AIPLA
American Intellectual Property Law Association

June 26, 2019

The Honorable Lindsey O. Graham
Chairman
Committee on the Judiciary
U.S. Senate
Room 224 Dirksen Senate Office Building
Washington, D.C. 20510-6275
c/o Jason Covey, Hearing Clerk (via email)

Re: AIPLA Responses to Questions for the Hearing Record

Dear Chairman Graham:

On behalf of the American Intellectual Property Law Association ("AIPLA"), I write to offer the attached responses to the questions submitted to us for the record of the June 5th hearing, "The State of Patent Eligibility in America: Part II."

AIPLA appreciates the consideration of our views and we stand ready to respond to any further questions you or the Members of the Committee may have. We would be pleased to work with you on this legislation as the process moves forward.

Sincerely,

Barbara A. Fiacco
President – Elect
American Intellectual Property Law Association

Questions From Senator Tillis

1. You represent the major intellectual property bar associations and the thousands of practitioners across the country. As practitioners in the field, how has the current state of patent eligibility impacted the ability of your clients to receive patent protection for new, innovative and emerging technologies?

The current state of patent eligibility has had an adverse effect on the ability to obtain patent protection for new technologies. Our membership surveys over the past six years have consistently identified Section 101 eligibility law as the single most important concern of our members. The uncertainty surrounding Section 101 law has created obstacles for patent applications claiming new, innovative and emerging technologies, leading to rejections by the U.S. Patent and Trademark Office that either delay or preclude consideration of the invention on the merits.

A 2017 study of datasets of USPTO rejections and issuances between 2013 and 2015 analyzed Section 101 rejections before and after the *Alice Corp. v. CLS Bank* decision.[1] The study reported that PTO rejections of patent applications in the chemical engineering field doubled (from 1.5% to 3.2%), rejections in the mechanical arts space nearly doubled (from 3.7% to 6.1%), and rejections of patent applications directed to networks and video technology increased by more than one-third (from 10.2% to 15.5%).[2]

The Supreme Court's recent jurisprudence has narrowed the pipeline of inventions that are eligible for patenting in the United States, while applications directed to the same inventions are obtaining patent protection in other key jurisdictions. The 2017 study mentioned above reports that 17,743 U.S. patent applications received a final rejection on Section 101 grounds and were later abandoned between August 1, 2014 and September 27, 2017.[3] No patent was granted on these applications or on any related application in the United States. By comparison, 1,694 patent applications claiming the same or similar applications were granted by either the European Patent Office and/or the Chinese Patent Office.[4]

The 2017 article describing this study highlighted that some patent applications rejected by the USPTO on eligibility grounds but issued by the European and Chinese Patent Offices were directed to diagnostic inventions. These included applications directed to methods and compositions for diagnosing cancer, apparatuses and methods for user interactions during

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[1] *See* Kevin Madigan & Adam Mossoff, *Turning Gold Into Lead: How Patent Eligibility Doctrine is Undermining U.S. Leadership in Innovation*, 24 Geo. Mason L. Rev. 939, 953-54 (2017) (citing Robert Sachs, *Alicestorm update for Q1 2017*, BilskiBlog (Apr. 6, 2017), https://www.bilskiblog.com/?s=2017).

[2] Madigan & Mosoff at 953-54 (internal citations omitted).

[3] *Id.*at 955-56.

[4] *Id.*

ultrasound imaging, and a medical device for peritoneal dialysis.[5]

2. As experts on this issue, how confusing is the current state of judicial exceptions to Section 101? In other words, if you were advising a client who wants to undertake hundreds of millions, if not billions, of dollars in research and development about what an "abstract idea" "law of nature" or "natural phenomena" is, what would you say? Could you give them any level of certainty or predictability?

The current state of patent eligibility law, including the judicial exceptions to Section 101, is unacceptably confusing and does not provide the foundation for a strong, predictable patent system that will accelerate technological progress and economic growth.

The Supreme Court decisions over the past decade have increasingly blurred the objective analytical framework of the 1952 Patent Act by importing aspects of the novelty and non-obviousness analyses into the eligibility inquiry. In addition, the Court has provided insufficient guidance to the lower courts, the USPTO, and the innovation community as to the bounds of its judicial exceptions to patent eligibility. At present, the patent system does not have understandable and predictable rules of eligibility 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.

These are the concerns that we have heard directly from our members over several years. Our member surveys for the past six years have consistently identified Section 101 as ***the single most important concern*** today. Our members have faced significant challenges in advising clients about whether they will obtain patent protection for claimed inventions, particularly (but not exclusively) in the diagnostic and software fields. Likewise, they have faced significant challenges in advising clients about the value and enforceability of certain issued patents due to uncertainty about the courts' application of the "abstract idea," "law of nature" and "natural phenomenon" judicial exceptions.

This lack of certainty is underscored by the dramatic increase in the number of Federal Circuit appeals on Section 101 issues. In 2009, the year before the Supreme Court's *Bilski* decision,[6] 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.[7]

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[5] *Id*. at 957-958

[6] *Bilski v. Kappos*, 561 U.S. 593 (2010).

[7] *See* 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).

Questions From Senator Blumenthal

1. Striking the appropriate balance between encouraging innovation and protecting consumers is a key goal of our patent system.

a. What impact will broadening the subject matter that can be patented have on industry?

As a preliminary matter, the Discussion Draft's proposed amendment to Section 101 will not necessarily "broaden" the subject matter that "can be patented." The proposed amendment to Section 101 will simply ensure that we are not cutting off the pipeline of innovation at the start (or before it starts) and will restore the subject matter that "can be patented" to the categories identified in the 1952 Patent Act.

Section 101 was intended as a separate enabling provision in the 1952 Act, identifying particular categories of subject matter eligible for patent protection. Many inventions that may be "eligible" for patenting under the proposed amendment to Section 101 will not meet the stringent requirements for patenting imposed by existing Sections 102, 103, and 112. Those provisions set out the "conditions of patentability" and provide a yardstick for judging novelty, non-obviousness, the sufficiency of disclosure in the specification, and the definiteness of the claims. Inventions that do meet the objective, well-developed requirements of Sections 102, 103 and 112 will be well positioned for further investment. Our nation's record of incredible success fostering innovation is strong evidence that the 1952 Patent Act struck the correct balance required for encouraging creativity and competition.

A recent study of 475 venture capital and private equity investors analyzed the impact of the Supreme Court's eligibility decisions on their firms' decisions to invest in companies developing technologies across a range of fields.[8] The survey reported that 74% of investors agreed that patent eligibility is an important consideration in the decision whether to invest in companies developing a particular technology. On average, investment in a wide range of industry would decrease with reduced patent eligibility; moreover, decreased patent eligibility has a differential impact on investment in various industries. For example, 77% of investors responded that reduced patent eligibility would decrease their investment in biotechnology, 79% would decrease their investment in medical devices, and 73% would reduce their investment in the pharmaceuticals.[9]

The impact on industry of legislation that restores patent eligible subject matter to the standard intended by Congress will be to encourage investment in life-altering innovations that have changed society and our economy. It will remove the categorical obstacles to the possibility

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[8] David O. Taylor, *Patent Eligibility and Investment*, Cardoza L. Rev. (forthcoming), https://ssrn.com/abstract=3340937 (describing results of a survey of venture capital and private equity investors revealing reduced investment in research and development due to the Supreme Court's recent eligibility decisions).

[9] *Id*. at 9.

of patent protection in every technology and return judgments on patentability to the merits and details of the invention. The current judicial exceptions have resulted in diminished opportunities for investment-generating patent protection with vague and subjective categories that are backward-looking and that have discouraged industry from taking the necessary risks in innovation. The patent system must assure that risky investments in costly development and commercialization of innovation will not be lost due to a lack of patent protection. Those assurances include the promise of exclusive rights in the marketplace for a limited time in order to recover the investment that at the time was likely speculative at best.

Returning the patent system to an objective, forward-looking process is essential for stimulating industry to invest in risky innovative endeavors that could yield new and improved (and possibly life-altering) products and services for the American people. Our Founders understood that such assurances are indispensable to promote the progress of the arts and sciences.

b. What impact will broadening the subject matter that can be patented have on consumers?

As noted above, the Discussion Draft's proposed amendment to Section 101 will not necessarily "broaden" the subject matter that "can be patented." Rather, the proposed amendment to Section 101 will ensure that we are not cutting off the pipeline of innovation from the patent process. The amendment will anchor the law to its statutory underpinnings and make certain that both eligibility and patentability turn on the objective, analytical framework set out in the statute, as we have described above.

Consumers are the ultimate beneficiaries of an objective, forward-looking patent system that adds the "fire of interest to the fuel of genius"[10] by providing an incentive to risk money and time to develop and make available new products and services. Of course, brilliant science and engineering are required to put a currently unimaginable new product in our hands or discover a new life-saving remedy. But without the expectation of an exclusive opportunity to make a reasonable profit from that effort, such a product or remedy is much less likely to be made. An effective patent system needs to be open to previously unimaginable innovations and not constrained by traditional notions of technology.

c. Could these reforms increase consumer prices? If so, in what industries or on what products?

As noted above, increased investment incentives should result in more innovation and more

[10] Abraham Lincoln, Lecture on Discoveries, Inventions, and Improvements (Feb. 22, 1860), in SPEECHES AND PRESIDENTIAL ADDRESSES 1859-1865 (1907) ("Next came the patent laws. These began in England in 1624, and in this country with the adoption of our Constitution. Before then any man [might] instantly use what another man had invented, so that the inventor had no special advantage from his own invention. The patent system changed this, secured to the inventor for a limited time exclusive use of his inventions, and thereby added the fuel of interest to the fire of genius in the discovery and production of new and useful things.").

products for consumers. While many factors may impact the pricing of a particular product, an overall increased rate of innovation will most likely result in more competition to develop products that improve the quality of life for consumers. For example, personalized medicine offers the promise that targeted therapies that are more effective and efficient than prior medical treatments. The result is improved outcomes for individual patients and targeted expenditures on therapies that have a higher likelihood of success for a particular patient population.

AIPLA firmly believes that we need a patent system to promote the pipeline of innovation. If there are issues over access, pricing or other similar issues, they should be addressed through other avenues that do not broadly affect the incentives to invest in innovation. We need to ensure that the pipeline of innovation is not only kept wide open but that it is expanding.

Questions From Senator Hirono

1. Last year, Judge Alan Lourie and Judge Pauline Newman of the Federal Circuit issued a concurring opinion to the court's denial of *en banc* rehearing in *Berkheimer v. HP Inc.*, in which they stated that "the law needs clarification by higher authority, perhaps by Congress, to work its way out of what so many in the innovation field consider are § 101 problems."

Do you agree with Judges Lourie and Newman? Does § 101 require a Congressional fix or should we let the courts continue to work things out?

Yes, AIPLA agrees that the current state of patent eligibility law requires a legislative fix. We need Congress to step in and stop the judicial policy-making on Section 101. The Constitution charged Congress with the responsibility to make the policy decisions concerning patents. Congress did so with the 1952 Patent Act, and we think Congress should step in to restore the system to the objective and analytical framework of that statute.

When it enacted the 1952 Patent Act, Congress established the modern framework of our patent system with 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. In the 1952 Patent Act, Section 101 is 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, inventiveness (mandating non-obviousness as the standard), and sufficiency of disclosure in the specification, and clarity of the claims that define the metes and bounds of the invention. 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."[11]

[11] S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952)

However, in the past decade, Supreme Court decisions have improperly diverged from the basic framework of the 1952 Act as a whole, and of Section 101 in particular, by importing into the eligibility inquiry the conditions of patentability from other provisions. The Court's expansion of its "judicial exceptions," which put a gloss on the express categories set forth in Section 101 (process, machine, manufacture and composition of matter), has resulted inconsistent decisions and uncertain rules.

The Court has provided insufficient guidance to the lower courts or the Patent and Trademark 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. As noted above, 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.[12]

The Supreme Court has upset the statutory framework and balance with its continued reliance on policy-based exceptions to the statute, and in particular, with its new analytical framework for eligibility in *Bilski v. Kappos*, 561 U.S. 593 (2010), *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), and *Alice Corp. Pty, Ltd. v. CLS Bank Int'l*, 134 U.S. 2347 (2014). It did so by, among other things, setting forth quasi-patentability considerations that isolate 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.[13] The result has been a confusing conflation of eligibility and patentability by improperly parsing a claim into individual elements rather than focusing on the claim as a whole.

The Federal Circuit, the district courts, and the USPTO all have struggled to implement the

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https://www.ipmall.info/sites/default/files/hosted_resources/lipa/patents/Senate_Report_No_1979.pdf; H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952).

[12] 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).

[13] *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.").

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.[14] However, none of these decisions provides sufficient 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 give little concrete guidance and shed insufficient 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 apply 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."[15]

As noted in the question, the dissatisfaction of some Federal Circuit judges is readily apparent in various opinions. In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*,[16] 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."[17] 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."[18] 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,"[19] 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

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[14] *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).

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

[16] 788 F.3d 1371 (Fed. Cir. 2015), *en banc review denied*, 809 F.3d 1282 Fed. Cir. (2015).

[17] 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.")

[18] 788 F.3d at 1380.

[19] *Id.*

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."[20] 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.[21]

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 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,[22] but this ongoing activity suggests the futility of the task. The continuing effort of the Office 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.[23]

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

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[20] 809 F.3d at 1287 (concurring with *en banc* denial).

[21] *Id.* at 1284

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

[23] *Cleveland Clinic Foundation v. True Health Diagnostics, LLC*, No. 2018-2128, slip op. at 13 (Fed. Cir. Apr. 1, 2019) (nonprecedential) http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/18-1218.Opinion.4-1-2019.pdf.

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. 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.[24] 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 others that we cannot even predict today—could discourage investment in research and development, likely impeding innovation to the detriment of our economy and society as a whole.

AIPLA believes that the sweeping language of Supreme Court rulings and the application of those rulings by lower courts have closed off any possibility of returning to the framework and principles of the 1952 Act. A legislative fix is necessary to provide appropriately broad eligibility with a clear and objective test (including a clean break from the judicial exceptions to eligibility) and expressly reaffirmed the gatekeeping conditions of patentability in Sections 102, 103, and 112, as intended by Congress in 1952.

2. The draft legislation includes the requirement that an invention be in a "field of technology."

a. The European Union, China, and many other countries include some sort of "technology" requirement in their patent eligibility statutes. What can we learn from their experiences?

Although the European Patent Convention ("EPC") states that any invention in a "technical field" may be patented if it is novel, inventive, and susceptible to industrial application, [25] the "technical field" standard is not free from uncertainty. This is an important lesson for us.

According to the European Patent Office ("EPO"), for an invention to be in a technical field it need only to have a "technical character." [26] Technical character requires that the invention

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[24] 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), https://www.uspto.gov/about-us/news-updates/examination-software-patents.

[25] Article 52(1) EPC.

[26] *See* EUROPEAN PATENT OFFICE CASE LAW OF THE BOARDS OF APPEAL, § I.D.9.1.1, https://www.epo.org/law-practice/legal-texts/html/caselaw/2016/e/clr_i_d_9_1_1.htm ("In order to be patentable, the subject-matter claimed must therefore have a 'technical character' or to be more precise - involve a 'technical teaching', *i.e.*, an instruction addressed to a skilled person as to how to solve a particular technical problem using

relate to a technical field, be concerned with a technical problem, and have technical features. However, the technical character requirement is treated as a very low bar to eligibility. In practice, it is easily satisfied by including in a claim any technical means— for example, a computer. Any claim that requires a computing device is eligible.

The EPC includes a list of inventions that are, "***as such***," not patentable.[27] For example, a computer program — meaning, literally, a listing of program instructions— is not patentable as such. However, a method implemented using a programmed computer does not fall within the exception and is thus eligible. Other inventions that are, as such, not patent eligible are discoveries, scientific theories, mathematical methods; aesthetic creations; schemes, rules, methods for performing mental acts, playing games, doing business; and presentations of information. In practice, these exceptions would likely not meet the "technical character" test for eligibility. However, falling into one of these exceptions is easily avoided by drafting a claim to include an additional feature, no matter how conventional or trivial, so that the claim is to something more than exception as such.

One lesson to be drawn from Europe is that, by establishing a clear, predictable approach to eligibility determinations, eligibility itself should rarely be an issue. However, it would not be fair to conclude that the "technical field" standard has led to predictable outcomes in Europe, or that the outcomes are what they should be. That is because the question of whether a feature of a claim is technical or not comes up in an obviousness determination. In those analyses, claims are parsed into technical and non-technical features. Only technical features in a claim are considered when assessing the differences between the prior art and the claimed invention, and whether, when trying to solve the problem that the invention tries to solve, the differences in the claimed solution would have been obvious. Non-technical features are only considered as constraints on the technical problem that the claimed invention solves. What "technical" means has never been defined and whether a feature is or is not technical is not always clear, particularly for software-implemented inventions. It continues to be the subject of decisions assessing obviousness in Europe.[28]

In sum, the determination as to what is "technical" is difficult to define and there is often a reliance on what is traditionally considered to be "technical." Yet, if what is and is not technical determines whether or not an invention may be patented, it becomes an important issue for numerous areas of important innovation, including cutting edge technologies involving artificial intelligence.

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particular technical means.").

[27] See European Patent Office Guidelines for Examination, § G.II.3,. https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_3.htm.

[28] *See, e.g.*, Case T 1784/06 (EPO Boards of Appeal, 2012, https://www.epo.org/law-practice/case-law-appeals/pdf/t061784eu1.pdf, and Case T 1823/15 (EPO Boards of Appeal, 2019, https://www.epo.org/law-practice/case-law-appeals/pdf/t151823eu1.pdf; *see also*, AT&T Knowledge Ventures/CVON Innovations v. Comptroller of Patents [2009] EWHC 343 (Pat), https://high-court-justice.vlex.co.uk/vid/-52697227.

b. Is a claim that describes a method for hedging against the financial risk of price fluctuations—like the one at issue in the *Bilski* case—in a "field of technology"? What if the claim requires performing the method on a computer?

The answer depends on how a court would construe the word "technology." One dictionary definition of "technology" is "the application of scientific knowledge for practical purposes, especially in industry." However, the term has been used loosely to refer to all sorts of things, and we fear it will mean different things to different people. Consider, for example, Wikipedia's explanation of "technology:"

> Technology ("science of craft", from Greek τέχνη, techne, "art, skill, cunning of hand"; and -λογία, -logia[2]) is the collection of techniques, skills, methods, and processes used in the production of goods or services or in the accomplishment of objectives, such as scientific investigation. Technology can be the knowledge of techniques, processes, and the like, or it can be embedded in machines to allow for operation without detailed knowledge of their workings. Systems (e. g. machines) applying technology by taking an input, changing it according to the system's use, and then producing an outcome are referred to as technology systems or technological systems.[29]

With this understanding, the method at issue in *Bilski*, even if it is not being performed on a computer, could be argued to be "technology," as it would be used by an energy service provider to provide sufficient energy to meet consumer demand but at a fixed rate.

The European experience underscores the problems with a "field of technology" requirement: it is ambiguous and could 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.

c. What changes to the draft, if any, do you recommend to make the "field of technology" requirement more clear?

AIPLA continues to have concerns about the use of the "field of technology" requirement in the definition of "useful," but we continue to study and consider the language.

The "field of technology" requirement is inherently backward-looking, rather than forward-looking. As a result, there is a risk that the courts' interpretation of the phrase could foreclose patent eligibility for some as-yet unforeseeable cutting-edge innovation. In the process of developing jurisprudence around "field of technology," there is also a real risk that patent law shifts away from its longstanding tradition of technological neutrality which has served our innovation community so well.

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[29] https://en.wikipedia.org/wiki/Technology (last visited Jun. 26, 2019).

AIPLA believes that the appropriate balance for the law of patent eligibility can be restored by adding to the existing utility requirement and to the patentability requirements of Section 102, 103, and 112, two narrow and express exceptions to eligibility. Those exceptions would be: that which exists as a whole in nature independently of and prior to human intervention, and that which exists solely in the human mind.[30]

AIPLA has not concluded that a "field of technology" requirement is a necessary component of the Section 101 reform. Nevertheless, we have considered this question and have not identified a replacement phrase for "field of technology" as set forth in the Discussion Draft's Section 100(k) specifically to address the concerns expressed during the hearings about certain business method patents. Section 100(k)'s definition of "useful" includes the requirement that the invention have a "specific and practical utility in any technological field." The language of this proposed definition is ambiguous and could create continued uncertainty, resulting in years of litigation to determine what is meant by it. AIPLA notes that it is not clear what is meant by "utility ***in a technological field***." (emphasis added). Does this mean that the invention must be useful in a technological field? If so, does it preclude technologically-based inventions that are only useful in non-technical fields—for example, a novel musical instrument that is useful only for making music? If so, it seems to limit unnecessarily the scope of what should be patentable.

3. Sen. Tillis and Sen. Coons have made clear that genes as they exist in the human body would not be patent eligible under their proposal.

Are there other things that Congress should make clear are not patent eligible? There are already statutes that prevent patents on tax strategies and human organisms. Are there other categories that should be excluded?

First, AIPLA agrees that the "human intervention" requirement, which is also included in the Discussion Draft, would not allow genes as they exist in the human body to be patented.

AIPLA fully supports the Discussion Draft provision that retains the statutory categories contained in the current version of 35 U.S.C. §101 ("process, machine, manufacture, or composition of matter, or any useful improvement thereof"). AIPLA urges caution against

[30] AIPLA supports the retention of the utility requirement as it currently exists and is applied. "Useful" has been a requirement since the first patent laws were enacted and expectations about its meaning are largely settled. AIPLA has some concerns about the proposed language "***specific and practical utility*** in any field of technology." It is noteworthy that during the Subcommittee hearings, witnesses expressed different understandings of the impact of this provision. Some understood the definition to be codifying the existing utility requirement, while others express concern that the provision was intended to heighten the existing requirement. In interpreting this proposed language, the similar, overlapping meanings of the words in this provision ("useful," "practical," "utility," and technology") could lead to unpredictable results. Courts will likely assume that Congress must have intended a different meaning for each term and will attempt to divine what was meant. Legislative history ***may*** help guide interpretation. Courts will have to decide how to reconcile past decisions with this definition, and it would likely take many years for the case law to develop, and legislative history has often proven to be insufficient to avoid doubt and uncertainty.

expressly identifying categories of subject matter that are ineligible for patenting. First, we are acutely aware that any attempt to create a list of particular exclusions is handicapped by our inability to foresee the technology of the future. In addition, we are cognizant that the courts could, in construing new statutory language, attempt to expand the scope of ineligible subject matter by analogizing to the listed items. Likewise, the courts could apply a statutory interpretation rule that an express mention of one or more items of a particular class may imply the exclusion of others.

AIPLA also cautions that it is not prudent to call out certain technologies and carve them out of patent protection. The patent system should be technology-neutral and forward-looking in order to ensure that innovation is not stifled. This is particularly important today as we are increasingly seeing the convergence of different technologies. A legislative framework that includes a long list of exceptions would invite a wide range of special interest groups to bring their requests for exceptions to the table for a wide range of policy reasons wholly unrelated to the nation's need to incentivize innovation. This type of horse-trading on individual categories (which may be hard to delineate) could cut against the interests and underlying policies of the patent system as a whole.

4. I have heard complaints that courts do not consistently enforce Section 112 with respect to claims for inventions in the high tech space.

a. Are these valid complaints?

AIPLA does not agree with the sweeping generalization that courts do not consistently enforce Section 112 for inventions in the high tech space. As a preliminary matter, courts do not "enforce" Section 112; they decide the Section 112 issues that litigants choose to present to the courts. As a result, there may be a perception of inconsistency, in part because the case law in a given technology area may be more or less developed. The requirements of Section 112 are clear and require intensive, case-by-case analyses of the claims in light of the specification as viewed by one of ordinary skill in the art.

By way of background, Section 112 has a number of provisions and requirements regarding the sufficiency of the specification of a patent and the definiteness of the claims that work together. Section 112(a) includes both a written description requirement and an enablement requirement. Section 112(b) includes a definiteness requirement.

The written description requirement is intended to ensure that the specification describes the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the applications, *i.e.*, that the patentee invented what is claimed. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). The level of detail necessary to satisfy the written description requirement "varies with the nature and scope of the invention at issue, and with the scientific and technology knowledge already in existence." *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005); *see also Ariad*, 598 F.3d at 1351. The *en banc* Federal Circuit has noted that "[t]he law does not require the impossible. Hence, it does not require that an applicant describe in his specification every conceivable and possible future embodiment of his invention." *SRI Int'l v. Matsushita Elec. Corp. of Am*., 775 F.2d 1107, 1121 (Fed. Cir. 1985) (*en banc*); *see also Cordis Corp., v. Medtronic Ave, Inc*., 339 F.3d

1352, 1365 (Fed. Cir. 2003).

The enablement requirement is intended to ensure that the specification "teach those of skill in the art how to make and use the full scope of the claimed invention without undue experimentation." *Streck, Inc. v. Research & Diagnostic Sys*., 665 F.3d 1269, 1288 (Fed. Cir. 2012) (internal citations omitted). The enablement requirement is satisfied when a person of skill in the art, having read the specification, could practice the invention without undue experimentation. *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988). However, "a patent need not teach, and preferably omits, what is well-known in the art." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

The definiteness requirement is intended to ensure that a patent's claims, "viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). "The definiteness requirement mandates clarity, while recognizing that absolute precision is unattainable." *Id.*

During prosecution of patent applications, patent examiners routinely apply the requirements of Section 112 as part of the examination process.[31] In litigation, an accused infringer may, but will not necessarily, raise failure to meet one or more of the requirements of Section 112 as an invalidity defense. Because the analysis of whether ***each*** requirement has been met must be done on a ***claim by claim*** basis in light of the specification and viewed from the perspective of a "person of ordinary skill in the relevant art,"[32] when a Section 112 defense is raised in litigation, its application will depend on the specific patent specification and claims at issue.

In its 2014 decision of *Nautilus, Inc. v. Biosig Instruments, Inc.*, the Supreme Court explained the inherent tensions in applying Section 112:

> Section 112, we have said, entails a "delicate balance." On the one hand, the definiteness requirement must take into account the inherent limitations of language. Some modicum of uncertainty, the Court has recognized, is the "price of ensuring the appropriate incentives for innovation." One must bear in mind,

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[31] *See* Manual of Patent Examination and Procedure § 2163 (written description) (https://www.uspto.gov/web/ offices/ pac/mpep/s2163.html); § 2164 (enablement) (https://www.uspto.gov/web/offices/pac/mpep/s2164.html); § 2173 (definiteness) (https://www.uspto.gov/web/offices/pac/mpep/s2173.html). We are aware that, in the past, some have expressed concerns that the USPTO does not vigorously apply the requirements of Section 112. Any such concern is outdated. Recently, the USPTO has taken positive steps to police compliance with Section 112, and the experience of AIPLA members confirms this.

[32] Relevant factors for evaluating the adequacy of the disclosure for purposes of the written description requirement include "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*) (quoting *Capon*, 418 F.3d at 1359). The factors to consider when determining whether or not a disclosure requires undue experimentation include the quantity of experimentation necessary; the amount of direction or guidance presented; the presence or absence of working examples; the nature of the invention; the state of the prior art; the relative skill of those in the art; and the predictability or unpredictability of the art, and (8) the breadth of the claims." *Wands*, 858 F.2d at 737.

> moreover, that patents are "not addressed to lawyers, or even to the public generally," but rather to those skilled in the relevant art. . . .
>
> At the same time, a patent must be precise enough to afford clear notice of what is claimed, thereby "'appris[ing] the public of what is still open to them.'" Otherwise there would be "[a] zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims." . . .
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> To determine the proper office of the definiteness command, therefore, we must reconcile concerns that tug in opposite directions. Cognizant of the competing concerns, we read §112, ¶2 to require that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty. The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable. The standard we adopt accords with opinions of this Court stating that "the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter." . . .

134 S. Ct. 2120, 2129 (2014) (citations and footnotes omitted).

Through the courts' application of Section 112 requirements on a wide range of inventions across many fields of technology, the courts have struck a delicate balance that incentivizes disclosure of information and clarity of claims without imposing impossible burdens that will dissuade patenting and investment, ultimately impeding innovation. This delicate balance is necessary to ensure appropriate incentives for investment in innovation, even if there is some modicum of uncertainty at the margins.

b. Do the proposed changes to Section 112 adequately address those complaints and limit the scope of claims to what was actually invented?

The provisions are Section 112 are complicated, and AIPLA is still considering the impact of the proposed changes, including possible unintended consequences of the proposed amendment to Section 112(f) as it will also impact the application of other provisions of Section 112. At this time, it appears to us that the proposed changes to Section 112 provide a rule of claim construction that could add another written description requirement to the statute, and may have the effect of limiting patent coverage to ***less*** than what was invented. This is a cause for concern: the traditional "quid pro quo" of disclosure of the invention to be patented in exchange for a limited monopoly as to that invention could be upended.

Based on initial discussions within our Section 101 Task Force, AIPLA has concerns about the unintended consequences of the proposed amendment to Section 112(f). Current Section 112(f) is directed to a specific type of claim—one that uses triggering language such as "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; they use that triggering language in specific situations and understand the implications of drafting a "means-plus-function" claim. 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.

As drafted, the proposed amendment would seem to apply to all claims using functional language and not reciting specific structure or acts for performing that function. As such, it is not narrowly tailored to address concerns of inconsistent enforcement of Section 112 in the high tech space. If this proposed amendment is not limited in its application, it has the potential to disrupt a well-established tool for claim drafting that current Section 112(f) is intended to address. It is likely that those drafting patent claims may not know whether, at some point years down the road, a court may construe a claim term as "functional," thereby limiting its meaning to what has been expressly disclosed in the specification rather than as one of ordinary skill in the art would construe the claim term.

c. Are you concerned that the proposed changes will make it too easy for competitors to design around patent claims that use functional language?

Yes, as written, the Discussion Draft's proposed Section 112(f) change could be read to eliminate the application of the doctrine of equivalents in instances where a claim term is determined to be "functional." When there is a clear "functional" element in the claim, others would more likely be able to design around the narrowly claimed invention with ease. More broadly, as noted above, there would be uncertainty over what constitutes "functional" elements. In those circumstances, there will be uncertainty over the metes and bounds of the claim for both the patent owner and third parties unless and until a court interprets the claims.

As noted above, where the courts draw the line as to what constitute a "functional" claim element may not be easily discernable for many years. That uncertainty over claim scope could limit investment in the patent owner's own product development, out of concern that the patent will not provide enough assurance of a return on investment. That uncertainty could discourage others in the industry from investing in research and development due to a lack of clear understanding as to what falls outside the scope of the patent prior to judicial interpretation. This is not the basis for an efficient patent system that encourages investment in innovation.

AIPLA is also concerned that this proposal may create issues with respect to the definiteness of claim scope. As noted above, we remain concerned that the proposed changes to Section 112 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. 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.

For example, under current case law, if a person of ordinary skill in the art would be unable to recognize the structure in the specification and associate it with the corresponding function in the claim, a means-plus-function clause is indefinite. Assuming this "indefiniteness" rule were to apply to any claim limitation that uses functional language without reciting structure somewhere in the patent specification, then that claim would be invalid as indefinite. This rule of law could

apply even though the claim might use well-known functional language that a person of ordinary skill in the art would readily understand. While it seems unlikely that this is the intent of the proposed change to Section 112(f), we remain concerned about such unintended consequences that this change may cause.

5. There is an intense debate going on right now about what to do about the high cost of prescription drugs. One concern is that pharmaceutical companies are gaming the patent system by extending their patent terms through additional patents on minor changes to their drugs. My understanding is that the doctrine of obviousness-type double patenting is designed to prevent this very thing.

The Federal Circuit has explained that obviousness-type double patenting "is grounded in the text of the Patent Act" and specifically cited Section 101 for support.

Would the proposed changes to Section 101 and the additional provision abrogating cases establishing judicial exceptions to Section 101 do away with the doctrine of obviousness-type double patenting? If so, should the doctrine of obvious-type double patenting be codified?

No, the proposed changes to Section 101 and the additional provision abrogating judicial exceptions would not do away with or have any impact whatsoever on the doctrine of obviousness-type double patenting ("OTDP"). Neither the proposed changes to Section 101 nor the abrogation provision would change or affect the interpretation of wording in Section 101 that "grounds" OTDP in the statute. More importantly, the wording changes and abrogation provision have no bearing at all on the policy rationale for OTDP. Finally, the proposed legislative changes to Section 101 are not reasons to codify the doctrine of OTDP.

There are two types of double patenting in the United States: "statutory double patenting," also known as "same invention double patenting;" and "non-statutory double patenting," also known as "obviousness-type double patenting." Courts created both types of double patenting when patent expiry dates were tied to their issue dates and they justified both types using the same policy, namely, to prevent unjustified time-wise extension of the right to exclude.

Statutory double patenting precludes a patentee from owning more than one patent claiming the ***same invention***. Courts have stated that the first type of double patenting is directly based on Section 101's use of "a patent." *See* 35 U.S.C. § 101 ("Whoever invents or discovers any new and useful process . . . may obtain ***a patent*** therefor, subject to the conditions and requirements of this title.") (emphasis added). Granting two patents to the same inventor or patent owner for the same new and useful process, machine, manufacture, or composition of matter would violate the Patent Statute itself. Therefore, a second patent covering the same invention cannot validly issue to the same inventor or patent owner. *See, e.g., In re Boylan*, 392 F.2d 1017, 1021 (C.C.P.A. 1968) ("[I]f the appellant claims the same subject matter (i.e., the same invention) that he claimed in his copending, but earlier-issued patent, 35 U.S.C. § 101 bars the issuance of a second patent.").

Obviousness-type double patenting precludes a patentee from obtaining a second patent with a claim that is ***obvious*** compared with a claim in a first patent that the patentee owns if the

second patent would expire later than the first patent.[33] Although the Federal Circuit has stated that "obviousness-type double patenting is grounded in the text of the Patent Act," it is not "grounded" in the statute in the same way as statutory double patenting. *AbbVie v. Kennedy Inst. of Rheumatology*, 764 F. 3d 1366, 1372 (Fed. Cir. 2014). The Federal Circuit has more consistently described obviousness-type double patenting as a "judicially-created doctrine." *In re Berg*, 140 F.3d 1428, 1431–32 (Fed. Cir. 1998). Moreover, unlike statutory double patenting, OTDP can be avoided by filing a terminal disclaimer with the USPTO [34] A terminal disclaimer will not avoid invalidity under the statutory double patenting doctrine. *In re Knohl*, 386 F.2d 476, 480 (C.C.P.A. 1967). Any connection between OTDP and Section 101 is the result of the similarity of policy goals underlying statutory double patenting and OTDP.[35]

The proposed amendment to Section 101 should not cause any change to application of double patenting doctrines in the USPTO or courts whatsoever because it does not remove the words "a patent," to the extent that OTDP is grounded in that language of Section 101. Likewise, the proposed amendments to Section 101 would have no effect on the basic policy underpinning double patenting doctrines.

Likewise, the abrogation provision in the Discussion Draft would have no effect on OTDP because it only applies to the judicial exceptions, which have nothing to do with double patenting. The abrogation provision would not remove the words "a patent" from Section 101, and it would not change the policy grounds underlying the double patenting doctrines.

Because the proposed changes to Section 101 and the additional provision abrogating judicial exceptions ***would not do away with or have any impact whatsoever*** on the doctrine of OTDP, the proposed legislative changes to Section 101 are not reasons to codify the doctrine of OTDP.

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[33] The determination of whether there is obviousness-type double patenting involves: 1) construing the claim in the earlier-expiring patent and the claim in the later-expiring application or patent; 2) determining the differences between the claims; and 3) determining whether the differences between the claims render them patentably distinct. *Eli Lilly & Co., Inc. v. Barr Labs, Inc*., 251 F.3d 955, 968 (Fed. Cir. 2001). A later-expiring patent claim is not patentably distinct from an earlier-expiring claim if the later-expiring claim is obvious over, or anticipated by, the earlier-expiring claim. *Id*. The obviousness determination is carried out essentially in the same way as obviousness assessed pursuant to 35 U.S.C. § 103, except that the specification of the earlier-expiring patent cannot be used as prior art, but it can be used to construe the claim. *In re Vogel*, 422 F.2d 438, 441 (C.C.P.A. 1970); *In re Avery*, 518 F.2d 1228, 1232 (C.C.P.A. 1975).

[34] A terminal disclaimer, authorized under 35 U.S.C. § 253(b), must be submitted to the USPTO before the second patent issues to prevent invalidity under OTDP.

[35] The relationship between OTDP and Section 101 is indirect. *AbbVie*, 764 F. 3d at 1372. ("Thus, § 101 forbids an individual from obtaining more than one patent on the same invention, i.e., double patenting. As this court has explained, 'a rejection based upon double patenting of the obviousness type' is 'grounded in public policy (a policy reflected in the patent statute") (internal citations and quotation omitted).

6. In its *Oil States* decision, the Supreme Court explicitly avoided answering the question of whether a patent is property for purposes of the Due Process Clause or the Takings Clause.

What are the Due Process and Takings implications of changing Section 101 and applying it retroactively to already-issued patents?

In *Oil State Energy Services, LLC v. Greene's Energy Group, LLC*, 138 S. Ct. 1365 (2018), the Supreme Court narrowly decided the Article III constitutionality and 7th Amendment issues before the Court regarding *inter partes* review (IPR) proceedings. The Supreme Court determined that IPRs do not violate Article III's allocation of the "judicial power" to the courts, reasoning that patents belong to the class of public rights which Congress permissibly provided the Patent Office authority to grant and to reconsider those rights. Because the issues were not necessary for the Court to address, the Supreme Court left open whether the retroactive application of IPR proceedings to pre-AIA patents creates Takings or Due Process issues.

Whether a statute is to be applied retroactively should be addressed in the proposed legislation. *See, e.g., Landgraf v. USI Film Prods.*, 511 U.S. 244 (1994). While AIPLA does not yet have a position on the retroactive application of any changes to Section 101 to already-issued patents, some considerations that should be taken into account when considering the retroactivity question include the following:

- Many patents being challenged on Section 101 grounds were filed and/or issued prior to recent judicial changes in the application of Section 101 law;
- Patent rights are granted to patent applicants, and any alleged Takings should be considered from the perspective of patent owners;
- If members of the public have relied on current application of Section 101 laws in determining whether they have freedom to operate and not infringe any valid patent rights of others, then equitable considerations may warrant their continued activity;
- Likewise, if pending litigation involves the application of current Section 101, then equitable considerations may come into play with respect to the retroactive application of any changes in the law; and
- A statutory window for patent owners and possibly patent applicants to "opt out" of the application of changed Section 101 law may mitigate concerns about upending settled expectations and investments.