No. 12-398

In the Supreme Court of the United States

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, ET AL,
PETITIONERS

v.

MYRIAD GENETICS, INC., ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF OF THE AMERICAN BAR ASSOCIATION *AS AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Are human genes patentable?

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INTEREST OF THE *AMICUS CURIAE*[1]

The American Bar Association ("ABA") respectfully submits this brief in support of respondents Myriad Genetics, Inc. and the University of Utah Research Foundation. The ABA urges the Court to hold that isolated DNA compounds, corresponding to genes from humans or any other organisms that do not occur in nature in their isolated form ("Isolated DNA Compounds"), are not *per se* disqualified from patent-eligibility under 35 U.S.C. § 101. Further, the ABA also urges that determinations as to the patentability of Isolated DNA Compounds should continue to be made on a claim-by-claim basis consistent with the common-law tradition of incremental determination of patent-eligibility, and that the determination of patent-eligibility is distinct from, and should be made independently of, any considerations of the other requirements for obtaining a patent.

The ABA is the largest voluntary professional membership organization and the leading organization of legal professionals in the United States. Its nearly 400,000 members come from 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. They also include judges, legislators, law professors, law

[1] No counsel for a party authored this brief in whole or part, and no counsel or party made a monetary contribution to fund the preparation or submission of this brief. No person other than the *amicus curiae*, their members, and their counsel made any monetary contribution to its preparation and submission. The parties have consented to this filing.

students, and nonlawyer "associates" in related fields.[2]

The ABA's Section of Intellectual Property Law ("IPL Section") is the world's largest organization of intellectual property professionals. Its approximately 25,000 members represent patent owners, accused infringers, individual inventors, large and small corporations, research institutions, and public and private colleges and universities 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 and takes an active role in the consideration of proposed legislation, administrative rule changes and international efforts. The Section also presents resolutions to the ABA House of Delegates for adoption as ABA policy. These policies then provide a basis for the preparation of ABA *amicus curiae* briefs, which are filed primarily in this Court and the Court of Appeals for the Federal Circuit.[3]

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[2] 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.

[3] Only recommendations adopted by vote of the ABA's House of Delegates, but not the accompanying reports, become ABA policy. The House of Delegates is composed of 560 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.americanbar.org/groups/leadership/delegates.html, and ABA amicus brief information, *available at* http://www.americanbar.org/amicus.

Through a process for articulating and adopting a consensus position of the diverse members of the legal profession working in this field, the IPL Section developed proposed recommendations regarding the proper disposition of this case. These resolutions were adopted by the ABA's House of Delegates and, with their accompanying reports, are set out in full in the Appendices as ABA Resolution 111 (policy adopted Feb. 4, 2011) and ABA Resolution 101A (policy adopted February 11, 2013).

These ABA policies support a methodology that allows for a measured, balanced approach to the determination of patent-eligible subject matter. They support 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 conclusion of legal professionals working in this field that the determination of patent-eligibility should continue to be developed incrementally, rather than through categorical exclusions that would unreasonably stifle innovation by undermining longstanding biotechnology industry expectations and needs.

SUMMARY OF ARGUMENT

The ABA submits that this Court should hold that Isolated DNA Compounds, corresponding to genes from humans or any other organisms that do not occur in nature in their isolated form, are eligible for patenting under 35 U.S.C. § 101. To hold otherwise would be a material change in this Court's approach to determining the patent-eligibility of new technologies and upset decades of reliance on this Court's precedent, the Patent and Trademark Office's longstanding practice to allow claims to such subject matter, and Congress's evident approval of that practice.

This Court's recent decision in *Mayo Collaborative Servs.* v. *Prometheus Labs., Inc.,* 132 S. Ct. 1289 (2012) ("*Mayo*") does not change the analysis of the question presented here. *Mayo* dealt with distinguishing between method claims directed to a law of nature or the application of a law of nature. Here, the sole question before the Court is whether Myriad's compositions are a human-made invention or a product of nature. Under this Court's applicable precedent, because Myriad's Isolated DNA Compounds are not found in nature, they are eligible for patenting.

Finally, the ABA also urges that the Court set aside considerations relating to whether the subject matter claimed by Myriad is novel, nonobvious or sufficiently described and enabled in determining the patent-eligibility of Myriad's claims. Subject matter eligibility is a separate and distinct inquiry from, and resolved independently of, the other statutory requirements and conditions for patentability.

ARGUMENT

I. Categorical Disqualification of Isolated DNA Compounds, Human or Otherwise, from Patent-Eligibility Would Be a Material Change in this Court's Approach to Determining Patent Eligibility and Would Undercut Reasonable Investment-Backed Expectations and Needs.

Isolated DNA Compounds, corresponding to genes from humans or any other organisms that do not occur in nature in their isolated form, should remain patent-eligible subject matter. A *per se* or categorical disqualification of such claims would be a material change in this Court's traditional approach to determining patent-eligibility and would unjustifiably undercut significant investment-backed expectations and needs of the biotechnology industry, which has reasonably relied on longstanding precedents of this Court and others. The ABA therefore endorses the Court's continued application of its traditional incremental, common-law approach to determining the patent-eligibility of claimed subject matter.

Section 101 makes eligible for patent "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. This Court has repeatedly recognized the "extremely broad" scope of eligible subject matter under § 101. *J.E.M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.,* 534 U.S. 124, 130 (2001) (citing *Diamond* v. *Chakrabarty*, 447 U.S. 303, 308 (1980)). "In choosing such expansive terms * * * modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws

would be given wide scope." *Bilski* v. *Kappos*, 130 S. Ct. 3218, 3225 (2010) (quoting *Chakrabarty*, 447 U.S. at 308). Because "[t]he subject-matter provisions of the patent law have been cast in broad terms," Congress need not "expressly authorize protection for new patentable subject matter," *J.E.M. Ag Supply*, 534 U.S. at 130-131 (citing *Chakrabarty*, 447 U.S. at 315), and the Court has recognized only "three specific exceptions" to the otherwise expansive language of § 101: "laws of nature, physical phenomena, and abstract ideas." *Bilski*, 130 S. Ct. at 3225 (quoting *Chakrabarty*, 447 U.S. at 309).

This Court has uniformly applied these principles incrementally to determine the patent eligibility of compositions and other subject matter; it has scrupulously avoided adopting "categorical rule[s] denying patent protection" in new, unforeseen, areas that "would frustrate the purposes of the patent law." *Bilski*, 130 S. Ct. at 3227 (quoting *Chakrabarty*, 447 U.S. at 315). For example, upon the advent of genetic engineering, the Court rejected efforts to categorically exclude living things from patent-eligibility and instead determined that claims directed to a genetically engineered bacterium were patent-eligible as directed to a "nonnaturally occurring manufacture or composition of matter." *Chakrabarty*, 447 U.S. at 309; see also *J.E.M. Ag Supply,* 534 U.S. at 133 (declining to exclude plants from patent-eligibility). More recently, in *Bilski*, the Court declined to adopt a categorical exclusion of "business methods" from § 101 "that might have wide-ranging and unforeseen impacts" on yet-to-be developed technology. *Bilksi*, 130 S. Ct. at 3227-3230. Instead, the Court resolved the case "narrowly" in view of its precedent prohibiting the patenting of abstract ideas. *Id.* at 3229. Likewise, the standards used to determine the

patent-eligibility of the Isolated DNA Compounds at issue here should be the same as those used to determine the patent-eligibility of other compositions derived from or related to natural materials. See *Chakrabarty*, 447 U.S. at 309-310. There is no basis in the language of § 101, or in the case law construing that provision, for treating Isolated DNA Compounds differently. Indeed, a departure from this Court's previously uniform approach to determining patent-eligibility would frustrate practitioners' ability to reliably advise clients on the patent-eligibility of new technologies. The ABA thus endorses this Court's continued reluctance to categorically exclude subject matter from patent-eligibility in favor of the determination of patent-eligibility under § 101 in an incremental manner.

The Court's traditional incremental approach to addressing patent-eligibility has the further benefit of retaining for Congress its role in determining the boundaries of patent law as new, unforeseen technologies emerge. "Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable." *Chakrabarty*, 447 U.S. at 316. Against that backdrop, this Court has recognized that the categorical exclusion of unforeseen, but otherwise patent-eligible, subject matter from § 101, is "a matter of high policy" best left to "the political branches of the Government." *Id.* at 317, see also *Bilski*, 130 S. Ct. at 3228, *J.E.M. Ag Supply*, 534 U.S. at 145-146; *Mayo,* 132 S. Ct. at 1305.

To date, those branches of the government have not excluded Isolated DNA Compounds from patent-eligibility. Indeed, a categorical rule excluding Isolated DNA Compounds from patent-eligibility

would reverse well over a decade of policy of the Patent and Trademark Office ("PTO") expressly allowing such claims. The PTO first issued claims relating to human genes in the early 1980s. Eric J. Rogers, *Can You Patent Genes? Yes and No*, 93 J. Pat. & Trademark Off. Soc'y 19 (2011). In 2001, relying in part on this Court's longstanding precedent, the PTO issued guidance reaffirming that claims directed to such compounds are eligible for patenting. See Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) (stating that isolated genes are eligible subject matter as compositions of matter not found in nature).

In the 30 years since the PTO began issuing claims directed to human genes, Congress has not expressed any disagreement with the PTO's policy of allowing claims to Isolated DNA Compounds. Congress is aware of these subject matter eligibility issues: While it has failed to pass legislation that would have excluded human genes or gene sequences from patent-eligibility, it recently enacted provisions excluding claims directed to or encompassing a "human organism" and directing the PTO to study ways to provide genetic testing where patents on genes and genetic testing exist. Compare Life Patenting Moratorium Act of 1993, S. 387, 103d Cong. § 3 (1993), with Leahy-Smith America Invents Act, Pub. L. No. 112-29, §§ 27, 33, 125 Stat. 284, 338-340 (2011). Consequently, the Court should "decline to narrow the reach of § 101 where Congress has given no indication that it intends this result." *J.E.M. Ag Supply*, 534 U.S. at 144-146 (declining to exclude plants from patent eligibility where, among other things the PTO had issued utility patents for plants for 16 years without action from Congress); cf. *Microsoft Corp.* v. *i4i Ltd. P'ship*, 131 S. Ct. 2238,

2252 (2011) (where Congress has "allowed the Federal Circuit's * * * interpretation of § 282 [of the Patent Act] to stand," "[a]ny re-calibration of the standard of proof remains in its hands").

Moreover, the biotechnology industry has substantially relied on this Court's precedent—and more directly the PTO's policy—to seek and obtain 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., National Academies Press, 2006). There are many more such patents today. Those patents help protect the significant 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*, 30, 47 (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 & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 Managerial and Decision Econ. 469, 475 (2007) (estimating that the development costs for new biologic-based therapeutics to be in excess of one billion dollars for each approved molecule). Dramatic shifts in the scope of patentable subject matter would unfairly undercut these investments and upset the reasonable expectations and needs of inventors who have acted against the backdrop of long-standing precedent interpreting § 101 broadly and incrementally. See *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722,

739 (2002) ("[C]ourts must be cautious before adopting changes that disrupt the settled expectations of the investing community").

For these reasons, the ABA endorses this Court's traditional practice of incrementally developing its jurisprudence for determining patent-eligible subject matter on a claim-by-claim basis. That consistent approach allows practitioners to reliably advise clients on the patent-eligibility of new technologies in the context of a stable regulatory framework and avoids dramatic shifts in the definition of patent-eligible subject matter, such as a *per se* disqualification of Isolated DNA Compounds, which would upset reasonable investment-backed expectations and undercut innovation in the important field of biotechnology.

II. Under the Applicable Precedent, Isolated DNA Compounds Are Patent-Eligible Subject Matter Because They Are Not Products of Nature.

This Court granted the Association for Molecular Pathology's earlier petition and remanded for further consideration in light of the intervening decision in *Mayo*. See *Ass'n for Molecular Pathology* v. *Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012). On remand, the Federal Circuit correctly determined that *Chakrabarty*, not *Mayo,* controls the question of patent-eligibility for the composition claims at issue here. *Ass'n for Molecular Pathology* v. *U.S. Patent & Trademark Off.*, 689 F.3d 1303, 1325-1327 (Fed. Cir. 2012) ("*Myriad II*"). Under *Chakrabarty*, Isolated DNA Compounds are patent-eligible subject matter because they are not products of nature.

A. *Chakrabarty*, Not *Mayo*, Controls the Patent-Eligibility of Isolated DNA Compounds.

This Court's decision in *Mayo* requires no change to its earlier precedents governing the analysis of the patent-eligibility of compositions. 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. *Mayo*, 132 S. Ct. 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 of matter claims at issue here 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 composition 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 309-310; *id.* at 313 (noting from the legislative history of § 101 that "the relevant distinction was * * * between products of nature * * * and human-made inventions"). *Mayo* did not address this question, much less purport to change how such claims are analyzed for eligibility under § 101.

Nor does the analysis in *Mayo* inform the determination whether the claimed DNA compounds exist in nature or are human-made inventions.

Adding merely "conventional or obvious [pre]-solution activity" is ordinarily not "sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." *Mayo*, 132 S. Ct. at 1298 (quoting *Parker* v. *Flook*, 437 U.S. 584, 590 (1978) (alterations in *Mayo*)). But that inquiry is irrelevant to whether a composition is a product of nature. 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.

B. Isolated DNA Compounds Are Patent-Eligible Because They Are Not Products of Nature.

As the Federal Circuit recognized, the claimed Isolated DNA Compounds at issue in this case are human-made, "free-standing" molecules that are markedly different in character from anything found in nature. See *Myriad II*, 689 F.3d at 1328. Under this Court's applicable precedent, Isolated DNA Compounds—from humans or any other organisms—are therefore patent-eligible subject matter. *Chakrabarty*, 447 U.S. at 309-310.

To be sure, some of the compositions claimed by Myriad correspond to portions of larger compounds that are found in nature—human chromosomes—but the claimed compositions meaningfully differ from those naturally occurring compounds. Most significantly, the Isolated DNA Compounds claimed by Myriad are distinct chemical structures that correspond to only a small fraction of a chromosome[4]

[4] A chromosome might include lengths of over a hundred million base pairs of DNA, while the *BRCA1* and *BRCA2* genes at issue here are only approximately 80,000 base pairs long.

and are created by human intervention, either by synthesis *de novo* or by cleavage from a chromosome. See *Myriad II*, 689 F.3d at 1328; Utility Examination Guidelines, 66 Fed. Reg. at 1093 ("The [human] body does not contain the patented, isolated and purified gene because genes in the body are not in the patented, isolated and purified form."). Although petitioners liken this to "isolating" a kidney from a human body or "isolating" leaves from trees, Pet'r Br. at 2, an intact organ or a leaf is not a distinct composition of matter or article of manufacture in the way molecules synthesized or cleaved from a chromosome are. The molecules, which are distinct chemical compositions that have been identified, located, and extracted (or synthesized) through human ingenuity, meaningfully differ from what occurs in nature in a way that an "isolated" intact organ or leaf simply does not.

More specifically, as distinct chemical structures, Isolated DNA Compounds have utility beyond that of their related, naturally occurring molecules. Petitioners' brief describes the unique usefulness of Myriad's claimed Isolated DNA Compounds for, among other things, genetic testing, therapeutics, biomedical devices and sequencing technologies. See, *e.g.*, Pet'r Br. at 44-45. This Court has relied on such acquired utility to distinguish between claims drawn merely to some patent-ineligible "handiwork of nature" and claims drawn to a patent-eligible manufacture or composition. Compare *Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 131-132 (1948), with *Chakrabarty*, 447 U.S. at 309-310.

Myriad II, 689 F.3d at 1328.

Other of Myriad's claimed compositions do not even correspond to any naturally occurring DNA molecule. cDNA molecules lack certain non-coding sequences, termed introns, that are found in the naturally occurring chromosome, and thus, relative to a chromosome, cDNA molecules have been further edited and recombined to create a molecule that does not exist in nature. See *Myriad II,* 689 F.3d at 1329. Accordingly, claims to such Isolated DNA Compounds do not implicate any naturally occurring DNA molecule found in any living organism, human or otherwise.

Claims to Isolated DNA Compounds are thus "not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character and use.'" *Chakrabarty*, 447 U.S. at 309-310 (quoting *Hartranft* v. *Wiegmann*, 121 U.S. 609, 615 (1887)). And under this Court's longstanding precedent, such subject matter is patent-eligible under § 101. *Id.*

C. Claims to Isolated DNA Compounds Neither Claim Nor "Tie Up" Laws of Nature.

Even if the biological information communicated by the sequence of nucleotides in an Isolated DNA Compound could be considered a "law of nature," that Isolated DNA Compound is nonetheless eligible for patent protection. "While a scientific truth * * * is not [a] patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be." *Mackay Radio & Tel. Co.* v. *Radio Corp. of Am.*, 306 U.S. 86, 94 (1939). Unlike the process claimed in *Mayo*, which "amount[ed] to nothing

significantly more than an instruction to doctors to apply the applicable laws [of nature] when treating their patients," a claim to an Isolated DNA Compound does not monopolize or otherwise prohibit the use of the underlying biological sequence information. *Mayo*, 132 S. Ct. at 1297-1298. Instead, such composition claims prevent the use of only their physical embodiments, *i.e.*, the non-naturally occurring, tangible compositions within the scope of the claims. 35 U.S.C. § 271 (precluding, among other things, making or using the "patented invention"); see also *Microsoft Corp.* v. *AT & T Corp.*, 550 U.S. 437, 449 (2007) (distinguishing between abstract ideas and physical embodiments). The intangible sequence information is therefore not "tied up" by the composition claim. See *Mahn* v. *Harwood*, 112 U.S. 354, 361 (1884) ("The public has the undoubted right to use, and it is to be presumed does use, what is not specifically claimed in the patent."). Indeed, Myriad's claims to "comparing" or "analyzing" the underlying sequence information were held patent-ineligible by the Federal Circuit. *Myriad II*, 689 F.3d at 1334-1335.

Thus, scientists are free to use the sequence information in Myriad's Isolated DNA Compounds, as well as the knowledge of a correlation between mutations in that sequence with the risk of developing breast cancer, to make further discoveries without making or using the claimed Isolated DNA Compounds. Indeed, the *BRCA1* and *BRCA2* cDNA sequences have been included in public biological sequence databases for nearly two decades. See GenBank Accession No. U14680 (*BRCA1*), *available at* http://www.ncbi.nlm.nih.gov/nuccore/555931 and GenBank Accession No. U43746 (*BRCA2*), *available at* http://www.ncbi.nlm.nih.gov/nuccore/U43746; see

also U.S. Pat. No. 5,747,282, col. 53, ll. 7-9. Those databases are used hundreds of thousands of times a day by scientists around the world to analyze and compare biological sequence information. See, *e.g.*, Dennis A. Benson *et al.*, *GenBank*, 41 Nucleic Acids Research D36 (2013); *Database Resources of the National Center for Biotechnology Information*, 41 Nucleic Acids Research D8 (2013); James Ostell, *Databases of Discovery*, 3 ACM Queue 40 (2005). Such computer-based analysis of biological sequence information has revolutionized life sciences research, underpinning a broad range of inquiry, from the study of the evolutionary relationships among organisms to the identification of the function of new genetic sequences. See, *e.g.*, Minoru Kanehisa & Peer Bork, *Bioinformatics in the Post-Sequence Era,* 33 Nature Genetics 305 (2003); Kenneth H. Wolfe & Wen-Hsiung Li, *Molecular Evolution Meets the Genomics Revolution*, 33 Nature Genetics 255 (2003). And with respect to the diagnostic screening of the BRCA genes at issue here, once a BRCA sequence has been determined, that sequence information may be freely analyzed for mutations correlating with a risk for developing cancer. *Myriad II*, 689 F.3d at 1334-1335. Composition claims to Isolated DNA Compounds therefore do not "tie up" the use of biological sequence information in a way that would "inhibit future innovation premised upon" the biological sequence information in the patent. *Mayo*, 132 S. Ct. at 1301-1302.

That Myriad's composition claims might, given the current state of the art,[5] effectively grant it exclusive

[5] Conventional sequencing approaches for a single gene typically involve making or using "isolated" versions of the gene, implicating patent claims to the corresponding Isolated DNA

rights to the determination of the particular sequence of an individual's BRCA genes—even when that information might have medical significance—reflects the normal operation of patent law, granting the inventor of a human-made molecule certain temporary rights in an effort to encourage the useful arts. Patents are routinely awarded for life-saving technologies such as pharmaceuticals and medical devices. Whether the practical implications of patent protection warrant making an exception to ordinary rules in an emerging area of technology presents a quintessential question of policy that this Court has traditionally left for Congress. And with respect to subject matter eligibility in particular, this Court has consistently refrained from categorically excluding subject matter from § 101 on the basis of such policy considerations. See *supra* at 6-7. Cf. *Gottschalk* v. *Benson*, 409 U.S. 63, 72-73 (1972) (declining to alter the bounds of § 101 where "[t]he technological problems tendered in the many briefs before us indicate to us that considered action by the Congress is needed."); *Mayo,* 132 S. Ct. at 1304-1305.

Compound. In the past several years, however, new sequencing approaches have been developed that avoid using Isolated DNA Compounds. Employing those approaches, one might be able to sequence a BRCA gene and analyze it without running afoul of any of Myriad's patent claims. See Christopher M. Holman, *Debunking the Myth that Whole-Genome Sequencing Infringes Thousands of Gene Patents,* 30 Nature Biotechnology 240, 241 (2012); W. Nicholson Price II, *Unblocked Future: Why Gene Patents Won't Hinder Whole-Genome Sequencing and Personalized Medicine*, 33 Cardozo L. Rev. 1601, 1606 (2012).

III. Subject Matter Eligibility under 35 U.S.C. § 101 Is Separate and Distinct from the Other Requirements for Patentability.

Finally, the analysis of whether claimed subject matter is *eligible* for patent protection should not import any of the additional, separate requirements for the issuance of a patent. In *Mayo*, the Court remarked, in dicta, that the patent-eligibility inquiry of § 101 "might sometimes overlap" with the novelty inquiry of § 102. 132 S. Ct. at 1304. That commentary sparked concern among practitioners that the Court was departing from its longstanding precedent that the other requirements for patentability, *e.g.*, novelty and obviousness, are not relevant to patent-eligibility analysis. See, *e.g.*, Jeffrey Fox, *Industry Reels as* Prometheus *Falls and* Myriad *Faces Further Reviews*, 30 Nature Biotechnology 373 (2012); Tamsen Valoir, Mayo v. Prometheus*: Natural Law or Mental Step,* 24 Intell. Prop. & Tech. L. J. 3, 5 (2012).

As noted above, *Mayo* dealt with whether the method claims there constituted a patent-eligible application of a law of nature. The Court consequently examined whether the claimed method added anything more than insignificant, "conventional or obvious" pre-solution activity "sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." *Mayo*, 132 S. Ct. at 1298. *Mayo* did not, therefore, import novelty into its patent-eligibility analysis generally.

Indeed, this Court has previously explained that patent-eligibility under § 101 is separate and distinct from the successive requirements for patentability in

the Patent Statute. Section 101 "is only a threshold test" and patent-eligible subject matter "must also satisfy 'the conditions and requirements of this title' * * * includ[ing] that the invention be novel, see § 102, nonobvious, see § 103, and fully and particularly described, see § 112." *Bilski*, 130 S. Ct. at 3225 (quoting 35 U.S.C. § 101); see also *Flook*, 437 U.S. at 593 ("The obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious."). Further, notwithstanding the words "new and useful" in § 101, novelty is not "an appropriate consideration under § 101" and "*is of no relevance* in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter." *Diamond* v. *Diehr*, 450 U.S. 175, 188-189 (1981) (emphasis added); *id.* at 190 ("The question therefore of whether a particular invention is novel is wholly apart from whether the invention falls into a category of statutory subject matter.") (internal quotation marks omitted); *Flook*, 437 U.S. at 588 (explaining that subject matter eligibility under § 101 "does not involve the familiar issues of novelty and obviousness"); see also *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. 470, 483 (1974) ("no patent is available for a discovery, however useful, novel, and nonobvious, unless it falls within one of the express categories of patentable subject matter of 35 U.S.C. § 101").

That subject matter eligibility is separate and distinct from novelty and non-obviousness follows from the fact that the requirements are set out as separate and distinct statutory provisions. This "statutory scheme" establishes, in the words of Judge Giles S. Rich, one of the drafters of the Patent Act of 1952, "three doors" that must be opened by inventors.

Section 101 is the "first door" and inquires "[w]hat kind of invention or discovery" the inventor seeks to patent. *In re Bergy*, 596 F.2d 952, 960 (C.C.P.A. 1979) (Rich, J.), *aff'd, sub nom. Diamond* v. *Chakrabarty*, 447 U.S. 303 (1980). Only if the invention "falls into any one of the named categories" in § 101, is the inventor "allowed to pass through to the second door," novelty, and then onto the "third door," non-obviousness. *Id.* at 960-961.

The ABA thus endorses the principle that the inquiry into subject matter eligibility under § 101 is a separate and distinct requirement from, and should be resolved independently of, the additional conditions and requirements for obtaining a patent set out in §§ 102, 103 and 112. Consequently, with respect to Myriad's claims here, petitioners' assertion that the techniques Myriad used to create its claimed Isolated DNA Compounds were well-known, routine or conventional at the time of invention, Pet'r Br. at 37, is irrelevant to whether that subject matter is patent-eligible. Likewise irrelevant are petitioners' assertions that the scope of Myriad's claims encompass subject matter beyond what Myriad invented and described in its application, Pet'r Br. at 11-17, 37. Those concerns may implicate other statutory conditions and requirements for the issuance of a patent, specifically, that the invention be novel (§ 102); nonobvious (§ 103); and fully described and enabled (§ 112). But the only question here is whether Myriad's claimed compositions are "products of nature" or "humanmade inventions." *J.E.M. Ag Supply*, 534 U.S. at 134 (quoting *Chakrabarty*, 447 U.S. at 313).

CONCLUSION

For the reasons set out above, the ABA respectfully requests that this Court hold that Isolated DNA Compounds, including those corresponding to genes from humans or other organisms, are patent-eligible subject matter. The judgment should be affirmed.

Respectfully submitted.

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MARCH 14, 2013

APPENDIX A

AMERICAN BAR ASSOCIATION

ADOPTED BY THE HOUSE OF DELEGATES

FEBRUARY 14, 2011

RESOLUTION 111

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

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[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.

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 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 en-

sure 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 mechani-

cal 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 crite-

ria 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 section 102. 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 includ-

ing "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

APPENDIX B

AMERICAN BAR ASSOCIATION

ADOPTED BY THE HOUSE OF DELEGATES

FEBRUARY 11, 2013

RESOLUTION 101A

RESOLVED, That the American Bar Association supports the principle that laws of nature, physical phenomena, and abstract ideas are not eligible for patenting as a process under 35 U.S.C. § 101, even if they had been previously unknown or unrecognized;

FURTHER RESOLVED, That the American Bar Association supports the principle that a process meets the requirements of Section 101 where—

(1) the claimed process as a whole, other than a mental process, is limited to a specific application of a law of nature, natural phenomenon, or abstract idea; or

(2) the claimed process requires or involves a transformation of matter.

FURTHER RESOLVED, That the American Bar Association supports the principle that the inquiry into subject matter eligibility for patenting under 35 U.S.C. §§ 101 is a separate and distinct requirement for patent eligibility which should be resolved independently from the conditions of patentability under Sections 102 and 103, and the requirements for obtaining a valid patent under Section 112;

FURTHER RESOLVED, That the American Bar Association opposes application of a patent eligibility test under Section 101 that imports into the patent eligibility analysis the criteria or analysis for determining patentability addressed by Sections 102 and 103, as well as the criteria required for obtaining a valid patent under Section 112.

REPORT

The Section of Intellectual Property Law requests that the House of Delegates approve this Resolution, which would support an Association *amicus curiae* brief in the U.S. Supreme Court in the case of *Association for Molecular Pathology v. Myriad Genetics*, Inc., Case No. 12-398. On September 24, 2012, the petitioners filed a petition for a writ of certiorari with the Supreme Court to review the decision of the U.S. Court of Appeals for the Federal Circuit (*Ass'n of Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012) (*Myriad II*)). On November 30, the Supreme Court granted the petition for certiorari. This report cannot be considered by the House of Delegates at a time later than the 2013 Midyear Meeting because the deadline for filing an amicus brief on the merits in the Supreme Court will be reached before the next meeting of the House of Delegates.

Introduction and Background

The resolution deals with an issue of fundamental importance to the patent bar and the public in general, namely, the interpretation of Section 101 of the patent statute (35 U.S.C. §§ 101). Section 101 defines

the types of inventions and discoveries that are eligible for patent protection. The *Myriad* case is currently under petition for a writ of certiorari by the Association for Molecular Pathology et al.

In 2010, the district court granted summary judgment for the plaintiffs, inter alia, holding one method claim from U.S. Patent No. 5,747,282 [hereinafter "Claim 20"] not patent eligible under 35 U.S.C. § 101 on grounds that certain steps claimed a basic scientific principle and other steps which were transformative were merely preparatory data gathering. *Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Off.*, 702 F. Supp. 2d 181, 237 (S.D.N.Y. 2010). In 2011, the Federal Circuit reversed the district court's summary judgment, finding Claim 20 patent eligible under Section 101 because it contained a transformative step ("growing transformed cells"). *Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Off.*, 653 F.3d 1329, 1357-58 (Fed. Cir. 2011) [hereinafter "*Myriad I*"]. Following its decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012) [hereinafter "*Mayo*"], the Supreme Court granted certiorari as requested by the Association for Molecular Pathology et al., vacated *Myriad I*, and remanded to the Federal Circuit for reconsideration under *Mayo*. 132 S. Ct. 1794 (2012). The Federal Circuit again held Claim 20 patent eligible because it comprises a step of "growing host cells transformed with an altered BRCA1 gene"—"altering a cell to include a foreign gene, resulting in a man-made, transformed cell with enhanced function and utility." *Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Off.*, 689 F.3d 1303, 1336 (Fed. Cir. 2012) (emphasis in original) [hereinafter "*Myriad II*"].

The ultimate question of patentability of the invention defined by Claim 20 is not before the Court; the question before the Court relates specifically to patent eligibility of the claim. The Federal Circuit concluded that Claim 20 "applies certain steps to transformed cells that . . . are a product of man, not of nature." Myriad II, 689 F.3d at 1336. The Section of Intellectual Property recommends support of the Federal Circuit's position that respondent's claims include steps directed to transformed, man-made subject matter and are therefore patent-eligible subject matter.

The Section of Intellectual Property Law recommends that the Association support a position that a claimed process is patent eligible under Section 101 where the claimed process as a whole, other than a mental process, is limited to a specific application of a law of nature, a natural phenomenon, or an abstract idea, or alternatively where the claimed process requires or involves a transformation of matter.

The Section further recommends that the determination of subject matter eligibility for patenting under Section 101 should be resolved separately and independently from other conditions and requirements for determining patentability under Sections 102, 103, as well as criteria required for obtaining a valid patent under Section 112. Thus, the Section recommends opposing a subject matter eligibility analysis which imports the requirements of any of Sections 102, 103, or 112 into the requirements for Section 101.

Claim 20 of the Myriad patent reads as follows:

> 20. A method for screening potential cancer therapeutics which comprises:
>
> 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.

The method defined by this claim involves screening a compound to determine its potential as a cancer therapeutic by growing host cells transformed with a man-made altered breast cancer gene in the presence and absence of the compound and comparing the growth rate. The petitioner argues that Claim 20 "patents the basic scientific process of observing the naturally-occurring growth rate of a cell with a BRCA1 mutation" and does not specify any inventive steps, tools, or compound. Pet. for Cert., p. 8. Thus, according to the petitioner, Claim 20 is similar to the claims which were held patent ineligible in *Mayo*, as both Claim 20 and the claims in *Mayo* "involve[d] examining a . . . cell's natural reaction to any potential drug." Pet. for Cert., p. 31. The petitioner contends that the Federal Circuit erred when it found that Claim 20 relates to measuring how the drug affects a

transformed call as opposed to the patient's body, thereby distinguishing the two types of claims and finding *Mayo* irrelevant to Claim 20's eligibility. The petitioner argues that the distinction is incorrect because Claim 20 "does not require that the cell be transformed by the patent holder." Pet. for Cert., p. 32. Comparing a compound's effect on cell growth is conventional and thus not patent eligible.

The petition for certiorari filed in this case stated the questions presented by the appeal as follows:

> Many patients seek genetic testing to see if they have mutations in their genes that are associated with a significantly increased risk of breast or ovarian cancer. Respondent Myriad Genetics obtained patents on two human genes that correlate to this risk, known as BRCA1 and BRCA2. These patents claim every naturally-occurring version of those genes, including mutations, on the theory that Myriad invented something patent eligible simply by removing ("isolating") the genes from the body. Petitioners are primarily medical professionals who regularly use routine, conventional genetic testing methods to examine genes, but are prohibited from examining the human genes that Myriad claims to own. This case therefore presents the following question:
>
> 1. Are human genes patentable?
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> 2. Did the court of appeals err in upholding a method claim by Myriad that is irreconcilable with this Court's ruling in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)?

> 3. Did the court of appeals err in adopting a new and inflexible rule, contrary to normal standing rules and this Court's decision in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), that petitioners who have been indisputably deterred by Myriad's "active enforcement" of its patent rights nonetheless lack standing to challenge those patents absent evidence that they have been personally threatened with an infringement action?

The November 30 order of the Supreme Court granted certiorari only to Question 1. The policy proposed in the first, third, and fourth paragraphs of this resolution is particularly applicable to Question 1. Given the breadth of Question 1 and the interrelationship of composition of matter claims and process or method claims in circumstances such as those present in the *Myriad* litigation, the Supreme Court's disposition of the case may inform the patent-eligibility of such process claims generally and may also impact the patent-eligibility of Claim 20. The policy proposed in this resolution would also be applicable in any future litigation or legislative reform involving the same issues.

The petitioner's primary argument is that, if valid, Claim 20 would preempt researchers from using this technology to find cancer treatments, and therefore is contrary to Supreme Court precedent.

The Federal Circuit interpreted Claim 20 to comprise a transformative step—growing transformed cells. The Section of Intellectual Property Law believes that the claims define patent eligible subject matter. Contrary to petitioner's argument, the method defined by claim 20, as construed by the Federal

Circuit, when considered as a whole, is not a law of nature, a natural phenomenon, or an abstract idea—subject matter which the Supreme Court has held are the only limitations on the scope of patent eligible subject matter under Section 101. *Bilski*, 130 S. Ct. at 3225. Instead, Claim 20 requires a transformative step, which does not fall within any of the three categories mentioned above as the only limitations on the scope of patent eligible subject matter under Section 101. The Section recommends that the Association take no position on whether Claim 20 complies with the other patentability criteria under the statute, namely Sections 102, 103, and 112. Patent eligibility for such methods is important to incentivize investment into the research and development.

The Court of Appeals Decisions

In its July 2011 decision, the Federal Circuit reversed the district court's summary judgment that Claim 20 was not patent eligible under Section 101. *Myriad I*, 653 F.3d at 1357-58. To determine patent eligibility, the Myriad court began with the machine-or-transformation test set forth in its decision in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), *aff'd*, *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). Under that test, "A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." *Id.* at 954. The Supreme Court later clarified that the machine-or-transformation test is not the sole test for patent eligibility, but may be an important and useful clue. *Bilski*, 130 S. Ct. at 3221.

According to *Myriad I*, the first step of Claim 20 was a transformative growing of cells, a step which

caused a physical manipulation of the cells. The second step, determining the growth rate of the cells, was also transformative because it, too, required physical manipulation of the cells. In that step, "determining" referred to an assay or physical test which measured the quantity of cells. Furthermore, the transformative steps were not extra-solution activities or merely data gathering steps, but instead, those steps were found to be central to the goal of the process. The court also reviewed whether the claims fell into the prohibited categories, determining that the claim was not "so 'manifestly abstract' as to claim only a scientific principle, and not a patent-eligible process." *Prometheus*, 628 F.3d at 1358 (citing *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 869 (Fed. Cir. 2010). Thus, the court held that Claim 20 claimed patentable subject matter under Section 101.

Following the decision in *Myriad I*, the Association for Molecular Pathology et al. filed a petition for certiorari with the Supreme Court.

In March 2012, while the *Myriad I* petition for certiorari was pending, the Supreme Court issued its decision in *Mayo*. In that decision, the Supreme Court reiterated its earlier statement in *In re Bilski* that the Federal Circuit's "machine or transformation" test, while providing a valuable clue in determining whether a patent claim is directed to patent-eligible subject matter, is not the sole test for Section 101 compliance. *Mayo*, 132 S. Ct. 1289, 1296 (citing *In re Bilski*, 130 S. Ct. 3218, 3221 (2010)).

The claims in *Mayo* dealt with a process for optimizing the therapeutic efficacy of a method for treating an immune-mediated gastrointestinal disorder,

such as Crohn's disease. A representative claim of the Prometheus patent reads as follows:

> A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
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> (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
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> (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,
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> wherein the level of 6-thioguanine less than about 230 pmol per 8 x 10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and
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> wherein the level of 6-thioguanine greater than about 400 pmol per 8 x 10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

In general, the method defined by this claim involved the administration of a pro-drug, such as a 6-mercaptopurine, to a patient suffering from immune-mediated gastrointestinal disorders. According to the patent, the pro-drug is metabolized in the human body to certain metabolites, such as 6-thioguanine. The patent indicated that patients treated with these types of drugs sometimes experienced toxic side effects if the dosage were too high or lack of efficacy if the dosage were too low. To solve that problem, the patent described a process that involved administer-

ing the pro-drug, determining the level of the metabolite in the bloodstream and comparing the metabolite blood levels to certain established minimum and maximum values, such that the dosage could be optimized to ensure therapeutic efficacy with minimal side effects.

Similar to *Myriad I*, the Federal Circuit had held that the *Mayo* claims required transformative steps—administering and determining. The Supreme Court disagreed. Finding the claims patent ineligible, the Court explained:

> First, the "administering" step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs. That audience is a pre-existing audience; doctors used thiopurine drugs to treat patients suffering from autoimmune disorders long before anyone asserted these claims. In any event, the "prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.'" *Bilski*, supra, at ___, 130 S. Ct. 3218, 3225 [2010] (quoting *Diehr*, 450 U.S., at 191-92, 101 S. Ct. 1048).
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> Second, the "wherein" clauses simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient. That is to say, these clauses tell the relevant audience about the laws while trusting them to use those laws appropriately where they are relevant to their decision making (rather like Einstein telling linear accelerator operators

about his basic law and then trusting them to use it where relevant).

Third, the "determining" step tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor or the laboratory wishes to use. As the patents state, methods for determining metabolite levels were well known in the art. '623 patent, col. 9, ll. 12-65, 2 App. 11. Indeed, scientists routinely measured metabolites as part of their investigations into the relationships between metabolite levels and efficacy and toxicity of thiopurine compounds. '623 patent, col. 8, ll. 37-40, id., at 10. Thus, this step tells doctors to engage in well understood, routine, conventional activity previously engaged in by scientists who work in the field. Purely "conventional or obvious" "[pre]solution activity" is normally not sufficient to transform an unpatentable law of nature into a patent eligible application of such a law. *Flook*, 437 U.S., at 590, 98 S. Ct. 2522; *see also Bilski*, 561 U. S., at ___, 130 S. Ct. 3218, 3225 ("[T]he prohibition against patenting abstract ideas 'cannot be circumvented by' . . . adding 'insignificant postsolution activity'" (quoting *Diehr*, *supra*, at 191-192, 101 S. Ct. 1048)).

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[T]he claims inform a relevant audience about certain laws of nature; any additional steps consist of well understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant be-

> yond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.

Mayo, 132 S. Ct. at 1297-98 (parallel citations omitted).

Following its decision in Mayo, the Supreme Court granted certiorari in *Myriad I*, and summarily vacated and remanded the decision, with instructions that the Federal Circuit reconsider its decision in light of the Supreme Court's decision in Mayo. On August 16, 2012, the Federal Circuit issued its decision in *Myriad II*, again finding Claim 20 to be drawn to patent eligible subject matter.

The Federal Circuit again found Claim 20 patent eligible under Section 101 because it comprises a step of "growing host cells transformed with an altered BRCA1 gene"—"altering a cell to include a foreign gene, resulting in a man-made, transformed cell with enhanced function and utility." *Myriad II*, 689 F.3d at 1336. Comparing Claim 20 to *Mayo*, the Federal Circuit stated:

> The Court, in its evaluation of the *Mayo* method claims, found that the additional steps of those claims were not sufficient to "transform" the nature of the claims from mere expression of natural laws to patent-eligible subject matter. By definition, however, performing operations, even known types of steps, on, or to create, novel, *i.e.*, transformed subject matter is the stuff of which most process or method invention consists. All chemical processes, for

> example, consist of hydrolyzing, hydrogenating, reacting, etc. In situations where the objects or results of such steps are novel and nonobvious, they should be patent-eligible. It is rare that a new reaction or method is invented; much process activity is to make new compounds or products using established processes. Thus, once one has determined that a claimed composition of matter is patent-eligible subject matter, applying various known types of procedures to it is not merely applying conventional steps to a law of nature. The transformed, man-made nature of the underlying subject matter in claim 20 makes the claim patent-eligible. The fact that the claim also includes the steps of determining the cells' growth rates and comparing growth rates does not change the fact that the claim is based on a man-made, non-naturally occurring transformed cell—patent-eligible subject matter.

Id. at 1336 (emphasis added).

Additionally, the Federal Circuit held that Claim 20 does not preempt all methods for determining the therapeutic effect of a potential compound. Instead, it is specifically related to certain host cells transformed with a certain gene. Thus, the court found Claim 20 to be patent eligible subject matter under Section 101. *Id*. at 1337.

Inventions Should Not Be Denied Patent Eligibility Under Section 101 Where the Claimed Process Is Limited to a Specific Application of a Law of Nature, Natural Phenomenon, or Abstract Idea, or Where the Claimed Process Requires or Involves a Transformation of Matter.

As the Supreme Court held in *Bilski*, a broad reading of Section 101 is mandated by both the expansive text of the statute and Supreme Court precedent. The Supreme Court's precedents provide three specific exceptions to the broad patent-eligibility principles of Section 101: laws of nature, natural phenomena, and abstract ideas. The Supreme Court has held that "these exceptions have defined the reach of the statute as a matter of statutory stare decisis going back 150 years." *Bilski*, 130 S. Ct. at 3225 (citation omitted).

A broad reading of Section 101 is also supported by the fact that "[t]he § 101 patent-eligibility inquiry is only a threshold test." *Bilski*, 130 S. Ct. at 3225; see also 35 U.S.C. § 101 (a claim drawn to patent eligible subject matter is entitled to a patent only "subject to the conditions and requirements of this title"). Thus, Section 101 is a coarse filter, with more rigorous patentability analysis required by 35 U.S.C. §§ 102 (novelty) and 103 (non-obviousness), and conditions for a valid patent under § 112 (adequate written description and enablement support, best mode disclosure and definiteness of claim language).

The petitioner challenges the claim at issue here by arguing that Claim 20, like the claims held by the Supreme Court to be patent ineligible subject matter in *Mayo*, involves examining the natural reaction of a patient's cell to a potential drug, broadly preempting the use of the process to screen any potential cancer therapeutic. The Federal Circuit rejected this argument and held that Claim 20 applies certain process steps to transformed cells—cells which are man-made, not natural—and does not preempt all use of the process. The inclusion of a transformation of

matter removes the claim from the three categories of excluded subject matter, passing the coarse filter requirement for patent eligible subject matter under Section 101. Thus, as long as the patent does not claim or preempt purely natural phenomena, methods or processes for screening potential therapeutics should be patent eligible under Section 101.

The claim at issue, when considered as a whole, does not cover prohibited laws of nature, natural phenomena, or abstract ideas. The first two steps of the claim require growing of host cells transformed with a specific altered gene in the presence or absence of a potentially therapeutic compound. This transformative "growing" step does not occur in nature because the cell which is grown does not occur in nature; an altered cell is required by the claim It requires a man-made object upon which to act. This step necessarily falls outside of the three exclusions for patent eligible subject matter laid out by Supreme Court precedent, thereby meeting the requirement for patent eligibility under Section 101. Whether the claim is overly broad under the statute (and therefore invalid) is a patentability issue under Sections 102, 103 and 112, and not a patent eligibility issue under Section 101.

The Analysis of Patent Eligible Subject Matter Under Section 101 Should Be a Separate and Distinct Analysis from a Patentability Analysis Under 35 U.S.C. §§ 102 or 103 or the Analysis of Conditions for Obtaining a Valid Patent Under Section 112.

In *Mayo*, the Supreme Court provided additional commentary relating to "further arguments in support of Prometheus' position" which did not contrib-

ute to the holding of the case. 132 S. Ct. at 1302-05. However, this commentary and its relation to the patent eligibility analysis in the case has led to much discourse among patent practitioners regarding the conflation of Section 101 with other sections of the patent law, particularly Sections 102, 103, and 112. In view of this, the process for analysis of patent eligible subject matter under Section 101 needs to be clarified.

Title 35 provides separate and distinct sections for determining the types of inventions which are (a) patent eligible (§ 101); (b) novel—a condition for patentability (§ 102); (c) non-obvious subject matter—another condition for patentability (§ 103); and (d) required conditions for obtaining a valid patent (§ 112). Each of these requirements is laid out separately and distinctly in the patent law. No section cross-references another section by stating that conditions for the cross-referenced section must also be met in order to meet the conditions of that particular section. Instead, the requirements are described as individual, non-dependent requirements, all of which must be met to obtain a valid patent.

The distinction between these requirements has been noted in court precedent as well.

> The § 101 patent-eligibility inquiry is only a threshold test. Even if an invention qualifies as a process, machine, manufacture, or composition of matter, in order to receive the Patent Act's protection the claimed invention must also satisfy "the conditions and requirements of this title." § 101. Those requirements include that the invention be novel, see § 102, nonobvi-

> ous, see § 103, and fully and particularly described, see § 112.

Bilski, 130 S. Ct. at 3225. This "threshold test" argument was submitted by the U.S. Government as amicus curiae in Mayo, saying that "virtually any step beyond a statement of a law of nature itself should transform an unpatentable law of nature into a potentially patentable application sufficient to satisfy § 101's demands." *Mayo*, 132 S. Ct. at 1303. Once the minimum requirements for patent eligibility have been met, the other conditions for obtaining a valid patent required by Sections 102, 103 and 112 may be adequately used to determine patentability and validity.

The *Mayo* court responded to the Government's threshold test argument, saying:

> We recognize that, in evaluating the significance of additional steps, the § 101 patent eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap. But that need not always be so. And to shift the patent eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.

Id. at 1304. This dicta in *Mayo* has disrupted the settled precedent, which states:

> It has been urged that novelty is an appropriate consideration under § 101. Presumably, this argument results from the language in § 101 referring to any "new and useful" process, machine, etc. Section 101, however, is a general statement of the type of subject matter

that is eligible for patent protection "subject to the conditions and requirements of this title." Specific conditions for patentability follow and § 102 covers in detail the conditions relating to novelty. The question therefore of whether a particular invention is novel is "wholly apart from whether the invention falls into a category of statutory subject matter." *In re Bergy,* 596 F.2d 952, 961 (C.C.P.A. 1979) (emphasis deleted). *See also Nickola v. Peterson*, 580 F.2d 898 (6th Cir. 1978). The legislative history of the 1952 Patent Act is in accord with this reasoning. The Senate Report stated:

> Section 101 sets forth the subject matter that can be patented, 'subject to the conditions and requirements of this title.' The conditions under which a patent may be obtained follow, and Section 102 covers the conditions relating to novelty."
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> S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952) (emphasis supplied).

It is later stated in the same Report: "Section 102, in general, may be said to describe the statutory novelty required for patentability, and includes, in effect, an amplification and definition of 'new' in section 101." Id. at 6.

Finally, it is stated in the "Revision Notes": "The corresponding section of [the] existing statute is split into two sections, section 101 relating to the subject matter for which patents may be obtained, and section 102 defining statutory novelty and stating other conditions for patentability." *Id.* at 17.

> In this case, it may later be determined that the respondents' process is not deserving of patent protection because it fails to satisfy the statutory conditions of novelty under § 102 or nonobviousness under § 103. A rejection on either of these grounds does not affect the determination that respondents' claims recited subject matter which was eligible for patent protection under § 101.

Diamond v. Diehr, 450 U.S. 175, 190-91 (1981). Based on Supreme Court precedent and legislative history, clearly, the different sections of Title 35 are separate and distinct requirements. Contrary to the dicta in Mayo, the analysis of patent eligibility for subject matter of a claimed invention under Section 101 should not overlap with the analyses of patentability under Sections 102 and 103 or the requirements for obtaining a valid patent under Section 112. To conflate any one of these requirements with another would violate the principle of stare decisis and frustrate the legislative intent of the Patent Act.

Because Sections 101, 102, 103, and 112 are separate and distinct inquiries which should be resolved independently from one another, the Section of Intellectual Property recommends opposing any formulation of a patent eligibility test under Section 101 that imports into the patent eligibility analysis the criteria or analysis for determining patentability addressed by Sections 102 and 103, as well as the criteria required for obtaining a valid patent under Section 112.

Conclusion

A process such as that in Claim 20 does not fall within the noted exclusions from patent eligible subject matter. Contrary to the petitioner's arguments, Claim 20 involves more than a law of nature, natural phenomenon, or abstract idea; it requires a transformative step on a man-made host cell which has been transformed to include a specific altered gene. Nor does it preempt all use of a law of, natural phenomenon, or abstract idea. This process is used to screen potential drugs by growing man-made cells. A basic purpose of the patent system is to provide an economic incentive to inventors and investors to discover and develop new methods and products for the overall benefit of society. Denying patent eligibility to methods that involve a transformative step simply because the methods involve genes and cells—even man-made genes and cells—would remove this incentive.

Respectfully submitted,

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