity. In addition, IPO believes that method claim 20 is directed to patentable subject matter under § 101 because it does not preempt other uses of the naturally occurring BRCA1 gene. Finally, any ban on patenting isolated human DNA or gene-based diagnostic screening methods would negatively impact research, technology and innovation in this country and upset the settled expectations of entire industries, contrary to the constitutional and congressional policies at the heart of U.S. patent law.

Respectfully submitted,



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APPENDIX

APPENDIX

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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 INTELLECTUAL PROPERTY OWNERS ASSOCIATION, Counsel for *Amicus Curiae* 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.

Unless otherwise noted, 12 copies have been filed with the Court on the same date via hand delivery.

June 15, 2012

