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Joshua D. Sarnoff Answers to Questions for the Record of Senator Richard Blumenthal, Submitted to Senate Judiciary Committee Chairman, Hon. Lindsay O. Graham
June 4, 2019 Subcommittee on Intellectual Property Hearing on
"The State of Patent Eligibility in America: Part I"
June 26, 2019

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?**

To answer this question definitively would require not only predicting an uncertain future, but also resolving debates that have been unresolved in the legal and economic patent literature for a long time. For example, in 1958, the Senate Judiciary Committee issued a report by the foremost economist of the patent system, Fritz Machlup. *An Economic Review of the Patent System,* Study of the Subcommittee on Patents, Trademarks, and Copyrights, Study No. 15, 85th Cong., 2d Sess. (Committee Print 1958). In that study, at page 80, Machlup famously concluded that:

> If one does not know whether a system "as a whole" (in contrast to certain features of it) is good or bad, the safest "policy conclusion" is to "muddle through"—either with it, if one has long lived with it, or without it, if one has lived without it. If we did not have a patent system., it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it.

In a more recent study, Michelle Boldrin & David K. Levine extended this reasoning in light of decades more evidence of the operation of the patent system in the U.S. *The Case Against Patents,* Research Division, Federal Reserve Bank of St. Louis, Working Paper 2012-035A (Sept. 2012). As they stated at pages 19-20, referencing this statement by Machlup:

> One might imagine that if it would be irresponsible to recommend abolishing it, it would be even more irresponsible to further extend it. Moreover, one might hope that if it is indeed worth preserving such a large government intrusion into private activity that that during the intervening six decades evidence would emerge that patents do indeed serve the desired purpose of encouraging innovation. Sadly the story of the past six decades is the opposite. In new industries such as biotechnology and software where innovation was thriving in the absence of patents – patents have been introduced. Given this continued extension has there been a substantial increase in innovation in recent years? On the cont[r]ary, it is apparent that the recent explosion of patents in the U.S., the E.U. and Japan, has not brought about anything comparable in terms of useful innovations and aggregate productivity.

In my submitted testimony, I referenced some recent empirical evidence that *constricting* eligible subject matter (as a result of the Supreme Court's interpretations of Section 101) *increased* innovation (measured by research and development) in various industries. *See* Sridhar Srinivasan, *Do Weaker Patents Induce Greater Research Investments* (Dec. 22, 2018), https://ssrn.com/abstract=3185148 (providing causal evidence "that innovation, measured by R&D, responds *positively* to *weakened* patent protection," following the decision in *Alice Corp. v. CLS Bank, Int'l,* 573 U.S. 208 (2014)) (emphasis added). *See generally* Mark Schankerman, *How Valuable Is Patent Protection? Estimates by Technological Field,* 29 RAND J. ECON. 77 (1998). Wesley M. Cohen et al, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not),* NBER Working Paper 7552. It is not clear, however, that these analyses would accurately predict in reverse the effects that would result on particular, current industries from expanding eligibility. Nevertheless, this best, most current, and most relevant evidence does suggests that broadening subject matter to permit eligibility of claims of inventions (that were excluded from eligibility by the Supreme Court's post-*Diamond v. Diehr* precedents beginning with *Bilski v. Kappos,* and the subsequent interpretations of those precedents by the Federal Circuit) would cause overall ***disinvestment in and retard innovation of many (if not most) industries.***

As I also explained in my written testimony, utilitarian concerns regarding investment, invention, innovation, and research and product development are far from the only concerns with patent subject matter eligibility. And, for the reasons I discussed in my written testimony, extending protection to currently ineligible discoveries of science, nature, and ideas, or even to uncreative but practical applications of such ineligible discoveries, would be bad utilitarian innovation policy, bad moral and religious policy, contrary to human rights, and otherwise a bad idea (without specific regard to the effects on industry). And, as your next question asks, such extensions of patent eligibility would adversely affect consumers.

Further, as has been understood by economists for decades, it is largely a matter of faith rather than evidence whether the "static" consumer welfare losses resulting from patents are outweighed by any "dynamic" gains to innovation that patents may provide. Thus, it is entirely unclear whether patents in fact result in greater innovation in industries or in increased consumer welfare from technological developments that (by hypothesis) such patents induced to occur more rapidly than would have occurred in the absence of such patents. *See generally* Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law,* 5 J. ECON. PERSP. 29 (1991). But it is also important to note that the comparisons are not "patents or nothing" as incentives for innovation, as numerous alternatives exist to granting patent rights when funding and incentivizing innovation. *See generally, e.g.,* Joshua D. Sarnoff, *Government Choices in Innovation Funding (with Reference to Climate Change),* 62 EMORY L.J. 1087 (2013). Unfortunately, decisions on the "best" methods of funding innovation and promoting industries tend to rely more on political views and various dysfunctions rather than on actual empirical analyses of likely comparative benefits of different approaches (and even then, such comparative institutional analyses are often unable to be performed due to data limitations and predictive uncertainties). *See generally, e.g.,* Joshua D. Sarnoff, *The Likely Mismatch Between Federal R&D Funding and Desired Innovation,* 18 VAND. J. OF ENT. & TECH. L. 363 (2016).

In summary, it is unclear and entirely speculative that restoring broader subject matter eligibility will positively affect any or many industries, but rather doing so is likely to (further) harm some or many industries. Anyone who tells you otherwise is simply not telling the truth about the nature of the limits of economic understanding of the patent system and what the current evidence (such as it is) tells us.

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

As with the effects on industry, ***the effects on consumers in the long run are highly uncertain,*** given the inability to predict how patents affect dynamic innovation and how industries within markets will choose to license, compete, and price products and services (subject to different government regulatory, antitrust, and other policies). Nevertheless, we know that patents in general impose so-called "deadweight" losses on society by increasing costs and decreasing access to patented goods relative to the competitive alternatives that might be available in markets in the absence of such patents. Thus, ***we can be reasonably sure that patents will adversely affect consumers in the short run, and cannot have any confidence that patents will increase consumer welfare in the long run.***

As I indicated in my written testimony, granting patent rights by extending patent eligibility imposes numerous harms in many fields of "technology" (or for products or processes that cannot be considered technological inventions) to which the patent system will be extended. But knowing that these harms may occur is different from accurately predicting their specific nature and magnitude. The opportunity costs of such eligibility extensions are likely immense. But the specific harms and their magnitude also are essentially unknowable. To evaluate such costs would require predicting and valuing outcomes that would not otherwise occur and thus could be assessed only in a counter-factual universe.

Further, the belief that the patent system may increase consumer welfare in the long run through dynamic innovation gains that would not occur in the absence of patents may simply be a widely believed myth (as well as being untrue). It is *at least* equally possible that patents may both increase static costs while limiting access to technologies *and* reduce dynamic innovation and consequent social welfare that would result in the absence of patents. *See, e.g.,* James Bessen & Eric Maskin, *Sequential Innovation, Patents, and Imitation,* 40 RAND J. ECON. 611, 611 (2009) ("[W]hen innovation is 'sequential' … and 'complementary'… patent protection is not as useful for encouraging innovation…. Indeed, society and even inventors … may be better off without such protection… [and] an inventor's prospective profit may actually be enhanced by competition and imitation … [This] appears to explain evidence from a natural experiment in the software industry.").

Again, predicting whether and when patents would decrease or increase consumer welfare depends on their effects on innovation in particular industries, as well as the licensing, competition, and pricing policies of the patent holders in those industries. This simply is

unknowable in advance, particularly as it is always possible for the government to regulate prices (as it does with many regulated industries) or to impose mandatory terms on licensing requirements and provision of access (as it often does through antitrust policy). ***Thus, it is important not to address patent policy without simultaneously considering market regulatory policies (including Supremacy Clause "purposes and objectives conflicts" preemption of contractual provisions that would effectively override such regulatory policies).*** *See, e.g., Hines v. Davidowitz,* 312 U.S. 52 (1941) (preempting state laws that stand as an "obstacle to accomplishment" of federal legislative goals).

In summary, determining the social welfare harms or benefits for particular sets of consumers who would rely on the innovations developed by particular industries and their patent holders as a result of expanding the patent system is highly speculative. Deciding whether to extend the patent system on this basis would place reliance on decision-making criteria that are neither economically sound nor evidence-based. In contrast, ***it may be entirely appropriate not to expand patent eligibility (and to further restrict eligibility) based on entirely different decision-making criteria.*** For example, many economists and others believe that the costs of health care innovation and access do not warrant granting patents at all, much less making the public pay both to subsidize research and development and to pay the costs of patent rights in inventions developed with such subsidies. Rather, they suggest that other means of funding medical innovations should be developed. *See, e.g., Time to Fix Patents: Ideas fuel the economy. Today's patent systems are a rotten way of rewarding them,* The Economist (Aug. 8, 2015), at https://www.economist.com/leaders/2015/08/08/time-to-fix-patents; Joseph E. Stiglitz & Arjun Jayadev, *Medicine for tomorrow: Some alternative proposals to promote socially beneficial research and development in pharmaceuticals,* 7 J. GENERIC MED. 217 (May 25, 2010); Joseph E. Stiglitz, *Prizes not Patents,* 42 POST-AUTISTIC ECONOMICS REVIEW 48 (May 18, 2007).

The main point is simply that ***you should reject any argument suggesting that expanding the patent system will lead to increased investment, increased innovation, and increased consumer welfare. Ask for the evidence – and you will find it lacking as a matter of proof.*** But then you must decide based on your own what decisional criteria to apply to make legislative decisions in the absence of accurate predictions of outcomes, inadequate empirical evidence, and insufficient economic theory.

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

As indicated above, ***the proposed reforms could and likely will increase prices simply by the fact that patents provide rights to exclude competition that would otherwise occur and that might then lead to decreased prices and increased access to the same or similar products.*** But predicting whether they would increase prices significantly in particular industries, or for which particular products, would require speculation for which concrete evidence and theory are lacking.

More importantly, the specific amount of price increases for particular industries or products will depend on numerous factors, including: (1) the scope of claims granted in particular patents; (2) the degree to which competitors develop substitute technologies that can be produced for the public that do not infringe patent rights, and complementary technologies that must be cross-licensed in order to produce products for the public; and (3) regulatory and antitrust policies. A vigorous debate currently exists, *e.g.,* as to whether on the one hand "fair, reasonable, and non-discriminatory" (FRAND) licensing policies adopted by standard-setting organizations (SSOs) are sufficient to assure that patent rights do not result in excessive prices for consumers and that patents can be efficiently cross-licensed to produce complex consumer products, and on the other hand whether such requirements sufficiently protect SSO-participating patent holders against holdouts by non-participating patent holders and against infringers (in the absence of injunctive relief). *See generally, e.g.,* THE CAMBRIDGE HANDBOOK OF TECHNICAL STANDARDIZATION LAW: COMPETITION, ANTITRUST, AND PATENTS (Jorge L. Contreras ed. 2017).

But whatever the current state of affairs ***in regard to the degree of price increases that might result from granting additional patent rights, it bears noting that Congress can always alter those consequences, if it can muster the political will to do so.*** For only one example, consider that most countries impose price controls on medical innovations through national health-care systems. Further, Congress can always impose conditions on how patents are licensed, whether those patents are developed through private funding or through government contract funds or other grants or subsidies under the Bayh-Dole Act, 35 U.S.C. §§ 201 et seq. The fact that the U.S. Government to date has chosen not to exercise "march-in" rights or its statutory royalty-free license to produce goods for public benefit at lower costs than supplied by patent holders so as to expand access simply reflects continued (although not necessarily rational) beliefs in the patent system and the markets for such products. *See, e.g.,* Jennifer Penman & Fran Quigley, *Better Late than Never: How the U.S. Government Can and Should Use Bayh-Dole March-In Rights to Respond to the Medicines Access Crisis,* 54 WILLAMETTE L. REV. 171 (2017). *See generally, e.g.,* John R. Thomas, *March-In Rights under the Bayh-Dole Act,* Congressional Research Service Report R44597 (Aug. 22, 2016).

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Joshua D. Sarnoff Answers to Questions for the Record of Senator Mazie K. Hirono, Submitted to Senate Judiciary Committee Chairman, Hon. Lindsay O. Graham June 4, 2019 Subcommittee on Intellectual Property Hearing on "The State of Patent Eligibility in America: Part I" June 26, 2019

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?

As I stated in my oral testimony, one needs to determine what the problem is that one is trying to solve in order to properly solve it. ***To the extent that the Supreme Court has continued to construe Section 101 of the Patent Act to exclude from patent eligibility*** (a) ***novel (or old) discoveries of science, nature, and abstract ideas as such*** and (b) claimed inventions that embody only ***uncreative practical applications*** of such categorically ineligible discoveries, ***there is no problem that needs to be addressed.*** Consequently, there is no need for Congress or the courts to revise ***that*** approach. Rather, changing that approach would lead to the kinds of utilitarian and deontological moral social and innovation harms that I described in my written testimony.[1]

[1] Although the Supreme Court's recent precedents arise under the 1952 Patent Act, as indicated in my written testimony Section 101's scope was not materially changed by legislative language since the 1793 Patent Act (but has been subject to inconsistent interpretation over this period and since). In contrast, although the Leahy-Smith America Invents Act of 2011 was not generally intended to alter Section 101's scope of application: (a) it explicitly did so by enacting uncodified provision Section 33 ("no patent may issue on a claim directed to or encompassing a human organism"); and (b) implicitly affected patent eligibility by enacting uncodified Section 14 ("any [tax liability] strategy … shall be deemed insufficient to differentiate a claimed invention from the prior art"), thereby effectively precluding patents on claimed inventions that are based solely on the tax liability creativity embodied as a claimed invention. (Note that all patents are "directed to" a "human organism" in the sense of being intended for use by persons, so this language could be understood to prohibit all patents unless a more specialized meaning is interpreted for the term "directed to." Similarly, the term "encompassing" is ambiguous in regard to how to distinguish a "human organism" from hybrid organisms such as might be created by prosthetics, partial transplants, etc., and may be likely in the future to engender significant uncertainty of interpretation and application. The prohibition, moreover, was likely wholly unnecessary, *see, e.g.,* Yaniv Heled, *On Patenting Human Organisms or How the Abortion Wars Feed Into the Ownership Fallacy,* 36 CARDOZO L. REV. 241, 277-80 (2014) (discussing 13th Amendment, Section 102 lack of novelty, and product of nature eligibility prohibitions on owning human organisms, and also failed to address treating such discovered natural products or phenomena as prior art against patent applicants.)) Further, the AIA added a definition of claimed invention to Section 100(j), without altering Section 100(b)'s definition of process and without changing any of the language of Section 101. Accordingly, my comments assume that Congress has not significantly altered eligibility law since the 1793 Act, leaving such law to the courts to interpret, and that the courts have done so inconsistently over the course of about two centuries.

In contrast, as I indicated in my oral and written testimony, ***if the problem is the inconsistency of judicial precedents and consequent uncertainty of application of the legal doctrine, then legislative action likely is needed.*** The first and best legislative step would be to codify and clarify the law clearly as just stated above, so that the courts, the U.S. Patent and Trademark Office (PTO), and the public can understand that law fully and can apply it correctly, without having to resort to authoritative adjudication.[2] In interpreting Section 101 to date, the courts have failed to be clear about what goals eligibility law is supposed to achieve, have vacillated in what the standards are for distinguishing eligible from ineligible subject matter, and thus have generated both uncertainty and inconsistency when determining in adjudications applying those legal standards what cannot and should not be patented (as either a constitutional or a legislative matter, respectively). Further, the courts have also applied inconsistent reasoning (even in the same opinion), and have failed to follow their own precedents without acknowledging that their decisions are in conflict or fail to make sufficient analogical distinctions to warrant different outcomes.

As I stated in both my oral and my written testimony, Congress can likely do a lot to improve judicial and administrative interpretations ***by providing significantly greater clarity and specificity of legislative language itself (and not just as legislative history)*** for ***whatever*** legislative goal Congress chooses to adopt. However, as I also noted, if Congress ***expands*** eligibility (particularly by eliminating exclusions for novel discoveries of science, nature, and abstract ideas as such), it may trigger constitutional challenges that may also create significant uncertainty.

Much of the problem of uncertainty can and should be addressed by the courts themselves, by improving their own reasoning processes and by following their own precedents and rules. E.g., as I stated in both my oral and written testimony**,** the Federal Circuit has, by en-banc precedent, required that earlier-in-time panel precedents control in the event of a conflict, absent en-banc reversal of the earlier precedent. But many recent Federal Circuit eligibility decisions fail even to cite – much less seek to analogically distinguish – earlier precedents that conflict with the decisions being made and the more recent precedents on which those decisions rely. Similarly, as I indicated, the PTO in its recent guidance for examiners failed to follow the actual holdings

[2] I agree with the general consensus in the testimony received by the Subcommittee that the courts and the PTO are issuing numerous, inconsistent precedents, following the *Bilski* decision. In contrast, the fact that numerous motions to dismiss based on lack of subject matter eligibility may have been granted in patent infringement suits says nothing particularly informative (except that, assuming those cases were corrected decided, the PTO has issued numerous patents that it should not; if not correctly decided, then there is a different problem entirely). Because of selection effects, one would expect motions to dismiss (and summary judgment motions) to be filed either when they are reasonably likely to be successful or when the costs, combined with the relatively lower probability of success, warrant doing so as a cost-benefit strategy to reduce litigation expenses or overall exposure. Anecdotally, I have been informed by some patent litigation counsel that their clients are increasingly unwilling to pay the costs for such uncertain-to-be-successful legal motions. So, to infer that there are "too many" granted motions to dismiss, one would have to disaggregate not only the relative costs and likelihood of success of such motions relative to potential liability, but also the relative willingness of clients to pay for those costs. Such information is not available. Anecdotally, moreover, I have also been informed that such counsel think ***too few*** motions to dismiss on eligibility grounds are being filed, particularly after the *Berkheimer* decision decreased the likelihood that such motions would be granted, based on potential factual and claim construction disputes (especially at Step Two of the *Mayo-Alice* analysis).

and reasoning of Supreme Court precedents, as well as of many earlier (and thus binding over later-in-time, conflicting) Federal Circuit panel precedents.

But such improvements in judicial and administrative reasoning are unlikely to occur on their own, and the Supreme Court since the *Alice* case has not granted certiorari to overturn Federal Circuit precedents that appear to be inconsistent with the Supreme Court precedents since *Bilski.* Nevertheless, there is hope that the Supreme Court could accept for decision the pending *Hikma v. Vanda* case, and in issuing a decision could clarify its own approach to interpretation of Section 101 in a way that would provide greater clarity and certainty for subsequent application of the law.

The most important clarifications that either the Supreme Court or Congress could make to existing eligibility law would be to: (1) expressly state that eligibility requires the underlying creativity of a claimed invention that is embodied as a product or process and that *practically* applies a novel but ineligible discovery of science, nature or an abstract idea to be a "*creative* [or inventive] *application*" of that ineligible discovery (even if the discovery was first made by the patent applicant); (2) to clearly establish as part of the legal test for assessing eligibility of any claim (construed as a whole) that such an ineligible discovery is to be treated as prior art (even against an applicant who first makes such an ineligible discovery and first discloses it in the patent application itself); (3) to make clear that "preemption" of all or most practical applications of such an ineligible discovery by the claimed invention has nothing at all to do with the test of eligibility, that specificity of the claimed practical application does not make it eligible, and that all such issues of claim scope are to be addressed by Section 112 considerations; and (4) to expressly abrogate the courts' inconsistent precedents, such as *Diamond v. Diehr* and *LeRoy v. Tatham,* expressly acknowledging that those precedents have always been inconsistent with *Funk Brothers Seed Co. v. Kalo Inoculant Co.,* and *Parker v. Flook,* and are inconsistent with the more recent Supreme Court decisions since *Bilski.* This would go a very long way to clear things up, leaving to the courts the role of fleshing out further the requisite amount of the necessary *kind* of creativity that is required for a claimed practical application to be considered a creative application and thus a utility patent eligible invention.

Of course, Congress could seek to provide even more guidance for judicial "common-law-like" interpretive reasoning and analogical application decisions in adjudications of patent eligibility. For example, Congress could adopt more specific legislative language regarding the *amounts* of required *kinds* of creativity that constitute a "creative application" of an otherwise-ineligible discovery, and thus that warrant granting utility patent rights. For example, Congress could specify general time, effort, and monetary investment thresholds for the mental and experimental efforts that justify a utility patent, as detailed in the amicus brief that I filed in regard to similar questions under Section 103's non-obviousness standard. *See Brief of Economists and Legal Historians as Amici Curiae in Support of Petitioner,* KSR International Co. v. Teleflex, Inc., 550 U.S. 398 (2007). Similarly, Congress could specify more clearly the *kinds* of mental or experimental creativity that (when embodied as a practical application) should qualify a claimed invention for utility patent rights. For example, Congress could expressly and categorially exclude from eligibility considerations embodied mental or experimental discoveries that reflect aesthetic creativity, medical practice creativity, and many other forms of creativity, in addition to the already-excluded categories of scientific, natural, and abstract idea discoveries. This greater

specificity would result in better judicial reasoning and analogical applications of the law to the facts (and, as discussed in regard to the next question, focus on a more appropriate inquiry than whether the claimed invention that physically and practically embodies such creativity is "technological").

As I also indicated in my oral and written testimony, in addition to clarifying the law by adopting more specific legislative language (along the lines above), Congress could expressly abrogate all prior (and thus inconsistent) precedents, could provide for mandatory judicial jurisdiction to resolve conflicts of precedents that may develop in applying existing or any new legal standards for eligibility, and could adopt other measures to improve the quality of judging and of judges. Similar improvements of interpretation and adjudication could be adopted for patent administration, including by providing all persons with the power to trigger *pre-grant oppositions* to challenge patent grants that are inconsistent with judicial or other precedents, and by extending statutory standing to the full extent permitted by Article III of the Constitution for all persons to appeal post-grant challenges under existing mechanisms. Further, to the extent that Congress thinks that the Patent Office would do a better job than the courts in further specifying legislative eligibility and patentability requirements, Congress could grant the PTO explicit substantive rulemaking authority, subject to judicial review for conformity to the Patent Act.

Note that these measures go far beyond the relatively simple and comparatively expedient approach of clarifying or changing the legal standard for eligibility. But such measures are needed to address the problem of inconsistent judicial and administrative interpretation and application of the law, whether or not Congress chooses to revise the language of Section 101. Changing the law without addressing the "root cause" of the uncertainty may minimize the problem, but will not eliminate it. It particularly will not eliminate the problem of uncertainty if judicial and administrative interpreters dislike the legislative policy, and thus will find ways to (intentionally or unintentionally) misinterpret the law and to (inadequately) distinguish its intended application when interpreting and applying the law to concrete facts in adjudication.

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"?**

As I stated in my oral and written testimony, defining "technology" or "field of technology" is an exceptionally complex undertaking. There are differing historical meanings for "technology" and no agreed-upon international meanings for the terms "technology" and "field of technology." Defining "technology," "field of technology" or "technological arts" will likely prove much more difficult than trying to determine the proper type of creativity embodied in claimed inventions that should warrant consideration for utility patent eligibility. Of greater importance, the question posed focuses on the wrong concern. The principal concern for eligibility should not be the ***type of product or process*** claimed, nor ***the uses to which a claimed invention can be put***, but rather the proper ***kind*** (and amount) **of *creativity*** that went into claiming a "technological"

product or process, in any "technological" field for which utility patent rights are thought to be justified.

It is exceptionally easy (as a matter of utility patent claim drafting) to fit a claim of invention (based on almost any kind of creativity) into one of the four statutory categories of Section 101: "machine, "manufacture," "composition of matter," or "process." In my written testimony, I provided two examples: (1) aesthetic creativity – or the aesthetically functional creativity of making the wearer appear slimmer – that is claimed as a cheerleading uniform invention (a statutory "manufacture"); and (2) sports creativity – a method of using a golf-putter. But the same is true for ***all*** of the disputed categories of eligible subject matter that should be of concern. Thus, one can readily claim what ***should be*** ineligible "inventions" (based on the nature of the creativity being embodied) as "technologies," by writing claims to, e.g.: (a) diagnostic methods or products for use in such methods, that are derived from natural discoveries of biological processes or products and are claimed as human-created processes or as human-created machines, manufactures, or even compositions of matter; (b) methods of medical treatment that simply add a step of adjusting doses of administered medications, based on newly discovered biological correlations ("laws of nature"); (c) methods of performing business (where the creativity is in simply transferring old – or even new – practices to a modern computation environment, and thus the "inventions" are claimed as processes performed on general or on specifically programmed computers or other devices; (d) software designed to achieve useful results through novel computations with data, which can be claimed as a system, a manufacture (such as a program encoded in a tangible medium of expression), or a process of performing steps on general purpose or specifically programmed computers; etc.

Normally, the question for eligibility should not be "is this claimed practical application (embodying some form of creativity) a technology?" Almost anything involving tool-based extensions of human capabilities or the human body – and possibly even non-tool-based means of using the human body through mental control, as in yoga techniques or in sports moves like the Fosbury flop high jump – could be considered a "technology." *See, e.g.,* Dictionary.com, *Technology,* https://www.dictionary.com/browse/technology ("the branch of knowledge that deals with the creation and use of technical means and their interrelation with life, society, and the environment, drawing upon such subjects as industrial arts, engineering, applied science, and pure science[;] the application of this knowledge for practical ends[;] the terminology of an art, science, etc.; technical nomenclature[;] a scientific or industrial process, invention, method, or the like[;] the sum of the ways in which social groups provide themselves with the material objects of their civilization"); American Sociological Association, *Technology,* https://www.asanet.org/topics/technology ("Technology involves the use of techniques, processes, and material objects to produce goods, provide services, and connect people."). Rather, the question should be whether we should grant a *utility* patent to the *kind* of creativity that went into claiming a practical process or product that we recognize as "technological."

Not "'everything under the sun made by man'" is or should be utility patent eligible. In *Diamond v. Chakrabarty*, 443 U.S. 303 (1980), the Supreme Court recited the quoted language from one statement in the 1952 Senate Committee Report. *Id.* at 308-09 (quoting S. Rep. No. 82-1979, at 5 (1952)). But that statement was not true then, and has not been true anywhere in the world at any time in history. It also is not the law now. For example, the claimed but

ineligible processes in *Alice* used generic computers and were no doubt "technological" in the sense of being made by man and requiring human intervention to exist, as computers do not exist by themselves. *See, e.g., Alice Corp. Pty. Ltd. v. CLS Bank, Intern.,* 573 U.S. 208, 223 (2014) ("These cases [including *Diamond v. Diehr*] demonstrate that the mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention").[3] This should help to demonstrate why the focus on the technological character (or not) of the embodied claimed applications is a misguided inquiry, and why the focus should be on the kind of creativity that is embodied by those applications.

Given the expansive definition of "technology," expanding patent eligibility doctrine to permit *all* processes and products that constitute embodied "technology" to be eligible for utility patent rights is likely again to draw the patent system into disrepute. It is particularly likely to do so without further defining what fields of human activity and endeavor and what kinds of tools and methods should *not* be considered "fields of technology" or "technologies," respectively. Doing so also will subject virtually every sort of human activity to utility patent rights, even though those rights are not needed to incentivize research, development, and innovation in many fields as I discussed in my written testimony. Further, even if the correct *categories of human activity and types of tools and methods* (as opposed to the kinds of creativity) ***could be*** delineated in legislative language, line drawing issues will invariably arise at the boundaries of these new legislative categories. (This is particularly likely given artful claim drafting by patent lawyers.) And it will cause serious harms to innovation and to society (such as by prohibiting second medical opinions) without creating corresponding "experimental use" and "fair use" exceptions to such rights.[4] Thus, any such expansions to patent eligibility based on defining "technology" should at a minimum not only include categorical exceptions to eligibility, but also should aopt simultaneously experimental and fair use exceptions to such patent rights.

Moreover, if Congress seeks to expand eligibility ***without*** defining categorical exceptions to "fields of technology" or "technological" tools, the revised legislation will pose more strongly the important constitutional question of whether every "technology" so defined is within the scope of the "useful Arts" language of Article I, Section 8, clause 8. As noted in my written

[3] As indicated in my written testimony, many countries choose to address the issue of what kinds of fields of human endeavor warrant utility patent rights and to exclude some kinds of "inventions" from their patent systems under the doctrine of "industrial application," rather than by trying to define "field of technology." Further, as indicated in the decision of a dispute panel of the World Trade Organization (WTO) in *Canada--Patent Protection of Pharmaceutical Products*, improper "discrimination" by "field of technology" in regard to patent granting and rights criteria is not the same as (and thus the TRIPS Agreement Article 27.1 does not preclude) normatively justified "differentiation" of different kinds of subject matter. *See* WT/DS114/R, ¶ 7.94 (Mar. 17, 2000) (adopted Apr. 7, 2000), available at http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf. Accordingly, one can *differentiate* eligibility by field of technology, and in any event one must first define what is and is not "technology" and a "field of technology" before Article 27.1's prohibition on discrimination becomes relevant. Because these terms are not defined, and have different interpretations around the world, there should be no concern posed in regard to the current eligibility issues with regard to lack of harmonization or to WTO treaty compliance.

[4] Although I have employed the term "exception," the statutory language should make clear that such experimental or fair uses are not, in the first instance, conduct that is prohibited by patent rights. Accordingly, they are not "exceptions" to infringement that courts should construe narrowly, nor require pleading as an affirmative defense in litigation. Rather, the patent holder must plead and prove that the alleged infringer has engaged in a form of prohibited conduct using the patented invention in the first instance.

testimony, that language may restrict utility patents to the kinds of "Discoveries of … Inventors" that were historically understood to be embodied technologies within the "useful Arts" and subject to utility patent grants, and not based on other forms of human activity such as the fine Arts, the liberal Arts, etc. Although only four Justices in *Bilski* would have interpreted the current *statute t*o preclude at least business methods from the scope of the patent system, the Court as a whole did not directly address the constitutional question. Sorting out in the courts whether "useful Arts" imposes a significant constitutional limit that excludes utility patents from fields such as business methods or cooking recipes (even though some patents were granted in those fields in the early 19th century[5]) will take a long time, but the litigation will surely ensue. Further, additional constitutional restrictions exist. But even without constitutional limits, Congress must decide – likely in the absence of social consensus and adequate empirical assessments, as discussed in my response to questions posed by Senator Blumenthal – whether granting such patents is good utilitarian social welfare or deontological moral policy.

As I also indicated in my written testimony, there is no simple way to define "technical" or "technological." Europe (and some other jurisdictions) focus on the "technical effect" of the various creative inputs that are embodied by the claimed invention. But they do not permit the creativity of ineligible subject matter "as such" to be considered to contribute to the technical effect for analysis of the nature and degree of any inventive step embodied by the claimed invention. Again, in those jurisdictions, the proper analysis is focused on the nature of the ***creativity contributing to the claimed invention***, and not to the ***kind of practical application*** to which the claimed invention may be put.[6] In contrast, current U.S. eligibility law has the benefit of treating categorically ineligible subject matter (at least for the categories of discoveries of science, nature, and ideas) ***as prior art*** against the applicant, which prevents uncreative but "technological" practical applications of such discoveries from being considered eligible inventions.

In summary, the whole premise of trying to displace the required line drawing of what kinds of "inventions" should potentially qualify as eligible for utility patent rights by focusing on whether the claimed products or processes are "technological" is a category error. This "cure" would be worse than the current "disease" of application uncertainty that exists in the law (particularly as that uncertainty is largely the result of poor judicial reasoning and inconsistent precedents). Nor is there any need to focus on whether the invention is "technological," although some language in the *Alice* decision seems to adopt that approach. *See, e.g., Alice,* 573 U.S. at 222-23 ("Thus, "*Flook* stands for the proposition that the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of [the idea] to a particular technological environment."… In other words, the claims in *Diehr* were patent eligible because they improved an existing technological process, not because they were implemented on a computer."). With

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[5] *See, e.g.,* Michael Risch, *America's First Patents*, 64 FLA. L. REV. 1279, 1327 (2012) ("Semiconductors, computers, telephone communications, radio communications, pharmaceuticals, biotechnology, nanotechnology, automobiles, and other technology areas were unforeseen in 1790 when Congress enacted the first patent statute…. [T]here are a sufficient number of patents relating to nonmanufacturing methods, describing both business methods and nonbusiness methods, to infer that early patentees did not believe that patents were limited to 'mechanical arts' or 'technological arts,' as some have argued the term 'useful arts' means").

[6] I also indicated in my written testimony how such other jurisdictions may nevertheless impose moral and other restrictions on granting patents that are intended for use in particular fields of human endeavor, such as through the "ordre publique" and "industrial application" criteria.

the one exception of *In re Nuitjen,* 500 F.3d 1346 (Fed. Cir. 2007), involving claims to intangible, propagated signals that conveyed information ("[a] signal with embedded supplemental data, the signal being encoded with a given encoding process …"), there is almost never a dispute as to whether a claimed invention falls within a technological category as a "machine", "manufacture," "composition of matter," or "process."[7] Thus, there is not normally any need to focus on the technological character of the thing created or the process performed by the claimed invention, but rather on the kind of creativity that went into "inventing" it.

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?

In other jurisdictions, the difficult line-drawing determinations regarding eligibility have largely been displaced to the "inventive step" patentability doctrine, rather than seeking to define "technology" as a matter of "industrial application" or (as proposed by the pending legislative draft) under the corresponding U.S. "utility" doctrine. Many have criticized the "technical effect" requirements for inventive step as lacking in adequate definitions of "technical" or "technological," and thus as requiring detailed case-law development based on factual determinations that may be at least as uncertain as current U.S. eligibility law. *See, e.g.,* EPO, Case Law of the Boards of Appeal, Part I.D. § 9.1.5, https://www.epo.org/law-practice/legal-texts/html/caselaw/2016/e/clr_i_d_9_1_5.htm ("The assessment of inventive step can only be based on those elements and aspects of the invention in respect of which a technical effect can be established. Whether an invention causes a technical effect is essentially a question of fact.").

But as indicated in my written testimony, current U.S. eligibility law has the advantage of treating the embodied creativity of ineligible subject matter as if it were prior art. In contrast, in many countries, the categorically ineligible subject matter is ***only precluded from contributing to the "technical effect" for the inventive step*** (not industrial application or utility) analysis. *See, e.g.,* EPO Guidelines for Examination, Part G, Ch. VII, § 5.4 ("Claims comprising technical and non-technical features), https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vii_5_4.htm; Natasha Fairbairn, UK: New EPO Guidelines on Patentability of Computer Programs, MONDAQ, http://www.mondaq.com/uk/x/743714/Patent/New+EPO+Guidelines+On+Patentability+Of+Computer+Programs (Oct. 9, 2018) (a "computer program must produce a 'further technical effect' when run on a computer, beyond the normal physical interactions between the program and the computer on which it is run"; also describing the need to demonstrate the "further technical effect" has a "technical character"). *See generally* World Intellectual Property Organization

[7] Note that the Federal Circuit held that Nuitjen's claimed signals were none of these categories, although they were clearly human-created, practical and useful, specific applications. They likely *should* have been considered to be "manufactures" within the meaning of Section 101, but should nevertheless have been held ineligible because the creativity they embodied was not in the encoding process but in the data itself. However, having decided that anything "useful, concrete, and tangible" was eligible subject matter in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.,* 149 F.3d 1368, 1373 (Fed. Cir. 1998), and earlier in *In re Alappat,* 33 F.3d 1526, 1544 (Fed. Cir. 1994) (en banc), the Federal Circuit panel chose this method of finding ineligibility. *See, e.g.,* Damien Howard, *A Discussion on the Patentability of Signals: Examining* In re Nuitjen, 8 NW. J. TECH. & INTELL. PROP. 131 (2009).

(WIPO), Standing Committee on the Law of Patents, Study on Inventive Step, SCP/22/3 (July 6, 2015). Why this kind of line drawing is thought to be preferable to the line drawing currently required in U.S. eligibility law to determine the requisite kind (and amount) of embodied creativity remains a mystery (particularly given the above analysis). *Cf., e.g.,* European Commission, Final Report: The trends and current practices in the area of patentability of computer implemented inventions within the E.U. and the U.S., Executive Summary (2016) ("both the EPO and U.S. methodologies for determining subject-matter eligibility involve legal uncertainty and present difficulties for practitioners, applicant and patent holders. Today, it cannot be concluded that one or the other methodology is clearly more liberal in finding CI inventions to be subject-matter eligible across all contexts."). But many people fervently (and in my opinion wrongly) believe that the kind of creativity (and not just the amount of it) should ***only*** be assessed in the inventive step *patentability* inquiry, and should be assessed by asking about the ***technological character*** of the embodied application.

Nevertheless, we can learn two important things from these foreign experiences. First, ***greater consistency in adjudication*** of such line-drawing determinations to decide what kinds of inventions should receive utility patent rights is often provided by highly technologically proficient adjudicators. As indicated in my oral testimony, it might be possible (after the *Oil States* decision, discussed further in regard to takings below) to place all adjudication of patent infringement and validity disputes in expert agencies. If one believes that technically expert adjudicators can better determine than generalist judges (or worse, juries) the nature and amount of embodied creativity ***or*** the technological character of the embodiments, then it should improve the patent system to remove all patent adjudication from the courts. But even then, there will be significant inconsistencies of adjudication without adequate definitional guidance.

Second, by studying the detailed and nuanced adjudicatory determinations of these jurisdictions that employ experts trained in both technology and law, U.S. adjudicators could seek to adopt similar standards to distinguish between inventions having technical character in their inventive step (non-obviousness assessment in Section 103), and those that do not. But as noted in my written testimony, the current approach of focusing on the creative contribution under Section 101 eligibility doctrine remains preferable, as it treats any ineligible creativity as if it were prior art and as it thereby assures that any non-technical creativity does ***not*** contribute to the assessed eligibility of the claimed invention. In contrast, these other jurisdictions not only focus on the technological character of the embodied invention for eligibility, but only exclude such ineligible creativity from contributing to the inventive step technological kind and amount inquiry (and do not treat the ineligible creativity as prior art). It thereby grants patent rights where the claimed technological applications ***are obvious in light of the ineligible discoveries that cannot contribute technological character,*** and which discoveries should be free for all to use for such obvious, practical, technological applications. Thus, the U.S. should not adopt these jurisdictions approaches, even if studying them may provide better concepts for further defining the types and amounts of required creativity (or even if Congress adopts a "technology"-based approach).

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?

As explained above, such a method could be considered a technology in a field of technology, particularly if it requires use of artifacts (e.g., a written record of a transaction, even without computer calculation) to perform a useful process. And as explained above, this is the wrong question to ask. The correct question should be whether the claimed methods of hedging embody the right kind of creativity beyond mere application of the abstract idea of hedging financial risks in a particular context, and if so whether the amount of such creativity should be considered sufficient to constitute an "invention" (*i.e.,* to reflect an "inventive concept").

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

For the reasons explained above, I would recommend changing the approach of the draft entirely, and abandoning the effort to define "field of technology" as a restriction on patent eligibility. Rather, Congress should focus on codifying the judicial statements that: (1) certain kinds of discoveries should be treated as prior art, even when newly discovered by the applicant; and (2) some different and *additional* inventive creativity of the requisite character (and not mere practical application of such an ineligible discovery) is required for utility patent eligibility of a claimed invention.

But to the extent that Congress were to follow the current approach of the pending legislation (seeking to define technology under the "utility" doctrine), I would suggest that Congress ***first*** perform a study to review all of the adjudicatory decisions of other jurisdictions, in order to try to better define what constitutes a technical effect and a technical contribution to a claimed, practical and useful embodiment. Only after such detailed consideration should Congress ***then*** determine whether to adopt such line-drawing criteria of those jurisdictions or to modify them, placing any statutory criteria for such distinctions clearly in legislative language of the Act itself. Congress thus should not seek to act precipitously in regard to such an important and complicated subject for legislation, and without adequate information about what kinds of activities or creative contributions should be considered "technological." And the important point is that Congress should provide the maximum level of specificity that can be achieved.

Nevertheless, there may be many fields of human endeavor that simply should not be subject to utility patent rights, even if those criteria would treat claimed "inventions" in those fields as "technologies." Many people think that the utility patent system should not apply (for example) to sports moves and cooking recipes, whether or not they were patented in the past. And most countries prohibit utility patents on medical and veterinary methods, even if these creative, embodied discoveries may be considered "technologies." (In contrast, U.S. law currently does not exclude such "inventions" from eligibility, but rather limits remedies for infringement, and only against certain institutions and doctors. *See* 35 U.S.C. § 287(c).) As indicated in my written testimony, in many fields of human endeavor, adequate incentives already exist for innovation without resort to patent rights. Providing patent protection in those field thus may retard innovation and diminish social welfare, as well as being immoral. More controversially,

some people think that patents should not exist even for pharmaceutical products on social welfare and moral grounds, and that providing (at least product) utility patent protection is bad industrial policy. For example, "[b]etween 1919 and 1949, chemical products were excluded from patent protection [in Great Britain] to counter the threat posed by the superior German chemical industry." B. Zorina Khan, An Economic History of Patent Institutions, https://eh.net/encyclopedia/an-economic-history-of-patent-institutions/. In sum, should Congress authorize utility patents based on the claimed inventions being "technologies," Congress should also expressly exempt some fields of human endeavor from such patents and their exclusive rights.

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?

The most important things to exclude from eligibility (as indicated in my oral and written testimony) are the ineligible discoveries of science, nature, and ideas, and uncreative applications of those ineligible discoveries. This would include not just genes ***as they exist in the body***, but also genes (and any other natural products or phenomena) as isolated from or derived from nature (and only the first but not the second was held ineligible in regard to iDNA and cDNA in the *Myriad* case). Such things would only become utility patent eligible inventions if sufficient ***additional*** creativity of the proper kinds were supplied in the process of modifying or using the naturally derived products or phenomena, in ways that are ***sufficiently different*** from the structures, properties, and uses of those products and phenomena as they exist in nature. In other words, ineligible discoveries do not become patent eligible simply because they are "made by man." Rather, such claimed inventions must be sufficiently transformed from their structures *and* properties as discovered in nature.

As also indicated in my written testimony, Congress should expressly codify the "non-analogous" use standard of the Supreme Court's *Ansonia Brass and Electric* case for processes, as well as the "markedly different" standard of *Diamond v. Chakrabarty* for products. Additional legislative clarity and specificity regarding ***the degree of difference*** that should be considered "non-analogous" and "markedly different" would also be helpful. Such guidance could be developed by reviewing the extensive case law that has been developed in this country over the course of centuries.[8]

Further, as many ***other things and fields of human endeavor*** should be excluded from the utility patent system as economic analysis can tell us would improve innovation policy and social welfare, or are otherwise justifiably excluded on moral grounds. As noted in my written

[8] Further, to avoid confusion, Section 101 should be amended to add "utility" in front of "patentable" in the caption and in front of "patent," to make that section's application clear and to distinguish it from the eligibility provisions of Section 161 (plant patents) and Section 171 (design patents).

testimony, many industries and areas of human activity do not need patents to incentivize innovation, and granting patents in these fields will actually decrease innovation or cause greater static social welfare losses than any associated, dynamic innovation and future welfare gains. Unfortunately, as indicated in my answers to Senator Blumenthal's questions, economic analysis is usually insufficient to tell us ***which*** particular industries and areas of human activity and ***which*** particular kinds of creative applications possess these characteristics. Nor can economic analysis answer what should not be patented on moral grounds.

Nevertheless, one can use as a start for analysis – and Congress might adopt the same set of categorical exclusions from utility patent eligibility, specified as fields of "technology" – the categories of activity that have been adopted as categorical exclusions from the definition of "invention" when claimed "as such" in the European Patent Convention in Article 52(2). Those exclusions recognize that these areas of human endeavor are unlikely to need technical (or technological) creative contributions to be incentivized by the utility patent system. But Congress should not limit those exclusions from eligibility "as such." Rather, Congress should simply exclude utility patents in those fields entirely. Further, if Congress were to grant the PTO substantive rulemaking authority, Congress might also provide authority to the PTO to study and to ***add to the categories of excluded things and fields.*** *Cf., e.g.,* 17 U.S.C. § 1201 (requiring the Copyright Office to engage in triennial rulemaking proceedings to determine exceptions to anti-circumvention prohibitions in copyright law).

Thus, in addition to codifying the existing eligibility exclusions for science, nature, and ideas (or per Art. 52(2)(a) "discoveries, scientific theories and mathematical methods"), claimed as such or as practically applied without additional creativity of the required kind, Congress should also exclude from utility patent rights any and all (b) "aesthetic creations"; (c) "schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers"; and (d) "presentations of information." This will involve the PTO and the courts in line-drawing determinations to decide when a claimed invention falls within or outside of any of these categories. But unlike the EPC approach, Congress should also treat any novel (even highly creative, time-intensive, and costly) discoveries in these fields as prior art against the patent applicants, even when the claimed inventions are adjudicated to fall outside of those fields.

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?

As noted in my oral testimony, courts have not adequately enforced the Section 112(b) definiteness requirement, which also relates to the Section 112(f) functional claiming language requirement and the Section 112(a) written description requirement. Much legal uncertainty

could be avoided by further specifying in legislation the legal standards for such claim precision, language, and scope.[9]

In regard to claim definiteness, although the Supreme Court recently indicated that the Federal Circuit had adopted a linguistic test of indefiniteness ("insoluble ambiguity" and "amenable to construction") that failed to correspond to the 1952 Act and to earlier Supreme Court precedents, analysts generally believe that the Federal Circuit has simply reconstructed its prior indefiniteness precedents under the new (actually old) Supreme Court interpreted standard for distinct claims of "reasonable certainty." *See Nautilus, Inc. v. Biosig Instruments, Inc.,* 572 U.S. 898, 910 (2014) (requiring claim language to "inform those skilled in the art about the scope of the invention with reasonable certainty"); Jason Rantanen, Teva, Nautilus, *and Change Without Change,* 18 STAN. TECH. L. REV. 538, 538 (2015) ("The Federal Circuit continues to routinely reject indefiniteness challenges and grant no formal deference to district courts in reversing their claim constructions. Meanwhile, its formal doctrinal analyses look virtually identical to those before the Supreme Court intervened."). In part, this is because the Supreme Court did not define "reasonable" or "certainty," nor explain what would make a particular degree of uncertainty "unreasonable." In part, this is because the lower courts inconsistently favor protecting patent applicants from invalidation of claims having uncertain meanings and protecting the public from the uncertain scope of such ambiguous or vague claims (until authoritatively construed in adjudication). In theory, reasonable certainty requires the ability of the public to understand the scope of meaning of utility patent claims *without resort to authoritative litigation to impose a fixed meaning on claim language through claim construction.* Thus, under a meaningful definition of "reasonable certainty," literally thousands of issued patent claims that have not yet expired should and would be held invalid.

In regard to functional claiming, any claim language that is construed not to be limited to structural embodiments of the claim language disclosed in the specification or to structural embodiments that are known (at least to skilled persons in the relevant field) at the time of filing of the invention to be equivalent substitutes to those disclosed structures ***effectively*** transforms that claiming language into functional claiming language. For this reason, the Federal Circuit correctly held in *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.,* 145 F.3d 1303, 1310–11 (Fed. Cir. 1998) that – because after-arising technology could not be disclosed in a patent – so-called "literal" interpretation of functional claiming language cannot be construed to apply to after-arising technologies.[10] Accordingly, the entire set of doctrines around

[9] I also noted in my written testimony that much confusion could be avoided by recognizing that any concerns with "preemption" of ineligible discoveries "as such" by specific claimed applications has nothing to do with the actual legal test for eligibility, and that any such concerns should be addressed by Section 112 claim scope doctrines, particularly claim interpretation doctrines that address the scope of future technologies – if any – that claimed inventions may validly embody, the doctrine of equivalents in regard to such future technologies, and the written description doctrine and its requirement that the applicant objectively demonstrate subjective recognition and mental possession of the full scope of any such claims for validity and infringement determinations. However, a detailed evaluation of how to codify these provisions more clearly is beyond the scope of the question posed here.

[10] Whether such after-arising technologies should be protected by utility patents at all is a hotly disputed issue, but at least under current patent law doctrines such infringement protection is available only under the so-called "doctrine of equivalents." *See generally* Joshua D. Sarnoff, *The Historic and Modern Doctrine of Equivalents and Claiming the Future, Part I: 1790-1870,* 87 J. PAT. & TRADEMARK OFF. SOC'Y, 371, 391-99 (2005) (Sarnoff, DOE Part I); Joshua D. Sarnoff, *The Historic and Modern Doctrine of Equivalents and Claiming the Future, Part II: 1870-1952,* 87

presumptions for and against construing particular claiming language to be functional claiming language subject to Section 112(f) is largely misguided. The decision in *Williamson v. Citrix Online, LLC,* 792 F.3d 1339, 1348-49 (Fed. Cir. 2015), which abandoned the "strong" presumption that the absence of the term "means for" or "step for" indicates structural claiming language, has reduced somewhat the improper analysis. The pending legislation would further improve the situation, by effectively codifying *Williamson.* But the legislation fails to go far enough in recognizing that functional language may be a function (pun intended) of the interpretation rather than of the language itself.

Accordingly, to provide greater certainty in regard to functional claiming language – and thereby to further assist in providing "reasonable certainty" to claiming language in general – Congress will need to address and impose by legislative language required methodologies for claim interpretation and construction that bind administrative and judicial adjudicators to assure that claims are legally construed as Congress intended, unlike how Section 112(f) and its predecessors have been construed in light of the rule of claim construction articulated there. More importantly, Congress will need to further address whether and to what extent claim language can apply to undisclosed embodiments of construed claim language, whether or not known to be substitutes for the disclosed embodiments, and whether or not the embodiments (foreseeably or not at the time of application) arise after the specification has been filed and the applicant therein objectively discloses what he or she mentally recognizes as falling within the scope of claiming language.[11] Further, the requisite legal standard will invoke the Section 112(a) written description requirement, and there is also a need to provide the courts with better guidance regarding when generic functional or structural language (of varying construed breadth, limited or not to the time of filing of the application) should be held to be adequately supported (and thus the claim to be valid and justified) by the scope of the embodiments disclosed in the specification. That law is currently a mess, lacking any clear guidance for how much disclosure is sufficient. Nevertheless, the *Ariad* decision, 598 F.3d at 1349-50, adopted and imposed en banc the approach to disclosure sufficiency of the earlier panels in *Univ. of Rochester v. G.D. Searle & Co.,* 375 F.3d 1303, 1307 (Fed. Cir. 2004), and *Regents of the Univ. of California v. Eli Lilly & Co.,* 119 F.3d 1559, 1567-68 (Fed. Cir. 1997).

Again, further legislative clarification is warranted, and Congress should commission a study of how to articulate better the standards for such disclosure sufficiency and claim construction methodologies relating to functional and structural claiming language. In particular, Congress should consider codifying the *Halliburton* decision, which precluded the use of functional claiming language (and presumably intended to preclude constructions that effectively rendered structural terms into functional claiming language) at the point of novelty. *See Halliburton Oil Well Cementing Co. v. Walker* case, 321 U.S. 1, 8 (1946). The predecessor to Section 112(f) overturned that aspect of *Halliburton* but simultaneously adopted the restrictive claim construction methodology used for functional claiming language.

J. PAT. & TRADEMARK OFF. SOC'Y 441, 474-81 (2005); Joshua D. Sarnoff, *Abolishing the Doctrine of Equivalents and Claiming the Future After* Festo, 19 Berkeley Tech. L.J. 1157, 1191-92, 1213-24 (2004).

[11] In this regard, the current written description requirement of Section 112(a) as construed by *Ariad Pharm., Inc. v. Eli Lilly & Co.,* 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) would be better understood as reflecting a legal requirement imposed by the "regards as the invention" language of Section 112(b) and its predecessors.

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

As just explained, much more legislative work and much greater legislative specificity to establish claiming and claim scope doctrines is needed to properly revise Section 112. Only with such revisions will patent law avoid both doctrinal uncertainty and unreasonable uncertainty of understanding of the meaning of patent claims, even before resort to authoritative adjudication.

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

I am not at all concerned that the proposed changes will make it too easy for competitors to design around (validly) claimed inventions. For one thing, patent law policy favors "designing around" patent claims. For another, the applicant can always draft claims to cover those design-arounds, so long as the applicant has actually invented what the competitors would design, and thus can disclose in the specification that the applicant actually recognized and mentally possessed (and disclosed for public benefit) a scope of invention that would apply to those design arounds. This just restates the point that I made above in regard to subsection a. of this question 4. Congress needs to provide more guidance regarding the difficult question of the scope of the "principle" of a disclosed invention that an applicant should be entitled to claim using generic language, based on the objectively disclosed scope of the invention that the applicant subjectively "regards as invention" at the time of filing its application.

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?

Statutory double patenting derives directly from an interpretation of the statutory language of Section 101. There, Congress has authorized only one patent for any claimed invention. *See* 35 U.S.C. § 101 ("may obtain ***a*** patent therefor") (emphasis added). In contrast, obviousness-type double patenting is a judicially developed doctrine more broadly interpreting Section 101, which precludes patent holders from ***effectively*** gaining additional patent term. Applicants could gain such additional term by separating inventions that are obvious in light of each other into different patent applications, and those applications are further subject to potentially different ownership.

(Thus, the public not only would have to pay patent licensing costs for a longer time, but also may have to pay multiple licenses in order to practice the claimed invention.) Even when the claims in different applications are not identical (and thus they may not constitute a patent on "the same" invention subject to statutory double patenting), the subject matter of the claims – as obvious in light of the other application – may overlap. To prevent such overlapping (but not identical) claims from effectively granting additional patent term to what can be considered the "same" invention (because the claims are not "patentably distinct," as they are obvious in light of the applicant's own disclosure and earlier claims), courts have adopted the obviousness-type double patenting restriction through statutory interpretation.[12]

Statutory double patenting can apply even to patent applications filed at the same time. "Patents claiming overlapping subject matter that were filed at the same time still can have different patent terms due to examination delays at the PTO…. So too where, as here, the applicant chooses to file separate applications for overlapping subject matter and to claim different priority dates for the applications, the separate patents will have different expiration dates since the patent term is measured from the claimed priority date. When such situations arise, the doctrine of obviousness-type double patenting ensures that a particular invention (and obvious variants thereof) does not receive an undue patent term extension." *Abbvie, Inc. v. Mathilda and Terence Kennedy Institute of Rheumatology Trust,* 764 F.3d 1366, 1373 (Fed. Cir. 2014). Accordingly, obviousness-type double patenting rejections can be avoided by so-called "terminal disclaimers." In contrast, such disclaimers cannot overcome obviousness rejections that are based on the prior art under Section 102.[13] *See, e.g.,* PTO, Manual of Patent Examining Practice § 804 (Double Patenting Rejections).

Because Congress has not *clearly* specified in legislative language either statutory or obviousness-type double patenting doctrines, and because that interpretation of Section 101 has salutatory functions, it would be prudent to codify the doctrine even without any further change to Section 101. This is because, without expressly codifying these requirements, courts might feel free to revise them. The same is true if Section 101 were amended.

In response to the question posed, however, it is important to understand that the problem of evergreening of pharmaceutical (or related medical) patent protection largely does not reflect failures of the ***double-patenting*** doctrine. Rather, it reflects ***failures of the stringency of the obviousness standard itself.*** Current obviousness law permits granting of utility patents on many new uses, new combinations, new formulations, etc., even though the claims do not reflect any significant therapeutic (or other non-analogous) functional advance.[14] Similarly,

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[12] Note that it is a common error to treat such requirements as "common law" or as "judge-made" law, when they are in fact statutory interpretations. That these interpretations are not compelled by the clear language of a statute only goes to the lack of legislative specificity in provision of the Act and to disputes over whether legislative language should be interpreted in light of legislative history and policies, or not.

[13] Again, this demonstrates the importance of treating ineligible discoveries "as such" as prior art against applications.

[14] Note that at one time, all new use claims for patented inventions were considered unpatentable, because the patent on the thing itself was considered to encompass all of its potential uses. In this regard, a patent for a product need only disclose a single utility for that product, but continues to provide so-called "absolute"

comparative efficacy has not to date been a consideration under "utility" doctrine, which only requires "operable utility" and "substantial utility," not "better" or "greater" utility. If Congress adopts the approach of relying for eligibility on the "technological" character of being "useful," it should likely impose such a comparative efficacy requirement.

More importantly, Congress simply does not require comparative efficacy evaluations in order to authorize the marketing and sale of such evergreened medical products. Nor does Congress prohibit doctors, pharmaceutical institutions, or pharmaceutical companies from prescribing and dispensing such higher-cost (and even sometimes improved) products, where the therapeutic benefits may not warrant the increased costs (on either an individual basis or a societal basis). Further, Congress generally fails to regulate the practice of medicine itself (even without regard to inadequate regulation of abuses of so-called "detailing" and incentives through legal or illegal means to encourage such dispensing). These concerns warrant much more detailed analysis and scrutiny, but are not particularly germane to the pending revisions to the patent system.

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?

First, it is important to recognize that the restrictions on patenting science, nature, and ideas "as such" likely have constitutional origins and should be understood as constitutionally required, as I noted in my earlier written testimony. This may also be true for claimed inventions that do not add any inventive creativity when applying such categorically ineligible discoveries, as patents on such uncreative applications constrict the public domain in such discoveries. We have yet to get definitive holdings of the Supreme Court on the questions of what if any limits on patenting are contained in Article I, Section 8, clause 8 ("Authors and Inventors" Clause), and on how the First Amendment will apply to patents that restrict various forms of thought and communication. The over-extension of the existing patent system has so far been avoided through judicial interpretation of existing Section 101 and its predecessor provisions. To the extent that any legislative revision seeks to overturn such limiting interpretations, then the legislation itself likely ***should*** be held unconstitutional facially or as applied, without the need to consider Due Process or Takings law under the Fifth Amendment.

To the extent that Section 101 as currently written were ***not*** cabined by such judicial interpretations that avoid any such constitutional limits, either by new legislation or by revised judicial interpretations explicitly or implicitly abrogating earlier precedents, then such Article I power and First Amendment concerns would have to be addressed directly. Many patents that

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protection for all uses of that product even if non-obvious. However, now many new uses are also patent eligible – so long as they are non-analogous to prior uses, per the *Ansonia Brass and Electric* standard discussed above. But that standard is largely ignored by the courts, even though Section 100(b) of the 1952 Act was held in *Application of Ducci* to have intended to recodify rather than to replace that standard, as indicated in my written testimony.

would then issue under such legislation (and some patents that have been issued under the existing legislation, notwithstanding the Supreme Court's restrictive interpretation, given inconsistent application of that legal standard by the Patent Office and the U.S. Court of Appeals for the Federal Circuit) may then be held unconstitutional, as exceeding Article I power or as violating the First Amendment. Again, there should be no Due Process or Takings clause implications of retroactively holding through adjudication any such patents to be unconstitutional and thus invalidly granted. Such patents simply would not have been within Congress' power to grant in the first instance.

Conversely, ***legislatively codifying*** these existing, interpreted, potentially-Constitutional restrictions on the scope of existing Section 101 legislation and "imposing" these judicial interpretations "retroactively" by express statutory language also does not pose any Due Process or Takings concerns. Rather, it merely codifies existing interpretations of the law under which the patents at issue were granted. That is true without regard to whether that law was properly followed by the Patent Office when granting some such patents, and thus whether some such granted patents may be invalidated by the currently interpreted law, as so codified. Further, revised judicial interpretations of pre-existing legislation also do not normally trigger any Due Process or Takings concerns, although sometimes courts choose to make their changed interpretations apply only prospectively. *See generally, e.g.,* C.J.S. § 198 (Retrospective operation – Factors considered); *NLRB v. Wyman-Gordon,* 394 U.S. 759, 765-66 (1966).

Of greater significance, ***nothing*** in the Constitution ***requires*** Congress to authorize the grant of ***any*** patent. Article I, Section 8, clause 8 only grants ***power*** to Congress; it does not impose a duty to exercise that power. So, there cannot be any Due Process or Takings concern when Congress refuses to ***further extend*** patent eligibility beyond what the current legislation authorizes (even assuming that such an extension would be constitutionally permissible). Thus, any concern with Due Process and Takings in this context is simply unwarranted, unless and until Congress were to significantly ***constrict*** patent eligibility from the scope of the current law (as it has been interpreted).

Further, such Due Process and Takings concerns could only ***potentially*** arise, in regard to invalidation of ***previously granted*** patents, as a result of constricting eligibility law. Because ***prospectively*** limiting such patent eligibility is fully within Congress' power, Congress may do so as long as it adopts legislation bicamerally and with presentiment and Presidential signature or veto override. And there can be no Takings concern when the U.S. government decides not to create a property interest in the first place. *Cf. Am. Mfrs. Mutual Ins. Co. v. Sullivan,* 526 U.S. 40, 61 (1999) ("Having concluded that respondents' due process claim falters for lack of a property interest in the payment of benefits, we need go no further."); *id.* at 62-63 (Breyer, J. concurring) ("I agree with Part III insofar as it rejects respondents' facial attack on the statute and also points out that respondents 'do not contend that they have a property interest in their claims for payment, as distinct from the payments themselves.' ... I would add, however, that there may be individual circumstances in which the receipt of earlier payments leads an injured person reasonably to expect their continuation, in which case that person may well possess a constitutionally protected 'property' interest.").

Further, ***retroactive*** legislation would necessarily meet ***procedural due process*** requirements, either because legislative adjustments to property rights are not subject to Due Process Clause restrictions or because legislative process provides all the process that is due. *See, e.g., Bi-Metallic Inv. Co. v. State Bd. of Equalization,* 239 U.S. 441, 445 (1915) ("There must be a limit to individual argument in such matters if government is to go on."). *Cf. Londoner v. City and County of Denver,* 210 U.S. 373 (1908). Such retrospective legislation also will be upheld under ***substantive due process*** law, so long as Congress has a rational basis for its decision, *i.e.,* a rational relationship to a legitimate state interest. *See, e.g., Romer v. Evans,* 517 U.S. 620, 632 (1996); *Lenhausen v. Lake Shore Auto Parts Co.,* 410 U.S. 356, 364 (1973). Further, ***retroactive legislation*** would be upheld even if it restricted the eligibility of ***previously granted*** patents, without violating any procedural or substantive due process rights of patent holders. Congress may impose ***retrospective*** statutory changes, even those having significant economic consequences or that may be viewed as "unfair," so long as it does so clearly enough to overcome any presumption of prospectivity. *See, e.g., Perez v. Elwood,* 294 F.3d 552, 558 (3rd Cir. 2002) ("Congress may apply civil laws retroactively as long as: (1) it indicates clearly its intention to do so; and (2) it would not violate the Constitution for it to do so.") (citing *Landgraf v. USI Film Products,* 511 U.S. 244, 267-88 (1994)); *Usery v. Turner Elkhorn Mining Co.,* 428 U.S. 1, 14-20 (1976) ("our cases are clear that legislation readjusting rights and burdens is not unlawful solely because it upsets otherwise settled expectations."). *But cf. Eastern Enterp. v. Apfel,* 542 U.S. 498, 547-50 (1998) (Kennedy, J., concurring) (rejecting the Court's four-Justice plurality opinion's approach to find a Taking from retroactive imposition of liability not tied to specific property, while finding – as a sole Justice – that such retroactive legislation constituted a substantive Due Process violation, because the liability imposed by the statute bore "no legitimate relation to the interest which the Government assert[ed] in support of the statute").

In contrast, ***the Takings clause concern with such retrospective legislative invalidation of previously granted patents is somewhat more substantial***. Nevertheless, as explained below, should that issue ever present itself for any legislative revisions to eligibility doctrine, there are reasons why previously granted patent rights might not be subject to Takings clause protection. This is true even if Congress had earlier chosen to provide such patent rights "with the attributes of personal property," subject to the provisions of the Patent Act. 35 U.S.C. § 261(a), para. 1.

Significantly, as the Court recently held in *Oil States Energy Services LLC v. Greene's Energy Group LLC,* 138 S.Ct. 1365, 1373-74 (2018), patent grants reflect a special form of legislatively created property right, a "public franchise." A public franchise is a "public right," and thus susceptible to adjudication of validity outside of the Article III courts. *See id.* ("the decision to *grant* a patent is a matter involving public rights—specifically, the grant of a public franchise…. the determination to grant a patent is a 'matte[r] involving public rights.' ... It need not be adjudicated in Article III court."). However, the Court expressly warned against reading its holding to cast doubt on whether patents are constitutional property for purposes of Due Process or the Takings clause. *See id.* at 1379 ("our decision should not be misconstrued as suggesting that patents are not property for purposes of the Due Process Clause or the Takings Clause) (citing *Florida Prepaid Postsecondary Ed. Expense Bd. v. College Savings Bank,* 527 U.S. 627, 642 (1999); *James v. Campbell,* 104 U.S. 356, 358 (1882)). *Cf. Florida Prepaid Postsecondary*

Ed. Expense Bd., 527 U.S. at 642 & n.7 (refusing to consider alleged state-based Takings of patent rights – by infringement combined with state sovereign immunity from suit – as a justification for abrogating state sovereign immunity, but holding that patents "are surely included within the 'property' of which no person may be deprived by a State without due process of law"); *James,* 104 U.S. at 357-58 ("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…. The government of the United States, as well as the citizen, is subject to the Constitution; and when it grants a patent the grantee is entitled to it as a matter of right, and does not receive it, as was originally supposed to be the case in England, as a matter of grace and favor."); *id.* at 359 (noting sovereign immunity and jurisdictional concerns; "If the jurisdiction of the Court of Claims should not be finally sustained, the only remedy against the United States, until Congress enlarges the jurisdiction of that court, would be to apply to Congress itself.").[15]

When a patent grant is rescinded or held invalid, the ***entire*** value of the patent franchise as means of excluding competition or of collecting licensing revenue is ***prospectively*** rescinded, and thus there is no need to engage in the traditional analysis under "regulatory takings" principles of whether a statutory or regulatory change unduly diminishes the value of the property at issue.[16] *See, e.g., Lingle v. Chevron U.S.A., Inc.,* 544 U.S. 528, 539 (2005) ("The Court in *Penn Central [Transp. Co. v. New York City,* 438 U.S. 104, 124 (1978),] acknowledged that it had hitherto been 'unable to develop any "set formula"' for evaluating regulatory takings claims, but identified 'several factors that have particular significance.'… Primary among those factors are '[t]he economic impact of the regulation on the claimant and, particularly, the extent to which the regulation has interfered with distinct investment-backed expectations.' … In addition, the 'character of the governmental action'—for instance whether it amounts to a physical invasion or instead merely affects property interests through 'some public program adjusting the benefits and burdens of economic life to promote the common good'—may be relevant in discerning whether a taking has occurred."). It should be obvious that adjusting patent eligibility doctrine would be adjusting the benefits and burdens of economic life to promote the common good, but that may not be dispositive of the question of whether legislative repeal of a patent constitutes a Taking.

In depriving patent holders of prospective revenue from a public franchise, the patent holder does not lose any tangible property or money that is in its possession, but rather only potential future income that might be due (absent provisions in earlier licensing agreements that require repayment of licensing fees that were thought be due when the patent grant was in force and that formed some of the consideration for any such contractual obligation).[17] Whether the legislative

[15] Note that nothing in *James* dicta calls into question the basic premise that Congress is ***not*** required to grant any patent, by exercising the constitutionally vested legislative patent power in the first instance.

[16] However, validity is assessed on a claim-by-claim basis, potentially requiring such analysis. *See* 35 U.S.C. § 288.

[17] Further, such contractual payment provisions may be thought to conflict with the doctrine of licensee estoppel and the encouragement of licensees to challenge the validity of patent grants, and thus to be preempted under Supremacy Clause purposes and objective conflict preemption principles. *See, e.g., Lear v. Adkins,* 395 U.S. 653

termination of such statutory benefits is a property interest protected by the Takings clause (or the Due Process clause) is therefore subject to serious question, just as statutory grants of public welfare benefits may be rescinded even when there is an expectancy of continuing to receive accrued benefits, without violating due process and without any suggestion that doing so would effectuate a Taking. *See, e g., Flemming v. Nestor,* 363 U.S. 603, 611 (1960) ("We must conclude that a person covered by the Act has not such a right in benefit payments as would make every defeasance of 'accrued' interests violative of the Due Process Clause of the Fifth Amendment."). *See generally* Davida H. Isaacs, *Not All Property is Created Equal: Why Modern Courts Resist Applying the Takings Clause to Patents, And Why They Are Right to Do So,* 15 GEO. MASON L. REV. 1 (2007).

As then-Professor Isaacs explained, *id.* at 5-6:

> [R]egulatory takings claims need not afflict patent policy…. Some scholars have relied on nineteenth century precedent to reach the opposite conclusion, but that precedent is far from dispositive. Moreover, one should give those cases little weight, because those statements were effectively meaningless at a time before the Fifth Amendment was self-executing, and before the Supreme Court recognized regulatory takings claims. As a result, the nineteenth century courts were free to discuss takings without having to consider the potential impact of patent claims on policy. Indeed, one recent Supreme Court opinion notably failed to cite those cases, and another opinion expressed skepticism that patentholders are entitled to a Takings Clause remedy.
>
> Consideration of decisions regarding other federal benefits reveals that application of the Takings Clause is not compelled by the categorization of patents as "property." As governmental benefits, patents fall within the class of federal benefits which the modern Supreme Court has found to be entitled only to the Fifth Amendment's Due Process Clause protection (specifically, procedural due process), not Takings Clause protection. Indeed, despite the Court's repeated insistence that patents are some form of "property," the Court itself has obliquely expressed skepticism that patents are entitled to Takings Clause protection. Furthermore, although the Court has suggested that Congress could choose to create a property right that is due the full scope of protections, no evidence of such intent to endow patents with that status exists.

Other early 20th and 19th century Supreme Court cases, however, might (but need not) be interpreted to subject the legislative withdrawal of a publicly granted franchise to some form of a constitutional Taking requirement. *See, e.g., Frost v. Corporation Commission,* 278 U.S. 515, 519-25 (1929) (franchises for performance of public services that granted rights to obtain tolls for use of cotton gins were property under the Fourteenth Amendment, even if the exclusivity could be diminished by the grant of other franchises, but a proviso dispensing with such

(1969). *Cf. Medimmune, Inc. v. Genetech, Inc.,* 549 U.S. 118 (2017) (a licensee is not required to breach licensing payment obligations in order to sue for declaration judgment of invalidity of a patent, so as to be prospectively removed from any contractual obligation to pay royalties).

franchising for certain other businesses operated to effectuate an Equal Protection clause violation); *West River Bridge Co. v. Dix,* 47 U.S. (6 How.) 507, 522-49 (1848) (opinions of various Justices affirming the power of eminent domain to abolish public franchises, notwithstanding arguments that doing so unconstitutionally impaired contracts in violation of the Contracts clause of Article I, Section 10, clause 1). *But cf., e.g., New York Elect. Lines Co. v. Empire City Subway Co.,* 235 U.S. 179, 194-96 (1914) (state-granted franchises are subject to implied conditions that do not make them irrevocable by legislation, without suggesting that legislative revocation would create any Takings liability) *Atlantic & P. R. Co. v. Mingus,* 165 U.S. 413, 426-42 (1897) (explaining how government grants of land patents can be legislatively revoked based on failure to conform to conditions of the grants, even when other remedies are provided for such failure, without suggesting any need to provide just compensation for the transfer of land patent title to another party after the legislative revocation). It is thus unclear what kinds of conditions for public benefit should be *implied* on the grant of patents when considered to be public franchises (including the potential for legislative revision to the conditions justifying the grant), so that the legislature may revoke the grant of patents for the public good without being obligated to pay compensation under the Takings clause.

In summary, the issue whether retrospective legislative changes to patent eligibility law that would invalidate previously granted patents in their entirety (much less invalidate only particular claims of a patent) would create a constitutional Taking requiring just compensation is a very complex and difficult issue. When enacting the AIA, Congress explicitly dismissed Takings concerns that were raised in regard to new adjudicatory procedures that might invalidate previously granted patents that otherwise would have been upheld by the Courts, based on different adjudicatory claim construction standards and the presumption of patent validity. *See, e.g.,* 157 Cong. Rec. H4421 (daily ed. June 22, 2011) (statement of Rep. Lamar Smith) ("The application of these new reexamination procedures to existing patents is not a taking or otherwise a violation of the Constitution.'") (quoting a letter from former Judge Michael McConnell, U.S. Court of Appeals for the 10th Circuit). But there can be no concern with the Takings clause if any new, more restrictive legislative provisions on eligibility (or patentability) are only applied prospectively, as was provided in uncodified Sections 14 and 33 of the AIA. And there can be no concern with the Takings clause if Congress (constitutionally or not) further extends patent eligibility by legislation.