

AIPLA

Testimony of

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hearing on

“The State of Patent Eligibility in America: Part II”

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I. Introduction

Chairman Tillis, Ranking Member Coons, and distinguished members of the Judiciary Committee, I appreciate the opportunity to present the views of the American Intellectual Property Law Association (AIPLA) on Patent Eligibility. We are grateful for the time, resources and leadership you and your staffs have devoted to this most significant issue, and for your continued attention to the challenges facing the U.S. patent system. As will be discussed in detail, AIPLA conceptually supports the direction and approach of the Discussion Draft. That said, we have some concerns with parts of the Draft that we believe require further consideration, and we look forward to working with you on this important legislative effort.

My name is Barbara Fiacco, and I am a partner at the law firm Foley Hoag in Boston. I have been practicing intellectual property law for more than 20 years, with a particular emphasis on patent law. My law practice focuses on innovations in the life sciences including therapeutic proteins, monoclonal antibodies, small molecule compounds, drug delivery, molecular diagnostics, and medical devices. Currently, I am a member of the Board of Directors of AIPLA, President-Elect of the Association, and Chair of AIPLA's Section 101 Task Force. I come here today to represent the views of AIPLA, and not necessarily those of my firm or the firm's clients.

Founded in 1897, AIPLA is a national bar association with approximately 13,500 members engaged in private and corporate practice, in government service, and in the academic community. AIPLA's members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. AIPLA's mission is to promote an intellectual property system that stimulates and rewards invention, creativity, and investment while accommodating the public's interest in healthy competition, reasonable costs, and basic fairness.

Our patent system plays a critical role in fostering innovation, which is the lifeblood of the U.S. economy. Innovators in high-technology industries spend many billions of dollars on high-risk R&D. A strong and predictable patent system allows innovators to be confident that they will be able to obtain a return on their investments should they successfully develop new technologies. In particular, the patent system must have understandable and predictable rules on which industry and investors can rely to obtain patents, sell or license their patent rights, and enforce those patent rights when they are infringed.

As a nation, we have had incredible success fostering innovation. However, over the past decade, using a strained interpretation of Section 101 of the Patent Act, the Supreme Court has developed subjective rules of patent ineligibility and, in doing so, has undermined our patent system. The Court's decisions have created significant uncertainty about what is eligible for patenting in the United States. This has reduced investment in new technologies, produced inconsistency and uncertainty about patent rights and their enforceability, cast a cloud over licensing and other intellectual property transactions, and driven industry to foreign jurisdictions that are more welcoming to their innovations.¹

Because a strong and predictable patent system is important to accelerating technological progress and economic growth, AIPLA has concluded that legislation is required to restore the fundamental principles underlying our patent system on which our modern innovation economy rests.² We are therefore appreciative of your understanding that resolving the issues around 35 U.S.C. §101 is basic to the effective operation of our patent system.

¹ See David O. Taylor, *Confusing Patent Eligibility*, 84 TENN. L. REV. 157 (2016); see also Kevin Madigan and Adam Mossoff, *Turning Gold into Lead: How Patent Eligibility Doctrine is Undermining U.S. Leadership in Innovation*, 24 Geo. Mason L. Rev. 939 (2017), available at http://georgemasonlawreview.org/wp-content/uploads/2017/11/24_4_Madigan_Mossoff_2.pdf.

² See "AIPLA Legislative Proposal on Patent Eligibility," 5/12/2017, https://www.aipla.org/docs/default-source/advocacy/aipla-legislative-proposal---patent-eligible-subject-matter.pdf?sfvrsn=7e208efe_2.

II. Background: The Law of Patent Eligibility

The need for exclusive rights for patented innovations is explicitly recognized in the U.S. Constitution.³ Article I, Section 8 authorizes Congress to confer such exclusive rights “for limited times” in order to promote innovation, reflecting an intention to balance the benefits of a limited patent monopoly against the benefits of our competitive economic system. This is the crucial balance that patent laws must strike: they must provide sufficient rewards of exclusivity in the marketplace for all forms of innovation in exchange for disclosing the details of new inventions and discoveries to allow for others to build on them, without undermining the public’s interest in healthy competition, reasonable prices, and basic fairness.

When it enacted the 1952 Patent Act, Congress established the modern framework of our patent system, putting into place an objective, evidence-based analysis for awarding patent protection. Prior to 1952, courts combined the eligibility inquiry with their analysis of conditions of patentability because a single statute, Revised Statutes § 4886, contained both requirements. Section 101 of the 1952 Patent Act was enacted as a separate enabling provision, identifying particular categories of subject matter eligible for patent protection. By contrast, Sections 102, 103, and 112 set out the “conditions of patentability” and were intended to provide a yardstick for judging novelty, non-obviousness, and the sufficiency of disclosure in the claims and specification. Importantly, Section 101 was not intended as the threshold standard for deciding whether a particular innovation or improvement should receive patent protection. Indeed, the legislative history of the 1952 Patent Act makes clear that Congress intended statutory (i.e., patent eligible) subject matter to “include anything under the sun that is made by man.”⁴

³ Art I, Section 8, para. 8: “The Congress shall have the power ... To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries; ...”

⁴ S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952).

However, in the past decade, Supreme Court decisions have improperly diverged from the basic framework of the 1952 Act as a whole and Section 101 in particular by importing into the eligibility inquiry the conditions of patentability required by other provisions of the Act. While the “judicial exceptions” to the express categories set forth in Section 101 have been long recognized (laws of nature, natural phenomena, mathematical formulae, and abstract ideas), the Supreme Court has expanded the judicial exceptions without having any basis in the statute to do so. At the same time, the Court has provided insufficient guidance to the lower courts or the Patent Office as to the bounds of what is eligible for patenting. Industry has also been left wondering whether, how and where to allocate research and development investment dollars. This change in the law has also added uncertainty to patent enforcement and licensing, which is underscored by the number of Section 101 appeals heard by the Federal Circuit. In 2009, the year before the Supreme Court decided *Bilski*, the Federal Circuit heard only two appeals on Section 101 issues; by contrast, from 2011 to 2018, the Federal Circuit has heard at least 115 appeals on Section 101.⁵

In *Bilski v. Kappos*, 561 U.S. 593 (2010), the Court found patent claims directed to a process of hedging risk in the field of commodities trading was ineligible for patenting under Section 101 because they claim an abstract idea. Although the Court purported to recognize the distinction between Section 101’s eligibility inquiry and the conditions of patentability under Sections 102, 103 and 112, in practice it ignored the distinction. In addition to the Court’s 16-page opinion, there was also a separate concurrence by Justice Kennedy, as well as additional concurrences by Justices Stevens and Breyer. In short, the Court’s fragmented decision failed to put any coherent guidance on Section 101 in 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 using naturally occurring correlations between the dosage and red

⁵ USPTO, Chart of Subject Matter Eligibility Court Decisions, https://www.uspto.gov/sites/default/files/documents/ieg-sme_crt_dec.xlsx (last updated February 1, 2019).

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 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 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.

These decisions fail to adhere to the sole purpose of Section 101 as a patent eligibility inquiry, instead applying shortcut patentability considerations to isolated elements of a claim in search of an “inventive concept.” According to these decisions, a patent claim that recites an abstract idea or natural law must include other claim elements that are not routine or conventional in order to demonstrate that the patent claims something “significantly more” than the abstract idea or natural law. This analysis contradicts fundamental principles of patent law, including that claims are to be considered as a whole and that novelty or non-obviousness considerations are not part of the eligibility analysis.⁶ The result has been a confusing conflation of eligibility

⁶ *Diamond v. Diehr*, 450 U.S. 175, 193 n. 15 (1981) (“The fact that one or more of the steps in respondents’ process may not, in isolation, be novel or independently eligible for patent protection is irrelevant to the question of whether the claims as a whole recite subject matter eligible for patent protection under §101.”); *see also* 35 U.S.C. §102 (novelty); 35 U.S.C. § 103 (“A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.”)

and patentability, based on the improper parsing of a claim into individual elements rather than a focus on the claim as a whole.

The Federal Circuit, the district courts, and the USPTO all have struggled to implement the Supreme Court's test in a predictable and consistent manner. And their frustration has been obvious as they attempt to find a principled formula to guide their decision-making. When the *en banc* Federal Circuit considered the *Alice* case, the result was a 58-word *per curiam* decision, with five individual concurring or dissenting opinions. This reflects the division and confusion on the very court that Congress created to hear all patent appeals and ensure uniformity in the law.

Some recent Federal Circuit opinions have attempted to develop a methodology that ties the eligibility inquiry more closely to the claims and specification.⁷ However, none of these decisions provides guidance as to what aspect of the claimed invention is enough to transition subject matter from ineligible to eligible. Those decisions give a more detailed treatment of the subject matter itself for the eligibility decision, but 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."⁸ This is not a basis for a strong, predictable patent system.

The dissatisfaction of some Federal Circuit judges is readily apparent in the multiple opinions issued in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *en banc*

⁷ 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 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).

⁸ See *Jacobellis v. Ohio*, 378 U.S. 184, 197 (1964) (Stewart, J., concurring, on trying to define hard core pornography).

review denied, 809 F.3d 1282 Fed. Cir. (2015). The patent in that case is directed at a process for detecting paternally-inherited fetal DNA in maternal blood samples, permitting a prenatal diagnosis of possible birth defects without highly intrusive measures. The Federal Circuit found the claimed process patent ineligible under *Mayo* because it claims well-understood, routine, and conventional steps that act on a natural phenomenon, even though the invention was acknowledged to be “groundbreaking.”⁹ Judge Linn concurred with the panel ruling “only because I am bound by the sweeping language of the test set out in [*Mayo*], which had the effect of “excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain.”¹⁰ He pointed out that historically “even though all the constituents of the combination were well-known and in common use before the combination was made,”¹¹ that did not preclude patent eligibility of the combination. Concurring in the denial of *en banc* review, Judge Dyk nonetheless expressed a concern “that a too restrictive test for patent eligibility under 35 U.S.C. § 101 with respect to laws of nature (reflected in some of the language in *Mayo*) may discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new natural laws and phenomena.”¹² Also concurring in denial of *en banc* review, Judge Lourie expressed his reservations about the law of Section 101 as it has evolved:

The claims might be indefinite or too broad in that they do not specify how to amplify and detect, or how to separate, detect, and diagnose. Or they perhaps attempt to claim all known methods of carrying out those steps. But the finer filter of § 112 might be better suited to treating these as questions of patentability, rather than reviewing them under the less-defined eligibility rules.¹³

The USPTO has been just as diligent at trying not only to find the right rules 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

⁹ 788 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.”)

¹⁰ 788 F.3d at 1380.

¹¹ *Id.*

¹² 809 F.3d at 1287 (concurring with *en banc* denial).

¹³ *Id.* at 1284

trials under the America Invents Act. The multiple examination guidelines that have been issued and updated by the agency represent a continuing effort to develop administrable rules consistent with the evolving interpretation of Section 101 law,¹⁴ but this ongoing activity suggests the futility of the task. The continuing effort of the USPTO to untangle the Supreme Court positions is particularly intense in view of the daily need of examiners, Patent Trial and Appeal Board judges, and the innovation community to understand and rely upon the eligibility rules.

The effect of the USPTO's most recent guidance on the law was clouded by the Federal Circuit's recent *Cleveland Clinic* decision, where Judge Lourie wrote the following:

While we greatly respect the PTO's expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance. And, especially regarding the issue of patent eligibility and the efforts of the courts to determine the distinction between claims directed to natural laws and those directed to patent-eligible applications of those laws, we are mindful of the need for consistent application of our case law.¹⁵

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 case 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 the previously discussed *Ariosa* case concerning a process for diagnosing possible birth defects without highly intrusive measures. In his concurrence with the denial of *en banc* review in that case, Judge Lourie suggested that the Supreme Court rules may have put the whole category of diagnostic claims at risk, observing that a crisis of patent law and medical innovation may be upon us: “ In sum, it is unsound to have a rule that takes inventions of this nature out of the

¹⁴ See 84 Fed. Reg. 50 (Jan. 7, 2019); available at <https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility>.

¹⁵ *Cleveland Clinic Foundation v. True Health Diagnostics, LLC*, Fed. Cir. No. 2018-2128, 4/1/2019 (nonprecedential); slip op. at page 13, available at <http://www.ca9.uscourts.gov/sites/default/files/opinions-orders/18-1218.Opinion.4-1-2019.pdf>.

realm of patent eligibility on the grounds that they only claim a natural phenomenon plus conventional steps, or that they claim abstract concepts.”¹⁶

Likewise, software-implemented inventions are frequently deemed unpatentable as claiming abstract ideas. However, software-implemented innovations power our modern world and deserve to be considered for patent protection.¹⁷ 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). While software is now a common way to implement inventions, that was not always the case. Years ago, such inventions were implemented in hardware. Simply because an invention is implemented through a particular medium should not take it out of the bounds of patent eligibility, particularly since the form of implementation may well impact the patentability determination required by Sections 102, 103 and 112. AIPLA believes that closing the eligibility door on certain advances in the life sciences and software industries (including some that we cannot even predict today) could impede innovation to the detriment of our economy and society as a whole.

In sum, the expanding application of judicial exceptions to patent eligibility has had an adverse impact on a wide variety of innovations in the United States. Moreover, recent Section 101 jurisprudence has put the United States patent system at risk of falling behind those of other developed countries in promoting and securing innovation.¹⁸ The recent Supreme Court decisions have strayed too far from the intended purpose of Section 101 as an enabling provision, which was to identify categories of statutory subject matter, not to serve as a surrogate for the conditions of patentability.

¹⁶ 809 F.3d at 1287.

¹⁷ 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.

¹⁸ See Kevin Madigan and Adam Mossoff, *Turning Gold into Lead: How Patent Eligibility Doctrine is Undermining U.S. Leadership in Innovation*, 24 Geo. Mason L. Rev. 939 (2017), available at http://georgemasonlawreview.org/wp-content/uploads/2017/11/24_4_Madigan_Mossoff_2.pdf.

III. AIPLA's Legislative Proposals

In 2014, AIPLA established its Section 101 Task Force to study the problems surrounding current patent eligibility law and consider alternative solutions; at the same time, AIPLA filed amicus briefs in the Supreme Court whenever this issue was presented. The work of our Section 101 Task Force did not initially seek a legislative solution, but rather examined current case law in search of positive developments. After three years of careful analysis, it became clear to AIPLA that the sweeping language of Supreme Court rulings and the application of those rulings by lower courts had closed off any return to the framework and principles of the 1952 Act.

In the hope the Congress might intervene, we developed a legislative proposal, subsequently working with Intellectual Property Owners Association (IPO) on a joint proposal.¹⁹ AIPLA and IPO also engaged with the ABA's Intellectual Property Law Section (ABA-IPL) to agree on basic principles that we believe must inform efforts at patent subject-matter eligibility reform.²⁰

Ultimately, AIPLA and IPO agreed upon the Joint AIPLA-IPO proposal, which made a clean break from the judicial exceptions to eligibility by identifying two narrow and clearly defined statutory exceptions. The proposal was intended to provide appropriately broad eligibility with a clear and objective test; it expressly reaffirmed the gatekeeping conditions of patentability in Sections 102, 103, and 112, as intended by Congress in 1952.

In our view, the Joint AIPLA-IPO Proposal faithfully encompassed the spirit and purpose of Section 101. It would have reversed the judicial conflation of the subject matter eligibility inquiry and the patentability requirements to restore the independence of the eligibility inquiry. The proposal would have retained the basic eligibility categories: process, machine,

¹⁹ See "Joint AIPLA-IPO Proposal on Patent Eligibility," <https://www.aipla.org/policy-advocacy/legislative/joint-aipla-ipo-proposal-on-patent-eligibility>; see also "AIPLA Legislative Proposal on Patent Eligibility," 5/12/2017, section-by-section analysis of AIPLA's Legislative Proposal, pp. 11-13, https://www.aipla.org/docs/default-source/advocacy/aipla-legislative-proposal---patent-eligible-subject-matter.pdf?sfvrsn=7e208efe_2.

²⁰ See "AIPLA/IPO/ABA-IPL Joint Principles Paper on Section 101," <https://www.aipla.org/policy-advocacy/legislative/aipla-ipo-aba-joint-principles-paper-on-section-101>.

manufacture, composition of matter, or any improvement thereof. It also would have retained the requirement that inventions are “useful” to carry out the broad, gatekeeping role of Section 101, but would have eliminated the word “new” to prevent courts from conflating the eligibility analysis with the patentability analysis.

The Joint AIPLA-IPO legislative proposal would have codified the analytical framework for patent eligibility requiring that the claimed invention be considered as a whole, not parsed into individual elements. This is of critical importance because, as is well recognized, every invention is a new combination of old elements. The proposal would have rejected the existing judicial exceptions. However, because we recognize that not everything should be eligible for patenting, AIPLA and IPO also proposed two clearly defined, exclusive statutory exceptions to eligibility: (a) inventions that as a whole exist in nature independently of and prior to any human activity or (b) inventions that are performed solely in the human mind. AIPLA concluded that these two subject matter categories, narrowly and clearly defined, required express exclusion because they may not be adequately susceptible to a rigorous patentability determination under Sections 102, 103 and 112.

Finally, the Joint AIPLA-IPO proposal would have expressly differentiated the Section 101 eligibility inquiry from the conditions of patentability required by Sections 102, 103, and 112. The proposal included a provision stating that the determination of eligibility must be made without regard to (i) the requirements or conditions of Sections 102, 103, and 112 of this title; (ii) the manner in which the claimed invention was made or discovered; or (iii) whether the claimed invention includes an inventive concept.

IV. Discussion Draft

The Discussion Draft, circulated on May 22, 2019, is a serious and impressive step toward untangling the Gordian Knot that the Supreme Court’s patent eligibility decisions have become. AIPLA is grateful for the understanding of the problem that this Draft represents and for the

effort to restore balance to the Patent Act which is indispensable for an effective patent system. While APLA is generally supportive of the Discussion Draft and the direction it takes, we have some concerns with parts of the Draft that need further consideration.

Most importantly, however, the Discussion Draft proposal for Section 101 adheres to the hallmarks of the 1952 Patent Act, a framework that has nurtured an unprecedented wave of innovation by American industry over the past 57 years. In particular, the Discussion Draft restores the clear distinction between patent eligibility under Section 101 and the separate, rigorous patentability requirements of Sections 102, 103, and 112. This approach is critical to a healthy, robust culture of innovation.

APLA also lauds the Discussion Draft's technology-neutral approach to the Section 101 enabling provision. This is particularly important as technology fields converge more and more, such as in personalized medicine where "big data," medical diagnostics and therapeutic products are working together to produce more efficient and effective healthcare solutions.

We think that Draft Section 101(a) properly retains the current categories of eligibility. United States patent law has long provided patent protection for any invention or discovery that qualifies as a "useful process, machine, manufacture, or composition of matter, or any [] useful improvement thereof" and it should continue to do so. We also agree with the Draft's deletion of the term "new" from Section 101; as explained above, it is very important to delineate clearly the eligibility determination from the novelty and non-obviousness analyses. Draft Section 101(b) further clarifies the eligibility determination by requiring a focus on the claimed invention as a whole and all claim limitations. This analytical model addresses a significant element of the confusion created by the case law in this area.

With respect to the first Additional Legislative Provision, APLA conceptually agrees that the provisions of Section 101 should be construed in favor of eligibility. As noted, Section 101 originally was intended and should continue to be an enabling provision. One way to express

that presumption of eligibility for any “useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” would be to replace “Whoever invents or discovers . . . **may obtain a patent**” with “Whoever invents or discovers . . . **shall be entitled to a patent**” subject to the conditions and requirements of Title 35. AIPLA welcomes the opportunity to continue discussions about the implementation of this Additional Legislative Provision.

AIPLA also conceptually agrees with the second Additional Legislative Provision eliminating the judicial exceptions. These judicially created exceptions to eligibility have given rise to subjective rules that cannot be implemented with any reasonable precision or certainty. AIPLA notes that, in light of recent Supreme Court precedent addressing Congressional intent, it is imperative for the provision to clearly state that judicial exceptions and the cases establishing or interpreting the judicial exceptions are abrogated. For example, the Supreme Court recently held that the legislative record accompanying a revision of the general venue statute provided insufficient evidence that Congress intended a corresponding change to the patent venue statute. *See TC Heartland LLC v. Kraft Foods Group Brands LLC*, 137 S. Ct. 1514 (2017); *see also Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628, 633-634 (2019). For these reasons, AIPLA agrees that a clear statement of abrogation is an important component to the Section 101 reform efforts.

AIPLA wholeheartedly agrees with the third Additional Legislative Provision expressly stating that patent eligibility shall be determined without regard to how the invention was made, whether the elements of the invention are well-known, routine or conventional, the state of the art at the time of the invention, or any other consideration relating to Sections 102, 103, and 112. AIPLA firmly believes that these principles should be included in an express provision of Section 101.

We have some concerns with the proposed Section 100(k). As phrased, the proposed definition of “useful” creates uncertainty. The existing utility requirement in Section 101 has an

established meaning rooted in Supreme Court and Federal Circuit decisions, as well as U.S. Patent and Trademark Office guidelines,²¹ and has not been a recent source of major controversy in the USPTO or the courts. AIPLA is concerned about any provision that would create an additional “usefulness” requirement beyond the utility requirement.

We are also concerned about the proposed Section 100(k)’s use of the phrase “in any field of technology.” As a preliminary matter, it is unclear what term or phrase “in any field of technology” is intended to modify in Section 100(k). More importantly, the phrase itself is ambiguous and could therefore invite new, unpredictable interpretations of the bounds of eligibility. In particular, courts could have different views of what “counts” as “technology,” which could lead to confusion and uncertainty. Moreover, judicial attempts to define “technology” necessarily are grounded in historical conceptions of technology whereas Section 101 should be forward-looking and flexible enough to embrace entirely new unimaginable fields of endeavor.

With respect to the use of the phrase “through human intervention,” we are not opposed to a limitation that requires some degree of human intervention in order for the claimed invention to be patent eligible. However, we believe that further consideration should be given to how the language of this proposed limitation would impact inventions made through the use of artificial intelligence, which is or will be driving innovation in many different technical fields.

Finally, we have some concerns with the proposed amendment to Section 112(f). This amendment is directed at “[e]nsuring that simply reciting generic technical language or generic functional language does not salvage an otherwise ineligible claim.” However, the specific proposed amendment appears to extend well beyond concerns with “generic technical” or “generic functional” claim language, which is really an issue of patentability, not eligibility.

²¹ See *Brenner v. Manson*, 383 U.S. 519 (1966); *In re Fisher*, 421 F. 3d 1365 (Fed. Cir. 2005); and “Utility Examination Guidelines,” 66 Fed. Reg. 1092 (Jan. 5, 2001).

As drafted, the proposed amendment is a rule of claim construction that would apply to all claims using functional language and not reciting specific structure or acts for performing that function. While this proposal may be motivated by some concerns about claims in certain technology areas using functional language that is construed too broadly, the Discussion Draft's proposed amendment is not limited in its application and has the potential to disrupt a well-established claim-drafting tool that current Section 112(f) is intended to address. Moreover, this is the type of issue that current Sections 102, 103 and 112 should guard against in the patentability determination.

Section 112 is a complex provision with many parts that have a long and complicated history in the case law. Part of Section 112 is directed to making sure the patent specification is adequate and meets certain requirements. Current Section 112(f) is directed to a specific type of claim - one that uses "means for" or "step for" language for performing a specified function without reciting, in the claim, the structure, material, or acts for performing that function. This has long been an important tool of patent prosecutors for claim drafting. While its application has not been perfect, the proposed amendment to Section 112(f) appears to eliminate this claim-drafting tool and instead apply a rule of construction for all patent claims using functional claim language, regardless of "means for," "step for" or similar triggering language. Indeed, it is likely that there would be significant litigation over what constitutes "functional" language, and its bounds may not be apparent for years to come, risking a new area of malleable patent law. This proposed amendment could be treated by examiners and the courts as an additional "written description" requirement and have further implications in patent drafting generally. Such a development could be even more problematic if the proposed amendment were applied retroactively.

In sum, we are concerned that the proposed amendment to Section 112(f) would be applicable to a broad swath of claims that are not the subject of current industry concerns, i.e., those that may be associated with attempts to assert "generic" functional language (such as "computer implemented") to cover products and processes that were not intended by the patentee.

While AIPLA appreciates the concerns motivating this proposal, we fear the proposed amendment to Section 112(f) poses a risk of unintended consequences, particularly as the provision would be applicable to all inventions using functional claim language and would disrupt both claim drafting and claim construction. We welcome the opportunity to continue the discussions on how to craft a narrow, focused approach to address the concerns.

V. Conclusion

Once again, AIPLA appreciates the substantial effort of this undertaking by the Subcommittee and the opportunity to participate in the development of a very important reform to the patent laws. We will continue to study and consider the language and will be happy to respond to any questions you may have. We look forward to working with the Subcommittee on this matter as the process moves forward.