Questions for the Record

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United States Senate Committee on the Judiciary
Subcommittee on Intellectual Property

Hearing on

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

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QUESTIONS FROM SENATOR RICHARD 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?**

Industry is not monolithic. Many in various industries oppose broadening patent eligibility because it would do harm to or may even destroy their business models. In the gene sequencing and testing market, companies like Color[1] and Invitae[2] have said that broadening subject matter eligibility by eliminating the exceptions for laws and products of nature will upend the entire industry of diagnostic testing. It will lead, again, to thickets of patents on various genes, mutations of genes, segments of genes, or naturally occurring associations between gene mutations and diseases.

The effect will be to hinder the goal of providing genetic testing and targeted therapies at human population scale in at least two ways. First, patient access to testing will decrease because the cost of testing will increase as a direct result of the need to compensate patentees. Second, the quality and comprehensiveness of testing could stagnate, as could the continued development of therapeutic treatments. Currently, as people are tested or their whole genomes are sequenced novel mutations are discovered on a near constant basis and that information is immediately shared with databases like ClinVar,[3] which is run by the National Institute of Health, quickly enabling research to be conducted. Exclusive rights to information about particular mutations, segments, or combinations of genes would incentivize the rights holders to restrict access and information sharing, hindering the development of a more complete understanding of genes, their functions, and their associations with disease. Such hindrance could, in turn, slow the development of new precision therapies. Exclusive rights can also limit the comprehensiveness of testing and sequencing if permission or licenses must be acquired to examine certain patented gene segments, combinations, or mutations.

Prior to the Supreme Court's *Myriad* decision, the Secretary of Health and Human Services' Advisory Committee on Genetics, Health and Society (SACGHS) issued a report finding that patents covering genetic material are unnecessary to protect scientific innovation, and harm patient welfare by limiting access to and reducing the quality of potentially lifesaving genetic testing.[4] The report found that the patent monopoly *does not* play a major role in driving genetic

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[1] Othman Laraki, *Proposed Patent Legilslation Would Block Research, Stifle Innovation, and Harm Patients*, STAT (June 6, 2019), https://www.statnews.com/2019/06/06/proposed-patent-legislation-stifle-innovation-harm-patients/.
[2] *The State of Patent Eligibility in America: Part III: Hearing Before the Subcommittee on Intellectual Property of the S. Comm. On the Judiciary*, 116th Cong. (2019) (statement of Sean George, Ph.D., Chief Exec. Officer, Invitae Corp.), https://www.judiciary.senate.gov/imo/media/doc/George%20Testimony.pdf.
[3] Nat'l Inst. Of Health, ClinVar, https://www.ncbi nlm nih.gov/clinvar/.
[4] SACGHS, *Gene Patents and Licensing Practices and their Impact on Patient Access to Genetic Tests* (2010). *See also*, Nele Berthels, et al., *Impact of Gene Patents on Diagnostic Testing: A New Patent Landscapting Method Applied to Spinocerebellar Ataxia*, 2011 Eur. J. Hum. Genetics 1; Heidi L. Williams, *Intellectual Property Rights and Innovation: Evidence from the Human Genome* 26 (Nat'l Bureaus of Econ. Research Working paper 16,213, 2010); Mildred K. Cho, et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3-8 (Feb. 2003) (finding that clinical geneticists feel their research is hindered by patents).

research. And, perhaps most importantly for the Subcommittee's interests, the report found evidence that gene patents serve the opposite ends of the patent system: gene patents impeded innovation. Eighty scientists led by Drs. Harold Varmus and David Baltimore have written a letter expressing concerns that the current proposal would increase the number of patents, thereby having an unintentional negative effect on the conduct of basic scientific research.[5] They are urging Congress, before taking any action to expand patent-eligibility as the draft proposal would, to direct the National Academy of Science to study the issue and make recommendations.

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

For gene sequencing, testing, and therapies, patients could see higher prices and reduced access to targeted therapies and comprehensive testing. On the day before the *Myriad* decision, testing for BRCA1/2 mutations could cost $4000. On the day the decision was handed down at least five labs announced that they would enter the market, providing competition, driving down costs and catalyzing the golden age of targeted therapies that we are currently experiencing.[6] Today, through a company like Color or Invitae a patient can receive comprehensive testing for $250 dollars.[7] At Color, if a patient tests positive for a harmful mutation, the company offers testing to all of that patient's first-degree family members for $50 dollars each. Access to the information is cheaper and the information itself is more valuable in large part because the absence of patent-monopolies has encouraged industry competition and information sharing that improves both the prices and the testing itself.

An estimated 80% of people with pathogenic mutations are unaware.[8] Companies like Color and Invitae are trying to change that by offering affordable testing to all who want it. Moreover, the National Institute of Health has undertaken the All of Us program with a goal of sequencing more than one million people's genes, 80% of whom will be from underserved populations, as most of what we currently know about genes comes from sequencing the genomes of Caucasian people.[9] The proposed reforms could hinder that process, slowing that important work.

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

Yes. Patents impact prices by granting a 20-year monopoly over the fruit of the inventive process.[10] The Constitution provides for patent-protection (as well as other intellectual property

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[5] Letter from Drs. David Baltimore, Harold Varmus, et. al, to Sen. Thom Tillis, Sen. Chris Coons, Rep. Doug Collins, Rep. Hank Johnson, and Rep. Steve Stivers (June 23, 2019).

[6] Andrew Pollack, *After Patent Ruling, Availability of Gene Tests Could Broaden*, NY TIMES (Jun. 13, 2013), https://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-of-genetic-tests-could-broaden.html.

[7] *The State of Patent Eligibility in America: Part III: Hearing Before the Subcommittee on Intellectual Property of the S. Comm. On the Judiciary*, 116th Cong. (2019) (statement of Sean George, Ph.D., Chief Exec. Officer, Invitae Corp.), https://www.judiciary.senate.gov/imo/media/doc/George%20Testimony.pdf.

[8] Bill Hathaway, *Eight of Ten People with Cancer Risk Genes Don't Know It*, SCIENCE DAILY (Sept. 21, 2018), https://www.sciencedaily.com/releases/2018/09/180921113441 htm

[9] Nat'l Inst. Of Health, All of Us, https://allofus nih.gov/.

[10] ACLU Comment, Request for Comments and Notice of Public Hearing on Genetic Diagnostic Testing, USPTO, Docket No. PRO-P-2012-0003, at 3 (Mar. 26, 2012).

rights) because the founders adjudged these rights to be worthwhile in order to encourage innovation and the advancement of science and other useful arts to the benefit of the public.[11] Follow-on innovation results from others' access to information about the patented matter, allowing them to innovate around the patent, or improve upon the patented invention once it becomes part of the body of public knowledge when the patent expires. However, "'monopolization of [the basic tools of scientific and technological work] through the grant of a patent might tend to impede innovation more than it would tend to promote it,' thereby thwarting the primary objective of the patent laws."[12] To address that risk, the Supreme Court has long recognized important exceptions to the patent eligibility statute.[13] Laws of nature, natural phenomena, and abstract ideas are not patentable.[14]

Under these reforms, prices could rise across all industries and products in which subject matter currently not patent-eligible would be patented. Low cost testing for genetic mutations became possible on the day the Supreme Court decided that human genes, isolated from the body, are products of nature that are not eligible to be patented. This proposal would reverse that decision. Because of the Supreme Court's decisions in *Mayo v. Prometheus Labs* and *Association for Molecular Pathology v. Myriad*, when cell free fetal DNA was discovered in maternal blood, multiple companies could develop tests to detect fetal abnormalities in that DNA, obviating the need for more invasive and dangerous testing. That competition in offering testing meant not just lower prices for patients but the development of technological alternatives in testing that may not have been possible if incremental improvements were being made by only one exclusive rights holder. The proposed reforms would overturn those decisions and would have allowed one firm to provide testing, arguably raising prices, decreasing testing quality, and decreasing the rapidity of the adoption of these revolutionary tests.

Rewriting Section 101 as the draft legislation proposes will raise the price of healthcare in many ways. Scientists, researchers, and small companies could be forced to pay royalties to patent-holders on patented naturally occurring correlations, human genes isolated from the body, and abstract concepts, if they are allowed to engage in research at all. Patent-holders will be able to exclude others from whole fields of knowledge and will charge monopoly prices to the public. Patients will lack access to confirmatory testing. Market-participants will be unable to improve upon inventions or testing accuracy during the patent-period. Each of these effects is contrary to the purpose of the patent law. Current Supreme Court precedent provides the solution. Laws of nature, natural phenomena, and abstract ideas are not patent-eligible and they should not be made so legislatively.

[11] U.S. Const. Art. 1, §8, cl.8.
[12] Alice Corp. Pty. Ltd. v. CLS Bank Intern., 573 U.S. 208, 216 (2014)(quoting Mayo Collaborative Services v. Prometheus Labs., 566 U.S. 66, 71 (2012)).
[13] Assoc. for Molecular Pathology v. Myriad, 569 U.S. 576, 589 (2013).
[14] *Id*.

QUESTIONS FROM SENATOR MAZIE K. HIRONO

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

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

At this juncture, it is more prudent to allow courts to continue to work things out. Article I, Section 8, Clause 8 and the First Amendment limit the intellectual property laws.[15] The judicial exceptions to Section 101 of the Patent Act are best understood as compelled by the Constitution. As the Court has explained, "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work."[16] These "basic tools" must remain ineligible for patenting, because their monopolization "might tent to impede innovation more than it would tend to promote it,"[17] contravening Article I, Section 8, Clause 8's directive to "promote the Progress of Science and the useful Arts." Furthermore, the ability to gather information and think without constraint is central to human autonomy and a cornerstone of First Amendment doctrine. [18] Patents claiming exclusive rights to abstract ideas, laws of nature, and natural phenomena conflict with that doctrine directly. [19] A legislative proposal wiping away the court decisions explaining the patent-eligibility exceptions for laws of nature, products of nature, and abstract ideas would expand patent-eligibility and allow the Patent Trademark Office (PTO) to issue patents that violate these constitutional provisions by permitting government-sanctioned monopolies to private parties over fields of knowledge, limiting information sharing and free experimentation. In short, it would disrupt the delicate balance courts have been trying to strike to provide the proper scope of patent-eligibility under the Constitution.

Furthermore, by eliminating over a century's worth of doctrine, the proposal would introduce even greater uncertainty into the patent system than that which is currently alleged to exist. The patent bar has been so vocal in its opposition to these decisions because the courts have been invalidating patents properly under the precedent. The problem is not these decisions, but the failure of the PTO for decades to enforce the case law. It appears, therefore, that the patent bar is

[15] Brief for Petitioners, The Assoc. for Molecular Pathology, et. al, 566 U.S. 66 (2012) (No. 12-398); Brief for the Am. Civil Liberties Union, as Amicus Curiae Supporting Petitioners, 573 U.S. 208 (2014) (No. 13-298); Brief for the Am. Civil Liberties Union, as Amicus Curiae Supporting Petitioners, at 8, 566 U.S. 66 (2012) (No. 10-1150).
[16] Gottschalk v. Benson, 409 U.S. 63, 67 (1972).
[17] Alice Corp. Pty. Ltd. v. CLS Bank Intern., 573 U.S. 208, 216 (2014)(quoting Mayo Collaborative Services v. Prometheus Labs., 566 U.S. 66, 71 (2012)).
[18] *See* Whitney v. California, 274 U.S. 357, 375 (1927 (Brandeis, J., concurring) (stating that the First Amendment protects the "freedom to think as you will and to speak as you think"); Laurence Tribe, *American Constitutional Law* § 12-1 (2d ed. 1988); Thomas Emerson, *The System of Freedom of Expression* 6 (1970).
[19] *See*, Intellectual Ventures, LLC v. Symantec, 838 F. 3d 1307, 1322 (Fed. Cir. 2016) (Mayer, J. concurring) (arguing that "patents restricting constricting essential channels of online communication run afoul of the First Amendment); In re Bilski, 454 F. 3d 943, 1004 (Fed. Cir. 2008) (Mayer, J. concurring) (noting that patents on methods of conducting business raise "significant First Amendment concerns by imposing broad restrictions on speech and the free flow of ideas.").

concerned about the outcome of these cases, not any alleged confusion with their application, and clarity in the application of the case law will come with time. The Supreme Court issued its decision in *Alice v. CLS Bank* five years ago. Lower courts are only just beginning to apply the test and develop a consistent approach to its central holdings. Additional time is necessary to identify the scope of the issues, if any, and to craft properly and narrowly tailored solutions, again, if any are necessary to incentivize 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"?

No. The draft legislation contains no definition of "field of technology." Fifty years ago it may have been difficult, if not impossible, to envision examination of the human genome as a field of technology. It is therefore nearly impossible to predict what, fifty years from now, will also be a "field of technology" in which useful discoveries might be patent-eligible and, therefore, patentable. "Field of technology," without more, appears to be a potentially meaningless limitation on subject matter eligibility.

    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?

I am not well-versed in the patent laws of either the European Union or China or in their "technology" requirements and hesitate to provide answers. I do suggest that the Subcommittee solicit the advice and expertise of Shobita Parthasarathy, a professor at the University of Michigan, whose perspective and expertise will be helpful as the Subcommittee thinks through these issues.

One thing worth noting here is that there is nothing stopping a patentee in the United States from also obtaining intellectual property rights in other jurisdictions where they would seek to market their invention. Indeed, many do, regardless of where the event of invention occurred. Many foreign companies, entities, and governments also hold U.S. patents.[20]

    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?

This depends entirely on how the term "technology" is defined and the bill does not provide a definition. One possible definition of technology is "a capability given by the practical

[20] PTO, *Foreign Applicants for U.S. Patents*, https://www.uspto.gov/patents-getting-started/general-information-concerning-patents#toc-foreign-applicants-for-u-s-patents.

application of knowledge."[21] Another possible definition is "a manner of accomplishing a task especially using technical processes, methods, or knowledge."[22] It is at least arguable that use of a computer is a manner of accomplishing a task using a technical process and that using a computer to perform a method of hedging risk would be an "invention or discovery that provides specific and practical utility in any field of technology through human intervention." Without the abstract idea exception to patent-eligibility currently embodied in the Supreme Court's interpretation of Section 101, the questions resolved by the Supreme Court's *Bilski* decision would be unresolved once again.

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

Explicitly preserving the exceptions to patent-eligibility currently embodied in Section 101 doctrine in any legislation amending that provision would improve clarity.

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 debate about the proposal's application to genes was never about whether the proposal would apply to genes when they exist in the human body. The debate in *Myriad* was not about genes when they are "in the body," but about the PTO's policy of granting patents on "isolated DNA" (DNA isolated from the cell), and related broad methods of comparing genetic sequences. The PTO argued, as did Myriad, that the human intervention in "isolating" DNA justified the patents on isolated DNA.[23] This was the argument the Supreme Court rejected, but that the draft bill would permit as sufficient justification for patents. In *Myriad*, the Supreme Court unanimously concluded that the location and order of the nucleotides that make up BRCA1 and BRCA2 existed in nature and the process of isolating them from the genome did not significantly alter the genes from their natural state. Myriad did not invent the genes or add anything to them.[24] For those reasons, the court found that genes, when isolated from the human body through human intervention, are products of nature and cannot be patented, even when isolated from the body by processes of human invention.

To be clear, the patents that were approved by the PTO before the Supreme Court decision were on human genes. These patents covered thousands of genes[25] and the isolation of these genes/DNA did not change the fact that the patents claimed human genes.

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[21] *Technology*, MERRIAM WEBSTER DICTIONARY (ONLINE ED. June 25, 2019), https://www.merriam-webster.com/dictionary/technology.
[22] *Id*.
[23] Assoc. for Molecular Pathology v. Myriad, 569 U.S. 576, 589 (2013).
[24] *Id*. at 593-94.
[25] Jeffrey A. Rosenfeld and Christopher E. Mason, *Pervasive Sequence Patents Cover the Entire Human Genome*, GENOME MED. (Mar. 25, 2013), https://www ncbi nlm nih.gov/pmc/articles/PMC3706854/.

The fact that the genome now has been published also would not mitigate the potential harmful effects of expanding patent-eligibility to allow for the patenting of isolated genes/DNA once again. We know that variants are continuously being identified, as well as connections between portions of DNA with various conditions, etc..[26] If the prohibition on patenting laws of nature, products of nature, and abstract ideas is erased, there is nothing in patent law that would categorically stop these types of patents in the future (as evidenced by the fact that they were issued before the Supreme Court's decisions). While it is true that, if the proposal were enacted, Myriad wouldn't be able to suddenly re-assert the patents that were invalidated, it and many others could seek patents on new variants, genetic correlations, etc. that they identify if the draft bill is adopted. The point of the *Myriad* litigation was to end that practice.

Consequently, to properly address and preserve the Supreme Court's holding in *Myriad*, any legislation should preserve the current judicial exceptions to patent-eligibility for products of nature, which the Supreme Court interpreted isolated human genes to be. Furthermore, the decisions in *Mayo v. Prometheus*, invalidating a patent that claimed a law of nature, and *Alice v. CLS Bank*, invalidating a patent that claimed an abstract ideas, like *Myriad*, are best understood as compelled by both Article 1 Section 8 of the Constitution and the First Amendment, as noted above. The draft bill wiping away these decisions will expand patent-eligibility and allow the PTO to issue patents that violate these constitutional provisions by permitting government-sanctioned monopolies to private parties over fields of knowledge, limiting information sharing and free experimentation. Therefore, in addition to preserving the product of nature exception, any legislation should preserve the current judicial exceptions to patent-eligibility for laws of nature and abstract ideas as well.

Eighty scientists led by Drs. Harold Varmus and David Baltimore have written a letter expressing concerns that the current proposal would increase the number of patents, thereby having an unintentional negative effect on the conduct of basic scientific research.[27] They are urging Congress, before taking any action to expand patent-eligibility as the draft proposal would, to direct the National Academy of Science to study the issue and make recommendations. Any changes to the patent-eligibility statute or its existing doctrinal interpretations should be informed by clear, independent, and verifiable evidence that the proposed change would solve an identified harm to innovation or to the progress of science and the useful arts.

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

    a. Are these valid complaints?

The ACLU does not have a position on whether or to what extent Section 112 is consistently enforced with respect to claims for inventions in the high tech space.

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[26] *See The State of Patent Eligibility in America: Part III: Hearing Before the Subcommittee on Intellectual Property of the S. Comm. On the Judiciary*, 116th Cong. (2019) (statement of Sean George, Ph.D., Chief Exec. Officer, Invitae Corp.), https://www.judiciary.senate.gov/imo/media/doc/George%20Testimony.pdf.

[27] Letter from Drs. David Baltimore, Harold Varmus, et. al, to Sen. Thom Tillis, Sen. Chris Coons, Rep. Doug Collins, Rep. Hank Johnson, and Rep. Steve Stivers (June 23, 2019).

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

The proposal's tightening of Section 112's specification requirements do not alleviate ACLU's concerns with the proposal overall.[28] Even with language narrowing the breadth of individual patents, our concerns remain because the overall effect will be to eliminate the principle that it is in the public interest that certain building blocks of human innovation should not be reserved to anyone's exclusive use.

When the Patent Office adopts an unlawful policy of granting certain categories of patents – e.g., on human DNA – Section 101 must be robust in order to disallow these patents at an early stage in the litigation. Section 112 analysis is case-specific and would not result in a determination that an entire category of patent violates the law.

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

The ACLU takes no position on the effects of the proposed changes to Section 112's specification requirements, except to the extent that we believe those changes would not resolve the fundamental issues raised by the proposal to eliminate the current eligibility exceptions for laws of nature, products of nature, and abstract ideas.

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?

It is unclear whether the doctrine prohibiting obviousness-type double patenting would be abrogated by the proposal, because it is unclear whether that doctrine is rooted within the Section 101 precedents that the draft would explicitly abrogate. This lack of clarity exemplifies another danger inherent in the proposal to amend Section 101 and to abrogate over 150 years of court precedent interpreting and explaining the law of nature, product of nature, and abstract idea

[28] Section 112(f) would be amended to read "An element in a claim expressed as a specified function without the recital of structure, material, or acts in support thereof shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." Press Release, Sens. Coons and Tillis and Reps. Collins, Johnson, and Stivers release draft bill text to reform Section 101 of the Patent Act (May 22, 2019), https://www.coons.senate.gov/newsroom/press-releases/sens-coons-and-tillis-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act.

exceptions to patent-eligibility. There may be other doctrines beyond the ones specifically mentioned that could be affected by the proposed changes. All potential consequences should be identified and assessed before any changes to the current eligibility statute are adopted.

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?

The ACLU does not take a position at this time on the Due Process or Takings Clause implications of changing Section 101 and applying it retroactively to already-issued patents. However, applying such an extraordinary change retroactively could allow the reinstatement of patents that even the proposal's sponsors would disagree with. For instance, the decision in *Myriad* set precedent invalidating all patents that claimed isolated DNA, even those not subject to the litigation. Retroactive application of Section 101 reform as currently drafted could revive disputes regarding some of those patents, though the proposal's sponsors have said that is not their intention or their policy goal.