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Tillis and Coons: What We Learned At Patent Reform Hearings (<https://www.tillis.senate.gov/2019/6/tillis-and-coons-what-we-learned-at-patent-reform-hearings>)

The United States has long been a nation of innovators and entrepreneurs. The American people's ability to create solutions to problems that evaded others for centuries has propelled our unrivaled technological, economic and military leadership. This ability to generate exciting breakthrough innovations is due in large part to our founders' decision to harness the creative genius of American inventors through strong intellectual property laws.

If you have watched the popular prime-time show "Shark Tank," you have probably seen that the ability to secure patent protection plays a vital role in securing funding for new ideas. A patent can easily make or break the dreams of an

entrepreneur. That same patent-protection calculus plays out in equally high-stakes boardroom meetings, as investors and executives decide how to allocate limited resources.

As one former director of the U.S. Patent and Trademark Office explained to the Senate Judiciary Committee's intellectual property subcommittee, which we lead together, "inventions deemed eligible today drive tomorrow's jobs, national competitiveness, economic prosperity, and even national security."

But a critical question is: What is patent eligible today? Over time, courts have clouded the line to exclude critical medical advances like life-saving precision medicine and diagnostics. Recent decisions have also made it difficult to predict whether exciting and important technologies like artificial intelligence make the cut.

For that reason, we have engaged in thorough, thoughtful, bipartisan and bicameral legislating. Most recently, the Senate IP subcommittee held three public hearings on the state of patent eligibility, following the release of draft legislative text with Reps. Hank Johnson, D-Ga., Doug Collins, R-Ga., and Steve Stivers, R-Ohio, to serve as the basis for discussion. We heard from 45 witnesses, ranging from inventors to scholars, patient advocates to trade groups, former USPTO officials and the former chief judge of the Federal Circuit to business leaders. We appreciate the feedback we received. Some like what we're doing, and some don't, but it was important to us that everyone had the opportunity for their views to be heard.

The hearings reinforced what we've been hearing for years – the U.S. patent system with regard to patent eligibility is broken and desperately needs to be repaired. The U.S. Supreme Court has confused and narrowed Section 101 of the Patent Act to the point that investors are reluctant to pursue the innovations that propel our country forward. We heard about studies showing that investors familiar with the current lack of clarity invest less in critical research and development in areas like medical diagnostics and artificial intelligence, at least in the United States.

The current director of the USPTO recently noted that inventors and judges alike struggle on a daily basis to determine “what is in and what is out” and wondered whether even Thomas Edison’s famous phonograph patent would survive the courts’ recent tests for eligible subject matter.

Likewise, two former USPTO directors testified to this disturbing lack of clarity, and the former chief judge of the U.S. Court of Appeals for the Federal Circuit characterized patent eligibility as “the number one problem in our patent system today.” He noted that, despite having personally drafted over 800 patent opinions, he struggled to predict the results in any given case. His view is shared by current Federal Circuit judges, one of whom recently wrote that the lack of clarity in the law made it “near impossible to know with any certainty whether the invention is or is not patent eligible.”

If these experts can’t figure it out, how can we possibly expect inventors, executives or investors to make informed decisions? If they can’t be confident that they will recoup the time and money required to bring a new product to market, won’t they stop investing? Indeed, that is exactly what we heard at the hearings. When organizations like the Cleveland Clinic Foundation express concerns about developing new medical diagnostic technology because of the patent system, we should all take note.

Another point that came through loudly and clearly was the necessity for Congress to intervene. Witnesses explained that the Federal Circuit and the USPTO cannot salvage this situation because they are constrained by recent Supreme Court precedent.

We also heard about the Supreme Court's denying over 40 petitions for certiorari on this topic since its disruptive decision in the Alice case five years ago. So dire is the situation that several sitting Federal Circuit judges have called on Congress to act. In one prominent case, for example, the court invalidated claims to a revolutionary

prenatal test for Down syndrome and other conditions that allowed doctors to avoid invasive procedures. As one judge lamented, he saw “no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible.”

We agree. Without the guarantee of patent protection to compensate for the decades and hundreds of millions of dollars necessary to bring a U.S. Food and Drug Administration-approved product to market, who will find tomorrow’s cures? As one patent expert testified, those undiscovered treatments are “not available to the patient at any price.”

Not everyone agrees that reform is needed. Some witnesses cautioned that the status quo provides a mechanism to terminate baseless patent infringement lawsuits quickly and efficiently. We hear these concerns, and we invite suggestions to mitigate them. We cannot permit the courts, however, to destabilize our patent system for the sake of deterring nuisance litigation. We can consider legislative provisions directly targeting the behavior of bad actors, and we welcome additional feedback on this point.

Several witnesses urged us not to permit patenting of scientific research per se, mere abstract ideas and nontechnical methods of doing business. It is not our intent to do so. To be clear, our patent system was never intended to protect artistic creations, methods of investing, or items found in nature. Our

framework attempts to provide a positive definition of eligibility to focus courts on subject matter that is eligible while eliminating the confusing and unreliable judicially created tests that dissect patent claims looking for “abstract ideas” and “inventive concepts.”

Our proposed abrogation of the court cases establishing those tests does not mean that the results of each case should have turned out differently. While some decisions have wrongly excluded important subject matter from the patent system, others reached the correct result only after navigating an unnecessarily confusing maze of precedent.

In addition, as several witnesses reminded us, patent eligibility is far from the only requirement for obtaining a patent. Existing laws preclude patents on ideas that would have been obvious or are not adequately described and clearly claimed. It is the effort to collapse these distinct inquiries into the threshold evaluation of eligibility under Section 101 – which used to serve only as a “coarse filter” – that has led to many of the problems we heard about over the past two weeks.

That said, we want to ensure that these provisions pull their weight. To that end, we proposed amendments to other portions of the Patent Act to guard against the types of overly broad, functional patent claims frequently cited by those concerned about abuse.

At bottom, changes are needed. We must fix a system in which something as seemingly technical and concrete as a networked charging station for electric vehicles was recently struck down as ineligible for patent protection regardless of whether it was novel – an example cited by multiple witnesses.

Others, including American innovation leaders like Qualcomm Inc. and International Business Machines Corp., testified that the uncertainty surrounding patent eligibility is affecting the development of technologies like 5G, quantum computing and artificial intelligence – innovations that not only promise to make life better for Americans, but also to protect our national security. We heard about how inventions like these are receiving patents in Europe and China, but not in the United States. Why should we cede our competitive edge at this critical juncture?

Even some witnesses advocating against broad reform conceded that there are problems with the current system, particularly in the life sciences. A leading academic who defended some aspects of the status quo nonetheless characterized this area of the law as “a mess,” and a trade association representing high-tech companies opposing reform nonetheless recognized the challenges

facing stakeholders in the life science industry. These admissions reflect the overwhelming concerns expressed to us in recent years about how the courts have discouraged research and development in this area.

Other witnesses, including the American Civil Liberties Union, expressed concerns about the patenting of human genes. As we stated at the hearing, it is not our intent to allow such patents, and several witnesses, including the Association of American Universities and the Intellectual Property Owners Association, disagreed that our proposal would enable that result.

Testimony at the hearings further clarified that – because the entire human genome has been mapped for many years – these concerns are misplaced. That said, we want to be very clear on this point, and we welcome proposals to clarify our proposed legislation.

We do want to incentivize research and development into the exciting prospects of individualized diagnostics and precision medicine, which is tied to genetics. We are working hard to ensure the protections that will enable our innovators to bring these products to market while safeguarding research into the next generation of medical advances.

For example, we are considering a provision that would exempt research and experimentation from infringement liability. This type of exception is common around the world. It would allow basic research to continue unimpeded by patents, which are designed to control commercialization, not stifle research. We will be reviewing any additional suggestions we receive that would promote research without discouraging product development.

The alternative to Section 101 reform would, in our view and the view of many witnesses, suppress research. Multiple witnesses explained that decreased confidence in the patent system to protect their inventions and discoveries triggers resort to trade secret protection. It may seem obvious, but trade secrets require secrecy. They do not permit the free flow of information among competing scientists.

The patent system, on the other hand, is built on a fundamental bargain in which we offer inventors limited exclusivity in exchange for public disclosure of their inventions. That way, others can build upon those discoveries, verify their effectiveness and explore alternative solutions. That is how the system used to work and can work again.

Now that the hearings have concluded, we continue to welcome input from all stakeholders as we consider necessary adjustments before we introduce a bill. In addition to clarifying our proposal regarding the eligibility of gene patents, we will investigate ways to sharpen the “field of technology” requirement to ensure that critical advances like artificial intelligence and medical diagnostics qualify, but not economic transactions or social interactions.

We will also consider ideas for reinforcing Section 112 of the Patent Act, which should operate to prevent inventors from claiming all possible solutions to a problem while also serving to protect inventors against those seeking to profit on trivial modifications.

We know change is needed, and we know that we have additional work to do. We seek your feedback as we craft a legislative solution to support the exciting and often life-saving work of our entrepreneurs and innovators, whether in garages or multimillion-dollar labs. We feel confident that, working together, we can ensure that the United States patent system reclaims its reputation as the gold standard for promoting innovation.

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