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Patentable Subject Matter Reform

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Summary

The term "patentable subject matter" refers to the requirement of Section 101 of the Patent Act of 1952 that an invention must consist of a "process, machine, manufacture, or composition of matter" in order to be patented. The Leahy-Smith America Invents Act (AIA) of 2011, P.L. 112-29, additionally stipulated that "no patent may issue on a claim directed to or encompassing a human organism." The AIA also limited the availability of patents claiming tax avoidance strategies.

The courts and the U.S. Patent and Trademark Office (USPTO) have generally construed the language of Section 101 broadly. As a result, inventions from many different fields of human endeavor may be patented, so long as other statutory requirements such as novelty and nonobviousness are met. However, the courts recognize several implicit exceptions to the four statutory categories of patentable subject matter. In particular, laws of nature, natural phenomena, and abstract ideas have been held to be unpatentable.

For many years, Section 101 was arguably used only infrequently to invalidate an issued patent or reject an application pending at the USPTO. This situation changed over the past decade due in large part to four decisions issued by the Supreme Court of the United States since 2010 addressing patentable subject matter. In each instance the Court concluded that the invention before it was unpatentable. The four cases were

- *Bilski v. Kappos*, pertaining to a business method;
- Mayo Collaborative Services v. Prometheus Laboratories, considering a method of medical diagnosis;
- Association for Molecular Pathology v. Myriad Genetics, addressing human genes; and
- *Alice Corp. v. CLS Bank*, relating to computer software.

These decisions collectively hold that an invention is unpatentable if (1) it consists of a law of nature, natural phenomenon, or abstract idea; and (2) does not include additional, inventive elements that indicate the claim applies one of the three excluded subject matters, rather than being a fundamental concept *per se*. With regard to this second step, the Court analyzes a patent claim to determine if it covers every practical application of a fundamental concept. Claims with this preemptive scope cannot be patented under Section 101. In addition, the Court does not consider a claim's recitation of routine, nominal hardware—such as a general-purpose computer—to ameliorate concerns over Section 101 eligibility.

Since the Supreme Court issued these decisions, Section 101 has been more frequently invoked to invalidate issued patents in the courts and in certain administrative patent revocation proceedings, and also to reject pending patent applications at the USPTO. Further, numerous patents granted by the USPTO under earlier standards would likely be held invalid if they were subject to scrutiny today.

If the current situation is deemed acceptable, then no action need be taken. However, several stakeholder groups have recommended legislative reforms to Section 101. In general, these proposals assert that an invention should be deemed patentable subject matter unless it exists in nature independently of human activity or it can be performed solely in the human mind. These proposals also state that whether an invention is implemented through conventional means is irrelevant to whether it is patentable subject matter or not. As of the date of publication of this report, legislation has yet to be introduced before Congress addressing reform of the law of patentable subject matter.

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Introduction

Some Members of Congress have expressed interest in the rules governing patentable subject matter for many years. The term "patentable subject matter" refers to the requirement of Section 101 of the Patent Act of 1952 that an invention must consist of a "process, machine, manufacture, or composition of matter" in order to be patented.[1] Most recently, the Leahy-Smith America Invents Act (AIA) of 2011[2] stipulated that "no patent may issue on a claim directed to or encompassing a human organism."[3] The AIA also limited the availability of patents claiming tax avoidance strategies.[4]

The courts and the U.S. Patent and Trademark Office (USPTO) have historically understood the language of Section 101 to allow an expansive range of patentable subject matter.[5] However, the courts have long held that several implicit exceptions exist to the four categories of patentable subject matter set out in Section 101. In particular, laws of nature, natural phenomena, and abstract ideas have been held to be unpatentable.[6]

For many years, Section 101 was arguably a coarse filter that was rarely used to invalidate an issued patent or reject an application pending at the USPTO.[7] This situation changed over the past decade due to a series of decisions issued by the Supreme Court of the United States. Four Supreme Court opinions have issued since 2010 addressing patentable subject matter.[8] In each instance the Court concluded that the invention before it was unpatentable under Section 101. Since the Supreme Court issued its decisions, Section 101 has been more frequently invoked to invalidate issued patents and reject pending patent applications at the USPTO.[9] Further, numerous patents granted by the USPTO under earlier standards would likely be held invalid if they were subject to scrutiny by the agency or the courts.[10]

Views differ on whether the recent prominence of Section 101 in the U.S. patent system has been desirable. Concerned observers have declared the U.S. patent system to be in a "state of crisis" due to "confusing" legal standards established by the Supreme Court.[11] The former Chief Judge of the U.S. Court of Appeals for the Federal Circuit, the tribunal with exclusive jurisdiction over patent appeals, reportedly described the Supreme Court decisions as creating "total chaos" and

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[1] 35 U.S.C. §101.

[2] P.L. 112-29, 125 Stat. 284 (2011).

[3] Ibid at §33(a).

[4] Ibid at §14.

[5] Michael Risch, "Everything Is Patentable," *Tennessee Law Review*, vol. 75 (Summer 2008), p. 591.

[6] *Diamond v. Diehr*, 450 U.S. 175 (1981).

[7] Timothy R. Holbrook and Mark D. Janis, "Patent-Eligible Processes: An Audience Perspective," *Vanderbilt Journal of Entertainment and Technology Law*, vol. 17 (Winter 2015), p. 349.

[8] *Alice Corp. Pty. v. CLS Bank Int'l*, 134 S.Ct. 2347 (2014); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012); *Bilski v. Kappos*, 561 U.S. 593 (2010).

[9] Jasper L. Tran, "Two Years After Alice v. CLS Bank," *Journal of the Patent and Trademark Office Society*, vol. 98 (2016), p. 354. Petitioners may challenge issued patents on section 101 grounds through two USPTO proceedings: post-grant review, introduced in section 6 of the AIA; and a "transitional program for covered business method patents," introduced in section 17 of the AIA.

[10] Halie Wimberly, "The Changing Landscape of the Patent Subject Matter Eligibility and its Impact on Biotechnological Innovation," *Houston Law Review*, vol. 54, pp. 995, 1007.

[11] David O. Taylor, "Confusing Patent Eligibility," *Tennessee Law Review*, vol. 84 (Fall 2016), p. 157.

marking "a very harmful and completely unnecessary departure from a sensible patent policy."[12] Other observers believe that these decisions may lead to patents of appropriate scope,[13] curb abusive patent litigation,[14] and encourage patent lawyers to draft and procure higher quality patents.[15]

This report reviews the current law governing patentable subject matter and recent proposals for legislative reform. It begins by providing a basic overview of the patent system and introducing the principles of patentable subject matter. It then considers the leading Supreme Court decisions construing Section 101 of the Patent Act. The report then considers the implications of these decisions within the information technology and life sciences industries. The report closes with a review of legislative reform options.

Patent System Fundamentals

Individuals and enterprises must prepare and submit applications to the USPTO if they wish to obtain patent protection.[16] USPTO officials, known as examiners, assess whether the application merits the award of a patent. Under the Patent Act of 1952, a patent application must include a specification that so completely describes the invention that skilled artisans are able to practice it without undue experimentation.[17] The Patent Act also requires that applicants draft at least one claim that particularly points out and distinctly claims the subject matter that they regard as their invention.[18] The patent acquisition process is commonly known as "prosecution."[19]

While reviewing a submitted application, the examiner will determine whether the claimed invention fulfills certain substantive standards set by the patent statute. Two of the most important patentability criteria are novelty and nonobviousness. To be judged novel, the claimed invention must not be fully anticipated by a prior patent, publication, or other knowledge within the public domain.[20] The sum of these earlier materials is termed the "prior art." To meet the standard of nonobviousness, an invention must not have been readily within the ordinary skills of a competent artisan based upon the teachings of the prior art.[21] The invention must also be useful, a requirement that is satisfied if the invention is operable and provides a tangible benefit.[22]

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[12] Gene Quinn, "Judge Michel Says Alice Decision 'Will Create Total Chaos,'" IPWatchdog, August 6, 2014, http://www.ipwatchdog.com/2014/08/06/judge-michel-says-alice-decision-will-create-total-chaos/id=50696/.

[13] Margaret Kubick, "An Uncertain Future: The Impact of Medical Process and Diagnostic Method Patents on Healthcare in the United States," *Northwestern Journal of Technology & Intellectual Property*, vol. 9 (Fall 2010), p. 280.

[14] Daryl Lim, "Standard Essential Patents, Trolls, and the Smartphone Wars: Triangulating the End Game," *Penn State Law Review*, vol. 119 (2014), pp. 1, 82.

[15] Jacob S. Sherkow, "The Natural Complexity of Patent Eligibility," *Iowa Law Review*, vol. 99 (Mar. 2014), pp. 1137, 1190.

[16] 35 U.S.C. §111.

[17] 35 U.S.C. §112(a).

[18] 35 U.S.C. §112(b).

[19] John R. Thomas, "On Preparatory Texts and Proprietary Technologies: The Place of Prosecution Histories in Patent Claim Interpretation," 47 *UCLA Law Review* (1999), p. 183.

[20] 35 U.S.C. §102.

[21] 35 U.S.C. §103.

[22] *In re Fischer*, 421 F.3d 1365 (Fed. Cir. 2005).

Even if these requirements of novelty, nonobviousness, and utility are met, an invention is not patentable unless it falls within at least one category of patentable subject matter. Section 101 of the Patent Act provides

> 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 therefor, subject to the conditions and requirements of this title.[23]

The statute defines the term "process" to mean a "process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."[24] Process patents claim a series of steps that may be performed to achieve a specific result. Process patents typically relate to methods of manufacture or use.[25] A process patent may claim a method of making a product, for example, or a method of using a chemical compound to treat a disease.

The other three categories of patentable subject matter pertain to products. The Supreme Court has held that the term "machine" includes "every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result."[26] The Court has construed to term "manufacture" to mean "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery."[27] The term "composition of matter" has been held to mean "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."[28]

Although the wording of Section 101 is quite broad, courts and the USPTO have nonetheless established certain limits upon the sorts of processes that may be patented. In particular, laws of nature, natural phenomena, and abstract ideas have been judged not to be patentable.[29] The Supreme Court has described these sorts of inventions as the "basic tools of scientific and technological work"[30] that should be "free to all men and reserved exclusively to none."[31] As explained by Supreme Court Justice Stephen Breyer, this rule "reflects a basic judgment that protection in such cases, despite its potentially positive incentive effects, would too severely interfere with, or discourage, development and the further spread of future knowledge itself."[32]

If the USPTO determines that a patent application satisfies Section 101 and the other requirements for patenting, it will allow the application to issue as a granted patent. The patent proprietor then obtains the right to exclude others from making, using, selling, offering to sell or importing into the United States the claimed invention.[33] The term of the patent is ordinarily set at

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[23] 35 U.S.C. §101.

[24] 35 U.S.C. §100(b).

[25] *In re Pleuddemann*, 910 F.2d 823, 826 (Fed. Cir. 1990).

[26] *Corning v. Burden*, 15 How. 252, 267-68 (1854).

[27] *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

[28] Ibid.

[29] *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006) (opinion of Justice Breyer, dissenting from dismissal of writ of certiorari as improvidently granted) (hereinafter "LabCorp.").

[30] *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

[31] *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

[32] *LabCorp., supra*, at 128.

[33] 35 U.S.C. §271.

twenty years from the date the patent application was filed.[34] Patent title therefore provides inventors with limited periods of exclusivity in which they may practice their inventions, or license others to do so. The grant of a patent permits inventors to receive a return on the expenditure of resources leading to the discovery, often by charging a higher price than would prevail in a competitive market.

A patent proprietor bears responsibility for monitoring its competitors to determine whether they are using the patented invention. Patent owners who wish to compel others to observe their intellectual property rights must usually commence litigation in the federal courts. Although issued patents enjoy a presumption of validity, accused infringers may assert that a patent is invalid or unenforceable on a number of grounds.[35] The Federal Circuit possesses national jurisdiction over most patent appeals.[36] The Supreme Court retains discretionary authority to review cases decided by the Federal Circuit.[37]

Patentable Subject Matter at the Supreme Court

Until its recent spate of decisions, the last time the Court addressed the law of patentable subject matter was nearly four decades ago. In its 1980 decision in *Diamond v. Chakrabarty*,[38] the Court held that a genetically engineered microorganism could be patented. Similarly, in its 1981 opinion *Diamond v. Diehr,*[39] the Court ruled that a process for curing artificial rubber through the use of a computer and a mathematical formula was patentable. These two decisions arguably set the stage for a period where the range of patentable subject matter was quite broad, both for information technologies and the life sciences. Since they issued, the lower courts and USPTO arguably made only occasional use of Section 101 to invalidate issued patents or reject pending patent applications.[40]

The Supreme Court revisited the law of patentable subject matter in a series of four decisions issued from 2010 through 2014. In each instance, the Court held each invention it considered to be unpatentable under Section 101. As one commentator asserts: "No one can reasonably deny that the Supreme Court's decisions narrowing patent eligibility have had a significant impact on the patent system."[41] This report discusses each decision in the order of issuance.

Business Methods and *Bilski v. Kappos*

In its 2010 decision *Bilski v. Kappos*,[42] the Supreme Court considered the patentability of a method of hedging risk in the field of commodities trading. The patent application before the Court claimed:

[34] 35 U.S.C. §154(a)(2).

[35] 35 U.S.C. §282.

[36] 28 U.S.C. §1295(a)(1).

[37] 28 U.S.C. §1254(1).

[38] 447 U.S. 303 (1980).

[39] 450 U.S. 175 (1981).

[40] Rebecca S. Eisenberg, "Diagnostics Need Not Apply," *Boston University Journal of Science and Technology Law*, vol. 21 (Summer 2015), p. 256.

[41] Taylor, supra, at 159.

[42] 561 U.S. 593 (2010).

> A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of:
>
> initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;
>
> identifying market participants for said commodity having a counter-risk position to said consumers; and
>
> initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.[43]

The USPTO rejected the application as claiming subject matter that was ineligible for patenting under Section 101.

On appeal, the Federal Circuit characterized the "true issue before us then is whether Applicants are seeking to claim a fundamental principle (such as an abstract idea) or a mental process." The Federal Circuit explained

> 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.[44]

Applying this standard, the Federal Circuit concluded that Bilski's application did not claim patentable subject matter. The Court of Appeals acknowledged Bilski's admission that his claimed invention was not limited to any specific machine or apparatus, and therefore did not satisfy the first prong of the Section 101 inquiry. The Federal Circuit also reasoned that the claimed process did not achieve a physical transformation. According to then-Chief Judge Michel, "[p]urported transformations or manipulations simply of public or private legal obligations or relationships, business risks, or other such abstractions cannot meet the test because they are not physical objects or substances, and they are not representative of physical objects or substances."[45] As a result, the USPTO decision to deny Bilski's application was affirmed.

After agreeing to hear the case, the Supreme Court issued a total of three opinions, consisting of a plurality opinion for the Court and two concurring opinions. No single opinion was joined by a majority of Justices for all of its parts. The opinion for the Court, authored by Justice Kennedy, agreed that Bilski's invention could not be patented. But the plurality rejected the Federal Circuit's conclusion that the machine or transformation test was the sole standard for identifying patentable processes. Rather, that standard was deemed "an important and useful clue."[46]

The Court instead resolved the case based on the traditional rule that abstract ideas were not patentable subject matter. Justice Kennedy reasoned that hedging was a "fundamental economic practice long prevalent in our system of commerce and taught in any introductory finance class."[47] He explained that "[a]llowing petitioners to patent risk hedging would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea."[48]

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[43] Ibid at 599.

[44] Ibid at 600.

[45] 545 F.3d 943, 965 (Fed. Cir. 2008).

[46] 561 U.S. at 603.

[47] Ibid at 611.

[48] Ibid at 611-612.

Justice Stevens, joined by Justices Breyer, Ginsburg, and Sotomayor, issued a lengthy concurring opinion on the day of his retirement from the Supreme Court. He agreed that the machine-or-transformation test was "reliable in most cases" but "not the exclusive test."[49] In his view, the Court should "restore patent law to its historical and constitutional moorings" by declaring that "methods of doing business are not, in themselves, covered by the statute."[50]

Justice Breyer also issued a concurring opinion that Justice Scalia joined in part. Justice Breyer identified four points on which all nine justices agreed: (1) the range of patentable subject matter is broad but not without limit; (2) the machine-or-transformation test has proven to be of use in determining whether a process is patentable or not; (3) the machine-or-transformation test is not the sole standard for assessing the patentability of processes; and (4) not everything that merely achieves a "useful, concrete, and tangible result" qualifies as patentable subject matter.[51]

Diagnostic Methods and *Mayo v. Prometheus*

In its next Section 101 case, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,[52] the Supreme Court shifted focus from information technologies to the life sciences. Prometheus Laboratories, Inc., is the sole licensee of two patents (U.S. Patent Nos. 6,355,623 and 6,680,302) claiming methods for determining optimal dosages of thiopurine drugs used to treat autoimmune diseases. Stated generally, the patents claim methods of (a) administering a thiopurine drug to a patient, and (b) determining the levels of the drug or the drug's metabolites in red blood cells in the patient. The measured metabolite levels are then compared to known metabolite levels. If the measured metabolite levels in the patient are outside the known range, then the physician should increase or decrease the level of drug to be administered so as to reduce toxicity and enhance treatment efficacy. Claim 1 of the `623 patent, which reads as follows, was representative of the claims of the two patents at issue:

> A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
>
> (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
>
> (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,
>
> wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and
>
> wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.[53]

In a unanimous decision authored by Justice Breyer, the Supreme Court concluded that the claims were directed towards natural laws and were therefore unpatentable. The Court reviewed its precedents in order to explain that phenomena of nature and abstract concepts could not be

[49] Ibid at 613 (Stevens, J., concurring).

[50] Ibid at 657.

[51] Ibid at 658-60 (Breyer, J., concurring).

[52] 566 U.S. 60 (2012).

[53] Ibid at 74.

patented because the "monopolization of these basic tools through the grant of a patent might tend to impede innovation more than it would tend to promote it."[54] The earlier cases recognized that all inventions at some level embody or apply laws of nature, however, and that processes that applied natural laws in a particular, useful way were eligible for patenting under Section 101 of the Patent Act.

Applying these principles to the case at hand, the Court recognized that the claims in part recited "laws of nature," in particular relationships between the concentration of thiopurine metabolites and the likelihood that a dosage of a thiopurine drug will prove ineffective or harmful. However, the claims included steps in addition to the law of nature—in particular, they called for "administering" the thiopurine drug and "determining" the level of the relevant metabolites, "wherein" the drug dosage should be adjusted. According to Justice Breyer, the question before the Court was whether the claims amounted merely to the natural laws, or whether they added enough to the statement of the correlations to qualify as patent-eligible processes that applied natural laws.[55]

The Court reasoned that the three additional claimed steps did not suffice to render the claimed inventions patentable subject matter. Justice Breyer explained that the "administering" step referred simply to the relevant audience of the invention, namely, physicians who treat patients with certain diseases with thiopurine drugs. However, merely limiting the use of a natural law to a particular technological environment cannot render the principle patentable.[56]

Similarly, the "determining" step merely advised physicians to measure the level of metabolites in a patient's blood—a step that had been done for years and was routine in the field. Justice Breyer stated that conventional or obvious pre-solution activity did not convert an unpatentable law of nature into a patent-eligible application of such law.[57] Finally, the "wherein" clauses simply informed physicians that they should take account of pertinent natural laws in their practices. According to Justice Breyer, an unpatentable law of nature does not become patentable merely by advising individuals to use the law. As a result, the Court concluded that the three steps recited in the claim did not "transform unpatentable natural correlations into patentable applications of those regularities."[58]

The Supreme Court's opinion in *Mayo v. Prometheus* addressed a number of additional contentions raised during the litigation. First, the Court rejected the argument that the Prometheus patents satisfied the machine-or-transformation test. The Federal Circuit had reasoned that the patents-in-suit transformed both human blood (by analyzing it to measure metabolite levels) and the human body (by administering a thiopurine drug). Justice Breyer countered that the claims at issue required only that the metabolite levels be measured, not that human blood be transformed. And he also explained that the transformation of the human body was not pertinent to the patentability determination, for that claim limitation merely identified the group of individuals who might be interested in applying the law of nature.[59]

The Court also responded to the position that virtually any step beyond a statement of a law of nature should be deemed to fulfill Section 101 standards. Under this view, Section 101 might be

[54] Ibid at 71.

[55] Ibid at 77.

[56] Ibid at 78.

[57] Ibid at 79.

[58] Ibid at 80.

[59] Ibid at 87-88.

satisfied fairly readily; other requirements imposed under the Patent Act, including novelty and nonobviousness, would play a more significant role in deciding whether the patent should issue or not. Justice Breyer rejected this proposal, stating that the policy concerns that underlie Section 101 were distinct from those of the other patentability requirements.[60]

Third, the Court responded to concerns that rejecting the Prometheus patents would discourage diagnostic research. Justice Breyer observed that other interested parties had asserted that patents claiming the body's natural responses to illness and medical treatment should not be granted because they might limit physician access to critical scientific data. In view of these competing views, the Court was reluctant to depart from precedent denying patents on natural laws.[61]

Genetic Materials and the *Myriad* Case

In a June 2013 decision, the Supreme Court of the United States ruled in *Association for Molecular Pathology v. Myriad Genetics, Inc.,*[62] that genomic DNA was ineligible for patenting under 35 U.S.C. §101 because of the "product of nature" doctrine. Under longstanding case law, products of nature (preexisting substances found in the wild) may not be patented, *per se*. However, the courts have also determined that such a product of nature may be patentable if significant artificial changes are made. By purifying, isolating, or otherwise altering a naturally occurring product, an inventor may obtain a patent on the product in its altered form.[63]

Adopting the view that isolated and purified genomic DNA satisfied this exception to the "product of nature" doctrine, the USPTO issued over 50,000 patents relating at least in part to DNA.[64] However, some experts believed that the decision to patent human genes misconstrued the "product of nature" principle. In their view, the fact that scientists have isolated a gene is a "technicality" that did not allow genes to be patented.[65]

The Supreme Court decision in *Myriad* reflects this latter position. The litigation commenced on May 12, 2009, when the Association for Molecular Pathology and 19 other plaintiffs, including individual physicians, patients, and researchers, filed a lawsuit against the USPTO, Myriad Genetics, Inc., and the Directors of the University of Utah Research Foundation. The plaintiffs challenged several patents owned by Myriad that claim isolated human genes known as BRCA1 and BRCA2.[66] Certain alterations or mutations in these genes are associated with a predisposition to breast and ovarian cancers. Due to its intellectual property rights, Myriad was the sole commercial provider of genetic testing related to breast and ovarian cancer associated with the BRCA1 and BRCA2 genes. The plaintiffs asserted that Myriad's gene patent claims were invalid because, in their view, human genes are naturally occurring products that do not constitute patentable subject matter.

[60] Ibid at 89.

[61] Ibid at 91-92.

[62] 133 S.Ct. 2107 (2013).

[63] *Diamond v. Chakrabarty*, 417 U.S. 303 (1980).

[64] Guyan Lian, "Molecules or Carriers of Biological Information: A Chemist's Perspective on the Patentability of Isolated Genes," 22 *Albany Law Journal of Science and Technology* (2012), 133.

[65] Eileen M. Kane, "Splitting the Gene: DNA Patents and the Genetic Code," 71 *Tennessee Law Review* (2004), 707.

[66] For example, claim 1 of U.S. Patent No. 5,747,282 recites: "An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the [following] amino acid sequence…."

The U.S. District Court for the Southern District of New York sided with the plaintiffs and held that Myriad's gene patent claims were invalid under 35 U.S.C. §101.[67] Judge Sweet reasoned that Myriad's claimed isolated DNA was not "markedly different from native DNA as it exists in nature" and therefore could not be patented.[68] Following an appeal, the Federal Circuit reversed this holding.[69] The Court of Appeals reasoned that "isolated" DNA is not merely "purified" DNA—rather, it has been "manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body."[70] Under this reasoning, human genes consist of patentable subject matter.

The Supreme Court subsequently agreed to hear the *Myriad* case but did not issue a ruling in the matter. Rather, on March 26, 2012, the Court vacated the judgment and remanded the matter back to the Federal Circuit with instructions to reconsider the appeal. The Federal Circuit responded by once again upholding Myriad's claims.[71] The Supreme Court then agreed to hear the case.

Justice Thomas, writing for the Court, initially observed that Myriad had neither created nor altered the generic information encoded in the BRCA1 and BRCA2 genes. Rather, Myriad had discovered the precise location and genetic sequence of those genes. According to Justice Thomas, then, "Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention."[72] The Supreme Court also was unimpressed that Myriad claimed DNA that had been isolated from the human genome through the severing of chemical bonds, with a non-naturally occurring molecule as a result. According to Justice Thomas, "Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA"[73]

The Court took a more favorable view of a second set of claims pertaining to "complementary DNA," however. More commonly known as cDNA, these claims were directed to synthetic DNA in which the sequence of bases is complementary to naturally-occurring DNA. Observing that "cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived," Justice Thomas concluded that cDNA did not constitute a "product of nature" and therefore could be patented.[74]

Justice Thomas also found it important to note what the *Myriad* opinion did not implicate. The case involved neither an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, the Court explained, nor new applications of knowledge about those genes. The Court also indicated that it had not considered the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Instead, the Court "merely [held] that genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material."[75]

[67] 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

[68] Ibid at 232.

[69] 653 F.3d 1329.

[70] Ibid at 1352.

[71] 689 F.3d 1323 (Fed. Cir. 2012).

[72] 133 S.Ct. at 2117.

[73] Ibid at 2118.

[74] Ibid at 2119.

[75] Ibid at 2119-20.

The opinion of Justice Thomas was joined in full by seven of his colleagues. Justice Scalia contributed a one-paragraph concurring opinion that joined the judgment of the Court and all of its opinion except those portions "going into fine details of molecular biology."[76] Justice Scalia found himself "unable to affirm those details on my own knowledge or even my own belief."[77] This shortcoming did not prevent him from concluding that isolated genomic DNA was identical to its natural state, however, while cDNA could be patented because it was a synthetic creation not found in nature.

Computer Software and *Alice v. CLS*

In the most recent of its Section 101 decisions, the Supreme Court considered the patentability of a computer-implemented financial exchange system. The inventions at issue in *Alice Corp. v. CLS Bank International*[78] were designed to mitigate "settlement risk"—the risk that only one party to a financial transaction will pay what it owes. The patents at issue were more specifically directed to (1) a method for exchanging financial obligations (the method claims); (2) a computer system used to carry out those methods (the computer system claims); and (3) a computer-readable medium, such as disk or memory stick, containing program code for performing those methods (the computer-readable media claims).[79] The district court concluded that the inventions were unpatentable because they represented a "basic business or financial concept" that "remains a fundamental, abstract concept."[80]

The patent owner appealed the decision to the Federal Circuit, which affirmed the district court's ruling.[81] The Supreme Court agreed to hear the case in order to address "whether claims to computer-implemented inventions—including claims to systems and machines, processes, and items of manufacture—are directed to patent-eligible subject matter within the meaning of section 101."[82] The Supreme Court unanimously upheld the Federal Circuit's determination that the patents were directed to a patent-ineligible abstract idea.[83]

Writing for the Court, Justice Thomas explained that the Court's Section 101 precedent established a two-part test for identifying patents that claim laws of nature, natural phenomena, and abstract ideas. First, the claim should be analyzed to determine whether it claims one of these types of excluded subject matter. If it does, then the claim should be reviewed to determine whether the claim recites additional elements that transform the claim into a patent-eligible application of a law of nature, natural phenomenon, or abstract idea. Justice Thomas described this second test as determining whether the claim incorporates an "inventive concept" that amounts to more than merely applying the law of nature, natural phenomenon, or abstract idea to a particular technological environment.[84]

[76] Ibid at 2120 (Scalia, J., concurring)

[77] Ibid.

[78] 134 S.Ct. 2347 (2014).

[79] Ibid at 2353.

[80] 768 F.Supp.2d 221 (D.D.C. 2011).

[81] 717 F.3d 1269 (Fed. Cir. 2013).

[82] 134 S.Ct. 734 (2013).

[83] Justices Sotomayor, Ginsburg, and Breyer joined the majority opinion, but wrote separately that business methods should be excluded from patent eligibility under section 101. 134 S.Ct. at 2360-61.

[84] Ibid at 2355.

With this framework established, Justice Thomas turned first to the method claims. Applying the two-step process it established in *Mayo v. Prometheus,* the Court first determined that the method claims were drawn to the abstract idea of intermediated settlement—a fundamental and longstanding economic practice. The Court then turned to the second prong of the *Mayo* inquiry—namely, whether the claim contains "an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application." The Court determined that the patented claims amounted to nothing more than implementation of an abstract idea on a computer. According to Justice Thomas, the "mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention." To hold otherwise, he explained, would allow any abstract principle to become patentable simply by incorporating everyday computer hardware into the claim.[85]

The Court rejected the computer system and computer-readable media claims for the same reason. Justice Thomas explained that the claims recited only generic computer hardware that failed to do more than generally link the invention to a specific technological environment—that is to say, computer implementation. Because these claims were not meaningfully restricted by these system and media limitations, they too were unpatentable.[86]

Analysis

The Supreme Court decisions in *Bilski, Mayo v. Prometheus, Myriad,* and *Alice* present the current law of the land with respect to whether a particular invention is eligible for patenting. Several key themes may be gleaned from these four opinions. First, the courts and USPTO conduct a two-part test developed from the case law. That test asks (1) whether the claim recites a law of nature, natural phenomenon, or abstract idea; and (2) if so, whether the claim includes additional, inventive elements that indicate the claim applies one of the three excluded subject matters, rather than being a fundamental concept *per se*.[87]

With regard to this second step, the Court will analyze a patent claim to determine if it preempts a field of activity. If a claim covers every practical application of a fundamental concept, then it cannot be patented under Section 101.[88] In addition, the Court does not consider a claim's recitation of routine, nominal hardware—such as a general-purpose computer—to ameliorate concerns over Section 101 eligibility. Finally, although the machine-or-transformation test does not exclusively govern the patent eligibility of processes, it remains a useful guidepost within the decisionmaking process.[89]

Section 101 determinations have proven amenable to resolution early within the process of litigation, often at the pleading stage or a prompt summary judgment motion.[90] In addition, the courts have often not required a formal construction of the patent's claims in order to resolve

[85] Ibid at 2357-58.

[86] Ibid at 2360.

[87] Amy Landers, "Patentable Subject Matter as a Policy Driver," *Houston Law Review*, vol. 53 (2015), p. 505.

[88] Jeffrey A. Lestin, "The Three Faces of *Prometheus*: A Post-*Alice* Jurisprudence of Abstractions," *North Carolina Journal of Law & Technology*, June 2015, pp. 647, 664-65.

[89] Samuel Roger, "It's Not So Obvious: How the Manifestly Evident Standard Affects Litigation Costs by Reducing the Need for Claim Construction," *Texas A&M Law Review*, vol. 1 (Spring 2014), pp. 729, 737.

[90] Jacob Koering, "The Rise of the Patent-Eligibiity Defense: The Absurd Abstraction of Alice," *Aspatore*, vol. 2016 WL (April 2016), pp. 2984927, at *7.

Section 101 challenges.[91] Statistical analyses suggest that when these motions are raised, the moving party enjoys a good probability of invalidating the challenged claims. In particular, one empirical study concluded

> As of June 19, 2016 (i.e. *Alice*'s two-year mark), courts have examined 568 challenged patents brought under §101 motions citing *Alice*, resulting in 190 valid patents and 378 patents invalidated with an average invalidation rate of 66.5%. Specifically, the Federal Circuit upheld 3 patents and invalidated 34 patents—an average invalidation rate of 91.9%. The [USPTO] has rejected over 36,000 published patent applications under *Alice*, where over 5,000 such applications were abandoned.[92]

Notably, these statistics do not suggest that approximately two-thirds of all issued patents do not comply with Section 101. Rather, they indicate that when attorneys assert that a particular patent claim is invalid in view of the existing law of patentable subject matter or a nonfrivolous argument for modifying existing law, they have a good chance of success.[93] Such motions are not routinely brought with regard to such claimed subject matter as chemicals, consumer devices, electronics, medical devices, pharmaceuticals, tools, vehicles, and any number of other technologies. However, these statistics may be read to suggest that recent Supreme Court interest in patentable subject matter has animated a patent validity doctrine with implications for both information technologies and the life sciences.[94] This report briefly considers these two fields next.

Implications for Information Technology

The implications of recent Supreme Court case law have arguably been most keenly felt with respect to information technologies. The courts have invalidated numerous patents on computer-related inventions following the standards established in *Bilski* and *Alice*. As a general matter, patent claims that do not describe specific solutions to a problem, or identify an "improvement in the functioning of technology,"[95] tend to be the most vulnerable to a Section 101 challenge. Among the patent claims invalidated were those directed towards the following inventions:

- a computer system of generating a second menu from a first menu that allows users to select particular categories and items;[96]
- a computer system and method for collecting, analyzing, and displaying information relating to an electric power grid using conventional computer and network technology;[97]
- a method of (1) extracting data from hard copy documents using an automated digitizing unit such as a scanner, (2) recognizing specific information from the

[91] Timothy J. Busse, "The Relativity of an Abstract Idea: A Practicable Approach to *Alice*'s Inventive Concept," *Houston Business and Tax Law Journal*, vol. 16 (2016), p. 252.

[92] Jasper L. Tran, "Two Years After Alice v. CLS Bank," *Journal of the Patent and Trademark Office Society*, vol. 98 (2016), p. 354, 358-59.

[93] Federal Rule of Civil Procedure 11.

[94] Christopher M. Holman, "Patent Eligibility Post-Myriad: A Reinvigorated Judicial Wildcard of Uncertain Effect," *Geoge Washington Law Review*, vol. 82 (November 2014), p. 1796.

[95] *Trading Techs. Int'l, Inc. v. CQG, Inc.*, 675 Fed. Appx. 1001, 1005 (Fed. Cir. 2017).

[96] *Apple, Inc. v. Ameranth, Inc.*, 842 F.3d 1229 (Fed. Cir. 2016).

[97] *Electric Power Group., LLC v. Alstom S.A.*, 830 F.3d 1350 (Fed. Cir. 2016).

extracted data, and (3) storing that information in a memory, using conventional scanners and computers;[98]

- systems and methods for administering and tracking the value of life insurance policies in separate accounts;[99] and
- a computer-aided method and system for processing credit applications over electronic networks.[100]

The patent invalidated in another representative decision, *Affinity Labs of Tex. v. DIRECTV, LLC*,[101] claimed a broadcast system in which a cellular telephone located outside the territory of a regional broadcaster (1) requests and receives content from the broadcaster via a streaming signal, (2) downloads an application for performing those functions, and (3) contains a display that allows the user to select particular content.[102] Applying the Supreme Court's two-part test for patentable subject matter, the Federal Circuit first deemed the concept of providing out-of region access to a local broadcast to constitute an abstract idea. Judge Bryson explained that the "practice of conveying regional content to out-of-region recipients has been employed by nearly every form of media that has a local distribution," ranging from the mailing of local newspaper to distant locations, to the delivery of broadcasts of sporting events to a national audience.[103]

Second, Judge Bryson observed that "nothing in claim 1 [was] directed to how to implement out-of-region broadcasting on a cellular telephone. Rather, the claim is drawn to the idea itself."[104] In particular, the patent did not describe how the invention accomplished the claimed functions. It merely confined the idea to one particular technological environment—cellular telephones. Under Supreme Court case law, the Federal Circuit concluded, these circumstances did not satisfy Section 101.

The Federal Circuit has not accepted a Section 101 challenge in every case. For example, the court of appeals has upheld patents directed towards an e-commerce system and method,[105] an information management and database system,[106] a method and system of filtering Internet content,[107] and a method of automatically animating lip synchronization and facial expressions of three-dimensional animated characters.[108] As a general matter, claims have been more likely to survive Section 101 if they avoid broad functional language and recite discrete structures to achieve specific results.[109]

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[98] *Content Extraction and Transmission LLC v. Wells Fargo Bank, N.A.*, 776 F.3d 1343 (Fed. Cir. 2014).

[99] *Bancorp Services, LLC v. Sun Life Assurance Co*., 687 F.3d 1266 (Fed. Cir. 2012).

[100] *Dealertrack, Inc. v. Huber*, 674 F.3d 1315 (Fed. Cir. 2012).

[101] 838 F.3d 1253 (Fed. Cir. 2016).

[102] Ibid at 1256.

[103] Ibid at 1258.

[104] Ibid.

[105] *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245 (Fed. Cir. 2014).

[106] *Enfish, LLC v. Microsoft Corp*., 822 F.3d 1327 (Fed. Cir. 2016).

[107] *BASCOM Global Internet Services, Inc. v. AT&T Mobility LLC*, 827 F.3d 1341 (Fed. Cir. 2016).

[108] *McRO, Inc. v. Bandai Namco Games America Inc.*, 837 F.3d 1299 (Fed. Cir. 2016).

[109] Robert Mazzola, "The 101 Conundrum: Creating a Framework to Solve Problems Surrounding Interpretation of 35 U.S.C. §101," *Chicago-Kent Journal of Intellectual Property*, vol. 14 (Spring 2015), p. 400.

Implications for the Life Sciences

The Supreme Court decisions in *Mayo v. Prometheus* and *Association for Molecular Pathology v. Myriad Genetics* have held consequences for the life sciences industry. Due to *Mayo v. Prometheus*, predictive diagnostic methods that depend on the presence or absence of a biomarker, as well as diagnostic methods that measure that biomarker, may be subject to narrow patents or be difficult to patent at all. In turn, the *Myriad* case appears to make any isolated bodily substance, including genes, proteins, and cell lines, of doubtful patentability. On the other hand, even slightly altered genes and other naturally derived substances likely pass the §101 threshold.[110]

Fewer published judicial opinions have addressed the interaction of Section 101 with respect to the life sciences than to information technologies.[111] However, one such decision, the 2015 ruling of the Federal Circuit in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.,*[112] has been subject to considerable discussion within the patent community. That case involved a non-invasive pre-natal diagnostic method useful for determining the gender and blood type of the fetus, as well as whether the fetus was subject to any genetic disorders. Sequenom was the exclusive licensee of U.S. Patent No. 6,258,540. Claim 1 of that patent recited

> 1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises
>
> amplifying a paternally inherited nucleic acid from the serum or plasma sample and
>
> detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.[113]

The Federal Circuit explained that the inventors had discovered cell-free fetal DNA (cffDNA) in maternal plasma or serum. The inventors then used known laboratory techniques to implement a method for detecting the small fraction of paternally inherited ccfDNA in material plasma or serum to determine fetal characteristics. The Federal Circuit determined that this invention failed the two-part patentable subject matter test because: (1) the claims were directed to a naturally occurring phenomenon, cffDNA; and (2) the claims simply instructed physicians to apply well-understood, conventional techniques when seeking to detect cffDNA.[114]

Judge Linn contributed a concurring opinion that joined the majority but expressed dissatisfaction with the result. He explained that prior to the patented invention, prenatal diagnosis involved invasive techniques that could potentially harm the mother and the pregnancy. According to Judge Linn, "no reason, in policy or statute" suggested "why this breakthrough invention should be deemed patent ineligible."[115]

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[110] Hallie Wimberly, "The Changing Landscape of Patent Subject Matter Eligibility and Its Impact on Biotechnological Innovation," *Houston Law Review*, vol. 54 (2017), p. 995.

[111] *PerkinElmer, Inc. v. Intema Limited*, 496 Fed. Appx. 65 (Fed. Cir. 2012), provides one example. In that case the Federal Circuit held that a patent claiming screening methods to estimate the risk of fetal Down syndrome was invalid under section 101.

[112] 788 F.3d 1371 (Fed. Cir. 2015).

[113] Ibid at 1373-74.

[114] Ibid at 1376-78.

[115] Ibid at 1381.

Congressional Issues and Options

Congress possesses several apparent options with respect to the law of patentable subject matter. If the current situation is deemed acceptable, then no action need be taken. Congress could otherwise alter the law of patentable subject matter through legislation. As of the date this report was published, no bill has been introduced before Congress addressing the law of patentable subject since the enactment of the Leahy-Smith America Invents Act in 2011.[116] However, at least three different industry associations have suggested modifications to Section 101.

Two of these organizations, the American Intellectual Property Law Association (AIPLA), a voluntary bar association, and the Intellectual Property Owners Association (IPO), a trade association for proprietors of patents and other intellectual property rights, have generated highly similar proposals. The AIPLA proposal would replace the existing Section 101 with the following language:

> **35 U.S.C. § 101—Inventions Patentable**
>
> **(a) Eligible Subject Matter**.—Whoever invents or discovers any useful process, machine, manufacture, composition of matter, or any useful improvement thereof, shall be entitled to a patent therefor, subject only to the conditions and requirements set forth in this title.
>
> **(b) Sole Exceptions to Subject Matter Eligibility**.—A claimed invention is ineligible under subsection (a) only if the claimed invention as a whole exists in nature independent of and prior to any human activity, or can be performed solely in the human mind.
>
> **(c) Sole Eligibility Standard**.—The eligibility of a claimed invention under subsections (a) and (b) shall be determined without regard to the requirements or conditions of sections 102, 103, and 112 of this title, the manner in which the claimed invention was made or discovered, or whether the claimed invention includes an inventive concept.[117]

The IPO proposal reads almost identically.[118]

A third organization, the American Bar Association (ABA) Section of Intellectual Property Law, has offered a related proposal. The ABA proposal would amend Section 101 to read

> **§ 101. Conditions for patentability: eligible subject matter.**
>
> **(a) Eligible Subject Matter.-** Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, shall be entitled to obtain a patent on such invention or discovery, absent a finding that one or more conditions or requirements under this title have not been met.
>
> **(b) Exception.-** A claim for a useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may be denied eligibility under this section 101 on the ground that the scope of the exclusive rights under such a claim would preempt the use by others of all practical applications of a law of nature, natural phenomenon, or abstract idea. Patent eligibility under this section shall not be negated when a practical application of a law of nature, natural phenomenon, or abstract idea is the subject matter

[116] P.L. 112-29, 125 Stat. 284 (2011), at §§14, 33(a).

[117] American Intellectual Property Law Association, *AIPLA Legislative Proposal and Report on Patent Eligible Subject Matter*, May 12, 2017, http://www.patents4life.com/wp-content/uploads/2017/05/AIPLA-Report-on-101-Reform-5-12-17.pdf ("AIPLA Proposal"), at 4.

[118] Intellectual Property Owners Association, *Proposed Amendments to Patent Eligible Subject Matter Under 35 U.S.C. §101*, February 7, 2017, http://www.ipo.org/wp-content/uploads/2017/02/20170207_IPO-101-TF-Proposed-Amendments-and-Report.pdf ("IPO Proposal"), at 1.

> of the claims upon consideration of those claims as a whole, whereby each and every limitation of the claims shall be fully considered and none ignored. Eligibility under this Section 101 shall not be negated based on considerations of patentability as defined in Sections 102, 103 and 112, including whether the claims in whole or in part define an inventive concept.[119]

The AIPLA asserts that Section 101 was intended to act as an "enabling provision" rather than "provide the standard for whether a particular technical advance should receive patent protection."[120] Similarly, the ABA Section on Intellectual Property asserts that recent Supreme Court decisions "have injected ambiguity into the eligibility determination by requiring courts and the [USPTO] to apply criteria such as 'well known,' 'routine,' 'conventional or obvious,' factors that were previously relevant only to novelty and obviousness, in order to ignore limitations and render a claim patent ineligible and in effect have turned the gateway function of patent eligibility into a patentability test better left to the other statutory provisions.... "[121] For its part, the IPO explains that the Supreme Court's analysis "is contrary to [c]ongressional intent, too restrictive, technologically incorrect, unsound from a policy standpoint, and bad law."[122]

Not everyone agrees that legislative reform is necessary. One commentator finds no evidence that more restrictive patent eligibility rules "have affected innovation or investment in any meaningful way."[123] In his view, the proposed amendments would "essentially do away with any limits to software patenting."[124] Another observer believes that these proposals would "eliminate any real constraint on subject matter eligibility."[125] He also observes that the AIPLA proposal would also change the current statutory phrase "may obtain a patent subject to the conditions and requirements of this title" to "shall be entitled to a patent only subject to the conditions and requirements set forth in this title."[126] In his view, this language would have the perhaps unintended effect of eliminating other common law patentability standards, including the so-called "obviousness-type double patenting" rule.[127]

Concluding Observations

Patents in the fields of software and life sciences have proven controversial for decades. Recent Supreme Court interest in the topic of patentable subject matter, which has made patenting in these fields more difficult, has led to a heated debate. Many knowledgeable observers believe that

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[119] Letter from Donna P. Suchy, Chair, ABA Section of Intellectual Property Law, to The Honorable Michelle K. Lee, Director of the USPTO, March 28, 2017, http://www.patents4life.com/wp-content/uploads/2017/05/ABA-101-proposal.pdf ("ABA IP Proposal"), at 3-4.

[120] AIPLA Proposal at 2.

[121] ABA IP Section Proposal at 2.

[122] IPO Proposal at 2.

[123] Matt Levy, *Why IPO Is Wrong About Section 101*, February 7, 2017, https://www.patentprogress.org/2017/02/07/ipo-wrong-section-101/.

[124] Ibid.

[125] Josh Landau, *AIPLA Signs on to IPO's Misguided Proposal on 101*, Patent Progress, May 17, 2017, https://www.patentprogress.org/2017/05/17/aipla-signs-ipos-misguided-proposal/.

[126] The IPO proposal reads similarly. It states in relevant part, with emphasis added: "Whoever invents or discovers, and claims as an invention, any useful process, machine, manufacture, composition of matter, or any useful improvement thereto, shall be entitled to a patent for a claimed invention thereof, *subject only* to the exceptions, conditions, and requirements set forth in this Title."

[127] This doctrine prevents an inventor from obtaining a second patent on an invention that is an obvious variation of an invention claimed in a granted patent, unless the inventor agrees that the patents will expire on the same date and be subject to common ownership. See, e.g., *Gilead Sciences, Inc. v. Natco Pharma. Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014).

Section 101 helps ensure an appropriate balance between the innovative contributions of inventors and the scope of the rights that they receive. However, other experts express concern that the lack of availability of patent rights will decrease innovation and investment in the United States. Collectively, these debates may promote further inquiry into the sorts of inventions that may be appropriately patented.

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