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Answers to Written Questions for the Record
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Subcommittee on Intellectual Property

The State of Patent Eligibility in America: Part I
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Questions from Chairman Tillis

Professor Taylor, you've also written extensively on the subject of patent eligibility and the current confusion created by the judicially created exceptions. In your 2017 article *Amending Patent Eligibility* you wrote that:

> **The Supreme Court's recent treatment of the law of patent eligibility has introduced an era of confusion, lack of administrability, and, ultimately, risk of under-investment in research and development. As a result, patent law — and in particular the law governing patent eligibility — is in a state of crisis.**

What did you mean by patent law is in a state of crisis?

Patent law is in a state of crisis because there is intense disfunction with respect to the law of patent eligibility.

First, there is significant *confusion*. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,[1] the Supreme Court confused Congress's statutory scheme, the relevant policies, and its own precedent to create a confusing patent eligibility test. The test is particularly confusing with respect to claims that include computer hardware or software.

Second, the confusing test *lacks administrability*. Companies, investors, patent prosecutors, patent examiners, and judges cannot understand how to determine reliably what constitutes an "abstract idea" or an "inventive concept." There are no objective guidelines to make these determinations, and so these determinations by patent examiners and judges are unpredictable. Again, this is particularly true with respect to claims including computer hardware or software.

Third, the test generates *incorrect results*, particularly in the life sciences. While historically the patent system would reward novel discoveries put to practical uses, the Supreme Court's new test requires "something more" (the Supreme Court's unilluminating words in *Alice Corp. v. CLS Bank Int'l*[2]) than a practical use. As a result, the current test would not necessarily reward someone who discovers the cure to a disease and describes in her patent application how to cure that disease using her discovery.

Fourth, all this confusion and ineligibility has *negatively impacted investor behavior*. Investors report that they have reduced their investments and shifted their investments out of the

[1] *See generally* Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012)
[2] Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2355 (2014).

life sciences industries in particular.[3] I will discuss in more detail below my survey showing this. I mention it here to highlight the point that the patent system is not working as Congress intended.

To understand the general consensus about these problems amongst leaders in the patent community, I encourage you to read the sobering Final Report of the Section 101 Workshop that I helped convene at the University of California Berkeley.[4]

Beyond these significant problems, there also is a crisis because *the Supreme Court is highly unlikely to correct these problems*. The Court denied certiorari in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, a case in which the Federal Circuit and twenty-two amici—every single one in support of certiorari—practically cried out for guidance on how to apply the two-part test set forth in *Mayo* and *Alice*.[5] The Court didn't even ask the Solicitor General for the government's views in that case. Even more alarming, most recently the Court *did* request the views of the Solicitor General—but this time in a case (with little amici support) where the petitioner seeks to render ineligible patent claims to medical treatments of patients based on alleged inconsistency with the "inventive concept" requirement of *Mayo*, the opposite of the proposed reform of Section 101.[6]

What risks of under investment in research and development has your research demonstrated? Can you give some examples for the Committee of some of the major areas of innovation that are at risk?

My research has demonstrated risks of under investment in research and development as a direct result of the Supreme Court's recent patent eligibility decisions. This under investment primarily takes the form of reduced investment as well as shifting of investments out of particular industries. And my research shows that the most significantly impacted industries are the biotechnology, medical device, pharmaceutical, and software and Internet industries.

I conducted a survey of 475 venture capital and private equity investors to study the impact of the Supreme Court's patent eligibility cases on investment firms' decisions to invest in companies developing technology. The survey revealed several important things.

First, the investors who responded to the survey overwhelmingly believe patent eligibility is an important consideration when their firms decide whether to invest in companies developing technology. Overall 74% of the investors agreed that patent eligibility is an important consideration in firm decisions whether to invest in companies developing technology; only 14% disagreed. Likewise, investors reported that reduced patent eligibility for a technology makes it less likely that their firm will invest in companies developing that technology. For example, overall

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[3] *See generally* David O. Taylor, *Patent Eligibility and Investment*, __ CARDOZO L. REV. __ (forthcoming), *available at* http://ssrn.com/abstract=3340937.

[4] *See generally* Jeff Lefstin, Peter Menell, & David Taylor, *Final Report of the Berkeley Center Workshop: Addressing Patent Eligibility Challenges*, 33 BERK. TECH. L.J. 551 (2018).

[5] *See* Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (mem.) (2016).

[6] *See* Hikma Pharms. USA Inc. v. Vanda Pharms. USA, Inc., No. 18-817, 139 S. Ct. 1368 (2019) (mem.) (inviting the Solicitor General to file a brief expressing the views of the United States); Hikma Pharms. USA Inc. v. Vanda Pharms. USA, Inc., No. 18-817, 2018 WL 6819525 (U.S. Dec. 20, 2018) (petition for writ of certiorari) ("In the decision below, a divided Federal Circuit panel did exactly what *Mayo* forbids: it exempted all patent claims that are drafted as reciting a method of medically *treating* patients from [the required] analysis.").

62% of the investors agreed that their firms were less likely to invest in a company developing technology if patent eligibility makes patents unavailable, while only 20% disagreed.

Second, the survey revealed different impact on different industries. Investors, for example, overwhelmingly indicated that the elimination of patents would either not impact their firm's decisions whether to invest in companies or only slightly decrease investments in companies developing technology in the construction (89%), software and Internet (80%), transportation (84%), energy (79%), and computer and electronic hardware (72%) industries. But investors, by contrast, overwhelmingly indicated that the elimination of patents would either somewhat decrease or strongly decrease their firm's investments in the biotechnology (77%), medical device (79%), and pharmaceutical industries (73%). Thus, according to these investors, on average each industry would see reduced investment, but the impact on particular industries would be different. And the life sciences industries are the ones most negatively affected.

Third, the survey also reveals that the Supreme Court's eligibility cases have impacted many firms' investments and, more significantly going forward, their firm's investment behaviors. Almost 40% of the investors who knew about at least one of the Court's eligibility cases indicated that the Court's decisions had somewhat negative or very negative effects on their firm's existing investments, while only about 15% of these investors reported somewhat positive or very positive effects. On a going forward basis, moreover, almost 33% of the investors who knew about at least one of the Court's eligibility cases indicated that these cases affected their firms' decisions whether to invest in companies developing technology. These investors reported primarily decreased investments, but also shifting of investments between industries. In particular they identified shifting of investments out of the biotechnology, medical device, pharmaceutical, and software and Internet industries.

I encourage you to consider all of the survey's results, as well as limitations on the survey's results and findings, by reviewing my article going into more detail about these points.[7] For now, however, I want to stress that the results of the survey provide critical data for an evidence-based evaluation of competing arguments in the ongoing debate about the need for congressional intervention in the law of patent eligibility. The best that can be said by those that prefer the status quo is that most investors do not report changing their investment decisionmaking based upon the Supreme Court's eligibility decisions. A significant part of this group of investors, however, represents those uninformed about the Court's cases. The reality is that the results of the survey highlight the importance of patent eligibility and the negative impact of the Supreme Court's eligibility cases generally on investment, but particularly in the most important areas of technological development in terms of its impact on public health: the biotechnology, medical device, and pharmaceutical industries, in other words the life sciences industries. That said, it is important to highlight that the results show the Court's decisions have negatively impacted each and every area of technological development studied. And, as a consequence, the results do support the idea that the time has come for Congress to at least consider overturning the Supreme Court's new eligibility standard to prevent additional lost investment in technological development in the United States. Indeed, given the results of the survey, it seems likely that the Supreme Court's

[7] David O. Taylor, *Patent Eligibility and Investment*, __ CARDOZO L. REV. __ (forthcoming), *available at* http://ssrn.com/abstract=3340937.

eligibility decisions have resulted in lost investment in the life sciences that has delayed or altogether prevented the development of medicines and medical procedures.

Questions from Senator Blumenthal

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?

Broadening the subject matter that can be patented—to the extent Congress returns subject matter eligibility to its scope prior to the Supreme Court's decision in *Mayo*—will likely positively impact various industries. As my survey demonstrates, the Supreme Court's recent patent eligibility decisions have negatively impacted investment in every industry, but most significantly the life sciences industries.[8] Given the results of my survey, it seems likely that returning patent eligibility law to its historical foundation will result in increased investment in research and development in the biotechnology, medical device, pharmaceutical, and software and Internet industries.

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

Broadening the subject matter that can be patented—again to the extent Congress returns subject matter eligibility to its scope prior to the Supreme Court's decision in *Mayo*—will likely positively impact consumers. As I have mentioned, given the results of my survey, it appears likely to result in increased investment in research and development in all industries, but in particular in the biotechnology, medical device, pharmaceutical, and software and Internet industries. This increased research and development would likely lead to the development of new technologies and as a result consumers' access to new technologies. Particularly given the development of new technologies in the life sciences industries, returning patent eligibility to its historical scope would likely increase consumer's health given new medicines and medical procedures.

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

An accurate answer to this question must distinguish the static situation where one simply compares the prices of consumer products where they are protected by patents versus the prices of the same consumer products where they are not protected by patents. Of course it is possible that stripping patent protection from already-invented products would reduce the price of those products. Stripping patent protection would allow copiers to sell the same product without charging a price that includes any effort to recoup the cost of developing the product—the copiers by definition did not develop the product. Likewise adding patent protection to already-invented products might increase the price of those products. Adding patent protection would not allow

[8] *See generally id.*

copiers to sell the same product without charging a price that includes any effort to recoup the cost of developing the product. All of this, however, is dependent upon the level of competition in the market for the relevant products, and in most instances non-infringing products constrain the pricing of patented products. Anyway, this is not what I understand the proposed reforms seek to do. They do not seek to strip patent protection from already-invented products or add patent protection to already-invented products. Rather, the proposed reforms seek to return patent eligibility to its historical focus on practical utility. It also is unclear whether the proposed reforms would be given retroactive application. (One possibility, however, is restoring the historical scope of patent eligibility prior to the Supreme Court's decision in *Mayo* and applying this scope to already-issued patents. This would not strip patent protection from already-invented products or add patent protection to already-invented products, but instead for some already-invented products provide certainty that patents covering them meet the requirement of patent eligibility.)

The reality, moreover, is that the patent system operates in a dynamic situation; the patent system is built upon the idea that it spurs the creation of new products. As a result, to answer the question accurately one needs to compare the price of a first set of consumer products developed without the proposed reforms with the price of a second set of consumer products developed with the proposed reforms.

It is unlikely that the proposed reforms will increase the prices of consumer products already on the market. Those products will experience new competition from new products created on the basis of increased research and development. These new products will include enhanced features or will be produced more efficiently given new manufacturing technologies. Thus, existing products will face competition driving the cost of these products down.

With respect to the prices of consumer products created after these proposed reforms and covered by patents, there are two possibilities. One possibility is that new products created after these proposed reforms would not have been created but for the proposed reforms. For these new products, it is unclear whether their prices will be higher or lower compared to pre-existing products. The theory of the patent system is that it encourages the development of new technologies. These new technologies may improve features of products, or they may reduce costs of products. Some consumers may pay extra to have access to improved features. On the other hand, companies producing products at reduced cost will have the ability to maintain profitability even while reducing prices.

The other possibility is that new products created after these proposed reforms and covered by patents would have been created without the proposed reforms and not patented. There is a possibility that prices for these products will be higher than they otherwise would have been. On the other hand, one of the benefits of the patent system, again, is that it encourages the development of new technologies. These new technologies will compete on the market with any products that would have been created without the proposed reforms. As a result, these new technologies will constrain the ability to increase the prices of products that would have been created without the proposed reforms.

In short, the patent system encourages a well-functioning market that includes robust competition. The history of technological development and prices in modern industries supports

this idea. As just one example, consider the television industry, in which the technical complexity has significantly expanded while the prices have declined precipitously over the same time period. While there have been concerns that the pharmaceutical industry has utilized the patent system to raise prices unnecessarily, the patent system has long been viewed as essential to the creation of new medicines and treatments. It is an industry that both requires significant financial investment to develop new drugs and is subject to easy copying given the public disclosure requirements of the Food and Drug Administration. Congress, as a result, has taken significant steps to balance the interests of the developers of new drugs and public access to generic drugs at lower price points, including through the existing Hatch-Waxman regime.

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?

I agree with Judges Lourie and Newman that the law of patent eligibility needs clarification by Congress. We should not let the courts "continue to work things out."

First, courts below the Supreme Court have no power to overrule the Supreme Court's misguided test for patent eligibility. While various Federal Circuit judges, in particular, have indicated that the Supreme Court's test leads to incorrect outcomes,[9] the Federal Circuit of course cannot overrule the Supreme Court. Moreover, the Federal Circuit's case law is not providing workable guidance to patent examiners, district judges, attorneys, or investors to alleviate the concern with confusion and lack of administrability. The Federal Circuit is thus simply not able to work things out.

Second, the Supreme Court has proven that that it is unable or unwilling to work things out. The Supreme Court has repeatedly focused on the doctrine of patent eligibility (it heard eight cases in forty years on patent eligibility, and only four cases on any other patent doctrine during

[9] *See* Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1381 (Fed. Cir. 2015) (Linn, J., concurring) ("But for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible."); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282, 1287 (Fed. Cir. 2015) (Lourie, J., concurring in the denial of the petition for en banc rehearing, joined by Moore, J.) ("In sum, it is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps, or that they claim abstract concepts. But I agree that the panel did not err in its conclusion that under Supreme Court precedent it had no option other than to affirm the district court."); *id.* at 1293 (Newman, J., dissenting from the denial of en banc rehearing) ("I agree with my colleagues that this case is wrongly decided. However, I do not share their view that this incorrect decision is required by Supreme Court precedent. . . . In *Mayo* . . . the Court recognized the principle that patent eligibility is not disabled when science is put to practical use . . . ."); *id.* at 1287 (Dyk, J., concurring in the denial of en banc rehearing) ("I share the concerns of some of my colleagues that a too restrictive test for patent eligibility under 35 U.S.C. § 101 with respect to laws of nature (reflected in some of the language in *Mayo*) may discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new natural laws and phenomena.").

the same time period), but to no avail. It has been unable to settle upon a clear test that provides correct and predictable results. Furthermore, as discussed above, the Court recently refused to grant certiorari in a case where all twenty-two amici supported certiorari to address the impact of the *Mayo* test. As I go into detail in my written testimony on pages 9-12, moreover, even if the Court granted certiorari in a new case, it is unlikely that the Court would reverse its recent precedent in *Mayo* and *Alice*. In short, in *Alice* the Court already rejected calls to overturn *Mayo*'s test for patent eligibility. And even if the Court granted certiorari in a new case, it seems unlikely that the Supreme Court would reverse course in the area of patent eligibility given the Court's discussion of stare decisis in the recent patent case of *Kimble v. Marvel Enterprises*.[10]

With all that said, these are not just my views. At the Section 101 Workshop I helped convene, there was consensus amongst experts on these same points:

> [T]he workshop revealed a consensus that it is unlikely that the Supreme Court will reconsider the patent eligibility issue in the foreseeable future. Conferees also doubted that the Federal Circuit will confront the core concerns surrounding patent eligibility. Thus, legislative reform will be necessary to effect significant change in patent-eligibility standards.[11]

A Congressional fix is required.

2. **The Federal Circuit rejected a "technological arts test" in its *en banc Bilski* opinion. It explained that "the terms 'technological arts' and 'technology' are both ambiguous and ever-changing." The draft legislation includes the requirement that an invention be in a "field of technology."**

   a. Do you consider this a clear, understood term? If so, what does it mean for an invention to be in a "field of technology"?

I do not consider "technology" to be a clear, understood term at least with respect to some disputes. While there is intuitive appeal to the idea that the patent system should be limited to anything that is in a "field of technology," unfortunately this intuition does not lead to a test that provides clarity, at least on the margin.

As I mentioned at the hearing, the Oxford English Dictionary includes a definition of "technology" as "the branch of knowledge dealing with the mechanical arts and applied sciences." In turn it includes a definition of "mechanical arts" as "skilled activities or occupations predominately involving manual skills rather than mental ability; (in later use) such activities supported by the use of machines" and "art" as "a practical application of knowledge." This dictionary likewise defines "applied" to mean "put to a practical use; practical" and "science" to mean "a branch of study that deals with a connected body of demonstrated truths or with observed facts systematically classified and more or less comprehended by general laws, and incorporating

[10] Kimble v. Marvel Entm't, LLC, 135 S. Ct. 2401 (2015).

[11] Jeff Lefstin, Peter Menell, & David Taylor, *Final Report of the Berkeley Center Workshop: Addressing Patent Eligibility Challenges*, 33 BERK. TECH. L.J. 551, 603 (2018).

trustworthy methods (now esp. those involving the scientific method and which incorporate falsifiable hypotheses) for the discovery of new truths in its own domain."

Given these definitions, it seems apparent that "field of technology" would exclude purely mental activities, fine arts, and pure science, but it is unclear whether judges would exclude other things litigants would be sure to dispute. Going back to the Federal Circuit's rejection of this test in its *en banc Bilski* opinion, it is worth highlighting the competing arguments the court noted. The court compared the appellee's argument that "non-technological inventions" would exclude "activities whose ability to achieve their claimed goals depended solely on contract formation" with the argument in an amicus brief that "innovations in business, finance, and other applied economic fields plainly qualify as 'technological'" since "a fair definition of technological is 'characterized by the practical application of knowledge in a particular field'" and because modern economics has "a closer affinity to physics and engineering than to liberal arts like English literature."[12]

Given these types of arguments, the "field of technology" requirement might give substantial discretion to judges to make idiosyncratic determinations, which would undermine the predictability inventors and investors need. Patent examiners and judges will likely struggle to answer the question of what exactly is and is not a "field of technology," just like there is no clear demarcation between what is and is not a business method. In short, these questions will provide significant room for litigation and discretion. While I have indicated before that a field of technology test is a possible option to reform patent eligibility law,[13] in my view it is not the best approach because it is highly dependent upon the appropriate use of discretion by patent examiners and judges. Finally, this aspect of the proposal does not fare very well on the principle of flexibility. It might be understood to be a standard that codifies what is currently viewed as a "field of technology." Indeed, while it is fairly easy to distinguish between existing fields of technology (e.g., pharmaceuticals versus construction), it is much more difficult to identify what makes something qualify as a field of technology versus not, particularly when that something is new.

b. 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?

Notably, my understanding it that European patent examiners initially considered artificial intelligence to be ineligible based upon a similar "field of technology" requirement.[14] One thing I think we can learn from this is that when new developments do not fall within an existing "field of technology," some patent examiners and judges may not know whether the "field of technology"

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[12] In re Bilski, 545 F.3d 943, 960 (Fed. Cir. 2008) (en banc).

[13] David O. Taylor, *Amending Patent Eligibility*, 50 U.C. DAVIS L. REV. 2149, 2214 n.267 (2017) ("If the conclusion is that [an alternative] approach does not appropriately treat [problematic] types of claims, the next step is to consider the addition of an appropriate, narrowly-tailored patentability requirement, such as a limitation on patents to "technological arts" or "technological fields of invention.").

[14] Jeff Lefstin, Peter Menell, & David Taylor, *Final Report of the Berkeley Center Workshop: Addressing Patent Eligibility Challenges*, 33 BERK. TECH. L.J. 551, 601 (2018) ("One participant noted . . . that it is unclear how the technological arts test applies to new technologies. That participant noted that European patent examiners initially considered artificial intelligence to be ineligible.").

test is met. This is problematic given that a goal of the patent system is to encourage cutting-edge inventions.

c. 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?

It seems highly likely a court would conclude that a method for hedging against the financial risk of price fluctuations is not in a "field of technology." While the question is closer if the claim requires performing the method on a computer, it still seems likely to me that most courts would find that claim also ineligible.

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

Given the lack of clarity associated with the "field of technology" requirement at least on the margin, I recommend serious consideration be given to eliminating it from the proposed definition of "useful." The definition might be rephrased, for example, merely to recite that "'useful' means having practical utility as a result of human intervention."

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?

There may be other categories. Reform proposals in the area of patent eligibility should bring to the forefront of our collective consciousness the role of the patent system in encouraging use of technology some deem immoral or unethical. Patent law historically allowed judges to address moral and ethical concerns related to technology. Judges did so by determining on an ad hoc basis whether inventions were "injurious to the well-being . . . or sound morals of society" or, in other words, "mischievous or immoral."[15] While this historical approach resembles the modern contract doctrine of public policy, it is not the best approach. Indeed, given various considerations—certainty and predictability, clarity, expertise, and accountability chief among them—judges and agencies should not be tasked with determining which technologies should not be patent eligible based on moral or ethical concerns. The best approach is to address any moral or ethical concerns related to technology through legislation. At a minimum, Congress should consider readopting as statutory text the Weldon Amendment, which states that "no patent may issue on a claim directed to or encompassing a human organism."[16]

[15] Lowell v. Lewis, 15 F. Cas. 1018 (C.C.D. Mass. 1817) (No. 8,568) (Story, J.).

[16] Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340 (2011).

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?

Complaints that courts do not consistently enforce Section 112 with respect to claims for inventions in the high tech space do not appear to me to be valid. When called upon, courts apply the existing Section 112 doctrines with vigor, and I have not seen courts enforcing the doctrines of Section 112 inconsistently. As I explained in detail in my written testimony on pages 37-44, the existing written description, enablement, and definiteness requirements of Section 112 (along with other aspects of the existing statute, including the existing limitation on functional claiming and the non-obviousness requirement) already addresses concerns with claim breadth, vagueness, and abstractness using well-defined legal tests that provide certainty and predictable results in the high tech area (indeed in all areas of technology). I encourage you to review my detailed testimony on point, which discusses several examples of courts applying the current statutory doctrines.

On the other hand, a valid complaint I have heard in the high tech space (primarily from representatives of large companies) is that courts consider the written description requirement a question of fact, which does not lend itself to early resolution in cases. Indeed, while the Federal Circuit has consistently held that the enablement requirement is a question of law,[17] it has consistently held that the written description requirement is a question of fact.[18] This, however, is merely a procedural problem. Solving this problem would not require any change to any substantive aspect of Section 112, unlike the current proposed reform to Section 112(f). All that is required to address this procedural problem is to include a provision in the proposed reform stating, for example, that "compliance with the written description requirement of Section 112(a) shall be a question of law exclusively within the province of the court."

Changing the law to require that courts determine compliance with the written description requirement as a matter of law would be entirely appropriate. The Federal Circuit recently explained the analysis required by the written description requirement:

> The written description requirement of 35 U.S.C. § 112, ¶ 1 provides, in pertinent part, that "[t]he specification shall contain a written description of the invention." That requirement is satisfied only if the inventor "convey[s] with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention,' and demonstrate[s] that by disclosure in the specification of the patent." "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."[19]

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[17] *See, e.g.*, Trustees of Bos. Univ. v. Everlight Elecs. Co., 896 F.3d 1357, 1361 (Fed. Cir. 2018) ("Whether a claim satisfies § 112's enablement requirement is a question of law we review de novo.").

[18] *See, e.g.*, Nuvo Pharm. (Ireland) Designated Activity Co. v. Dr. Reddy's Labs. Inc., 923 F.3d 1368, 1376 (Fed. Cir. 2019) ("Whether a claim satisfies the written description requirement is a question of fact.").

[19] *Id.* at 1376-77 (footnote and citations omitted).

The written description requirement, in other words, requires an analysis of the patent's (or patent application's) specification to determine whether it alone demonstrates the applicant truly invented what is claimed as the invention. To the extent this analysis focuses on the specification rather than extrinsic evidence, it is perfectly suited for courts to do the analysis. And while it is an analysis done from the perspective of one skilled in the relevant field of art and furthermore may include limited fact finding, neither alone or in combination necessarily justifies treatment of written description as ultimately a matter of fact for a jury. Indeed, the Supreme Court concluded that claim construction (which similarly is done from the perspective of one skilled in the relevant field of art and may include limited fact finding) is ultimately a question of law for the court.[20]

Changing the law to require that courts determine compliance with the written description requirement as a matter of law would allow for early resolution in appropriate cases pursuant to Federal Rules of Civil Procedure 12(b)(6) or 56(a). It would thus address and resolve a legitimate concern with the current law governing Section 112.

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

The proposed changes to Section 112 go well beyond the complaints by representatives of large companies in the high tech space. While the changes seek to address concerns with generic computer language and claims to software algorithms, Section 112 covers every single patent element of every single patent. The changes therefore could cause a sea change with broad, significant ramifications in other areas, including life sciences. In short, depending upon how the changes are interpreted, this proposal might significantly constrain the breadth of all claims, substantially reduce the value of all patents given their narrower scope, greatly increase the costs of drafting all patents by requiring encyclopedic disclosures with respect to every part of every claim regardless of the knowledge of persons of ordinary skill in the art, complicate the analysis of patents given encyclopedic disclosure of already-known technology, and ultimately (as a result) lead to reduced investment in inventive efforts.

The proposed changes to Section 112 (unlike the procedural change discussed above) also are unnecessary. They relate to Section 112(f), but the existing statutory doctrines of Section 112(a), (b), and (f) (written description, enablement, definiteness, and functional claiming) already limit the scope of claims to what was actually invented. I mentioned above that I provided detailed written testimony on point. I will provide a short summary given the importance of the point.

The written description requirement mandates that the specification of a patent clearly allow someone of ordinary skill in the art to recognize that the inventor invented what is claimed.[21] In other words, the specification must convey to one of ordinary skill that the inventor "had possession of the claimed subject matter as of the filing date," where possession refers to

[20] Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996) ("We hold that the construction of a patent, including terms of art within its claim, is exclusively within the province of the court.").

[21] Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc) (reaffirming that the first paragraph of § 112 contains a written description requirement separate from the enablement requirement).

"possession as shown in the disclosure."[22] With respect to "genus" or "generic" claims in particular, compliance with the written description requirement may be made in two ways: possession may be shown through the disclosure of example species of the claimed genus, or through the disclosure of structural features common to members of the genus.[23] Moreover, the law includes a set of objective guidelines for making a determination of whether a claim to a genus meets the written description requirement.[24] These guidelines include identifying 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.[25] Thus, the law governing the written description requirement provides objective inquiries that help make the determination of compliance reasonably ascertainable. And if the named inventor has not shown through her patent application that she invented what is claimed, the claim is invalid. This limits the scope of claims to what was actually invented. Indeed, that is the point.

In turn, the enablement requirement mandates that the specification describe the "manner and process of making and using [the claimed invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same."[26] As applied by the Federal Circuit, the enablement requirement ensures that the specification includes sufficient disclosure to enable one of ordinary skill in the art to practice the claimed invention "without undue experimentation."[27] If there is evidence that some experimentation is needed to practice the claimed invention, the court refers to a set of objective guidelines or "factual considerations" to determine "whether the amount of that experimentation is either 'undue' or sufficiently routine such that an ordinarily skilled artisan would reasonably be expected to carry it out."[28] These factual considerations include

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.[29]

Yet again, the objective nature of these factual considerations allows for reasonable certainty with respect to the outcome of the analysis. Moreover, this analysis again ensures that the scope of claims is limited to what was actually invented. If someone cannot adequately explain how to make and use the claimed invention, there is (at least) a substantial question whether the person has actually invented it.

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[22] *Id.* at 1351.

[23] *Id.* at 1352.

[24] *Id.* at 1351 ("For generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure, including '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.'") (quoting Capon v. Eshhar, 418 F.3d 1349, 1359 (Fed. Cir. 2005)).

[25] *Id.*

[26] 35 U.S.C. § 112(a) (2012).

[27] Alcon Research Ltd. v. Barr Labs., Inc., 745 F.3d 1180, 1188 (Fed. Cir. 2014) (quoting Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1360 (Fed. Cir. 1998)).

[28] *Id.* (quoting In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988)).

[29] *In re Wands*, 858 F.2d at 737 (citing In re Forman, 230 U.S.P.Q. 546, 547 (B.P.A.I. 1986)).

Also consider the definiteness requirement. By ensuring that claims are reasonably certain,[30] the definiteness requirement ensures that a claim is not vague. While it may be true that, standing alone, the definiteness requirement cannot invalidate abstract claims—because the definiteness requirement "asks whether a person having ordinary skill in the art (PHOSITA) could understand the claims, regardless of how abstract or applied they might be"[31]—it does help ensure that claims are clear so that it is possible to determine their scope. Beyond eliminating vagueness (which really is one type of abstractness), therefore, the definiteness requirement serves an important helping function; only when a patent examiner or court can determine the scope of a claim can it determine whether that scope is supported by a disclosure in the specification that meets the written description, enablement, and utility requirements, which are the statutory doctrines that prevent claims from covering mere abstractions rather than what was invented.

Finally, consider the existing limitation on functional claiming expressed in § 112(f).[32] It allows for an element in a claim to be expressed in functional language ("as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof"), but limits the construction of this language "to cover the corresponding structure, material, or acts described in the specification and equivalents thereof."[33] Thus, while one might express a claim in terms of a result, the claim must be interpreted to be limited to the way to achieve the result that is identified in the specification (and its equivalents). Section 112(f) therefore already works to limit claims to specific embodiments or applications rather than abstract ideas—in other words to what is disclosed and equivalents to what is disclosed.

With respect to concern by large companies in the high tech sector in particular, let me highlight that the Federal Circuit has repeatedly used the existing limitation on functional claiming and indefiniteness requirement to invalidate claims to generic software functionality because the specifications of the relevant patents fail to include the required software algorithms. Indeed, it has long been the law that inadequate disclosure of algorithms to support functional language results in violation of the written description, enablement, definiteness, and functional claiming requirements. I provide an example in my written testimony on pages 43-44, *In re Katz Interactive Call Processing Patent Litigation*.[34] In that case the Federal Circuit invalidated several of Katz's claims that included functional language because there was inadequate supporting disclosure in the relevant patents' specifications. The proposed change to Section 112(f) is simply not necessary to limit the scope of claims to what was actually invented.

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, I am concerned that the proposed changes will make it too easy for competitors to design around patent claims. Every element of every claim arguably includes functional language

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[30] Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2124 (2014) ("[W]e hold that a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.").

[31] *See* Mark A. Lemley, Michael Risch, Ted Sichelman & R. Polk Wagner, *Life After* Bilski, 63 STAN. L. REV. 1315, 1331 (2011).

[32] 35 U.S.C. § 112(f) (2012).

[33] *Id*.

[34] In re Katz Interactive Call Processing Patent Litig., 639 F.3d 1303, 1315 (Fed. Cir. 2011).

to some degree, because every element is part of a utility patent, which by definition describes something functional. If courts determine that these elements must now be limited in scope to disclosed structures or methods (and equivalents), the result will be that the claims will not cover alternative structures and methods *even if only ordinary skill and no undue experimentation is needed to identify that alternative*.

Moreover, given that the intent of the person who drafted the elements will no longer be part of the analysis (because the current presumption-approach will be eliminated), one of two possibilities will exist: (1) the person may not have drafted the specification to cover all of the alternatives that mere ordinary skill and no undue experimentation would be needed to identify (particularly if the person did not anticipate Section 112(f) treatment); or (2) the person will have drafted the specification to cover all of the alternatives that mere ordinary skill and no undue experimentation would be needed to identify (if the person anticipated or recognized the risk of Section 112(f) treatment). In the first scenario, the incentive to invent is undermined by a narrow understanding of the inventor's right. In the second scenario, the law has encouraged the person drafting the patent to create an encyclopedic disclosure *of already-known structures and methods even though one of ordinary skill would already know those structures and methods*, which drives up the cost of drafting patents, by definition does not disclose anything new to the public, and will create difficulty for patent examiners and judges as they wade through long disclosures of already-known technology.

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 proposed changes to the *text* of Section 101 would not do away with the doctrine of obvious-type double patenting. Obvious-type double patenting is based upon the phrase "may obtain a patent" in the existing Section 101.[35] The proposed reform would not change this phrase.

That said, without clarification both the additional provision abrogating cases establishing judicial exceptions to Section 101 and the last additional provision distinguishing Section 101 from the approaches under Sections 102 and 103 might inadvertently do away with the doctrine of obviousness-type double patenting. I say "might" because some judges may conclude that obvious-type double patenting is an "exception[] to subject matter eligibility" and/or related to "eligibility

[35] *See* Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr., 764 F.3d 1366, 1372 (Fed. Cir. 2014) ("While often described as a court-created doctrine, obviousness-type double patenting is grounded in the text of the Patent Act.").

of a claimed invention under section 101" as recited in the second and third additional provisions of the proposed legislation. Other judges, however, may conclude that double patenting is not is an "exception[] to subject matter eligibility" and/or related to "eligibility of a claimed invention under section 101"; these judges may conclude that it is its own doctrine separate and apart from subject matter eligibility. I likewise say "inadvertently" because I do not understand the purpose of the proposed reform to abrogate the cases establishing and interpreting the obvious-type double patenting doctrine.

I tend to think double patenting is not a matter of subject matter eligibility but instead its own doctrine, and so no change to the additional provisions is necessary. To the extent the subcommittee disagrees, and in light of the risk of unintended consequences, however, the subcommittee may wish to clarify that the double patenting doctrine is not eliminated.

To my mind the best solution, though, would not involve codifying the obvious-type double patenting doctrine. Codifying the doctrine may inadvertently introduce possible change to the doctrine based on the language inserted into the statute. The best solution would be to clarify the additional provisions. All that needs be done to preserve obvious-type double patenting is to insert another additional provision making this clear. For example, a final additional provision might state: "Notwithstanding the forgoing, the provisions of Section 101 shall still prohibit double-patenting and obviousness-type double patenting."

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 States*, the Supreme Court actually stated that its decision "should not be misconstrued as suggesting that patents are not property for purposes of the Due Process Clause or the Takings Clause."[36] The Court has clearly held that patents are property for purposes of both. The Court long ago—in 1881 and 1885—stated that patents qualify as property for the purpose of the Taking Clause.[37] It more recently—in 1999—expressed the same conclusion with respect to the Due Process Clause.[38]

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[36] Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 138 S. Ct. 1365, 1379 (2018).

[37] James v. Campbell, 104 U.S. 356, 357-58 (1881) ("That the government of the United States when it grants letters-patent for a new invention or discovery in the arts, confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser, we have no doubt."); Hollister v. Benedict & Burnham Mfg. Co., 113 U.S. 59, 67 (1885) ("It was authoritatively declared in *James v. Campbell*, 104 U.S. 356, that the right of the patentee, under letters patent for an invention granted by the United States, was exclusive of the government of the United States as well as of all others, and stood on the footing of all other property, the right to which was secured, as against the government, by the constitutional guaranty which prohibits the taking of private property for public use without compensation.").

[38] Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 642 (1999) ("Patents . . . have long been considered a species of property. As such, they are surely included within the 'property' of which no person may be deprived by a State without due process of law.") (citations omitted) (citing Brown v. Duchesne, 60 U.S. (19 How.) 183, 197 (1856) ("For, by the laws of the United States, the rights of a party under a patent are his private property."); Consolidated Fruit-Jar Co. v. Wright, 94 U.S. 92, 96 (1876) ("A patent for an invention is as much property as a patent for land.")).

In my written testimony on pages 47-48 I briefly highlighted how it would be appropriate to apply Section 101 retroactively without the "field of technology" restriction on eligibility. In short, given that the amendments to Sections 100 and 101—at least to the extent they would define useful as "specific and practical" utility—would codify the longstanding understanding of the law as it existed prior to *Mayo* and *Alice*, serious thought should be given to making the amendment retroactive at least to patent applications already filed and issued patents still in force. This approach would likely comport with governing law. Here I will explain in more detail why.

Consider first the Due Process Clause, which "protects the interests in fair notice and repose that may be compromised by retroactive legislation."[39] The Supreme Court has explained that, "[p]rovided that the retroactive application of a statute is supported by a legitimate legislative purpose furthered by rational means, judgments about the wisdom of such legislation remain within the exclusive province of the legislative and executive branches.[40] Applied here, codifying the longstanding understanding of the law as it existed prior to *Mayo* and *Alice* (and, for many inventors, ensuring they retain the patent rights they anticipated when they filed their patent applications) to reward and encourage investment in inventive efforts would likely satisfy this test.[41]

Consider next the Takings Clause, which "prevents the Legislature (and other government actors) from depriving private persons of vested property rights except for a 'public use' and upon payment of 'just compensation.'"[42] Here, codifying the longstanding understanding of the law as it existed prior to *Mayo* and *Alice* would not deprive the patent owners of their patent rights. And the Supreme Court has repeatedly indicated it finds "no constitutional barrier to the legislative expansion of existing patents."[43]

In terms of *how* to undo the Supreme Court's recent change in its interpretation of Section 101 and make that change retroactive, the Supreme Court has explained:

> Congress, of course, has the power to amend a statute that it believes we have misconstrued. It may even, within broad constitutional bounds, make such a change retroactive and thereby undo what it perceives to be the undesirable past consequences of a misinterpretation of its work product. No such change, however, has the force of law unless it is implemented through legislation. Even when Congress intends to supersede a rule of law embodied in one of our decisions with

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[39] Landgraf v. USI Film Prod., 511 U.S. 244, 266 (1994).

[40] Pension Ben. Guar. Corp. v. R.A. Gray & Co., 467 U.S. 717, 729 (1984).

[41] *See, e.g.*, Gen. Motors Corp. v. Romein, 503 U.S. 181, 191 (1992) ("The statute in this case meets th[e] standard [for alleged violations of due process based on retroactivity]. The purpose of the 1987 statute was to correct the unexpected results of the Michigan Supreme Court's *Chambers* opinion. The retroactive repayment provision of the 1987 statute was a rational means of meeting this legitimate objective: It preserved the delicate legislative compromise that had been struck by the 1980 and 1981 laws . . . .").

[42] *Landgraf*, 511 U.S. at 266.

[43] Eldred v. Ashcroft, 537 U.S. 186, 202 (2003) (citing McClurg v. Kingsland, 42 U.S. (1 How.) 202 (1843) (stating that "the powers of Congress to legislate upon the subject of patents is plenary by the terms of the Constitution, and as there are no restraints on its exercise, there can be no limitation of their right to modify them at their pleasure, so that they do not take away the rights of property in existing patents")).

> what it views as a better rule established in earlier decisions, its intent to reach conduct preceding the "corrective" amendment must clearly appear.[44]

Thus, all that is needed is for any retroactive application of a so-called restorative statute is for retroactive application to be clear and stated in the legislation itself (not just the legislative history).

With that said, applying the "field of technology" limitation retroactively *would* arguably result in a taking of private property.

The argument that applying the "field of technology" limitation retroactively would result in a taking is that, even if it is a rational exercise of the legislature and therefore comports with due process, "that inquiry is quite separate from the question whether the enactment takes property within the prohibition of the Fifth Amendment."[45] Moreover, the "takings analysis is not necessarily limited to outright acquisitions by the government for itself."[46] Rather, "legislation might be unconstitutional if it imposes severe retroactive liability on a limited class of parties that could not have anticipated the liability, and the extent of that liability is substantially disproportionate to the parties' experience."[47] The Supreme Court has "identified several factors . . . that have particular significance" in this analysis: "[T]he economic impact of the regulation, its interference with reasonable investment backed expectations, and the character of the governmental action."[48]

Here, to the extent the "field of technology" limitation is applied retroactively and eliminates patent eligibility for business methods, there is a substantial risk that courts will find takings to have occurred under the Fifth Amendment. That is because the U.S. Patent and Trademark Office issued the patents and later the Supreme Court in *Bilski* rejected the categorical exclusion of business method patents as ineligible subject matter.[49] Thus, the categorical elimination of business method patents would represent "[t]he total destruction by the Government of all value of these" patents.[50] It would impose severe retroactive liability (the elimination of patent rights) on a limited class of parties (owners of business method patents) that could not have anticipated the liability (given that the U.S. Patent and Trademark Office issued the patents under laws that did not make business method patents ineligible, as later recognized by the Supreme Court). The extent of the liability (the elimination of patent rights) would be substantially disproportionate to the parties' experience (again given that the U.S. Patent and Trademark Office

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[44] Rivers v. Roadway Exp., Inc., 511 U.S. 298, 313 (1994).

[45] United States v. Sec. Indus. Bank, 459 U.S. 70, 75 (1982).

[46] *Id*. at 78.

[47] E. Enterprises v. Apfel, 524 U.S. 498, 528-29 (1998).

[48] *Id*. at 523-24 (citations omitted).

[49] Bilski v. Kappos, 561 U.S. 593, 602 (2010).

[50] *See* Armstrong v. United States, 364 U.S. 40, 48-49 (1960) ("The total destruction by the Government of all value of these liens, which constitute compensable property, has every possible element of a Fifth Amendment 'taking' and is not a mere 'consequential incidence' of a valid regulatory measure. Before the liens were destroyed, the lienholders admittedly had compensable property. Immediately afterwards, they had none. This was not because their property vanished into thin air. It was because the Government for its own advantage destroyed the value of the liens, something that the Government could do because its property was not subject to suit, but which no private purchaser could have done. Since this acquisition was for a public use, however accomplished, whether with an intent and purpose of extinguishing the liens or not, the Government's action did destroy them and in the circumstances of this case did thereby take the property value of those liens within the meaning of the Fifth Amendment.").

issued the patents under laws that did not make business method patents ineligible, as later recognized by the Supreme Court). The economic impact would be the total deprivation of an asset. The invalidation of patents would interfere with reasonable expectations of inventors and their investors. And the change in law would permanently appropriate these inventors' properties.

Given this analysis, if the "field of technology" limitation is used in the definition of "useful," then Congress probably should not make that aspect of the definition retroactive.