

CHAIR

Mark K. Dickson San Mateo, CA

CHAIR-ELECT

George W. Jordan III Houston, TX

VICE-CHAIR

June Besek New York, NY

SECRETARY

Adriana S. Luedke Bethesda, MD

FINANCIAL OFFICER

Willard Iones II Bethlehem, PA

REVENUE OFFICER

Susan E. McGahan Bedminster, NJ

CLE OFFICER

David Postolski Summit, NJ

MEMBERSHIP OFFICER

Kevin Greenleaf Lovettsville, VA

PUBLICATIONS OFFICER

Stephen E. Gillen Cincinnati, OH

SECTION DELEGATES TO THE HOUSE OF DELEGATES

Susan B. Montgomery (2019) Boston, MA

Joseph M. Potenza (2020) Washington, DC

William L. LaFuze (2021) Houston, TX

IMMEDIATE PAST CHAIR

Scott F. Partridge Houston, TX

COUNCIL MEMBERS

Scott M. Alter (2019)

Janet Fries (2019)

Barbara J. Gislason (2019) Heath W. Hoglund (2019)

Elizabeth Chien-Hale (2020)

Sharon A. Israel (2020)

Chris Katopis (2020) Christina N. Scelsi (2020)

James R. Davis II (2021)

Jonathan R. Sick (2021)

Joshua L. Simmons (2021)

Francine D. Ward (2021)

Steven P. Caltrider (2022) Thad Chaloemtiarana (2022)

Christina D. Frangiosa (2022)

Mary E. Rasenberger (2022)

Young Lawyer Council Member Jameson Ma (2019)

SECTION STAFF Michael G. Winkler

Director

Carey Farley Programming / Events

Amy Mandel Communications / Publications

Kira M. Alvarez Legislative Consultant Washington, DC kira.alvarez@americanbar.org

AMERICAN BAR ASSOCIATION

Section of Intellectual Property Law

321 N. Clark Street Chicago, IL 60654-7598 (312) 988-6254

E-mail: iplaw@americanbar.org www.americanbar.org/iplaw

June 21, 2019

The Honorable Lindsey Graham Chairman Committee on the Judiciary U.S. Senate

Dear Chairman Graham:

Washington, D.C. 20510

On behalf of the Section of Intellectual Property Law of the American Bar Association (the "Section"), attached are the answers to the questions for the record from Senators Tillis, Blumenthal and Hirono with respect to the hearing held on June 5, 2019 on The State of Patent Eligibility in America: Part II. The views expressed herein are presented on behalf of the Section. They have not been approved by the House of Delegates or the Board of Governors of the American Bar Association and, accordingly, should not be construed as representing the position of the Association.

The Section appreciates the efforts that the Judiciary Committee has taken in holding this important series of hearings to develop a legislative solution to address the ambiguity and uncertainty posed by the current Supreme Court jurisprudence on patent subject matter eligibility. Legislative reform is needed now to restore predictability to the patent system and to maintain incentives to invest in future cutting-edge technologies and discoveries.

Thank you for your attention to this important issue and for considering the views of the Section throughout the process. Please let us know if we can further assist your efforts as this process moves forward in the Senate.

Sincerely,

Mark K. Dickson

Chair, ABA Section of Intellectual Property Law

cc: Thom Tillis, Chairman, Subcommittee on Intellectual Property, Committee on the Judiciary, U.S. Senate

Richard Blumenthal, U.S. Senate

Mazie K. Hirono, U.S. Senate

Questions for the Record for Mr. Scott Partridge
Senate Committee on the Judiciary
Subcommittee on Intellectual Property
Hearing on "The State of Patent Eligibility in America: Part II"
June 5, 2019

QUESTIONS FROM SENATOR TILLIS

Questions for Barbara Fiacco and Scott Partridge

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?

As you know, the United States patent system is well recognized as providing significant incentives necessary to promote private investment in scientific research and the development of new technologies. For example, without patents, emerging businesses and universities would be at risk with respect to their ability to attract needed investment, and established businesses would risk losing an important mechanism for protecting their investment in new products, particularly when those new products are particularly vulnerable to copycats.

Well over a hundred years ago, the U.S. Supreme Court established a patent eligibility test that was reasonably successful in promoting the development of countless new technologies and scientific achievements. Throughout most of that period, the Supreme Court struck a proper balance between preventing the patenting of pure laws of nature, natural phenomena, or abstract ideas themselves, while authorizing the patenting of their practical application in particular fields. In general, the courts and the United States Patent and Trademark Office (USPTO) were required to assess eligibility of the claimed process as a whole, to ensure that if the invention involved a law of nature, natural phenomenon, or abstract idea, patent eligibility was available only to a specific application of that law of nature, natural phenomenon, or abstract idea. In parallel, Supreme Court precedent had established that considerations of novelty, nonobviousness, written description, and definiteness were to be applied only under their respective statutory sections, and not in a subject-matter eligibility determination under 35 U.S.C. § 101. Similarly, the Supreme Court had long held that the eligibility of a patent claim must be assessed when viewing all of the claim limitations as a whole, and that courts and the USPTO should not ignore or discount limitations of a claim in determining whether to render it patent ineligible.

Over the last few years, however, the Supreme Court has injected ambiguity into the subject-matter eligibility determination. The current jurisprudence on patent eligibility is confusing, creates uncertainty as to the availability and enforceability of patent assets, arguably risks the incentive to innovate provided by patents in technologies in which U.S. industry has historically led the world, and potentially places the U.S. in a less advantageous position on patent protection than our leading competitor nations. For example, by requiring courts and the USPTO to apply criteria such as "well known," "routine," "conventional or obvious," factors that were previously relevant only to substantive questions of patentability, the Court has enabled judges to ignore limitations in a patent claim and then render that claim ineligible as a matter of law. In effect the courts have turned the gateway function of patent eligibility into a patentability test better left to the other statutory provisions that specifically address patentability, like sections 102, 103, and 112. As recently noted by the Federal Circuit itself, that interpretation is potentially so narrow as to require lower courts to hold that "groundbreaking, innovative, or even brilliant discoveries" are to be excluded from patentability.

While the effects of the current interpretation of section 101 are still evolving, we do not believe it can be seriously and objectively disputed that a risk exists that the courts and the USPTO have rejected and will likely continue to reject the patenting of inventions that, consistent with the intent of the Framers of our Constitution, promote the advancement of technology and greatly benefit society. Much of the evidence in support is anecdotal - what lawyers in the IP Law Section report,

-

¹ In Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 10, 132 S. Ct. 1289 (2012) ("Mayo"), the Supreme Court rewrote the test for determining whether patents impermissibly claim a law of nature, natural phenomena, or abstract idea itself. The rewritten test contains ambiguities and has been inconsistently interpreted and applied by lower courts. For example, the manner in which the Court described what it believes is enough to satisfy its requirements have been measured against criteria traditionally used for novelty and nonobviousness. The Mayo court's reasoning evaluates what is enough against criteria such as "pre-existing," "well known in the art," "routine," "well-understood," "routine," "conventional or obvious" (factors that were previously relevant only to novelty and obviousness) in determining that claims were not eligible subject matter under Section 101. Mayo considered and rejected the analysis offered by the Solicitor General (an analysis that tracked the law under § 101 that had been understood for decades), that "virtually any step beyond a statement of a law of nature itself should transform an unpatentable law of nature into a potentially patentable application sufficient to satisfy § 101's demands." Mayo, 132 S.Ct. at 1303. Subsequently, in Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014) ("Alice"), the Supreme Court created uncertainty as to the patent eligibility of software inventions. The effect of these cases and their progeny has created the risk of a dampening of the availability of patent protection in at least the life sciences and computer fields.

² In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), the Federal Circuit agreed with Sequenom that the invention "reflects a significant human contribution... and utilized man-made tools of biotechnology in a way that revolutionized prenatal care." *Id.* at 1379. The court quoted the Supreme Court in *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013) when it said, "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." *Id.* The Federal Circuit said, however, that its hands were tied and that it could not uphold the patent even though the "The Royal Society lauded this discovery as 'a paradigm shift in non-invasive prenatal diagnosis," and that the inventors' initial article describing this invention has been cited well over a thousand times. The court held, therefore, that it was compelled to affirm the district court's finding that the claims were patent ineligible under the Supreme Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 10, 132 S. Ct. 1289 (2012), that effectively prohibits the patenting of any methods for detecting natural phenomenon, including the existence of fetal DNA in the mother's blood. *Id.* The U.S. Supreme Court denied Sequenom's petition for certiorari.

what lawyers and others say at frequent CLE events and other programs we sponsor on patent eligibility, and what many people have addressed in the public domain in speeches, articles and studies. The most comprehensive and the only sophisticated empirical data of which we are aware is found in a recent analysis and report by Associate Professor David Taylor of the Southern Methodist University Dedman School of Law. Professor Taylor was one of the witnesses at the Subcommittee Hearings, but limited discussion occurred about his forthcoming article entitled "Patent Eligibility And Investment" to be published in the Cardozo Law Review³. Professor Taylor conducted a survey of 475 investors at firms investing in various industries and at various stages of funding. His survey establishes that patent eligibility has been an important consideration in investment decision making, and that the negative impact of the current patent eligibility jurisprudence is clear, albeit that the impact varies from industry to industry. This study confirms our anecdotal evidence of the negative impact of the current state of jurisprudence on patent eligibility.

The effects of the current interpretation of section 101, however, are clear in one respect. Patents invalidated on the basis of eligibility in the U.S. are found to eligible in other countries.⁴ In a global economy, this puts at risk U.S. leadership in innovation. It is also problematic for the U.S. to be out of step with other industrialized countries. As Professor Timo Minseen notes, "Legal developments in patent law, while local in immediate effect, migrate within an increasingly global economy and may destabilize the objective of harmonizing an efficient world patent system."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?

As Mr. Partridge, speaking in his personal capacity, indicated in response to a similar question during the hearing on June 5th, advising a client with an acceptable level of certainty and predictability on patent eligibility in any case other than an exceptional case is fraught with risk. This is especially true when compared to the level of predictability associated with rendering advice on patentability issues such as novelty, obviousness and section 112 of the statute. If hundreds of millions, if not billions, of dollars are in play in any given situation, it would be a rare circumstance to rely on patent eligibility as a basis for such a business decision.

³ SMU Dedman School of Law Legal Studies Research Paper No. 414; found at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3340937## (last accessed on June 17, 2019).

⁴ See Minseen et al. Separating sheep from goats: a European view on the patent eligibility of biomedical diagnostic methods, *Journal of Law and the Biosciences*, 365–372 (available at https://academic.oup.com/jlb/article-abstract/3/2/365/1751248)

⁵ *Id*.

This view is underscored and backed up by what a number of Federal Circuit judges have said in cases in which they are reviewing patent eligibility determinations. For example, Judge Plager recently stated in *Interval Licensing LLC v. AOL*⁶ the following:

"Today we are called upon to decide the fate of some inventor's efforts, whether for good or ill, on the basis of criteria that provide no insight into whether the invention is good or ill. Given the current state of the law regarding what inventions are patent eligible, and in light of our governing precedents, I concur in the carefully reasoned opinion by my colleagues in the majority, even though the state of the law is such as to give little confidence that the outcome is necessarily correct. The law, as I shall explain, renders it near impossible to know with any certainty whether the invention is or is not patent eligible. Accordingly, I also respectfully dissent from our court's continued application of this incoherent body of doctrine."

This view by Judge Plager has been repeated by other Federal Circuit judges over the last year or so⁸. Placed in context, this is significant. Outside of the US Patent and Trademark Office, it is reasonable to assume that Federal Circuit judges see more patent eligibility cases than any other lawyers or others involved in the intellectual property field, and they are asked to apply Supreme Court precedent to these cases. If they cannot decide these cases with any level of certainty or predictability, then certainly lawyers and clients are likely even less able to do so.

Furthermore, the recent USPTO Guidelines on patent eligibility indicate the difficulty the US Patent and Trademark Office faces in attempting to implement current patent eligibility jurisprudence. Would these Guidelines even be necessary but for the lack of certainty and predictability in eligibility jurisprudence? Indeed, the guidelines go to great lengths in attempting to bring some degree of predictability to abstract ideas by creating three classes of abstract ideas under existing case law with each class having its own problems with respect to certainty and predictability. The Guidelines further attempt to explain the inventive concept step of the *Alice* two step test, as well as when the notion of whether a limitation can be found conventional, routine or well-known can be applied. Would this be necessary if the current jurisprudence itself offered a clear and certain test that could be objectively applied across the board? The answer is no. Indeed, because the US Patent and Trademark Office does not have substantive rule making authority, the efforts of the Office to bring some clarity and a degree of predictability to the *Mayo/Alice* test may not survive future Federal Circuit and Supreme Court jurisprudence.

⁶ 896 F.3d 1335 (Fed. Cir. 2018).

⁷ *Id.* at 1348 (Plager, J., concurring in part and dissenting in part).

⁸ See e.g., Berkheimer v. HP, 890 F.3d 1369 (Fed. Cir. 2018) (Lourie, J., concurring in the denial of the petition for rehearing en banc) We now are interpreting what began, when it rarely arose, as a simple § 101 analysis, as a complicated multiple-step consideration of inventiveness ("something more"), with the result that an increasing amount of inventive research is no longer subject to patent".

⁹ 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (January 7, 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?

We are unclear on what is meant by the phrase "broadening the subject matter" in the context of this question. Our lack of clarity about this question is not only based on the use of the word "broadening" but the juxtaposition of that word with the phrase "that can be patented." The question appears to conflate the separate issues of patent eligibility and patentability. If the question is intended to suggest that a larger number of patents would issue than currently issue under existing law, then the most appropriate answer is no. The legislative proposal's goal is to restore patent eligibility to its proper role; in other words, resetting eligibility more in line with its historical role as a gatekeeper for the categories of subject matter that have been part of our patent system since its inception. Despite its earlier precedent recognizing patentability and eligibility are separate issues, the Supreme Court through Mayo¹⁰ and Alice¹¹ conflated eligibility and patentability under sections 102, 103 and 112. This resulted in a patent eligibility test that became difficult to apply in a predictable and consistent manner. In fact, if the current legislative proposal becomes law, many of the inventions that might have failed the Supreme Court's Mayo/Alice test may yet fail the remaining patentability tests. This is a critical point in answering this question. It follows that it is speculative to conclude that the overall effect of this legislative proposal will be the broadening or expansion of the issuance of patents. Furthermore, for those patents that include claims using functional language, the effect of amended section 112(f) will more likely be the narrowing of those patents to their corresponding structure and equivalents. Thus, it is just as probable that better and stronger patents will issue based on application of the entire set of considerations that apply to obtaining patents and maintaining them in court. Most importantly, meritorious inventions —including potentially groundbreaking ones—that were ruled patent ineligible without the benefit of a proper patentability analysis under the patentability tests of Section 102, 103 and 112 will now have a proper, predictable and understandable eligibility determination.

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

As noted above, this legislative proposal would likely restore patent eligibility to its gatekeeper role while other sections of the statute perform their proper roles as well. Thus, when a complete analysis of the legislative proposal and the remainder of the conditions for patentability are taken into account, we are unaware of any perceptible impact on consumers. In general, restoring patent

¹⁰ Mayo Collaborative Services v. Prometheus Laboratories, Inc. 566 U.S. 66 (2012).r

¹¹ Alice Corp. v. CLS Bank Inter, 537 U.S. 208 (2014).

eligibility to its gatekeeper role is likely to benefit U.S. consumers by encouraging investment in innovation in fields of endeavor that have been negatively impacted by the uncertainty and unpredictability of current eligibility jurisprudence. A useful empirical survey to consider in this regard is the forthcoming article entitled "Patent Eligibility and Investment" by Associate Professor David O. Taylor of Southern Methodist University's Dedman School of Law.

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

We are not aware of any empirical data that addresses whether the limited nature of this legislative proposal - that is, providing a more certain and predictable test for patent eligibility while enabling other sections of the patent statute to perform their roles in assessing patentability - would increase or decrease consumer prices. For example, it may be just as plausible that advances in a particular field will be encouraged by this legislative proposal, and that those advances might reduce costs/prices incurred by consumers in seeking products or services in that field. Various examples of the potential for reduced costs/prices are not difficult to contemplate. Furthermore, the potential effect of revised 112(f) in clarifying that functional language in a claim should be interpreted based on the corresponding structure and its equivalents provides a more certain and predictable basis on which third parties can carry out legitimate design-around activities. The availability of legitimate design-arounds has the potential for increased competition and lower costs/prices. Ultimately, as you know, the goal of the patent system is to incentivize and reward investments in innovation, and when the system is working to satisfy that goal it serves to benefit consumers with breakthroughs that improve lives and benefit society across the board.

¹² <u>SMU Dedman School of Law Legal Studies Research Paper No. 414</u>; found at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3340937## (last accessed on June 17, 2019).

QUESTIONS FROM SENATOR MAZIE K. 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?

At this point in the evolution of patent eligibility case law, the short answer is yes. However, starting more than a decade or so ago (prior to the Supreme Court's Mayo and Alice decisions), the ABA and Section of Intellectual Property Law policy had been to "support[] application by the Supreme Court of the United States of the common law tradition of incremental development of jurisprudential doctrine for determining patent-eligible subject matter under 35 U.S.C. § 101."13 Unfortunately, instead of that common law tradition leading to a consistent, understandable, predictable test for patent eligibility, it led to the Mayo/Alice test. Then, following the creation of that test, the Supreme Court has now declined 42 opportunities to clarify the test, and the Federal Circuit has issued a large number of inconsistent and irreconcilable opinions attempting to apply the Mayo/Alice test. Thus, for at least the last five years, the Intellectual Property Law Section has taken the position that a legislative fix is necessary, and the Section has issued multiple letters in which we have encouraged a legislative fix. The Supreme Court was correct when it stated in Gottschalk v. Benson that the proper scope of coverage of our nation's patent system is a policy matter for Congress. 14 Legislative reform is needed now to restore predictability to the patent system and to maintain incentives to invest in future cutting-edge technologies and discoveries, and the proposal that has been drafted by Senators Tillis and Coons and Representatives Collins, Johnson, and Stivers provides an important step forward in improving our patent system.

- 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?

¹³ American Bar Association Resolution 302, adopted August 3, 2009, available at: https://www.americanbar.org/content/dam/aba/directories/policy/2009 am 302.pdf

¹⁴ 409 U.S. 63, 72-73 (1972).

As this question recognizes, the use of a patent eligibility test that incorporates a technology requirement is not uncommon. Europe, Japan, China and other countries have various forms of technical requirements. The European and Japanese requirements are the most established and have a longer history of interpretation. For example, Article 52(1) of the European Patent Convention (EPC) provides that an invention must belong "to any field of technology." To belong in a field of technology the invention must be of a technical character, be in technical field, concern a technical problem or have technical features defined in the claim (Rule 42(1)(a) and (c) and Rule 43(1)). As a consequence, the EPC is limited to any "field of technology," and the EPC has applied this limitation as requiring a concrete and technical character. This is analogous to the draft legislative proposal now being considered by this Committee in that it requires a "specific and practical utility in any field of technology."

It is noted that the EPC introduced a list of exclusions as part of EPC 2000. Since then, the EPO has issued further guidance in 2015, 2016, 2017 and 2018, and in the last ten years approximately 40% of decisions of the Enlarged Board of Appeal (analogous to *en banc* opinions in the US) have addressed the exclusions to patentability with the latest case being as recently as April 2019. This is clearly disproportionate and reflects the inherent ambiguity and uncertainty of codifying a list of exclusions or exceptions. The lesson to learn is that a list of exclusions *should not be part* of the US statute. The patent eligibility issue is best addressed by setting out the principles as the draft legislative proposal does in revised sections 101 and 112 (f) and new section 100 (k).

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?

Assessing the claims at issue in the *Bilski*¹⁵ case under the new legislative proposal requires consideration of more than simply the "field of technology" requirement in the definition of a "useful invention." The proposal also modifies section 112(f) in a way that makes functional claim limitations subject to the possibility of narrow interpretation based on the corresponding structures disclosed in the specification and their equivalents. The proposal further requires separation of patentability considerations from patent eligibility. As a consequence of the collective changes in the legislative proposal, claims like the claims in the patent at issue in *Bilski* could fail to satisfy the field of technology requirement, end up being found functional and thereby limited to the corresponding structure and its equivalents, or be found unpatentable as not novel, obvious or failing to meet the set of requirements of section 112. While this would be the case whether the claims specifically referenced the use of a computer or not, the main claims actually at issue in the *Bilski* case would likely fail the field of technology requirement unless the functional language in those claims finds structural support in the specification that would lead to an interpretation of the claims as limited to a field of technology set forth in the specification. Of course, that interpretation would be done as a matter of law under current jurisprudence. Thus, the overall

¹⁵ Bilski v. Kappos, 561 U.S. 593 (2010).

effect of the legislative proposal is to require a more sophisticated examination of the claims of certain patents - that is, in the event the claims contain functional language, the examination must take into account what the corresponding disclosure provides.

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

We do not have a recommendation as to the field of technology requirement at this time. We did recommend a few changes to the legislative proposal in our letter to the Subcommittee on June 14 but those changes did not address the field of technology requirement. While as noted above other countries have variations of a technology requirement, if the legislative proposal used terminology like "technical problem" or "technical solution," that terminology would still have to be interpreted by US courts on a case by case basis. That is the nature of our common law system of jurisprudence. Though it might be argued that the use of the same terminology used in other countries could lead to a more rapid interpretation of the US technology requirement and greater consistency in international standards, our courts are not bound by foreign interpretations in establishing our common law interpretation.

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?

No other categories of excluded subject matter are required. It is improvident to make specific or categorical exclusions. Indeed, it is impossible for any generation to avoid its historical limitations and to foresee inventions that may arise in the future. Limitations on patent eligibility that appear rational and sound today may, inadvertently, prevent development of beneficial innovations tomorrow. Worse still, zealous application of any such specific strictures in patent eligibility could prevent innovation (or commercialization thereof) due to the existence of the strictures themselves. The issue is best addressed by setting out principles, as the draft legislative proposal provides in revised Sections 100 and 101.

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?

The validity of the complaint is likely in the eye of the beholder. A patentee reaping the short-term benefit of overly broad claims in the hi-tech arts is undoubtedly content with the status quo. However, what is clear is that the patent system works best to promote innovation when overly broad, abstract and functional claims are addressed through Section 112, rather than Section 101. Indeed, the revisions proposed to section 112(f) are designed to address overbreadth due to

recitation of functional language in patent claims by interpreting such claims as limited to the corresponding structure in the specification and its equivalents. This revision should have a dual effect - it will narrow claims that should be interpreted more narrowly for both infringement and validity purposes.

Under current jurisprudence, the application of Section 112 to functional claim elements in the hi-tech arts has been a challenge, both because Section 101 has been conflated with Section 112 (that is, Section 101 is being used to invalidate claims that are properly assessed under Section 112) and because the "predictability in the art" has blurred the line between function and structure. This blurring has led to claiming inventions by what the invention does, rather than what the invention is.

The essence of the written description requirement is that a patent applicant, as part of the bargain with the public, *must describe his or her invention so that the public will know what it is* and that he or she has truly made the claimed invention. ... We have explained that "requiring a written description of the invention plays a vital role in curtailing claims . . . that have not been invented, and thus cannot be described." ¹⁶ (emphasis added)(internal citations omitted).

The ABA-IPL Section has provided commentary on the compliance of generic and functional claims, particularly in the hi-tech arts with Section 112 in 2014 and 2016.¹⁷ The USPTO has similarly issued guidance in an effort to clarify this body of law.¹⁸ Despite these efforts, the applicability of Section 112(f) is a problem that needs to be addressed, and the draft legislative proposal is a step forward in addressing the existing 112 problem.

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

Yes, the proposed changes to Section 112 will significantly clarify the law and limit overly broad, abstract and functional claims. Claim limitations expressed as a specified function will be limited to disclosed structures and equivalents thereof. The breadth of "equivalents thereof" will provide patentees reasonable scope of patent protection while preventing claims from preempting future innovation. Notably, the changes to Section 112 address the issue of overly broad, abstract and functional claims as an issue of claim construction. This preserves or saves an overly broad claim from invalidity under Section 112(a) and (b) by limiting the claim to the disclosed structures or acts and equivalents thereof.

¹⁶Abbvie Deutschland GmbH & Co. v. Janssen Biotech, Inc., 759 F.3d 1285, 1298-1299 (Fed Cir. 2014).

¹⁷ Letter from Donna Suchy to Mr. Robert Bahr, Deputy Commissioner for patent Examination Policy (Dec. 5, 2016), available at https://www.americanbar.org/content/dam/aba/administrative/intellectual_property_law/advocacy-20161205-comments.pdf; Letter from Lisa Dunner to Mr. Drew Hirshfeld, Deputy Commissioner for Patent Examination Policy (Oct. 28, 2014), available at https://www.americanbar.org/content/dam/aba/administrative/intellectual_property_law/advocacy/advocacy-20141028-comments.pdf.

¹⁸ See e.g. Federal Register Volume 84, Number 4 (Monday, January 7, 2019) [Pages 57-63] Examining Computer-Implemented Functional Claim Limitations for Compliance With 35 U.S.C. 112].

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

Good patent policy encourages design-around, rather than copying. As the Federal Circuit noted in *State Indus. v. A.O. Smith Corp*:

Conduct such as Smith's, involving keeping track of a competitor's products and designing new and possibly better or cheaper functional equivalents is the stuff of which competition is made and is supposed to benefit the consumer. One of the benefits of a patent system is its so-called "negative incentive" to "design around" a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace. ¹⁹

In sharp contrast, a functional claim element, reading on anything capable of performing the required function, precludes and pre-empts legitimate design-around efforts and future innovation.

Copying, on the other hand, is well-within the scope of new 112(f). If the corresponding structure differs insubstantially -- functions in the same way to produce the same result -- then it should properly be found to be an equivalent of the claimed element. The line between "copying" and "designing around" will always be determined on the facts of a given case.

The scope of equivalents under Section 112(f) is unchanged by the proposed amendments.

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?

The issue of obvious-type double patenting is wholly unrelated to the proposed amendments to Sections 101 and 112. Section 101 has served and will continue to serve as the basis for the double patenting bar. This bar does not permit two patents on the same or similar invention based on the phrase, "may obtain *a patent* therefor" (emphasis added). The language "a patent" is found in all proposed amendments to 35 U.S.C. § 101. This law will be unchanged by these amendments.

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.

_

¹⁹ State Indus. v. A.O. Smith Corp., 751 F.2d 1226, 1235-1236 (Fed Cir 1985).

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

As you know, the Oil States²⁰ case involved the application of the new inter partes review proceedings authorized by the America Invents Act to a patent issued prior to the effective date of that Act. The Supreme Court addressed the Article III considerations raised in that case whether the US Patent and Trademark Office, which is an Article I entity, could conduct an administrative proceeding to invalidate a patent that was concurrently under consideration by an Article III court. While the Court found no infirmity with respect to the Article III issue, it did not address Due Process and the Takings clause because those issues were not presented. By contrast, the issue presented by the current legislative proposal is one of substantive patent law rather than the creation of a new administrative proceeding that could invalidate previously existing patents in violation of Article III or a potential Due Process or Takings clause argument. That substantive law change is one that favors certainty and predictability in eligibility law rather than subjecting patents to an uncertain and unpredictable eligibility test that even judges acknowledge is the nature of that test under current law. So, in that context, it would be surprising if a legitimate argument as to the application of the Due Process and the Takings clause could be made. But assuming a rare circumstance might exist to the contrary, Congress is accustomed to addressing retroactivity with provisions that allow the exercise of an opt out by patent holders within a set time frame or allowing equitable principles to come into play on behalf of potential infringers. While the ABA-IPL Section has not yet taken a formal position on retroactivity, it would not appear to be a particularly unusual or difficult exercise to craft a legislative provision on retroactivity that would negate any potential Due Process or Takings claim by patent holders holding patents issued prior to the effective date of the legislative proposal or potential infringers who actually relied on existing patent eligibility law in their decision making.

²⁰Oil States Energy Services, LLC v. Greene's Energy Group, LLC, 138 S. Ct. 1365 (2018).