Docket No. 2010-1406

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 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,
Defendant-Appellants

On Appeal from the United States District Court for the Southern District of New York Judge Robert W. Sweet

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BRIEF AND APPENDIX OF THE AMERICAN BAR ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

Of Counsel:
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June 15, 2012

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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:

   N/A

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the parties represented by me are:

   None

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

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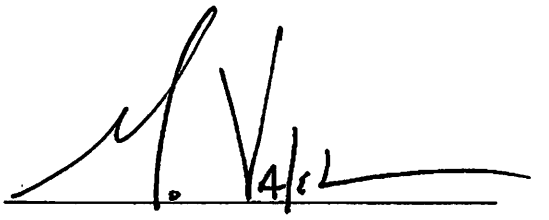

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STATEMENT OF INTEREST

The American Bar Association ("ABA"), as *amicus curiae*, respectfully submits this brief in support of neither party in response to this Court's request for briefs that address the applicability of the Supreme Court's decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) ("*Mayo*") to the isolated DNA claims at issue.[1] This brief is limited to addressing the question of whether isolated DNA compounds that do not occur in nature in their isolated form ("Isolated DNA Compounds") may be patent-eligible.[2] The ABA urges the Court to hold that Isolated DNA Compounds are not *per se* disqualified from patent eligibility under 35 U.S.C. § 101, that determinations as to their patentability should continue to be made on a claim-by-claim basis pursuant to the common-law tradition of incremental determination of patent-eligibility, and that the *Mayo* decision does not require otherwise.

The ABA is the largest voluntary professional membership organization and the leading organization of legal professionals in the United States. Its nearly

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[1] *Amicus Curiae* states that this brief has not been authored in whole or in part by counsel for either party and that no person or entity, other than *Amicus*, its members, or its counsel, has made a monetary contribution to the preparation or submission of this brief.

[2] Because the ABA has not developed and approved policy concerning the patent-eligibility of process claims such as Claim 20 of Myriad's patent, this brief addresses only the applicability of *Mayo* to the patent-eligibility of composition claims for Isolated DNA Compounds.

400,000 members span all fifty states and other jurisdictions, and include attorneys in private law firms, corporations, non-profit organizations, government agencies, and prosecutor and public defender offices, as well as judges, legislators, law professors, and law students.[3]

Twenty-five thousand ABA members belong to its Section of Intellectual Property Law ("IPL Section"), which is the world's largest organization of intellectual property professionals and is composed of lawyers representing patent owners, accused infringers, individual inventors, large and small corporations, and universities and research institutions across a wide range of technologies and industries. Formed in 1894, the IPL Section works to promote the development and improvement of intellectual property law. It presents resolutions to the ABA House of Delegates for adoption as ABA policy. These policies then provide the basis for the IPL Section's active role in the consideration of proposed legislation, administrative rule changes and international efforts, and as a basis for the preparation of ABA *amicus* briefs, which are filed primarily in the Supreme Court of the United States and in this Court.[4]

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[3] Neither this brief nor the decision to file it should be interpreted to reflect the view of any judicial member of the ABA. No member of the Judicial Division Council participated in the adoption or endorsement of the positions in this brief, nor was it circulated to any member of the Judicial Division Council before filing.

[4] All such actions must be supported by ABA policy; only recommendations adopted by vote of the ABA's House of Delegates, but not the reports, become

In 2011, after meeting with diverse members of the legal profession, the IPL Section presented four consensus resolutions to the ABA House of Delegates that directly relate to the Court's question concerning the patent eligibility of Isolated DNA Compounds. These resolutions and the accompanying report are set out in full in the Appendix as *ABA Resolution #111* (policy adopted Feb. 4, 2011). The rationale for this ABA policy, as set out in the accompanying report, supports a patent eligibility assessment of Isolated DNA Compounds that is no different than the assessment of other materials that are derived from or otherwise relate to natural materials or sources. The same rationale argues against the *per se* disqualification of Isolated DNA Compounds from patent eligibility under 35 U.S.C. 101 or the adoption of any "product of nature" doctrine that would automatically require the exclusion of such compounds from patent eligibility.

The extensive collaborative process undertaken in formulating this policy reflects a consensus view based on the experience of legal professionals working in this field that the determination of patent eligibility should be developed

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ABA policy. The House of Delegates is composed of more than 550 delegates representing states and territories, state and local bar associations, affiliated organizations, sections and divisions, ABA members and the Attorney General of the United States, among others. *See* ABA General Information, *available at* http://www.abanet.org/leadership/delegates.html, and ABA amicus brief information, *available at* http://wwww.abanet.org/amicus.

incrementally, rather than through categorical exclusions that would unreasonably stifle innovation by undermining current biotechnology industry expectations.

ARGUMENT

I. *Per Se* Disqualification of Isolated DNA Compounds from Patent-Eligibility Would Unjustifiably Undercut Significant Investment-Backed Expectations and Reasonable Reliance on Long-Standing Precedent.

In response to the Supreme Court's remand in this matter, this Court has requested *amicus* briefs addressed to the question of the applicability of the Supreme Court's decision in *Mayo* to Myriad's isolated DNA claims. The ABA respectfully responds that any application of *Mayo* to the patent eligibility determination of the Isolated DNA Compounds that worked a per se disqualification of such claims would be a material change in the law that is not required by *Mayo*. Indeed, such a change would unjustifiably undercut significant investment-backed expectations of the biotechnology industry that have been based on reasonable reliance on applicable long-standing Supreme Court and other precedent.

The Supreme Court has long recognized that language of Section 101 is "extremely broad" and encompasses human-made compositions that are derived from natural sources. *See J.E.M. AG Supply v. Pioneer Hi-Bred Int'l*, 534 U.S. 124, 130 (2001) (holding that claims to hybrid corn seed made by cross-breeding different varieties of corn were eligible subject matter for a utility patent);

Diamond v. Chakrabarty, 447 U.S. 303, 313 (1980) (holding that human-engineered bacteria made by transforming naturally-occurring bacteria using plasmids containing genes from other naturally-occurring sources were patentable subject matter). The standards used to assess the patent eligibility of Isolated DNA Compounds should be the same as those applied to these other compositions that are likewise derived from or related to natural materials, but that do not themselves exist in nature.

Indeed, the biotechnology industry has substantially relied on such precedent in seeking and obtaining patent claims to Isolated DNA Compounds. As of 2006, there were approximately 33,000 issued patents claiming nucleic acids. National Research Council, *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation and Public Health* 101 (Stephen A. Merrill & Ann-Marie Mazza eds., The National Academies Press, 2006). There are many more such patents today. These patents help protect the sizeable investment needed to develop and obtain regulatory approval for new products in the biotechnology industry. *See, e.g.*, Federal Trade Commission Report, "Emerging Health Care Issues: Follow-on Biologic Drug Competition," June 2009 (concluding that "[p]atent protection fuels the biotechnology industry's R&D engine" and is "necessary to attract the capital to fund high-risk investment"); Joseph A. DiMasi and Henry G. Grabowski, *The Cost of Biopharmaceutical R&D:*

Is Biotech Different? 28 Managerial and Decision Economics 469, 475 (2007) (estimating that the development costs for new biologic based therapeutics to be in excess of a billion dollars for each approved molecule). Dramatic shifts in the scope of patentable subject matter unfairly undercut these investments and upset the reasonable expectations of inventors who have acted against the backdrop of long-standing precedent interpreting Section 101 broadly.

For these reasons, the ABA endorses the continued application of the common-law precedent of incremental development of jurisprudential doctrine for determining patent-eligible subject matter on a claim-by-claim basis. Such continued application avoids dramatic shifts in the definition of patent-eligible subject matter, such as a *per se* disqualification of Isolated DNA Compounds, which would negatively impact innovation in the important field of biotechnology.

II. The *Mayo* Decision Has No Bearing on the Patent Eligibility of Composition Claims to Isolated DNA Compounds.

Mayo requires no change in this Court's claim-by-claim analysis of the patentability of Isolated DNA Compounds. The claims at issue in *Mayo* were process claims reciting a law of nature, namely the relationship between the concentration of a drug metabolite in the blood and the efficacy of the drug. *Id.* at 1296. Consequently, the sole question there was whether the challenged claims "add[ed] ***enough***" to their statement of this natural relationship "to qualify as

patent-eligible processes that ***apply*** natural laws." *Id.* at 1297 (emphasis in original).

In contrast, the composition claims at issue in the present case do not recite a law of nature, nor do they claim the application of one. Indeed, they are drawn to a different class of statutory subject matter, "composition of matter," than were the process claims in *Mayo*. 35 U.S.C. § 101. The relevant question for the patent-eligibility of these claims is whether the claimed Isolated DNA Compounds are "nature's handiwork" or rather a patent-eligible, human-made invention. *See Chakrabarty*, 447 U.S. at 309-10. *Mayo* did not address this question, much less purport to change how such claims are analyzed for eligibility under Section 101.

III. The Supreme Court's Rationale in *Mayo* Does Not Support Excluding the Isolated DNA Compounds at Issue From Patent Eligibility.

Even if *Mayo* did apply to the composition claims here, the analysis there does not *per se* disqualify Isolated DNA Compounds from the scope of patentable subject matter. The concern in *Mayo* was an attempt to "monopolize the law of nature itself." *Mayo*, 132 S.Ct. at 1297. But a claim to an Isolated DNA Compound *that does not exist in nature* carries no such concern because it is directed to a human-made chemical compound. *See Chakrabarty*, 447 U.S. at 313 (noting from the legislative history of Section 101 that "the relevant distinction

was . . . between products of nature . . . and human-made inventions.")[5] As this Court previously recognized, the claimed Isolated DNA Compounds are human-made "free-standing" molecules that are chemically distinct from the DNA found in nature.[6] *See Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1351-52 (Fed. Cir. 2011), *vacated*, 132 S. Ct. 1794 (2012). Accordingly, a claim to such an Isolated DNA Compound does not implicate any naturally-occurring DNA molecule found in any living tissue, cell, or chromosome.

Moreover, even if the biological information communicated by the sequence of nucleotides in an Isolated DNA Compound could be considered a "law of nature," a claim to an Isolated DNA Compound does not monopolize or otherwise prohibit the use of that information. This is different from the process claimed in *Mayo,* which "amount[ed] to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients." *Mayo,* 132 S.Ct. at 1298. Here, scientists are free to use the sequence information in Myriad's Isolated DNA Compounds, and knowledge of a correlation between mutations in

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[5] *See also SmithKline Beecham v. Apotex Corp.,* 403 F.3d 1331, 1360 (Fed. Cir. 2005) (Gajarsa, J., concurring) ("[T]he critical distinction guiding all section 101 inquiries into the patentability of subject matter is that human-made, or synthetic, products or processes are patentable, while products and processes of nature are not.").

[6] An isolated DNA molecule can be made by cleaving certain covalent bonds in a longer DNA molecule or by *de novo* synthesis. *See id.* Either way, it is a human-made invention with a different structure and use than the naturally-occurring DNA present in one's body.

that sequence with the risk of developing breast cancer, to make further discoveries without practicing the Isolated DNA Compound composition claims. Indeed, such claims do nothing to "tie up" the future use of that information. *Id.* at 1302.

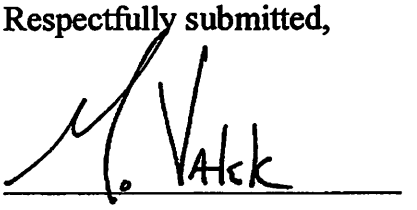
Nor does the analysis in *Mayo* inform in any way whether the claimed DNA compounds exist in nature or are human-made inventions. Adding merely "conventional or obvious" claim elements may not be "sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." *Id.* at 1298. But that inquiry is irrelevant to whether a chemical composition is or is not a product of nature. "[A] new mineral discovered in the earth or a new plant found in the wild," even one with extraordinary and unconventional features, "is not patentable subject matter." *Chakrabarty*, 447 U.S. at 309. Conversely, scientists could add a conventional chemical moiety with well-understood properties to a naturally-occurring compound to create a human-made, and thus patent-eligible, invention. There is no reason to treat the patent-eligibility of Isolated DNA Compounds differently from any other chemical compound derived from a natural material or source.

CONCLUSION

For the reasons set out above, the ABA respectfully requests that this Court hold that the Supreme Court's decision in *Mayo* does not affect the patent eligibility of claims to Isolated DNA Compounds, such as those at issue here, and

that jurisprudential doctrine for determining patent-eligible subject matter should continue to be incrementally developed in accordance with common law tradition.

Respectfully submitted,



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I hereby certify that on June 15, 2012, two (2) true and correct copies of the BRIEF FOR *AMICUS CURIAE* AMERICAN BAR 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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I certify that the forgoing BRIEF OF THE AMERICAN BAR ASSOCIATION AS AMICUS CURIAE contains 2,130 words as measured by the word processing software used to prepare the brief.

Respectfully submitted,

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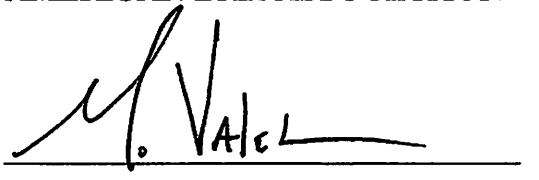

APPENDIX

AMERICAN BAR ASSOCIATION

ADOPTED BY THE HOUSE OF DELEGATES

FEBRUARY 14, 2011

RESOLUTION

RESOLVED, That the American Bar Association supports the continued recognition of judicially-created exceptions to patent eligibility for laws of nature, abstract ideas, or physical phenomena under 35 U.S.C. § 101, and the continued reliance on the separate statutory requirements for patentability under 35 U.S.C. §§ 102 and 103 for novelty and non-obviousness.

FURTHER RESOLVED, That the American Bar Association supports application of standards used in assessing patent eligibility under the provisions of 35 U.S.C. § 101 in a non-discriminatory manner that treats isolated DNA compounds no differently from other materials that are derived from or otherwise relate to natural materials or sources.

FURTHER RESOLVED, That the American Bar Association opposes *per se* disqualification from patent eligibility under 35 U.S.C. § 101 of isolated DNA compounds that do not occur in nature in their isolated forms.

FURTHER RESOLVED, That the American Bar Association opposes the adoption of any "products of nature" doctrine that would automatically require the exclusion of isolated DNA compounds from patent eligibility as "products of nature."

REPORT

Scientific advances in the use of DNA technology for diagnosis and treatment of disease have contributed substantially and measurably to improvements in human health, quality of life, and longevity. For more than two decades, our government has recognized these realities, and has appropriately provided incentives for continued advances in a number of ways, including financial support for further research and development, and patent protection for new inventions.

A fundamental challenge to the eligibility of any and all DNA technology to be considered for patenting is underway. One federal court has ruled that such technology is categorically ineligible, and that ruling is under appeal in the U.S. Court of Appeals for the Federal Circuit. Regardless of the outcome in that proceeding, in view of the importance and notoriety of this litigation, review by the full *en banc* Federal Circuit or further appeal to the Supreme Court of the United States is a distinct possibility.

Congress has also shown interest in the issue, as demonstrated by the introduction of legislation that would provide a statutory ban on patenting of DNA technology.

This resolution asks the House of Delegates to approve policy to express ABA opposition to the damaging reversal of policy called for by the District Court decision, and to support Association participation in further proceeding to resolve this issue.

A. The *Myriad* Case: Summary and Overview

In *Association for Molecular Pathology v. United States Patent and Trademark Office*, 2010 U.S. Dist. LEXIS 35418 (S.D.N.Y. Apr. 2, 2010) ("*Myriad*"), a critical issue before the court was whether an isolated DNA compound, which does not appear in nature in that form, qualifies as subject matter eligible for patenting under 35 U.S.C. section 101.[1] *Id.* at 3. The *Myriad* court held that it does not. *Id.* The court notes that subject matter is patent eligible if it is "markedly different" from a product of nature and then proceeds to find that isolated DNA was not markedly different because it is not "sufficiently distinct in its fundamental characteristics" from the corresponding DNA sequence found in nature. *Id.* at 144-145.

The *Myriad* court erred in its interpretation of section 101 and specifically in its application of the test for patent eligibility. Patent eligibility under the statute is broad, and the Supreme Court's precedents provide only three specific exceptions to those broad eligibility principles. Inventions seeking to capture laws of nature, physical phenomena, or abstract ideas may not be patented. While the Section does not believe that the "markedly different" test applied by the court is appropriate for determining patent eligibility, the isolated DNA compound at issue in *Myriad* was, in fact, markedly different from what occurs in nature. It does not fall under any of

[1] The requirements of Section 101 only serve as a threshold to consideration of the requirements that must be satisfied under Sections 102 (novelty), 103 (non-obviousness) and numerous other provisions of the Patent Act in order for any invention to be patentable or patented, Those requirements of patentability were not considered by the *Myriad* court and thus not determined or covered by the court's decision on summary judgment. An isolated DNA compound that meets the threshold requirements of Section 101 might not be patentable for failure to meet one or more of the patentability requirements.

the narrow exceptions to the wide scope of section 101 that have been articulated by the Supreme Court.

The isolated DNA compound claimed in the Myriad patent is a chemical compound. Moreover, in the isolated form that is claimed, it does not occur in nature and is not merely purified from natural DNA.

The isolated DNA compounds claimed in the Myriad patents are isolated forms of a gene called the "BRCA" gene. Through sophisticated research, the inventors discovered that mutations in the BRCA genes (i.e., small, inheritable, individual-to-individual variations of the sequences of the DNA building blocks making up the BRCA genes) correlate with a woman's risk of developing breast cancer. Thus, the isolated DNA claimed in the patents has become a useful tool for doctors to use to assess a woman's risk of breast cancer and provides valuable diagnostic and prognostic information which assists in selecting treatment options.

The BRCA gene is one of more than 20,000 genes that exist in the human genome. The genes exist in the nucleus of each cell on long strands of DNA called "chromosomes." Each chromosome consists of thousands of genes in which the DNA exists in a complex structure with proteins. The human genome consists of forty-six chromosomes. Thus, in its natural environment, the BRCA gene is a small part of a long strand of DNA existing on one of forty-six chromosomes. Each chromosome consists of millions of the DNA building blocks (called "nucleotides,") which, in turn, are contained in the cell nuclei. The cell is a complex milieu of enzymes and numerous other proteins, lipids, carbohydrates, salts and nucleic acids. The cells form the tissues of the human organism.

The isolated DNA claimed in the Myriad patents is a chemical compound that has been identified and excised from the chromosome. It is separated from all of the components of the chromosome, the nucleus, the cell and the tissue. In its isolated form, it is useful in diagnostic and prognostic procedures designed to ensure people's health and well being. In contrast, the DNA in its natural form, as it exists in tissues, cells and chromosomes, has no value in such diagnostic and prognostic procedures.

There can be no serious dispute that the isolated DNA compounds claimed in the Myriad patents are compositions of matter that did not occur in nature. They are the product of human ingenuity and intervention; they are man-made. They have a utility that the DNA in its complex natural environment does not have.

Isolated DNA compounds are not merely the product of purification. Isolating DNA entails, *inter alia*, a chemical re-arrangement -- breaking the covalent chemical bonds of chromosomal DNA to form a new chemical structure not found in nature. While isolated DNA may be *derived* from natural DNA, it is indisputably a man-made compound not found in nature and not purified from its natural environment. The claimed isolated DNA compound is a product of man, not nature.

The patent statute defines patent-eligible subject matter broadly to meet the Constitutional mandate to "promote the progress of science and the useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." U.S.

Constitution, Art. I, §8, cl. 8. A primary purpose of the patent system is to provide incentives for investment into research that enhances the quality of life and economic vitality of the country.

Although the *Myriad* court acknowledged the chemical distinctions between the claimed isolated DNA and the naturally occurring substance, the court found that such compositions of matter are not subject matter eligible for patent protection because the isolated DNA was not "markedly different" from natural DNA.:

B. 35 U.S.C. Section 101 and Its Scope

Section 101 defines the subject matter eligible for patenting under the Patent Act:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Section 101 thus specifies four independent categories of inventions or discoveries that are eligible for patent protection: processes, machines, manufactures, and compositions of matter. "In choosing such expansive terms . . . modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980). Congress took this permissive approach to patent eligibility to ensure that "'ingenuity should receive a liberal encouragement.'" *Id.* at 308-309 (quoting 5 Writings of Thomas Jefferson 75-76 (H. Washington ed. 1871)).

The Supreme Court's precedents provide three specific exceptions to section 101's broad patent-eligibility principles: laws of nature, physical phenomena, and abstract ideas. *Chakrabarty*, 447 U.S. at 309. A naturally occurring substance that has been isolated into a new and useful form not found in nature is a "composition of matter" that does not fall within the narrow exceptions to patent eligibility that have been identified by the Supreme Court. *Id.* at 310.

However, the exceptions to patentable subject matter should not be confused with the remaining requirements for patentability, particularly the requirement that the invention not be obvious. *Bilski v. Kappos*, 561 U. S. ____ (2010) at pages 5, 12-13 of the slip opinion. Thus, while a composition of matter may qualify as patent-eligible subject matter under section 101, what appears in nature may still render the composition of matter unpatentable as anticipated or obvious. Section 101 is a threshold requirement to define the subject matter that is eligible for patenting. Other sections define whether that subject matter is worthy of a patent.

C. Isolated DNA Constitutes Patent Eligible Subject Matter under Section 101

An isolated DNA sequence qualifies as a "composition of matter" under section 101. A "composition of matter" 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." *Chakrabarty*, 447 U.S. at 309. An "isolated

DNA sequence" constitutes a "composition of two or more substances" by definition, which the *Myriad* court provided in construing that term:

> "Isolated DNA" is therefore construed to refer to a segment of DNA nucleotides existing separate from other cellular components normally associated with native DNA, including proteins and other DNA sequences comprising the remainder of the genome, and includes both DNA originating from a cell as well as DNA synthesized through chemical or heterologous biological means.

Myriad at 99.

The isolated DNA sequence in *Myriad* also falls outside the Supreme Court's three limited exceptions to patentable subject matter: laws of nature, physical phenomena, and abstract ideas. *Chakrabarty*, 447 U.S. at 309. Accordingly, it is patent-eligible subject matter.

D. The *Myriad* Court Erred in its Application of a "Markedly Different" Test for Patent Eligibility

In *Chakrabarty*, the Supreme Court distinguished its earlier decision in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) by observing that, unlike the mixture of natural microbial cultures claimed in *Funk Bros.*, Chakrabarty's genetically engineered microorganism had "markedly different characteristics from any found in nature and [was] one having the potential for significant utility. 447 U.S. at 310. The *Myriad* court extrapolated from this language a conclusion that the Supreme Court's test for patent eligibility required that the claimed composition be "markedly different" from what occurs in nature. However, in distinguishing the nature of Chakrabarty's invention from that at issue in *Funk Bros.*, the Supreme Court did not hold that "markedly different" was a substantive requirement for patent eligibility. In fact, the Court emphasized in that case that Congress defined patent eligibility broadly, and "in choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplates that the patent laws would be given wide scope." 444 U.S. at 308-09.

By reading a "markedly different" requirement into section 101, the *Myriad* court interjects a nonobviousness requirement into the test for patent eligibility. But, in *Chakrabarty*, the Supreme Court made clear that the requirements of nonobviousness and novelty are distinct from patent eligibility under section 101. *Id.* n.5. Instead, the Supreme Court focused on the statutory categories of invention "manufacture" and "composition of matter" and held that inventions falling within those broad categories, as opposed to "laws of nature, physical phenomena, [or] abstract ideas" are eligible for patenting. 447 U.S. at 310. Once an invention is shown to satisfy these broad threshold requirements for patent eligibility, its differences from the prior art – including what occurs in nature – are assessed to determine if the statutory requirements of novelty and nonobviousness are satisfied under sections 102 and 103.

As noted by the United States Court of Customs and Patent Appeals, there are no extraordinary criteria apart from section 102 for determining whether subject matter is "new" under section 101:

> "The criteria for determining whether a given subject matter is "new" within the meaning of section 101 are no different than the criteria for determining whether the subject matter possesses the "novelty" expressed in the title of section102. The word "new" in section 101 is defined and is to be construed in accordance with the provisions of section 102."

In re Bergstrom, 427 F.2d 1394, 1401 (C.C.P.A. 1970). Thus, the interpretation of "markedly different" in *Chakrabarty* is not properly read to establish a new test for patent-eligibility. Rather, "markedly different" must be understood in the context of the statutory framework. A composition of matter is sufficiently different from the natural substance if it is new under section 102.

Courts have upheld patents that claim a composition of matter derived from, or otherwise related to, natural materials and meet the statutory criteria of being new and unobvious. See, e.g., *Merck v. Olin Mathieson Chemical Corporation*, 253 F.2d 156 (4th Cir. 1958). Compositions that have been held to be unpatentable "products of nature" are not new. *Id.* at 162. There is no statutory basis, and it is unnecessary to extend any concept of subject matter being "markedly different" beyond section 102. The test for whether subject matter is markedly different is wholly defined by statute.

The *Myriad* court, however, instead required the following more stringent standard for defining whether subject matter is markedly different:

> There will almost inevitably be some identifiable differences between a claimed invention and a product of nature; the appropriate section 101 inquiry is whether, considering the claimed invention as a whole, it is *sufficiently* distinct in its *fundamental* characteristics from natural phenomena to possess the required 'distinctive name, character, [and] use.'

Myriad at 137-138 (quoting *Chakrabarty*, 447 U.S. at 309-10) (emphasis added). Ultimately, in view of its finding that DNA is a 'physical embodiment of information', the *Myriad* court declared the chemical difference between native DNA and isolated DNA to be insufficient to meet the standard.

E. Claims to Isolated DNA are Claims to Chemical Compounds Not to Information

The Myriad court is correct that DNA communicates biological information when it noted that "DNA, and in particular the ordering of its nucleotides, therefore serves as the physical embodiment of laws of nature – those that define the construction of the human body". *Myriad* at 135. However, to the extent DNA communicates information, the information embodied in the DNA sequence is not part of the claimed (patented) composition. That is, the sequence information could be and is freely usable - to upload into a computer, to study similarities or differences with other genes, to understand mutations in some populations, and to make new discoveries and inventions. A claim to the chemical composition - a physical embodiment - does not prohibit the use of the scientific information that is communicated by the sequence data. The information aspect of a claim to isolated DNA is dedicated to the public once the patent

published. Accordingly, that DNA uniquely communicates biological information has little, if any, bearing on whether *isolated DNA compounds* are patent eligible subject matter under section 101.

F. The ABA Should Oppose Application of any "Products of Nature" Doctrine That Would Have the Effect of Producing a Subject Matter Exclusion From Patent Eligibility for Isolated DNA Compounds

The *Myriad* court supports its holding in its interpretation of the so-called "product of nature" doctrine. The origins and boundaries of this doctrine are debatable, particularly to the extent the "product of nature" doctrine defines *patent eligibility* rather than the old standard of "invention" in what is now embodied under sections 102 and 103. However, the ABA should oppose application of any "product of nature" doctrine that categorically excludes isolated DNA compounds from patent eligibility.

In *Am. Fruit Growers, Inc. v. Brodgex Co.*, 283 U.S. 1 (1931), the Supreme Court held that fruit whose skin had been treated with mold-resistant borax did not constitute a patentable article of "manufacture." *Id.* at 11-12. The Court focused on the word "manufacture" and found that there must be a "transformation; a new and different article must emerge having a distinctive name, character, or use." *Id.* at 13. The court noted that the borax-coated orange is patent-ineligible because it "remains a fresh orange, fit only for the same beneficial uses as theretofore." *Id.* at 12. However, the issue in *Myriad* was whether an isolated DNA sequence constituted a "composition of matter" and fell outside the limited exceptions to section 101. The issue was not whether the isolated DNA sequence also constituted a patentable article of manufacture. *Am. Fruit Growers* is thus inapposite to the issue in *Myriad*. Furthermore, as previously noted, isolated DNA compounds are no way found in nature and as a new chemical composition are different than natural chromosomal DNA. Thus, *Am. Fruit Growers* would not support the exclusion of isolated DNA compounds from patent eligibility.

In *Funk Bros.*, the Supreme Court held that a claim directed to a plurality of naturally-occurring bacterial strains that did not inhibit each other was invalid. *Id.* at 131-32. The Court found that the aggregation of naturally-occurring strains, which did not exhibit characteristics different from the individual strains themselves, "was not the product of invention." *Id.* at 132. This holding must be understood in the context of the pre-1952 statute, where "invention" was not statutorily defined, but rather it was a judicially applied test of what is now obviousness under section 103. Accordingly, the holding of the Court cannot be read as precluding patents to "products of nature" generally as ineligible subject matter; rather, products of nature that are not unobvious are unpatentable. However, even if the holding could be fairly interpreted to define patent eligibility of subject matter rather than patentability, it is clear that the Court merely required that the aggregation of strains exhibit some characteristic different from the individual strains themselves. *Id.* Accordingly, *Funk Bros.* also does not support excluding isolated DNA compounds from patent eligibility.

In *Chakrabarty*, discussed above, the Supreme Court found that a live, human-made micro-organism constituted patent eligible subject matter because it had "markedly different" characteristics from what appeared in nature. *Chakrabarty*, 447 U.S. at 310. It was unnecessary

for the Court in *Chakrabarty* to further define "markedly different" as being new under section 102 because that issue was not before the Court. However, the Supreme Court in *Chakrabarty* plainly did not articulate a new test for patent eligibility that the subject matter must be different more broadly than being new under section 102.

In *The American Wood-Paper Co. v. The Fibre Disintegrating Co.*, 90 U.S. (23 Wall.) 566, 593-94 (1874), the Supreme Court held that a purified product was not patentable merely because it was purified from a new source, when it had already been purified from another source. It was not new. The Court observed:

> There are many things well known and valuable in medicine or in the arts which may be extracted from diverse substances. But the extract is the same, no matter from what it has been taken. A process to obtain it from a subject from which it has never been taken may be the creature of invention, but the thing itself when obtained cannot be called a new manufacture.

Id. at 593-94. The Supreme Court suggested, however, that if the purified product had been purified for the first time, it would qualify as patent-eligible subject matter. *Id.* at 594. The *Myriad* court, however, misapplied *American Wood-Paper* in two respects – it confused patent eligibility with being new (novelty) and it also equated purifying a product from a natural source with chemically deriving isolated DNA from its chromosomal DNA. As previously noted, deriving isolated DNA entails chemical modifications to chromosomal DNA such that a new compound – not anywhere found in nature – is produced.

In *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 311 (1884), the Supreme Court rejected a patent on an artificial version of a natural, well-known dye called alizarine. The artificial version and the natural version were identical except in name. *Id.* Even assuming the Court was addressing patent eligibility as opposed to novelty, which is unclear from the record, the Court merely found that an invention that differed from a product of nature only in name could not be patented. *Id.*

Although the *Myriad* court also cited very old lower court decisions for support of its finding that isolated DNA compounds were ineligible subject matter as a "product of nature", those decisions, to the extent they contradict the Supreme Court's expansive interpretation of section 101 in *Chakrabarty*, are no longer good law. *See, e.g. Myriad* at *38 (citing *Gen. Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641 (3d Cir. 1928); *In re Marden*, 47 F.2d 957 (C.C.P.A. 1931); and *In re Marden*, 47 F.2d 958 (C.C.P.A. 1931)). Furthermore, each also finds the "product of nature" unpatentable (in contrast to being patent ineligible) when the requirements under the Patent Act are not otherwise met. That is, the claimed subject matter is not novel or unobvious under sections 102 and 103. A finding of subject matter being "unpatentable" confuses patent eligibility of the subject matter and patentability. See *Merck*, 253 F.2d at 162. The cited cases also provide claims to elements, which are not compositions under section 101 and therefore may also be readily distinguished. See *Chakrabarty*, 447 U.S. at 309 which defines the term "composition" under the act as including "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." Accordingly, none of the decisions cited by

Myriad support the proposition that isolated DNA should be placed in a category of patent-ineligible subject matter as a so-called "product of nature." Indeed, the ABA should oppose any such categorization as not being proper.

G. The IPL Section Supports the Application of Standards Used in Assessing Patent Eligibility under the Provisions of 35 U.S.C. Section 101 in a Non-discriminatory Manner

The standards used in assessing patent eligibility under the provisions of 35 U.S.C. 101 must be applied non-discriminatory manner that treats isolated DNA compounds no differently from other materials that are derived from or otherwise relate to natural materials or sources. The practical impact of the *Myriad* court's holding is that the isolated DNA is treated differently than other chemicals that may be derived from natural sources, such as proteins from biologic sources, antibiotics isolated from natural sources, microorganisms, or petroleum-based products. A claim for a particular isolated DNA compound, such as BRCA1 or BRCA2, should be subjected to the requirements for patentability under sections 101, 102 and 103. By creating a blanket subject matter exclusion for all isolated DNA compounds, the Myriad court would preclude full 101, 102 and 103 analysis and deprive of patent protection all those future inventions of isolated DNA compounds that meet the requirements of 102 and 103.

The IPL Section has long opposed application of the patent law in a manner that discriminates by subject matter and the ABA has adopted policy similarly opposing unduly restrictive judicial interpretation of patent eligibility under section 101. Most recent of these is the policy adopted by the House of Delegates at the 2009 Annual Meeting, expressing opposition to an unduly restrictive ruling by the Federal Circuit on patent eligibility under section 101. In its July 2010 decision in *Bilski v. Kappos,* the U.S. Supreme Court issued a decision in accord with that taken in an ABA amicus brief, and rejected the narrow standard for patent eligibility formulated by the Federal Circuit.

H. Patent Eligibility of Isolated DNA is Good Patent Policy

The publicity around the *Myriad* case has spurred considerable debate on the merits of patenting isolated DNA. This debate is generally summarized by the *Myriad* court. *Myriad*, at 71-83. One aspect of the debate is whether patents to isolated DNA are necessary because the NIH funds the majority of genomic research in the US. In view of this funding, it is posited that there are sufficient incentives for scientists to continue to identify new genetic sequences through grant funding and personal/career advancement through publication. In addition to non-patent incentives for genomic research, it is also argued that granting patents to isolated DNA enables the existence of a patent thicket/anti-commons, which is more likely to hinder the development of genetic technologies, as studies have shown that scientists tend to avoid working in areas/compounds that are heavily covered by patents. *Id.* at 72.

However, the patent eligibility of subject matter should be determined under the statute in a non-discriminatory manner. The availability of private or public funding or the lack of available funding should not act as a non-statutory threshold for whether compositions are patent-eligible subject matter under the Patent Act. Likewise, the availability, or not, of non-patent incentives

cannot properly distinguish a patent-eligible composition of matter under the Act from a patent-ineligible composition. Such ill-defined concepts, not rooted in section 101, should not be considered by the courts in assessing patent eligibility under section 101.

The assumptions underlying considerations of whether there are adequate incentives without patents, or whether the existence of patents creates a thicket/anti-commons, are clearly the subject of debate. This debate was noted by the *Myriad* court, which determined that the debate could not be properly resolved by the court. *Myriad* at 83. This debate is also not unique to isolated DNA. It is the same debate with other new technologies and goes to the heart of the patent system. Yet, each time this debate has reached the Supreme Court, the court has been consistent in providing an expansive definition of section 101. *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010).

There can be little debate that patents claiming isolated DNA have largely been the basis for the biotechnology industry, which provides a host of life altering innovation including therapeutic proteins, gene therapy, vaccinations, genetic testing, improved agriculture, and other future applications many of which are unforeseen today. The exclusion of isolated DNA as patent-eligible subject matter would dramatically impact the investment into biotechnology and slow, if not disable, future innovation. The U.S.patent system is a core driver of innovation in all technologies and that system must serve without discrimination against any one technology. Accordingly, the ABA should continue to advocate for an expansive scope of section 101 applicable to all technologies, including isolated DNA compounds.

Respectfully submitted,

Marylee Jenkins, Chair
Section of Intellectual Property Law
February 2011

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GENERAL INFORMATION FORM

Submitting Entity: Section of Intellectual Property Law

Submitted by: Marylee Jenkins, Section Chair

1. Summary of Resolution

The resolution calls for the American Bar Association to adopt policy supporting evaluation of inventions relating to DNA technology by the same uniform standards that apply in evaluating patent eligibility of inventions relating to other natural materials or subject matter, and to oppose new exclusionary rules for DNA that go beyond the long-standing exceptions to patent eligibility recognized by the U.S. Supreme Court.

2. Approval by Submitting Entity

The Section Council approved the resolution on October 12, 2010.

3. Has This or a Similar Recommendation Been Submitted to the House of Delegates or Board of Governors Previously?

See paragraph 4 that follows.

4. What Existing Association Policies are Relevant to This Recommendation and Would They be Affected by its Adoption?

At the 2009 Annual Meeting, the House of Delegates adopted policy opposing unduly restrictive judicial interpretation of patent eligibility under U.S. patent law. Although different subject matter is involved in this resolution, the same issues of patent eligibility are presented. The policy recommended in this resolution is consistent with that of the 2009 resolution, and that policy would not be affected by this resolution.

5. What Urgency Exists Which Requires Action at This Meeting of the House?

Issues concerning the proper treatment of DNA technology are being considered by courts and by Congress. A federal appeals court is currently reviewing an appeal of a district court ruling that technology relating to isolated DNA is categorically ineligible for patenting, and review by the U.S. Supreme Court in the near future is a distinct possibility. Bills have been introduced in Congress to provide a statutory exclusion, and new legislative proposals could be introduced as soon as January, 2011, when the 112th Congress convenes.

6. Status of Matter

The status of the issue is discussed in the preceding paragraph.

7. Cost to the Association (both direct and indirect costs).

Adoption of the recommendations would not result in additional direct or indirect costs to the Association.

Disclosure of Interest

There are no known conflicts of interest with regard to this recommendation.

9. Referrals

This recommendation is being distributed to each of the Sections and Divisions and Standing Committees of the Association.

10. Contact Person (prior to meeting)

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11. Contact Persons (who will present the report to the House)

Donald R. Dunner (See item 10 above)

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EXECUTIVE SUMMARY

1. Summary of the Resolution

The resolution calls for the ABA to adopt policy supporting evaluation of inventions relating to DNA technology by the same uniform standards that apply in evaluating patent eligibility of inventions relating to other natural materials or subject matter, and to oppose new exclusionary rules for DNA that go beyond the long-standing exceptions to patent eligibility recognized by the U.S. Supreme Court.

2. Summary of the Issue that the Resolution Addresses

For more than two decades, patents on biotechnological inventions utilizing DNA technology have been issued by the United States and upheld in the courts. However, challenges to the eligibility of any and all DNA technology to be considered for patenting are continuing, if not increasing. One federal court has ruled that such technology is categorically ineligible, and that ruling is under appeal in the U.S. Court of Appeals for the Federal Circuit. Further review by the full *en banc* Federal Circuit and/or appeal to the Supreme Court of the United States are distinct possibilities.

Congress has also shown interest in the issue, as demonstrated by the introduction of legislation that would provide a statutory ban on patenting of DNA technology.

3. Please Explain How the Proposed Policy Position will Address the Issue

The policy would provide authority for the ABA to express views to any appropriate and relevant policy-making body (judicial, legislative, or executive) in support of continued evaluation of patent eligibility of DNA inventions by the same standards that apply to other subject matter, and in opposition to expanding exclusions from patent eligibility beyond the narrow exceptions established by the Supreme Court, such expansion to result in the categorical exclusion from patent eligibility of DNA based inventions.

4. Summary of Minority Views

None known at this time.