Questions for Hans Sauer (from Chairman Tillis)

1. Some of the hyperbole I've heard from anti-reform advocates is that somehow doing something on patent eligibility is going to lead to an increase in drug prices or the patenting of "frivolous" or "useless" drug patents. I understand why anti-reform advocates are trying to make that argument, it's politically charged and is a good way to try and de-rail this project. However, as both of you know, that argument is totally inaccurate. Those arguments ignore the fact that patent eligibility is just the first of many steps in order to secure a valid patent. A patent still has to be novel, nonobvious, and meet numerous other requirements in order to issue. In addition, drug pricing is determined by a number of factors that have to deal with things beyond the actual patent.

   Can you briefly describe the minimal role patent eligibility plays in overall "drug pricing" and explain very clearly to this Committee how broadening the eligibility standard ***isn't*** going to lead to "bad patents" being issued?

   Chairman Tillis, I believe there is no connection between patent eligibility and drug prices. As I noted in my answer to Senator Blumenthal during panel 3 of the second hearing, the patents implicated by patent-eligibility are not the kinds of patents that critics of the biopharma industry are concerned about. In our technology space, section 101 problems affect patents on (i) medicinal substances that are derived from natural molecules, such as enzymes, antibiotics, hormone preparations, and anticancer molecules like the one described by witness Ms. Knowles; (ii) diagnostic and prognostic tests; and (iii) biomarker-assisted methods of drug treatment that help in selecting and administering the right drug for the right kind of patient.
   Such patents are not trivial. They protect the kinds of inventions without which it would often be impossible to bring a drug to market in the first place. In the biomedical space, patents that are affected by 101 problems

save money rather than drive increased costs. For example, by making it possible to give a particular drug only to the 10% of lung cancer patients who are likely to respond to it, healthcare dollars are saved and needless drug expenditures avoided. Or by being able to identify patients who are likely to suffer side-effects of a treatment, costly medical complications can be avoided.

2. One of the reasons I'm concerned by the current legal landscape is that I've heard from numerous companies that they are abandoning research into life-saving treatments and medications. You both probably heard Sherry Knowles testimony a bit earlier on this exact subject. It's easy to paint "pharma" companies as big bad boogeyman, but that ignores the point Sherry made so eloquently: if people don't develop new drugs to treat disease and improve currently existing treatments, people will die.

That concerns me. I want America to remain the world's leader in innovative health care and precision medicine. Can you describe briefly the impact the current legal framework is having on the willingness of your member companies to invest in the research and development needed to bring new medicines and treatment methods to market?

The connection between patent certainty and R&D investment in the therapeutic products sector is well-studied and well-understood. Biomedical product development is doubly sensitive to patent uncertainty because it requires high investments (upwards of USD 1 billion), sustained over long periods of time (a decade on average), with a high risk of development failure (approx.. 90%). Given this constellation of factors, it is understandable that patent uncertainty can become very highly leveraged in business decisions. Only a small additional patent risk can "tip" a business decision against developing a high-risk/high reward experimental product, in favor of developing a "safer," less innovative me-too product. If we want to encourage risk-taking in the development of pioneering breakthrough therapies, we should foster a climate where innovators can rely on properly examined and granted patents to build their businesses. Continued unpredictable evolution and "creep" in the judicial interpretation of the common-law exceptions to patent-eligibility will only scare investors, who might understand that patent-eligibility law is perhaps doing something important today, but who will worry what it might do next.

a. Looking out ten to fifteen years from now, if we don't address the current patent eligibility mess, what impact will that have on the delivery of healthcare for Americans? In other words, will America continue to be the go-to-country for groundbreaking medical research and innovation?

By the time we fully understand the negative impact of current patent-eligibility law on the next generation of treatments, it will be too late. Fifteen years from now we will often not be able to identify the cures and tests that were never developed. We do know, however, that our major trading partners are today not following our lead in this area of patent law. In fact, the state of our jurisprudence in this area has more in common with the patent laws of e.g. Brazil and India than it has with

the patent laws of Europe, Japan, Korea and even China. These other industrialized countries are actively challenging U.S. leadership in areas such as precision medicine. I don't believe it would be in the national interest if, 15 years from now, the United States became a net importer of biomedical innovation while a majority of the newest treatments originate outside the United States and become available to patients in other countries first.

~~a.~~b. If not, what is the practical consequence going to be for millions of Americans who depend on these types of innovative medicines and treatment mechanisms?

Your question raises an important point that is often underappreciated during the current debate over high healthcare costs. It is understandable that much of today's debate is focused on the legitimate concerns of our Nation's seniors, Medicare beneficiaries, the working poor, and the many people living with chronic medical conditions; i.e. people who need today's medicines today. But any good policy that looks 15 or 20 years into the future will also need to take account of people who today range from young adulthood to those who, in good health, are in their most productive years. What are *their* expectations for 20 years from now? I believe that sound science, supported by the patent system, provides opportunities and incentives to create cures for intractable conditions that won't be treatable for another decade or longer. Good policy should do nothing to interfere with those incentives.

3. Perhaps the most disingenuous arguments I've heard from anti-reform advocates is that our proposal will somehow allow the patenting of "human genes." That's not true. Neither the intent or effect of our proposal will be to allow the patenting of human genes. Period. Anyone who says differently is simply engaging in hyperbole and trying to fatten their own pockets through fundraising efforts.

   I want to dispel this notion that somehow we're going to allow the patenting of "Human genes." So, let me ask you a series of questions:

a. It's my understanding that the *Myriad* case already held that a particular gene form, cDNA, for example remains patent eligible. Is that correct?

Yes.

b. With respect to the argument that reform would change anything related to human genes, wouldn't it be accurate to say that argument is arguably specious?

I believe so. Naturally-occuring human genes were never patentable and will not become so under your legislation.

c. Second, and importantly, isn't it true that genomic DNA forms of human genes are not patentable under 102 and 103 because they have been in the public domain for about 20 years? In other words, even if Congress abrogates Supreme Court precedent, human genes, outside the cDNA form, would not be subject to patent protection. Correct?

That is correct. The human genome has been extensively studied and published. There is a mountain of readily-searchable prior art today that would preclude patenting. It is hard to imagine anyone, in this day and age, discovering a new previously unknown human gene and being able to take out a patent on it.

d. Finally, can you talk about the merits of providing patent protection for the isolation of certain genes and the use of the isolated genes in personalized medicine? No one is advocating for patent protection for genes in their pure form. No one. But, what is the value to the patient in encouraging companies and researchers to isolate genes and use that isolation to provide new and innovative treatments? How does that type of incentive ultimately benefit patients?

Contrary to what has been said, patents on isolated DNA molecules have never played an important part in diagnostics. For example, in my opinion the DNA claims in the Myriad Supreme Court decision would not even have been infringed if someone had engaged in unauthorized breast cancer genetic testing. That is because it is not necessary to make an "isolated" copy of a BRCA gene in order to conduct genetic testing – it's just not how such tests are done. For that reason, claims to "isolated genes" are much more important in applications that use the

"isolated gene" to produce proteins that have therapeutic or industrial applications. For example, biosynthetic genes from obscure bacteria and fungi may be useful in fermentation technology to make new antibiotics, immune suppressants, or industrial enzymes. In plant biotechnology, "isolated genes" may be useful to confer pest- or draught resistance on crop varieties.

4. The difference in the law between the United States and our competitors like the European Union and China has resulted in certain innovations being patent eligible in

Europe and China, but not in the US. What are those differences and what has been the impact?

There are many, but the clearest example in the biomedical space is in preparations of isolated, purified, or enriched substances that also occur naturally. For example, in Europe, China, Japan, Korea and Canada, a purified preparation of a naturally-occurring antibiotic substance of fungal origin (like penicillin) is patentable provided it meets the normal requirements of novelty, inventive step, industrial applicability and sufficient technical description. The underlying logic is that, by purifying and characterizing such a substance, human intervention for the first time makes it possible to formulate it in a pharmaceutical preparation and administer it in precise doses to treat infections, and thus confers a practical usefulness on it that did not exist before. Even in Australia, which has had its own Myriad "gene patents" decision, such substances continue to be patentable. But in the United States such preparations are no longer patent-eligible under a "product of nature" theory. Other differences affect patents on diagnostic tests. There are many instances where patent applications on diagnostic tests have been denied in the USPTO but granted in Europe.

5. Have we seen the types of harms described by the ACLU arise in Europe or China as a result of that difference?

We have not. Even though the kinds of patents ACLU complains about have long been granted in Europe and continue to be enforceable there, European science appears to progress unimpeded and patients have access to genetic testing.

6. We have heard the concern that scientists doing basic research would be blocked from doing so because of patents. Has this been the experience in the past? What would this proposed amendment to 101 do to alter that?

Concerns about patents interfering with basic research are part of a decades-old debate that never reached resolution or consensus. The question has been extensively studied in the early 2000's and I cite many publications in my written testimony. When the question was systematically studied, the consensus finding was that patents do not interfere with scientific research. I would only add that we have, in a way, conducted a natural experiment over the past 8 years: prior to the recent series of "Section 101 decisions" in the Supreme Court, U.S. rules on patent-eligibility conformed to normal historical standards. Yet despite patents, the U.S. by most accounts for decades had the scientifically most productive biomedical research environment in the world. If patents stifled research, such an effect was not detectable and it would be hard to explain why U.S. science was, in fact, particularly productive in an international comparison. Conversely, *after* the series of recent Supreme Court decisions, we would have expected a veritable explosion of scientific productivity if these now-removed patents had previously presented an obstacle to science. No such effect is visible today either.

7. We hear that patents are not necessary to stimulate research and development. We are told that scientists don't do what they do because of the promise of patents. What role, if any, do patents play in fostering research and development. Won't the availability of public research grants continue to motivate curious people to do science?

I believe in many (though not all) instances public research grants would indeed continue to motivate curious scientists to conduct research and make discoveries. But that is not the point of the patent system. Patents help raise the capital necessary to translate basic science inventions into real-life products; this is something public grants cannot achieve.

8. Should we be concerned about companies patenting our genomes? What would prevent them from doing this

The Patent Act would prevent them from doing so. The human genome has been extensively studied and is not novel. Moreover, the human genome does not fall within the categories of patentable subject matter because it is not a machine, not an article of manufacture (it wasn't manufactured by anyone), not a composition of matter (it wasn't composed by anyone), and it is not a process either. No judicial exceptions are needed to get the human genome "out" of patentability because the human genome is not "in" to begin with.

9. When Congress considered the America Invents Act, there was concern that patents would prevent patients who had a genetic test from being able to get a second opinion. Congress mandated a study by the Patent and Trademark Office on this question. What was the outcome of that study and what has been the experience since

then? How would this proposed legislation affect that situation?

The two USPTO hearings and the report found that actual demand for confirmatory “re-testing” of genetic diagnostic tests is small to negligible. In instances where there was a medical need for a second test, one was available from other sources or through the original provider. Overall, the study failed to identify systemic problems with the availability of, or access to, confirmatory genetic tests.

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

QUESTIONS FROM SENATOR BLUMENTHAL

1. Striking the appropriate balance between encouraging innovation and protecting consumers is a key goal of our patent system.
   a. **What impact will broadening the subject matter that can be patented have on industry?**
   In the first instance, reform of Section 101 of the Patent Act will conform U.S. standards with internationally-prevailing best practices, meaning that inventions that are patentable in other industrialized countries will also be patentable in the United States. This will help with the orderly dissemination of innovation, provide legal certainty, and help maintain U.S. technological leadership for investment-intensive innovative businesses in technology areas ranging widely from artificial intelligence, telecommunications, business software, to antibiotics, industrial enzymes, and biomarker-assisted methods of medical therapy.
   b. **What impact will broadening the subject matter that can be patented have on consumers?**
   I believe that, in the aggregate, consumers benefit from U.S. patentability standards that conform to internationally-prevailing standards. The question, at bottom, is whether the U.S. patent system should incentivize businesses to compete with ever-cheaper copies of the same basic products, or by out-innovating each other with new, improved, or disruptive innovative products that may be covered by patents. Both hold benefits for consumers and the law should reflect a balance between the two. But in my opinion the encouragement of investment in innovation that is inherent in a well-balanced patent system leads to more consumer choice in the long run, and better promotes overall welfare for consumers.
   c. **Could these reforms increase consumer prices? If so, in what industries or on what products?**
   In the first instance, consumer prices are often driven by competition between alternative or substitutable products, as well as competition between old products and new, innovative products. Generally, the introduction of new, improved products tends to cause a decrease of market prices of old, existing products, and consumer choice will dictate whether the value added by the innovation can command a price premium over the existing, old product. This general analogy works well with products that represent incremental innovation. On the other hand, the kind of invention that is predominantly affected by the current unclear state of Section 101 jurisprudence in the biopharmaceutical space fall more on the side of original or disruptive innovation: first-in class methods of biomarker-assisted medical treatments, or first-ever diagnostic or prognostic methods, or newly-discovered naturally-derived medicinal substances, which represent a jump, not an incremental step, over preexisting technology. For such treatments and tests, the patents that are affected by Section 101 problems are the very patents that make it possible to bring such a product to

market in the first place, and absent the availability for patent protection there may not ever be a product to price.

Senate Committee on the Judiciary, Subcommittee on Intellectual Property

"The State of Patent Eligibility in America, Part II"

June 5, 2019

Questions from Senator Mazie K. Hirono

Responses from Hans Sauer, PhD., Deputy General Counsel and Vice President for Intellectual Property, Biotechnology Innovation Organization (BIO)

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?

Answer: Yes, I do agree with Judges Lourie and Newman 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." While a number of court decisions have contributed to the great uncertainty clouding patent-eligibility, the Court's *Mayo Collaboration Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012) decision catalyzed the mounting instability in this area of the law. It has now been more than seven years since the *Mayo* decision, yet there continues to be unabated uncertainty about the patent-eligibility of many inventions, including in particular biotechnological inventions in the areas of diagnostics, prognostics, biomarker-assisted methods of drug treatment, fermentation products, industrial enzyme technology, and marker-assisted methods of plant breeding.

Congressional intervention is necessary and desirable. BIO acknowledges efforts by the United States Patent and Trademark Office and many lower courts to try to improve predictability in this area of patent law since *Mayo*. However, all of these entities are ultimately bound by the Supreme Court's prior § 101 decisions. Their hands are tied. And one cannot reasonably expect the Supreme Court to step in and remedy these problems. The instability in § 101 jurisprudence is a direct result of the Supreme Court's supra-statutory development of common law exceptions to patent-eligibility. Therefore, a Congressional fix would be the most reliable, effective, and efficient way to remedy the § 101 problems plaguing our patent system and threatening future innovation.

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"?

Answer: The term "field of technology" should be understood to include subject matter that promotes the progress of the useful arts. Subject matter that is not within a "field of technology" is, for example, primarily aesthetic or artistic creations, processes that can only be performed in the human mind, and subject matter existing outside human intervention like human organisms in the natural state. While it is always possible that there will be debate as to what specifically falls within the term "field of technology" it should be understood in context of the proposed legislation to be a broad term.

I do not share the concern that the terms "technological arts" and "technology" are "ever-changing." Of course technology is ever-changing. But that is why Section 101 should serve a broad gate keeping function. Overly prescriptive patent-eligibility requirements would disincentive investment in new types of innovations.

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?

Answer: Our members report significantly less hurdles in addressing patent-eligibility issues in their international patent procurement practices. They also report significantly less uncertainty as to whether their patents will be upheld if challenged on eligibility grounds post-issuance. A prominent example is the disparate treatment of technology invented by Sequenom, which is headquartered in San Diego, CA. Sequenom invented an undoubtedly a great improvement over preexisting methods for diagnosing fetal aneuploidies (chromosomal abnormalities) that reduced significant risks to both pregnant women and their unborn children. In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015) the United State Court of Appeals for the Federal Circuit held that Sequenom's patent was invalid as patent-ineligible. The U.S. Supreme Court subsequently denied Sequenom's petition for review of that decision. In contrast, just this month, a judge in the United Kingdom rejected a patent-eligibility challenge regarding the same technology, affirming the patent-eligibility and patentability of this novel and important innovation. *See* Davis, Sequenom Scores Patent Win Against Ariosa in the UK, IPLaw360 (June 18, 2019), https://www.law360.com/articles/1170416/sequenom-scores-patent-win-against-ariosa-in-the-uk.

What we can learn from this is that, when it comes to patent-eligibility, companies have significantly more certainty as to whether their patents will issue and be upheld in foreign jurisdictions than in the United States. It is very reasonable to expect that this makes securing investment and planning business activities in such foreign jurisdictions less complicated and more reliable. We know that when it comes to patenting of pharmaceuticals, new drugs are often introduced into countries in which robust patent protection is available long before they are introduced into other countries. [Hans – do you have a cite for this?] Because Section 101 affects a great array of technologies, it is important to ensure that our laws are at least as innovation friendly as those in other countries so that we can continue to expect the most pioneering and important inventions be made available in the U.S. as early as possible.

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?

Answer: Claims to methods for hedging against the financial risk of price fluctuation likely would not fall within a "field of technology." Disembodied methods relating to human activity are unlikely to promote the progress of the useful arts.

While it is difficult to analyze whether the requirement that a method for hedging risk be performed on a computer would place such a claim in a "field of technology" without viewing the actual claim, the European Patent Convention (EPC) and its implementation may lend useful guidance. Under Article 52 of the EPC, programs for computers as such are excluded from patentability. But claims to computer programs that contribute a further technical effect are consistently found patentable. *See* Report of the United States Patent and Trademark Office, Patent Eligible Subject Matter: Report on Views and Recommendations from the Public (July 2017), https://www.uspto.gov/sites/default/files/documents/101-Report_FINAL.pdf. With this in mind, one way to evaluate whether a claim to hedging performed on a computer falls within a "field of technology" under the current Section 101 proposal would be to consider whether it contributes a technical effect.

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

Answer: As noted in my response to question 2(c), further study of the implementation of Article 52 of the EPC may prove useful in clarifying the meaning of "field of technology." BIO is currently studying the Section 101 legislative proposal, including the "field of technology" requirement. BIO looks forward to continuing its work with interested member of Congress on further improving this aspect of the proposal if warranted.

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?

Answer: I generally urge caution in listing categories of inventions that should be excluded from patent-eligibility. Any such exclusions from patent-eligibility should be narrow and achieve something that cannot already be achieved with the other requirements of patentability in the statute (35 U.S.C. §§ 102, 103, and 112). In addition to the exclusions noted in the question, exclusions from patent-eligibility should be limited to those that stakeholders generally agree do not promote the progress of the useful arts, such as primarily aesthetic or artistic creations and processes that can only be performed in the human mind.

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?

Answer: I cannot speak to the enforcement of Section 112 with respect to claims for inventions in the high tech space, although I expect that any perceived lack of Section 112 enforcement may be due in part to the high number of these cases terminated at the motion to dismiss or judgment on the pleadings stage under Section 101. That is, because Section 101 has provided a convenient and expedient means to invalidate high tech patents early in these cases, we often do not know how a court would have enforced the provisions of Section 112.

I have observed rigorous enforcement of Section 112 in the life sciences space. There is well-developed jurisprudence concerning written description, enablement (including utility as it relates to enablement), and indefiniteness. Accordingly, I think courts are well-equipped to address Section 112 issues when given the opportunity.

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

Answer: As noted above, my focus is in the life sciences space, not high tech. However, I do note that the proposed changes to Section 112 address functional claiming which is traditionally handled under 35 U.S.C. 112(f). While functional claiming plays a role in claim specificity, it is only but a piece. Limiting the scope of the claims to what was actually invented is usually understood to be accomplished under 35 U.S.C. 112(b).

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

Answer: BIO is currently studying the proposed changes to Section 112(f). The proposed changes will likely increase the ability of competitors to design around patent claims, particularly if the legislation is retroactive. Accordingly, if the changes are adopted, I think they should be prospective only in order to provide patent applicants the full ability to draft their patent applications and claims with the new provision and its potential effects on enforceability and invalidity in mind. I am hopeful that BIO will be able to continue working with interested members of Congress on these proposed changes once we have had time to further study the proposal.

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?

Answer: No, the proposed changes to Section 101 and the additional provision abrogating cases establishing judicial exceptions to Section 101 would not do away with the doctrine of obviousness-type double patenting. Double-patenting is often discussed in terms of statutory double patenting and non-statutory obviousness-type double patenting. The statutory double patenting prohibition arises from the portion of Section 101 that specifies that an applicant may obtain "a patent" (i.e., one patent) for a given invention or discovery. Courts have interpreted this to mean that an applicant cannot have more than one patent on a given invention or discovery even if the claims vary slightly but in a patentably-indistinct manner. The proposed changes to Section 101 preserve this "a patent" language ("Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, ***may obtain a patent therefor***, subject to the conditions and requirements of this title." (emphasis added)). Non-statutory obviousness-type double patenting "is a judicially created doctrine grounded in public policy (a policy reflected in the patent statute) rather than based purely on the precise terms of the statute." *In re Longi*, 759 F.2d 887, 892 (Fed.Cir.1985). Accordingly, a change to the language of Section 101 would have no effect on non-statutory double patenting.

While patent-eligibility and double patenting doctrines find their roots in Section 101, they are distinct concepts. Accordingly, abrogating cases that establish or interpret judicially created exceptions to subject matter eligibility will have no effect on the prohibition against double patenting. The Section 101 cases to be abrogated identify categories of subject matter that are ineligible for patenting, meaning that ***no*** patent may be obtained on that subject matter. On the other hand, double patenting affirmatively permits patenting of subject matter, but does so in a way such that there can be only ***one*** patent for a given invention.

Although the proposed legislation, including the intent to abrogate certain cases relating to Section 101 patent-eligibility, will not adversely impact double patenting doctrines, I can report that double patenting jurisprudence has experienced new developments in recent years. BIO would welcome the opportunity to work on double patenting legislation with interested members of Congress.

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?

Answer: Ideally, any Section 101 legislation would not have an adverse effect on already-issued patents, as the intent of the legislation is to correct unduly narrow judicially-created exceptions to patent-eligibility. Nonetheless, the question correctly acknowledges the possible problems associated with a retroactive application of Section 101 legislation.

A patent should be considered a private property right for purposes of the Due Process Clause and the Takings Clause. "A patent is property." *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 187 (1933). It is freely assignable, *Transparent-Wrap Mach. Corp. v. Stokes & Smith Co.*, 329 U.S. 637, 642 (1947), and is treated "a species of property" "of the same dignity as any other

property." *Id.* at 643; *see also Cleveland v. United States*, 531 U.S. 12, 23 (2000) (re-affirming that a patent is protected "property"); *Consolidated Fruit-Jar Co. v. Wright*, 94 U.S. (4 Otto) 92, 96 (1876) ("A patent for an invention is as much property as a patent for land."); *Seymour v. Osborne*, 78 U.S. 516, 533 (1871) ("Inventions secured by letters patent are property in the holder of the patent, and as such are as much entitled to protection as any other property, consisting of a franchise, during the term for which the franchise or the exclusive right is granted."); 35 U.S.C. § 261 ("[P]atents shall have the attributes of personal property."). Indeed, in *Florida Prepaid Postsecondary Ed. Expense Bd. v. College Savings Bank,* 527 U. S. 627, 642 (1999), the Supreme Court made clear that patents are "within the 'property' of which no person may be deprived by a State without due process of law."

Under Supreme Court jurisprudence, patents should be considered constitutionally protected forms of private property, equivalent to other undisputed forms of property, under the Fifth Amendment's Takings Clause. "A patent 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." *Horne v. Department of Agriculture*, 135 S. Ct. 2419, 2427 (2015) (quoting *James v. Campbell*, 104 U.S. 356, 357- 58 (1881)). The Court has opined that it is "long [] settled" that "a patent is property, protected against appropriation both by individuals and by government" under the Takings Clause. *HartfordEmpire Co. v. United States*, 323 U.S. 386, 415 (1945). In *Cammeyer v. Newton*, 94 U.S. (4 Otto) 225 (1876), the Supreme Court explained that "an invention [secured by a valid letter-patent] is property in the holder of the patent, and . . . is as much entitled to protection as any other property." *Id*. at 234-35 (citations omitted); *see also McCormick Harvesting Mach. Co. v. C. Aultman & Co.*, 169 U.S. 606, 609 (1898) ("It has become the property of the patentee, and as such is entitled to the same legal protection as other property."). In *Crozier v. Fried, Krupp Aktiengesellschaft*, 224 U.S. 290 (1912), the Supreme Court applied to the patent context "the well-established and indeed elementary requirements in favor of property rights essential to be afforded in order to justify the taking by government of private property for public use." *Id*. at 306.

Given the foregoing, the safest course would be to make the legislation prospective. The Supreme Court has made clear that statutory enactments or repeals after a patent has issued "can have no effect to impair the right of property then existing in a patentee." *McClurg v. Kingsland*, 42 U.S. (1 How.) 202, 206 (1843). Although Congress has broad powers under the Intellectual Property Clause, subsequent statutory changes may "not take away the rights of property in existing patents." *Id*. At the time applicants filed for already-issued patents, they had the reasonable expectation that the validity of their patents would be adjudicated under the Patent Statute as it then existed. Indeed, Section 101 specifies that obtaining a patent would be "subject to the conditions and requirements of this title." There is no indication in that text to suggest that a patent applicant would be subject to a future change in the statute. "Where rights secured under the laws vest, they are protected from subsequent attempts by government to retroactively undo the law and legal expectations that secured those rights." Randolph J. May & Seth L. Cooper, The Constitutional Foundations of Intellectual Property 131 (2015).