

# AIPLA

American Intellectual Property Law Association



## **AIPLA Legislative Proposal and Report On Patent Eligible Subject Matter**

May 12, 2017

## Executive Summary

The Supreme Court’s subjective interpretation of patent eligibility law is undermining the fundamental principles underlying the 1952 Patent Act on which our modern innovation economy rests. Section 101 of Title 35 was intended as an enabling provision, identifying particular categories of subject matter that qualified for patent protection; it was not intended to provide the standard for deciding whether a particular technical advance should receive patent protection. Sections 102, 103, and 112 set out the “conditions of patentability,” and were intended to provide a yardstick for judging novelty, nonobviousness, and the sufficiency of disclosure in the specification and claims. The Supreme Court has applied its own subjective rules of patent ineligibility that have increasingly blurred these statutory functions, causing significant uncertainty in the law and driving innovation investments abroad.

Congress must intervene and return the law to what the 1952 Patent Act meant to provide: an objective, evidence-based analysis for awarding patent protection. The Federal Circuit, the district courts, and the U.S. Patent and Trademark Office are all struggling to find a principled formula to guide their decision-making, and the present uncertainty has weakened the U.S. patent system and discouraged investments in areas ranging from software to life-saving diagnostic tools and therapeutic medicines. An April 2017 study reports that “while applications in the U.S. are being rejected as ineligible for patent protection under Section 101 and then abandoned by the applicants, the E.U. and China are granting patents on the exact same inventions and discoveries.”<sup>1</sup> As a result, innovators are being “driven overseas to create and commercialize new technologies”<sup>2</sup> where the scope of patent protection is more certain, and where innovators are more confident that their investment in innovation will be protected. In sum, legislative reform is needed to restore predictability to the patent system and to maintain incentives to invest in future cutting-edge technologies that will not only enhance lives, but save them.

The AIPLA approach to a legislative reform retains the basic eligibility categories of Section 101, with a few amendments, and includes new provisions to expressly overrule the current judicially-created framework. This approach represents a clean break from the existing judicial exceptions to eligibility by creating a new framework with clearly defined statutory exceptions. It is intended to provide a clear, objective test that will result in appropriately broad eligibility; it also expressly reaffirms the gatekeeping conditions of patentability in Sections 102, 103, and 112 to address the concerns about over-claiming, as intended by Congress in 1952.

This forward-looking proposal permits the decision makers of today and the future to apply the statutory exceptions meaningfully to patent claims in new areas of research and development without using a wholly backward-looking, subjective test for patent eligibility that cannot be applied predictably to new patent claims.

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<sup>1</sup> Kevin Madigan and Adam Mosoff, *Turning Gold into Lead: How Patent Eligibility Doctrine is Undermining U.S. Leadership in Innovation*, forthcoming in *GEO. MASON L. REV.* (2017) (draft dated April 13, 2017) at 17. Available at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2943431](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2943431).

<sup>2</sup> *Id.*

## **I. Introduction**

As a bar association of intellectual property professionals, the American Intellectual Property Law Association<sup>3</sup> (AIPLA) is keenly interested in a healthy patent system which serves as an effective driver of innovation. In order to serve that function, the patent system must operate with predictable and understandable rules that define where exclusive rights begin and end. The rules established by the Supreme Court in their recent decisions of *Mayo* and *Alice* have created significant uncertainty about what is eligible for patenting in the United States, discouraging investment in future innovation in areas ranging from the life sciences to software.

AIPLA has concluded that legislation is needed to ensure the application of clear, unmalleable rules of patent eligibility with very limited statutory exceptions to provide the needed certainty in the law that is essential for encouraging investment in America's innovation economy. A statutory constraint on determinations of ineligibility will restore Section 101 to the coarse filter of subject matter categories provided in the statute, and will allow the remaining patentability doctrines to do the work of preventing undeserving claims from issuing in patents.

Section 101, as an enabling provision that identifies particular categories of inventive subject matter, is not meant to provide the standard for deciding whether a particular technical advance should receive patent protection. However, the Supreme Court established judge-made rules of ineligibility that have improperly imported the conditions of patentability found in Sections 102, 103, and 112 of the Patent Act into the wholly distinct eligibility standards found in Section 101.

The result has been confusion and inconsistency, aggravated by the sharp uptick in litigating Section 101 issues in the courts and before the Patent Trial and Appeal Board (PTAB). The lower courts have struggled with decisions about whether issued patents are directed to patent-eligible subject-matter, while more than 280 PTAB judges attempt to decipher Supreme Court decisions under tight time constraints. At the same time, the U.S. Patent and Trademark Office's thousands of examiners have struggled to apply the law on a day-to-day basis in their examination of patent applications across a wide range of art. After years of filing amicus submissions to the Supreme Court and Federal Circuit in an attempt to address this uncertainty and unpredictability, AIPLA has concluded that the Supreme Court is the wrong place to look for a remedy.<sup>4</sup>

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<sup>3</sup> Founded in 1897, the American Intellectual Property Law Association (AIPLA) is a national bar association with approximately 14,000 members who are primarily lawyers in both private and corporate practice and in government service, judges, patent and trademark office professionals and academicians. AIPLA's members represent a wide and diverse spectrum of individuals, companies, and institutions, and are involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law. Our members represent owners and users of intellectual property, as well as those who represent patent owners and accused infringers in the courts, who prosecute patent applications and litigate before patent and trademark office, and who are involved in licensing and other technology-related transactions.

<sup>4</sup> See John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1044 (2011) ("The federal judiciary's historic struggles with subject-matter issues suggest a lack of judicial facility for resolving problems in this area.").

AIPLA's Legislative Proposal offers a statutory amendment to eliminate the confusion as to the role of 35 U.S.C. § 101 and of the conditions of patentability found in Sections 102, 103, and 112 of the Patent Act. It is directed at the collection of "patent ineligibility" rules from the Supreme Court that have distorted the deliberately designed structure of the 1952 Patent Act to exclusively commit patentability questions to the novelty, nonobviousness, and disclosure requirements of Sections 102, 103, and 112. Establishing a strict and clear eligibility inquiry by statute would avoid the uncertainty caused by the confusing and malleable Section 101 analysis currently applied. At the same time, the well-developed and rigorous analyses required by Section 102, 103, and 112 mitigate the risk that patents can issue with undeserving claims.

## **II. Legislative Proposal**

AIPLA's Board of Directors has approved a resolution to amend 35 U.S.C. § 101 to address significant problems with current patent eligibility law. The resolution was developed by the AIPLA Patentable Eligible Subject Matter Task Force, which spent over two years considering the current state of the law and a wide variety of alternative solutions. It reads as follows:

RESOLVED that the American Intellectual Property Law Association (AIPLA) favors, in principle, amending 35 U.S.C. § 101 to recite the following:

### **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.

## **A. Summary of the Legislative Proposal**

Under the Legislative Proposal, most of the basic language in the current Section 101 for determining patent eligibility would be retained, but the ineligibility rules created by the judiciary would be replaced with a new framework. The proposed amendment would create three subsections in 35 U.S.C. § 101, with subsection (a) retaining the existing language of section 101 with a few amendments, a new subsection (b) defining the sole exceptions to subject matter eligibility, and a new subsection (c) expressly providing that the eligibility standard is wholly distinct from the conditions of patentability set forth in Sections 102, 103, and 112. AIPLA's proposed amendments to Section 101 are shown below with the relevant inserts and deletions:

**(a) Eligible Subject Matter.**—Whoever invents or discovers any new and useful process, machine, manufacture, ~~or~~ composition of matter, or any ~~new~~ ~~and~~ useful improvement thereof, ~~may obtain~~ shall be entitled to a patent therefor, subject only to the conditions and requirements ~~of~~ 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.

The Legislative Proposal retains the subject matter categories of Section 101 to preserve the statute’s original intended purpose of determining patent eligibility by asking whether the claimed invention falls within one of those patent-eligible categories. The proposal deletes the word “new” from the provision in response to judicial decisions that import into eligibility determinations a novelty-like consideration which is inconsistently applied and less well-developed than the novelty analysis required by 35 U.S.C. § 102. The proposal preserves the utility requirement of the current Section 101.

In a new Section 101(b), the Legislative Proposal provides that the sole exceptions to subject matter eligibility are (1) where the claimed invention as a whole exists in nature independent of and prior to any human activity, or (2) where it can be performed solely in the human mind. In a new Section 101(c), the Legislative Proposal clarifies that the eligibility standard identified in subsection (a) and the sole exceptions to eligibility in subsection (b) are not to be confused with the conditions of patentability contained in subsequent provisions of the patent statute.

## **B. The Problems with Current Law of Patent Eligibility**

### **1. The History of Section 101**

The current law of patent eligibility is clearly set forth in Section 101 of the statute, which states that patent protection is available for any invention or discovery that qualifies as a “useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” That standard has long been a part of the statute, although before the 1952 Act the eligibility standard was combined with the conditions of patentability in Revised Statutes § 4886.

In the mid-19<sup>th</sup> century, a series of Supreme Court decisions began to qualify these categories of eligibility with rules of ineligibility that excluded from patent protection claims directed to natural

phenomena, laws of nature, and abstract ideas.<sup>5</sup> These judicial exceptions were intended to ensure that fundamental concepts and materials which constitute the basic tools of innovation remain in the public domain. However, the judicial exceptions, as they have developed, have been applied in circumstances beyond the need to preserve the basic tools of innovation.

A hallmark of many of these eligibility decisions, which looked to the same statute (Revised Statutes § 4886) that contained the conditions of patentability, was the use of such phrases as “eligible for patent protection,” “patentable process,” “new and useful,” “inventive application,” and “patentable invention.” These phrases suggested a criterion that overlapped or transcended the requirement of novelty itself, and that addressed the practical uses that could be made of the claimed invention, although the metes and bounds of the criteria were generally illusive. The judiciary used this language to prevent patentees from preemptively overreaching in broad areas that suppress rather than incentivize innovation. *See, e.g., Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

The revisions to the patent statute made by the 1952 Patent Act removed the need to apply those criteria by putting in place statutory mechanisms for policing patentability and scope. However, the Supreme Court failed to acknowledge this fundamental change in its 1978 decision of *Parker v. Flook*. 437 U.S. 584 (1978). The *Flook* Court improperly made its patent eligibility determination by considering factors more appropriate to an assessment of nonobviousness under Section 103. The dissenting opinion in that case questioned the decision for finding ineligibility because *one step* in the process would not be patentable subject matter if considered in isolation. *Flook*, 437 U.S. at 599. Importantly, the dissent correctly predicted that the majority struck a “damaging blow at basic principles of patent law by importing into its inquiry under Section 101 the criteria of novelty and inventiveness.” *Id.* at 600.

Three years later, the Supreme Court’s decision in *Diamond v. Diehr*, 450 U.S. 175 (1981), reflected the analytical discipline intended by the 1952 Patent Act. The *Diehr* decision made it clear that, in a determination of patent eligibility: (1) the patent claims must be considered as a whole; (2) the claims are not to be dissected into old and new elements; (3) a new combination of process steps may be patentable even if all the constituents were well known before the combination was made; and (4) novelty “is of no relevance” in determining whether the claimed subject matter falls within the Section 101 categories for patent eligibility. *Diehr*, 450 U.S. at 189. The Court expressly repudiated a government argument that the *Flook* decision permitted

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<sup>5</sup> *See, e.g., Le Roy v. Tatham*, 14 How. 156, 175 (1853) (quoting *Househill Co. v. Neilson, Webster’s Patent Cases*, 683 (1843)) (“A patent will be good, though the subject of the patent consists in the discovery of a great, general, and most comprehensive principle in science or law of nature, if that principle is by the specification applied to any special purpose, so as thereby to effectuate a practical result and benefit not previously attained.”); *Le Roy*, 14 How. at 175 (“A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.”); *Corning v. Burden*, 15 How. 252, 268 (1854) (“[I]t is well settled that a man cannot have a patent for the function or abstract effect of a machine, but only for the machine which produces it.”); *Rubber-Tip Pencil Co. v. Howard*, 20 Wall. 498, 507 (1874) (“An idea of itself is not patentable.”).

dissection of a mathematical algorithm from the claim and permitted consideration of novelty in Section 101 determinations.<sup>6</sup>

## 2. Recent Case Law Has Distorted the Patent Eligibility Determination

In the past decade, cases at the Supreme Court have consistently and improperly diverged from the *Diehr* majority, importing into eligibility determinations the conditions of patentability from other provisions of the 1952 Patent Act, and ignoring *Diehr*'s rule that the claims must be considered as a whole and not dissected into parts. Courts have turned to Section 101 as an expedient way to address broad claiming, poor claim drafting, and the rise of patent-assertion entities. However, Section 101 is an enabling provision that identifies particular categories of patent-eligible subject matter; it does not provide the standard for deciding whether a particular technical advance should receive patent protection. The judicially-created exceptions have put a limiting gloss on Section 101's patent-eligibility standard which provides little guidance to the lower courts or the Patent Office, or to industry on how and where to allocate research and development investment dollars.

In *Bilski v. Kappos*, 561 U.S. 593 (2010), the Court found ineligible process claims to a series of steps instructing how to hedge risk and to a mathematical formula reflecting that concept. Although the Court made a record-specific analysis of key claims, it held that the claims fall outside of Section 101 because they claim an abstract idea. Although the Court purported to recognize the distinction between Section 101 and the conditions of patentability under Sections 102, 103 and 112, in practice it ignored the teachings of *Diehr*. The fragmented 5-4 decision rejected the Federal Circuit's attempt to use a "machine or transformation" test as a bright-line criterion, but in the process produced a 16-page opinion for the Court by Justice Kennedy, a separate concurrence by Justice Kennedy contained within the opinion for the Court, and additional concurrences by Justices Stevens and Breyer. In short, the Court took away the Federal Circuit's bright-line test but failed to put any coherent guidance in its place.

Two years later, in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), the Court used a two-part analysis, finding ineligible a process claim for administering the correct dosage of a drug by observing naturally occurring correlations between the dosage and red blood cell count. In *Mayo*, the Court held that (1) the claims were directed to a natural phenomenon, and (2) the claimed features did not amount to "significantly more" than a

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<sup>6</sup> *Diehr*, 450 U.S. at 189, n. 12 ("It is argued that the procedure of dissecting a claim into old and new elements is mandated by our decision in *Flook* which noted that a mathematical algorithm must be assumed to be within the 'prior art.' It is from this language that the Government premises its argument that if everything other than the algorithm is determined to be old in the art, then the claim cannot recite statutory subject matter. The fallacy in this argument is that we did not hold in *Flook* that the mathematical algorithm could not be considered at all when making the §101 determination. To accept the analysis proffered by the Government would, if carried to its extreme, make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious. The analysis suggested by the Government would also undermine our earlier decisions regarding the criteria to consider in determining the eligibility of a process for patent protection."). In fact, the views of the 1981 majority opinion in *Diehr* (Rehnquist, Stewart, Burger, Powell, White) are rooted in the 1978 *Flook* dissenting opinion (Stewart, Burger, Rehnquist), and the views of the 1978 majority opinion in *Flook* (Stevens, Brennan, Marshall, Blackmun, White, Powell) are relegated to the 1981 *Diehr* dissenting opinion (Stevens, Brennan, Marshall, Blackmun). The two decisions are inconsistent and cannot be reconciled in any meaningful way.

description of the natural correlations. In finding that the claim lacked an “inventive concept,” Justice Breyer wrote: “These instructions add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field.” *Id.* at 82.

In *Alice Corp. Pty, Ltd. v. CLS Bank Int’l*, 134 U.S. 2347 (2014), the Court applied the two-step analysis set forth in *Mayo* and struck down a patent on a computerized trading platform for exchanging obligations where “settlement risk” is eliminated by using a trusted third party. It was undisputed that the claimed invention fell into the Section 101 subject matter category of a “process.” However, the Court found the invention ineligible for patent protection because (1) the claim was directed to an abstract idea, and (2) the claim contained no “inventive concept” that transforms it into a patent eligible claim.

The analysis provided in *Mayo* and *Alice* not only fails to recognize the exclusive role of Section 101 in the patent eligibility determination, but also fails to recognize the import of the Court’s decision in *Diehr*. *Mayo* and *Alice* in practical effect revive the patent ineligibility analysis from *Flook*, which in many respects was limited or repudiated by the *Diehr* decision.<sup>7</sup> The result is confusion about whether the analysis incorporates some version of a novelty and nonobviousness inquiry and whether that is applied to each individual element or the claim as a whole.<sup>8</sup>

### 3. The Current State of Uncertainty

The Federal Circuit, the district courts, and the USPTO have all struggled to implement the Supreme Court’s test in a predictable and consistent manner. However, the frustration has been obvious as they attempt to find a principled formula to guide their decision-making and provide guidance. When the *en banc* Federal Circuit considered the *Alice* case, it was only able to render a 58-word *per curiam* decision, producing in addition five individual concurring or dissenting opinions that reflect the division and confusion on that specialty court.

In *Ultramercial, Inc. v. HuLu, LLC*, 722 F. 3d 1335 (Fed. Cir. 2013), the appellate court focused on the claim as a whole, and expressed concern that characterizations of claimed subject matter are often untethered from the details of the claims themselves. The Court pointed out that *Diehr* rejected the dissenters’ approach of ignoring process steps in the patent determined to be neither novel nor inventive. It quoted the statement “[T]here is no legally recognizable or protected ‘essential’ element, ‘gist’ or ‘heart’ of the invention” from *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 345 (1961).

At the same time, some recent Federal Circuit opinions have attempted to develop a methodology that ties the eligibility determination more closely to the claims and specification.<sup>9</sup> However, none

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<sup>7</sup> See John M. Golden, *Flook Says One Thing, Diehr Says Another: A Need for Housecleaning in the Law of Patentable Subject Matter*, 82 GEO. WASH. L. REV. 1765, 1779 (2014).

<sup>8</sup> *Id.* (“Commentators have repeatedly noted that Supreme Court opinions relating to patentable subject matter feature a confusing mishmash of principles and holdings, at least some of which appear inconsistent or just plain wrong.”).

<sup>9</sup> See *Enfish, LLC v. Microsoft Corp.*, 822 F. 3d 1327 (Fed. Cir. 2016) (software creating innovative logical model for computer database is not directed to an abstract idea); *McRO, Inc. v. Bandai Namco Games America Inc.*, 837 F.3d

of these decisions provide sufficient guidance as to what aspect of the claimed invention suffices for it to transition from ineligible to eligible. While those decisions give a more detailed treatment of the subject matter itself for the eligibility decision, they shed no light on the quantum of evidence needed for the claim to cross the threshold from abstract to concrete. Like all of the decisions attempting to conform to the Supreme Court's eligibility rules, to one degree or another the conclusions can often be characterized as "I know it when I see it."<sup>10</sup>

The USPTO has been just as diligent, not only in trying to find the right rule of law to convey to examiners, but also to ensure that judges on the Patent Trial and Appeal Board have a clear and consistent idea of how ineligibility is determined both in *ex parte* appeals and in administrative trials under the America Invents Act. The multiple examination guidelines and roundtables that have been issued and updated represent a continuing effort to develop administrable rules consistent with the evolving gloss on Section 101 law, but this continual activity suggests that the Patent Office is pursuing something inscrutable.<sup>11</sup> The continuing effort of the Office to untangle the Supreme Court positions is particularly intense in view of the daily need of examiners, PTAB judges, and agency policy makers to apply the eligibility rules. A well-known example of the eligibility confusion at the USPTO can be seen in the development of its position for the *Myriad* case. The patent in that case was granted under the agency's "Utility Examination Guidelines," which represented an extended analysis of the relevant case law of the time.<sup>12</sup> More than 12 years after those guidelines took the position that isolated DNA molecules could be eligible for patent protection, the Supreme Court turned that area of the law and the industry relying on it upside down. These are but a few of many examples, in both the life sciences and computer software that illustrate the constant adjustments that the Office has had to make to the shifting sands of patent eligibility law.

In our view, current section 101 jurisprudence has had a negative impact, in particular, on the life sciences and software industries. The Supreme Court has invoked a variety of extra-statutory policy concerns to justify narrowing the scope of patent-eligible subject matter. As a result, under existing law, more and more inventions relating to or involving life sciences are likely to be challenged and could be found ineligible under the overreaching and malleable *Mayo-Alice* test. The harm done to important innovations is well demonstrated in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *en banc review denied*, 809 F.3d 1282 Fed. Cir. (2015). The patent in the case is directed at a process for detecting paternally-inherited fetal DNA

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1299 (Fed. Cir. 2016) (claim to computer automated improvement over animation techniques is not directed to an abstract idea); *Bascom Global Internet Services, Inc. v. AT&T Mobility LLC*, 827 F.3d 1341 (Fed. Cir. 2016) (inventive concept for software patent is found in ordered combination of known elements); and *Rapid Litigation Management Ltd v. CellzDirect, Inc.*, 827 F.3d 1042 (2016) (process applying natural phenomenon is not directed to patent ineligible subject matter).

<sup>10</sup> See *Jacobellis v. Ohio*, 378 U.S. 184, 197 (1964) (Stewart, J., concurring, on trying to define hard core pornography).

<sup>11</sup> See <https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility>.

<sup>12</sup> 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) ("[A]n inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.").

in maternal blood samples, permitting a prenatal diagnosis of possible birth defects without highly intrusive measures. The Court found the claimed process patent ineligible under *Mayo* because it is directed to well-understood, routine, and conventional steps that act on a natural phenomenon, even though the invention was acknowledged to be “groundbreaking.”<sup>13</sup> In a concurrence to the denial of *en banc* review in the case, Judge Lourie suggested that the Supreme Court rules may have put the whole category of diagnostic claims at risk, creating a crisis of patent law and medical innovation may be upon us.<sup>14</sup>

Likewise, software-implemented inventions are frequently deemed unpatentable abstract ideas. However, software-implemented innovations power our modern world and deserve patent protection.<sup>15</sup> Software is the enabling technology for improving the way we provide healthcare (e.g., surgical robots), drive automobiles (e.g., automatic parallel parking systems), and communicate with people around the world (e.g., video conferencing). Failure to provide adequate patent protection in the life sciences and software industries could weaken competition and impede innovation.

The application of judicial exceptions to patent eligibility has had an adverse impact on innovation in the United States. Courts applying those exceptions have invoked policy concerns about the danger of extending exclusive rights to inventions that purportedly would tie up basic tools of science and products of nature, thereby inhibiting rather than incentivizing innovation. Contrary to recent Supreme Court decisions, Section 101 was simply intended to list categories of statutory subject matter, and was not intended to be used as a surrogate for conditions of patentability. In addition, recent Section 101 jurisprudence has put the United States at risk of falling behind the patent systems of other developed countries.<sup>16</sup>

### **C. AIPLA’s Proposal to Address the Problems with Current Patent Eligibility Law**

Over its two years of substantive discussions and deliberations, AIPLA’s Task Force considered a spectrum of approaches to address concerns over the application of section 101. While different approaches have merit, AIPLA ultimately endorsed an approach intended to return Section 101 to its intended purpose under the 1952 Patent Act. The approach retains the basic eligibility

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<sup>13</sup> 788 F.3d at 1379 (“Sequenom also notes that ‘the method reflects a significant human contribution in that [Drs.] Lo and Wainscoat combined and utilized man-made tools of biotechnology in a new way that revolutionized prenatal care.’ ... We agree but note that the Supreme Court instructs that ‘[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.’ *Myriad Genetics, Inc.*, 133 S.Ct. at 2117.”)

<sup>14</sup> 809 F.3d at 1285, 1287 (“In sum, it is unsound to have a rule that takes inventions of this nature out of the realm of patent eligibility on the grounds that they only claim a natural phenomenon plus conventional steps, or that they claim abstract concepts.”).

<sup>15</sup> David J. Kappos, Under Sec’y of Commerce for Intellectual Property, Keynote Address at the Ctr. for Am. Progress: An Examination of Software Patents, November 20, 2012.

<sup>16</sup> See “The Roots of Innovation,” U.S. Chamber International IP Index, Fifth Edition, February 2017, pp. 111-112 (weakness in U.S. patent system is in somewhat narrow interpretation of patentability of biotech and computer-related inventions compared with international standards); available at <https://www.uschamber.com/event/2017-international-ip-index-the-roots-innovation>.

categories of Section 101, with a few amendments, and includes additional provisions which expressly replace the current judicially-created framework with a new statutory test focused on whether the claimed invention is the result of human effort and is capable of being performed solely in the human mind. This approach is a clean break from the existing eligibility framework by creating a new framework with clearly defined statutory exceptions.

The Legislative Proposal wholly replaces the existing judicially-created two-step framework.<sup>17</sup> Instead, the patent eligibility inquiry, under proposed Section 101(a), would first look to see if the invention falls into one of the listed categories, i.e., a process, machine, manufacture, composition of matter, or any useful improvement thereof. Because these categories embody a coarse filter of eligibility, any invention that falls within one of these categories is entitled to a presumption of eligibility, which a challenging defendant would have to overcome. Should eligibility be challenged, the ineligibility determination would ask whether “the claimed invention as a whole exists in nature independently of and prior to any human activity, or can be performed solely in the human mind.” AIPLA’s Legislative Proposal provides that ineligibility would result only if a claimed invention fails to meet this test, eliminating the existing two-step *Mayo-Alice* test. By invoking the language “claimed invention as a whole,” the Legislative Proposal would also eliminate the ability of patent examiners and judges to dissect claims and disregard, for example, conventional elements of claims. Finally, the Legislative Proposal states that the eligibility test is conducted without regard to the other sections of the patent statute, the manner in which the invention was made or discovered, and whether the claimed invention includes an inventive concept.

The Legislative Proposal is intended to eliminate the current two-part test for eligibility. It introduces an objective and evidence-based approach to the limited question of eligibility, and commits any policy concerns about overbreadth in patent claims to the conditions of patentability. In particular, the Legislative Proposal recognizes that concerns for the existence of a so-called “inventive concept” were eliminated with the creation of the nonobviousness requirement in Section 103 by the 1952 Patent Act. In sum, the Legislative Proposal is intended to provide a clear test that will result in appropriately broad eligibility and that will minimize the uncertainty and unpredictability discouraging investment in research and development.

Below is a section-by-section analysis of AIPLA’s Legislative Proposal.<sup>18</sup>

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<sup>17</sup> The two-step inquiry asks whether a claim is directed to a law of nature, physical phenomenon, or abstract idea and, if so, whether the claim is nonetheless patent eligible because it includes an “inventive concept.” As noted above, the Supreme Court has described an “inventive concept” as something that is significantly more than the law of nature, physical phenomenon, or abstract idea and that is something more than routine or conventional. *Flook*, 437 U.S. at 594 (“Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented. Conversely, the discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application.”); *Mayo*, 566 U.S. at 72-73 (“[The Court’s precedents] insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an ‘inventive concept,’ sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.”)

<sup>18</sup> A summary description of the provisions in a table format may be found in the Appendix.

## 1. Subsection (a)

Subsection (a) is based upon the existing language in 35 U.S.C. § 101. What follows shows the differences between the language of subsection (a) of the Legislative Proposal and the language in current Section 101:

~~Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain~~  
shall be entitled to a patent therefor, subject only to the conditions and requirements  
~~of set forth in this title.~~

AIPLA's proposed Section 101(a) retains most of the basic language in the current Section 101. By retaining the subject matter categories, it preserves the original intended purpose of the patent eligibility inquiry: to determine simply whether the claimed invention falls within one of those patent-eligible categories. AIPLA's proposal also preserves the utility requirement. The rationale for retaining the basic language of Section 101 is rooted in the conviction that the judicially-created rules of ineligibility are not dictated in any way by the statutory language.

The first important difference between existing Section 101 and AIPLA's proposed amendment is the deletion of the word "new" before the subject matter categories. Use of the word "new" in the existing section governing patent eligibility may have created some confusion and led the Supreme Court to conflate the issue of eligibility with the issue of novelty, resulting in an eligibility analysis that involved comparing the invention to the prior art.

Section 101 was not intended to express the novelty requirement. The Patent Act of 1793 included the word "new."<sup>19</sup> In 1952, although Congress placed the word "new" in Section 101,<sup>20</sup> it made clear that novelty is not defined by Section 101 but instead by Section 102. The Senate Report, for example, states that Section 102 provides "in effect, an amplification and definition of 'new' in section 101."<sup>21</sup> Thus, Section 102—not Section 101—describes the novelty required for patentability. AIPLA's Legislative Proposal deletes "new" from Section 101 to confirm that novelty—and any comparison of the claimed invention to the prior art—is an inappropriate inquiry with respect to patent eligibility.

In this sense, AIPLA's Legislative Proposal returns patent eligibility law to the fundamental principle identified in *Diehr*, that "[t]he 'novelty' of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the Section 101 categories of possibly patentable subject matter."<sup>22</sup> The proposal is

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<sup>19</sup> See Patent Act of 1793, ch. 11, § 1, 1 Stat. 318 (1793).

<sup>20</sup> Patent Act of 1952, Pub. L. No. 82-593, 66 Stat. 792, 797 (codified as amended at 35 U.S.C. § 101).

<sup>21</sup> S. REP. NO. 82-1979, at 6 (1952), as reprinted in 1952 U.S.C.C.A.N. 2394, 2399.

<sup>22</sup> *Diehr*, 450 U.S. at 188–89.

intended to reject the contrary approach taken in *Mayo*,<sup>23</sup> where the Court condoned analyzing the novelty of individual steps of the claimed process.<sup>24</sup>

The second important change that AIPLA's proposal makes to existing Section 101 is the replacement of the phrase "may obtain" with "shall be entitled to." This amendment eliminates the suggestion that Congress has given the USPTO or courts discretion with respect to granting patents on patent applications that meet the requirements of the patent statute. The USPTO and courts do not have discretion as to whether applicants who comply with statutory requirements and conditions are entitled to patent rights. Patent applicants are entitled to patents when they file patent applications that meet those requirements and conditions.

The third important difference between AIPLA's proposed Section 101(a) and existing Section 101 is the replacement of "subject to the conditions and requirements of this title" with "subject only to the conditions and requirements set forth in this title." The insertion of the word "only" and the phrase "set forth in this title" clarify that the conditions and requirements of patentability are set forth in the patent statute, and the conditions and requirements set forth in the statute are the only conditions and requirements of patentability. Congress, for example, has not granted the USPTO or courts the ability to create conditions and requirements of patentability that are not set forth in the patent statute. Instead, this language expressly states that Congress has expressly set forth the only available exceptions to patent eligibility.

In sum, proposed Subsection 101(a) creates a presumption that any "process, machine, manufacture, composition of matter, or any useful improvement thereof" is eligible for patenting. AIPLA's proposal does not include a statutory mandate that claim construction be performed in order to establish patent eligibility in every case. To the contrary, claim construction is not necessary to determine eligibility to the extent that eligibility is presumed, although limited claim construction may be necessary in some cases for a determination of ineligibility under AIPLA's subsection 101(b) should such a challenge be raised.

## **2. Subsection (b)**

AIPLA proposes the addition of Subsection (b) which represents the heart of the new framework that replaces the current ineligibility standards. It expressly provides that the "sole exceptions to subject matter eligibility"—in other words the only conditions under which an invention may be found ineligible for patent protection. The sole conditions for finding ineligibility are where either "the claimed invention as a whole exists in nature independently of and prior to any human activity" or "the claimed invention ... can be performed solely in the human mind."

Notably, the ineligibility determination for both exceptions is to be made with respect to the claimed invention "as a whole." This language, for example, eliminates the ability of the USPTO or courts to identify the gist or heart of the claimed invention, identify what the invention is "directed to" rather than what the claim language states, restate the claimed invention in abstract

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<sup>23</sup> 566 U.S. 66 (2012).

<sup>24</sup> *Id.* at 77-80.

terms rather than using the claim language, and ignore claim limitations, such as by assuming claim limitations are in the prior art or by ignoring conventional claim limitations. In essence, this language is intended to return patent law to the fundamental principle expressed in *Diehr* but contradicted in *Mayo*, that claim limitations cannot be ignored or discounted in determinations of patent ineligibility.<sup>25</sup>

The exception for circumstances where the claimed invention as a whole “exists in nature independently of and prior to any human activity” provides an appropriate, clear, historically-grounded basis to determine patent eligibility. First, as a matter of policy, no one is entitled to a patent on something that exists in nature independently of and prior to any human activity. Albert Einstein, for example, was not entitled to a patent on  $E=mc^2$ . But a claim to anything beyond what existed in nature independently of and prior to any human activity ought to be eligible for patenting. Second, this test for patent eligibility is clear in that it should not be difficult for the USPTO and courts to identify whether the claimed invention as a whole existed in nature independently of and prior to any human activity. Third, this test has historical roots in the patent system. The subject matter categories themselves identify things that are the result of human effort: “process, machine, manufacture, or composition of matter, or any ... improvement thereof.”<sup>26</sup>

Indeed, dictionary definitions of “machine,” “manufacture,” and “composition of matter” contemporaneous with their introduction into the patent statute in 1790<sup>27</sup> and 1793<sup>28</sup> all share the concept of human effort.<sup>29</sup> Likewise, while Congress inserted “process” into the patent statute in 1952 to replace the term “art,” at that time Congress both provided a definition of “process” that included “art”<sup>30</sup> and also indicated in the legislative history that “art” and “process or method”

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<sup>25</sup> Compare *Diehr*, 450 U.S. at 188–89 (“In determining the eligibility of respondents’ claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.”) with *Mayo*, 566 U.S. at 79–80 (“To put the matter more succinctly, the 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 beyond 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.”).

<sup>26</sup> 35 U.S.C. § 101 (2012).

<sup>27</sup> Act of Apr. 10, 1790, ch. 7, 1 Stat. 109, 110 (1790) (introducing “machine” and “manufacture” into the patent statute).

<sup>28</sup> Act of Feb. 21, 1793, ch. 11, 1 Stat. 318, 319 (1793) (introducing “composition of matter” into the patent statute).

<sup>29</sup> SAMUEL JOHNSON, A DICTIONARY OF THE ENGLISH LANGUAGE 538 (10th ed. 1792) (defining “machine” as “[a]ny complicated piece of workmanship”); *id.* at 545 (defining “manufacture” as “[t]he practice of making any piece of workmanship” and “[a]ny thing made by art”); *id.* at 190 (defining “composition” as “[t]he act of forming an integral of various dissimilar parts,” as “[a] mass formed by mingling different ingredients,” and as “[t]he state of being compounded; union; conjunction,” where “compound” was defined as “[t]o mingle many ingredients together” and “[t]o form by uniting various parts; he *compounded* a medicine”).

<sup>30</sup> 35 U.S.C. § 100(b) (2012).

mean the same thing.<sup>31</sup> “Art,” which Congress introduced into the patent statute in 1790,<sup>32</sup> was defined in 1792 in a way that likewise connotes human effort.<sup>33</sup> A test searching for human effort, furthermore, reflects the holding of Judge Learned Hand in the celebrated case of the patent on isolated and purified adrenaline, where he decided that an inventor was entitled to a patent when he “was the first to make [an extracted product without change] available for any use by removing it from the other gland-tissue in which it was found,” such that “it became for every practical purpose a new thing commercially and therapeutically.”<sup>34</sup> In this way, Judge Hand emphasized the presence of human effort.

Likewise, in the legislative history accompanying the 1952 Patent Act, Congress indicated that eligibility extends to “anything under the sun that is made by man.”<sup>35</sup> However, the Supreme Court’s *Mayo-Alice* test, requires the claim to include an “inventive concept,” which is something “significantly more” than a natural phenomenon or natural law.<sup>36</sup> AIPLA’s Legislative Proposal therefore diverges from current eligibility law in that it permits *any* human contribution to meet the eligibility requirement.

The exception for circumstances where the claimed invention as a whole “can be performed solely in the human mind” provides an appropriate, clear, historically-grounded basis to determine patent eligibility, applying only to purely mental steps.<sup>37</sup> This language responds to Supreme Court law by drawing a clear administrable line that distinguishes claims directed purely to abstract ideas, i.e., claimed steps occurring *solely* in the human mind. Importantly, because the AIPLA proposal abandons any inquiry into the “abstract” nature of claims, patent eligibility would no longer be the tool for policing method claims that are implemented by conventional or routine hardware, be it a

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<sup>31</sup> S. REP. NO. 82-1979, at 5 (1952), *as reprinted in* 1952 U.S.C.C.A.N. 2394, 2398–99 (“[T]he word ‘art’ which appears in the present statute has been changed to the word ‘process.’ ‘Art’ in this place in the present statute has a different meaning than the words ‘useful art’ in the Constitution, and a different meaning than the use of the word ‘art’ in other places in the statutes, and it is interpreted by the courts to be practically synonymous with process or method. The word ‘process’ has been used to avoid the necessity of explanation that the word ‘art’ as used in this place means ‘process or method,’ and that it does not mean the same thing as the word ‘art’ in other places.”).

<sup>32</sup> Act of Apr. 10, 1790, ch. 7, 1 Stat. 109 (1790).

<sup>33</sup> SAMUEL JOHNSON, A DICTIONARY OF THE ENGLISH LANGUAGE 83 (10th ed. 1792) (defining “art” as “[t]he power of doing something not taught by nature and instinct”).

<sup>34</sup> *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (C.C.S.D.N.Y. 1911), *aff’d in part, rev’d in part sub nom. Parke-Davis & Co v. H K Mulford & Co*, 196 F. 496 (2d Cir. 1912).

<sup>35</sup> S. REP. NO. 82-1979 (1952), *as reprinted in* 1952 U.S.C.C.A.N. 2394, 2399.

<sup>36</sup> *Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2355 (2014) (describing *Mayo* as “set[ting] forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts”); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72-73 (2012) (describing the inquiry as searching for an “inventive concept,” which is something “significantly more” than a natural phenomena or natural law).

<sup>37</sup> *See, e.g., In re Heritage*, 32 C.C.P.A 1170, 1174 (1945) (“[P]urely mental acts are not proper subject matter for protection under the patent statutes.”).

general purpose computer or pencil and paper. The exception, for example, does not apply when any part of a claim requires the use of a physical device such as computer hardware or involves a physical test such as a diagnostic assay. It thus only excludes claims describing purely mental calculations or associations. In this way it also reflects the historical principle, appropriately applied, that any claim to a machine or transformation of matter represents eligible subject matter.<sup>38</sup>

Unless the claimed steps could be performed only in the human mind, they would be examined under the traditional patentability requirements of novelty, nonobviousness, written description, and enablement under Section 102, 103 and 112. Not only does this proposed amendment return the inquiry to well-developed legal principles, it also re-focuses the analysis on the prior art, which is now highly accessible due to technological improvements in search tools.

### **3. Subsection (c)**

AIPLA's proposed subsection (c) clarifies that the eligibility standard identified in subsections (a) and (b) is not to be confused with other standards under the Patent Act.

First, subsection (c) prohibits the USPTO and courts from determining patent eligibility using any of the requirements or conditions of patentability separately stated in Sections 102, 103, and 112 of the patent statute. This prohibition seeks to stop decision makers from conflating the patent eligibility inquiry with the novelty and nonobviousness inquiries under Sections 102 and 103. The well-developed, rigorous analysis required by Sections 102, 103, and 112 prevents applicants from obtaining patent claims to more than what they actually invented without perpetuating the confusion that has resulted from an overreaching and malleable Section 101 analysis. In *Mayo* the Supreme Court confused the eligibility inquiry with the novelty and nonobviousness inquiries by mandating that the significance of individual steps be analyzed to determine whether an inventive concept is present.<sup>39</sup> Subsection (c) of AIPLA's proposal also seeks to stop decision makers from confusing the patent eligibility inquiry with the enablement, written description, and definiteness inquiries under Section 112. In *Mayo*, the Supreme Court wrongly concluded that the enablement and written description requirements do not adequately address concerns with claim breadth.<sup>40</sup> In this regard, the Supreme Court confused its own early cases, which repeatedly compare the scope of claims to the scope of patent disclosures to determine whether claims are in fact too broad, an inquiry required by the enablement and written description requirements.<sup>41</sup>

Second, subsection (c) prohibits the USPTO and courts from determining patent eligibility by considering "the manner in which the claimed invention was made or discovered." This

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<sup>38</sup> See generally *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc) (adopting the machine or transformation test).

<sup>39</sup> See *Mayo*, 566 U.S. at 90 ("We recognize that, in evaluating the significance of additional steps, the § 101 patent-eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap.").

<sup>40</sup> *Id.* at 90-91.

<sup>41</sup> See generally *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245 (1928); *O'Reilly v. Morse*, 56 U.S. 62 (1853).

prohibition utilizes language similar to the prohibition in Section 103 that says that “[p]atentability shall not be negated by the manner in which the invention was made.” This prohibition may prove particularly useful in clarifying that the exception for claimed inventions that “exist[] in nature independently of and prior to any human activity” does not involve any inquiry into how the inventor made or discovered the claimed invention, but instead on what the invention is and how it operates.

Third, subsection (c) expressly prohibits the USPTO and courts from determining patent eligibility by considering “whether the claimed invention includes an inventive concept.” This language clearly overturns the second part of the current patent eligibility test articulated in *Mayo* and *Alice*.<sup>42</sup>

### **III. Conclusion**

AIPLA’s Legislative Proposal provides several benefits as compared to existing eligibility law. First, it ensures an appropriately broad eligibility to accommodate the advent of new and unforeseen technologies. Consistent with the Patent Act of 1952, AIPLA’s Legislative Proposal ensures that patent eligibility is a coarse filter focused on the “type of material which can be the subject matter of a patent.”<sup>43</sup> The Legislative Proposal ensures that “anything under the sun that is made by man” remains eligible,<sup>44</sup> so long as what is claimed as a whole did not exist in nature independent of and prior to any human activity, or is not a purely mental process. Constraining the eligibility inquiry in this way allows the remaining patentability doctrines to do the work of preventing undeserving claims from issuing in patents. This is beneficial because the law governing those other patentability doctrines (e.g., utility, novelty, nonobviousness, enablement, written description, and definiteness) has developed objective guidelines that provide clarity and predictability in the application of those doctrines.

Second, AIPLA’s Legislative Proposal provides clarity to increase predictability. It establishes a straight-forward, objective inquiry: whether a “claimed invention as a whole exists in nature independently of and prior to any human activity, or can be performed solely in the human mind.” The application of these exceptions should be predictable because the application will not involve the exercise of judgment regarding, for example, the extent of preclusion or the incremental value of the invention.

Third, AIPLA’s Legislative Proposal provides significant constraint on judicial intervention. In the last forty years, the Supreme Court has developed non-statutory judicial exceptions to address concerns about broad claims, poorly drafted claims, the rise of patent-assertion entities, and its own sense of the appropriate balance of the rights of creators and users of technology. As discussed above, AIPLA’s proposal expressly ends the common-law development of the so-called judicial exceptions to patent eligibility. It creates two statutory exceptions to patent eligibility and

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<sup>42</sup> *Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2355 (2014) (citing *Mayo*, 566 U.S. at 71).

<sup>43</sup> S. REP. NO. 82-1979, at 5 (1952), as reprinted in 1952 U.S.C.C.A.N. 2394, 2398–99.

<sup>44</sup> *Id.*

eliminates the ability of the Supreme Court to develop further exceptions as a matter of its common-law interpretation of the patent statute.

Finally, AIPLA's forward-looking proposal permits the decision-makers of today and the future to apply the statutory exceptions meaningfully to new patent claims in new areas of research and development. In contrast to other eligibility regimes, such as the European Patent Convention's list of ineligible subject matter<sup>45</sup> or a technological arts approach, AIPLA's proposal is not focused on prior determinations of eligibility based on prior patent claims. AIPLA's Legislative Proposal does not, in other words, put in place a wholly backward-looking test for patent eligibility that cannot be predictably applied to new patent claims. As a result, AIPLA's proposal should not be subject to tinkering in the future by the USPTO or courts. The exceptions in AIPLA's Legislative Proposal will be able to be used to determine the eligibility of future technologies.

For these reasons, AIPLA supports a proposed amendment 35 U.S.C. § 101 to eliminate the problematic two-part test established by the Supreme Court in favor of statutory-based, narrowly confined exceptions to the subject matter eligible for patent protection.

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<sup>45</sup> Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 254 (European Patent Convention), art. 52(2).

Below is a summary of the Legislative Proposal in chart form, including a comparison of the Legislative Proposal with current 35 U.S.C. § 101, followed by a more detailed discussion of the Legislative Proposal.

AIPLA’S Proposed Amendments to § 101	Comments
<b>35 U.S.C. § 101—Inventions Patentable</b>	AIPLA’s Legislative Proposal retains the existing title of § 101.
<b><u>(a) Eligible Subject Matter.—</u></b>	Consistent with the America Invents Act, the Legislative Proposal inserts subtitles for each subsection. Subsection (a) is entitled “Eligible Subject Matter” to accurately describe the matter addressed as eligibility. This preserves the original intended purpose of the patent eligibility inquiry, whether the claimed invention falls within one of the listed categories.
Whoever invents or discovers	This language from the existing statute is retained.
any <del>new and</del> useful process, machine, manufacture, <del>or</del> composition of matter, or any <del>new and</del> useful improvement thereof,	<p>The word “new” is deleted. Use of the word “new” may have confused the Supreme Court and caused it to conflate the issue of eligibility with the issue of novelty or, more generally, eligibility with any comparison with the scope of the prior art. Section 101 was never intended to express the novelty requirement.</p> <p>This amendment confirms that novelty—moreover any comparison of the claimed invention with the scope of the prior art—is an inappropriate inquiry with respect to patent eligibility. In this sense, the Legislative Proposal returns patent eligibility law to the concept identified in <i>Diamond v. Diehr</i>, that “[t]he ‘novelty’ of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.”<sup>46</sup></p>

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<sup>46</sup> *Diamond v. Diehr*, 450 U.S. 175, 188–89 (1981).

AIPLA’S Proposed Amendments to § 101	Comments
	<p>The Legislative Proposal eliminates the contrary approach taken in <i>Mayo Collaborative Services v. Prometheus Laboratories, Inc.</i>,<sup>47</sup> where the Court condoned analyzing the novelty of individual steps of the claimed process.<sup>48</sup> The Legislative Proposal preserves the utility requirement.</p>
<p><del>may obtain</del> shall be entitled to a patent therefor,</p>	<p>This amendment replaces “may obtain” with “shall be entitled to.” This eliminates any contention that Congress has given the USPTO or courts discretion with respect to granting patents on patent applications that meet the requirements of the patent statute. The USPTO and courts do not have discretion as to whether applicants who comply with statutory requirements and conditions are entitled to patent rights. Patent applicants are entitled to patents when they file patent applications that meet these requirements and conditions.</p>
<p>subject <u>only</u> to the conditions and requirements <del>of</del> <u>set forth in</u> this title.</p>	<p>This amendment replaces “subject to the conditions and requirements of this title” with “subject only to the conditions and requirements set forth in this title.” Use of the word “only” and the phrase “set forth in this title” clarify that the conditions and requirements of patentability are set forth in the patent statute, and the conditions and requirements set forth in the statute are the only conditions and requirements of patentability.</p> <p>Congress, for example, has not granted the USPTO or courts the ability to create conditions and requirements of patentability that are not set forth in the patent statute. In particular, this amendment clarifies that the days of the common law development of the so-called judicial exceptions to patent eligibility have passed. Instead, what this language highlights is that Congress in subsection (b) has set forth the only exceptions to patent eligibility, and they are the express statutory exceptions.</p>

<sup>47</sup> 566 U.S. 66 (2012).

<sup>48</sup> *Id.* at 78-79.

AIPLA’S Proposed Amendments to § 101	Comments
<b><u>(b) Sole Exceptions to Subject Matter Eligibility.—</u></b>	Subsection (b) is new and represents the heart of the new framework for patent eligibility. It expresses the “sole exceptions to subject matter eligibility,” in other words the only exceptions to what is described in subsection (a).
<b><u>A claimed invention is ineligible under subsection (a) only if</u></b>	This language states clearly that the only exceptions to eligibility are stated in this subsection. This language eliminates the judicial exceptions.
<b><u>the claimed invention as a whole</u></b>	<p>This language clarifies that both exceptions (identified below) apply only when the claimed invention “as a whole” either exists in nature or can be performed solely in the human mind. This language—“as a whole”—eliminates the ability of the USPTO or courts to, for example, identify the gist or heart of the claimed invention, to identify what the invention is “directed to” rather than what the claim language states, to restate the claimed invention in abstract terms rather than using the claim language, and to ignore claim limitations, such as by assuming claim limitations are in the prior art or by ignoring conventional claim limitations.</p> <p>At least in part, therefore, this language returns patent law to the concept expressed in <i>Diamond v. Diehr</i> but contradicted in <i>Mayo</i>, that claim limitations cannot be ignored or discounted for purposes of analyzing patent eligibility.<sup>49</sup></p>

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<sup>49</sup> Compare *Diehr*, 450 U.S. at 188–89 (“In determining the eligibility of respondents’ claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.”) with *Mayo*, 566 U.S. at 79-80 (“To put the matter more succinctly, the 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 beyond 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.”).

AIPLA’S Proposed Amendments to § 101	Comments
<p><b><u>exists in nature independently of and prior to any human activity,</u></b></p>	<p>The exception for circumstances where the claimed invention as a whole “exists in nature independently of and prior to any human activity” provides an appropriate, clear, historically-grounded basis to determine patent eligibility. As a matter of policy, no one is entitled to a patent on something that exists in nature independently of and prior to any human activity. Albert Einstein, for example, was not entitled to a patent on <math>E=mc^2</math>. But a claim to anything beyond what existed in nature independently of and prior to any human activity ought to be eligible for patenting. The Legislative Proposal diverges from current eligibility law in that it permits <i>any</i> human contribution to meet the eligibility requirement. For more details regarding this exception, see the discussion in the Report.</p>
<p><b><u>or can be performed solely in the human mind.</u></b></p>	<p>The exception for circumstances where the claimed invention as a whole “can be performed solely in the human mind” also provides an appropriate, clear, historically-grounded basis to determine patent eligibility. This exception applies only to purely mental steps.<sup>50</sup> This exception does not apply, for example, when any part of a claim requires the use of a physical device such as computer hardware or involves a physical test such as a diagnostic assay. It thus excludes only claims describing purely mental calculations or associations. In this way it also reflects the historical principle, appropriately applied, that any claim to a machine or transformation of matter represents eligible subject matter.<sup>51</sup></p>

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<sup>50</sup> See, e.g., *In re Heritage*, 32 C.C.P.A 1170, 1174 (1945) (“[P]urely mental acts are not proper subject matter for protection under the patent statutes.”).

<sup>51</sup> See generally *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc) (adopting the machine or transformation test).

AIPLA’S Proposed Amendments to § 101	Comments
<b><u>(c) Sole Eligibility Standard.—</u></b>	Subsection (c) is new. It clarifies that the eligibility standard identified in subsections (a) and (b) is not to be confused with other extraneous standards or concerns.
<b><u>The eligibility of a claimed invention under subsections (a) and (b) shall be determined without regard to</u></b>	This language in particular clarifies that the eligibility standard identified in subsections (a) and (b) are not to be confused with other extraneous standards or concerns.
<b><u>the requirements or conditions of sections 102, 103, and 112 of this title,</u></b>	<p>Subsection (c) first prohibits the USPTO and courts from determining patent eligibility using any of the requirements or conditions of patentability separately stated in §§ 102, 103, and 112 of the patent statute. This prohibition seeks to stop decision-makers from confusing the patent eligibility inquiry with the novelty and nonobviousness inquiries under §§ 102 and 103. In <i>Mayo</i> the Supreme Court confused the eligibility inquiry with the novelty and nonobviousness inquiries by mandating that the significance of individual steps be analyzing to determine whether an inventive concept is present.<sup>52</sup></p> <p>This prohibition, however, also seeks to stop decision-makers from confusing the patent eligibility inquiry with the enablement, written description, and definiteness inquiries under § 112. In <i>Mayo</i>, the Supreme Court wrongly concluded that the enablement and written description requirements do not adequately address concerns with claim breadth.<sup>53</sup> In this regard, the Supreme Court confused its own historical cases, which repeatedly compare the</p>

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<sup>52</sup> See *Mayo*, 566 U.S. at 90 (“We recognize that, in evaluating the significance of additional steps, the § 101 patent-eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap.”).

<sup>53</sup> *Id.* at 90-91.

AIPLA’S Proposed Amendments to § 101	Comments
	scope of claims to the scope of patent disclosures to determine whether claims are in fact too broad, an inquiry required by the enablement and written description requirements. <sup>54</sup>
<p><b><u>the manner in which the claimed invention was made or discovered,</u></b></p>	<p>Subsection (c) second prohibits the USPTO and courts from determining patent eligibility by considering “the manner in which the claimed invention was made or discovered.” This prohibition utilizes language similar to the prohibition in § 103 that says that “[p]atentability shall not be negated by the manner in which the invention was made.”</p> <p>This prohibition may prove particularly useful in clarifying that the exception for claimed inventions that “exist[] in nature independently of and prior to any human activity” does not involve any inquiry into how the inventor made or discovered the claimed invention, but instead on what the invention is and how it operates.</p>
<p><b><u>or whether the claimed invention includes an inventive concept.</u></b></p>	<p>Third, subsection (c) prohibits the USPTO and courts from determining patent eligibility by considering “whether the claimed invention includes an inventive concept.” This language clearly overturns the second part of the current patent eligibility test articulated in <i>Mayo</i> and <i>Alice</i>.<sup>55</sup></p>

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<sup>54</sup> See generally *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245 (1928); *O’Reilly v. Morse*, 56 U.S. 62 (1853). See also *LizardTech, Inc. v. Earth Resource Mapping Inc.*, 424 F.3d 1336, 1346 (Fed. Cir. 2005) (demonstrating use of the enablement and written description requirements to constrain claim breadth).

<sup>55</sup> *Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2355 (2014) (citing *Mayo*, 566 U.S. at 71).