The Senate Judiciary Committee Subcommittee on IP Hears Testimony on Proposed Changes to 35 U.S.C. § 101

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Article
6.6.19

On Tuesday, June 4, the Senate Judiciary Committee Subcommittee on Intellectual Property held the first of three hearings on "The State of Patent Eligibility in America," led by Senators Chairman Thom Tillis (R-N.C.) and Ranking Member Chris Coons (D-Del). In his opening statement, Senator Tillis noted that changes may need to be made to 35 U.S.C. § 101 to provide stability and predictability in examination and interpretation of patent claims in light of recent Supreme Court decisions. Senator Tillis indicated that if such changes were not made, the U.S. could lose a competitive advantage as innovation moves to Europe and China, where the issue of subject matter eligibility is much more clearly defined and predictable. He noted the competing interests of the tech industry, who opposes changes to 101, and those in the life sciences who consider the recent Supreme Court jurisprudence to be stifling investment. Senator Tillis acknowledged that non-practicing entities (NPEs) hamper competition, and stressed that both sides would be considered, but that we needed to consider the economy as a whole, and the U.S. as an innovator.

Senator Coons noted that the lack of clarity with respect to section 101 was eroding the U.S. stature as the "gold standard for patents," despite "heroic efforts" by USPTO Director Iancu, who has continued the attempt to provide clarity in the form of patent office written guidance and examples. He indicated that three quarters of investors consider the 101 conundrum to the "most challenging investment issue." Senator Coons referred to the "significantly misleading" article in the Washington Post alleging that the changes would result in patenting genes as they exist in nature, and to a recent case denying claims to what he characterized as a revolutionary non-invasive fetal diagnostic test. He noted that the issue to be considered with respect to patenting products arising from nature would be just how much human intervention is required to obtain the product sought to be patented.

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The first, and perhaps the most compelling witness was former Chief Judge of the Court of Appeals for the Federal Circuit, Paul Michel. Judge Michel indicated that the 101 issue was the "number one problem in patent law," and that he was "chagrined" to say that the courts have created these problems. He characterized the Supreme Court cases as "incoherent, inconsistent and chaotic," and fundamentally flawed in that they conflate sections 102, 103 and 112 with section 101, and ignore how section 101 works as to utility. He noted that as to the Federal Circuit, it was "the luck of the draw" as to which panel you got, and that the choice of panel influences the result an appellant gets. Judge Michel also noted that the Federal Circuit has refused to stand up and go *en banc* to rehear important cases on the issue, and the Supreme Court has likewise refused to grant certiorari to correct or overrule previous precedent. In these previous court decisions, Judge Michel noted that the terms "directed to" and "focused on" had been equated, and that the courts cannot ignore some claim limitations and consider other ones dominant. He was the first of several witnesses to note that the Supreme Court was the "wrong law giver" because patent law is statutory and designated under Article I of the Constitution to Congress. With respect to the implications of these decisions, he noted that this precedent was harming innovation, because if he, as the former Chief Judge on the Federal Circuit, could not predict eligibility, how can executives figure it out? He noted that this is costing the future of our economy waiting for the courts to fix this, and that meanwhile the U.S. is "bleeding badly" because money is going into entertainment rather than innovation, and is going to Europe and Asia where obtaining patent rights is more predictable. Rather than waiting for the courts to fix the problem, he indicated that the much-needed bill would abrogate all the Supreme Court law on this issue. He also cautioned the panel to "beware of slogans" when considering the evidence, presumably referring to opposing positions taken by the tech industry and those opposed to what they and the misleading Washington Post article refer to as the return of gene patenting. Regarding the language of the proposed legislation, Judge Michel cautioned against the use of the word "technology," calling it a "weasel word." This concern was echoed by several other witnesses.

On that issue, Senator Tillis later entered into the record from a professor who indicated that gene patents are not going to return, because all genes are now known after the sequencing of the human genome, and without additional "human intervention" as noted by Senator Coons, such claims would be anticipated under section 102.

Former USPTO Director Todd Dickinson was the second witness, who was the first to refer to section 101 as meant only to be a "coarse filter" that would identify statutory categories of invention, prior to the more rigorous analyses in sections 102, 103 and 112. He noted the previous Diehr and Chakrabarty Supreme Court decisions, and noted that the recent Supreme Court decisions use hindsight to expand narrow exclusions to patentability (e.g., mathematical formulas and algorithms). The broad application of the abstract idea exception to eligibility then leads innovators to pursue trade secrets, rather than patents, which provide the public with critical information regarding these innovations. Mr. Dickinson also referred to the fact that the Federal Circuit has recently noted in its opinions that it does not have to follow the guidelines that were issued by the USPTO in an attempt to provide some predictability to the public. He also noted that he agreed with the proposal that "the provisions of section 101 shall be construed in favor of eligibility."

Another former USPTO Director, David Kappos, was the next witness. He agreed that patent law is a "mess," "irreconcilable," and "incoherent" in view of the Supreme Court cases on 101. He noted, as did other witnesses and the panel chairman, that it is easier to get life science patents in Europe and China, (where they are "stimulating innovation" and "enhancing IP,") which is undermining investment and is critical to national security. In particular, he quoted statistical evidence that inventions relating to artificial intelligence (AI), 5G and quantum computers were overwhelmingly being rejected on 101 grounds, but identical cases were being allowed in Europe and China. Mr. Kappos also referred to 101 as being a "coarse screen" to "limit inventions manifestly lacking utility" and that eligibility should be "a backstop to one in a million cases." Finally, he noted that the USPTO guidelines were not ultimately helping investor concerns, and that the PTO is "at the bottom of the food chain" in being held to deference to the case law. When asked by Senator Coons, Mr. Dickinson and Mr. Kappos both asserted that they do not read the bill as providing for Chevron deference (or Auer deference, which the Supreme Court will be issuing an opinion on in the near future). Both emphasized that the bill should be read as a whole.

Mr. Charles Duan, Director, Technology & Innovation and Senior Fellow at the R Street Institute, was strongly against "gene patenting," noting that technology such as that of Myriad Genetics "shuts down testing," "bullies and suppresses true innovators," and stifles science. He alleged an effect on drug pricing, noted drug patent evergreening, and suggested that gene patents reduce the ability to obtain second opinions and "cut off competition." Mr. Duan suggested that the text of a patent does not always give the public enough information to practice the invention. Mr. Duan asserted that the current language of the bill allows patents on scientific discoveries, leading to the consequences noted here. He also suggested that patent law should lean less in favor of the right to exclude and more towards the right to license. Mr. Duan noted in his testimony that the exception to patent infringement for experimental use is not sufficient, being "very narrow and strictly limited." When asked by Ranking Member Coons whether a robust research exception would address his concerns, Mr. Duan indicated that would be a step in the right direction.

Professor Jeffrey Lefstin from the University of California Hastings College of the Law began by noting that according to current Supreme Court precedent, "gadgets are patentable and scientific discoveries are not." He noted that this precedent discourages innovation and increases trade secrets. Professor Lefstin stated that both inventions and discoveries should be patentable, and that patent rights should go to both those who discover and those who create. He warned that interpretation of section 101 should not be according to "I know it when I see it." He also suggested that the patentability of a "do it on a computer invention" should be resolved under sections 103 and 112, and recommended that the committee look to how Europe's Article 52 considers subject matter eligibility.

Robert Armitage, formerly Senior Vice President and General Counsel for Eli Lilly and Company, noted that without patents, there will be no investment in drugs. He stated that the price of a drug with no patents is $ 0, because the drug does not get to market and does not get to the patient (effectively an infinite cost). As a result of the uncertainty in being able to obtain a patent, the incentive is to seek as many patents as you can (like lottery tickets), and that more patents rather than better patents is not good for the public. He also noted that he was willing to devote all of his help to make sure drug prices do not increase as a result of the bill. Mr. Armitage suggested that what bothered the Supreme Court in rendering its flawed decisions was a fear of pre-empting the future, but that this is really a section 112

issue. He noted that patent "trolls created *Alice*." In reference to the overcompensation to the issue of NPEs, he likened the case law to using bubonic plague as a solution to a housing shortage. Mr. Armitage suggested that, although he supported 112(f) of the proposed bill, "reassuring" interpretative rules would need to be added. He also suggested that the proposed changes to patent eligibility should be both retroactive and prospective in allowing patent owners in previous cases the option to opt out.

Professor David Taylor, Co-Director of the Tsai Center for Law, Science and Innovation, and Associate Professor of Law at Southern Methodist University Dedman School of Law indicated that we are in a state of crisis and that there is confusion in the software arts and incorrect results in the life sciences. He referenced the impact of the crisis on decisions to invest, and that investors consider eligibility. Professor Taylor noted that the "abstract idea" is unintelligible, and that it is the written description requirement of section 112 that limits the breadth of a claimed invention to "possession." He also raised concern regarding section 112(f), noting that providing support for functional claims "could cause encyclopedic disclosures" to cover equivalents. Professor Taylor added that, according to surveys of investors, the recent Supreme Court cases have resulted in decreased investment by those "knowledgeable" (presumably about patent law) and increased investment by those not knowledgeable.

Ms. Sherry Knowles, an IP attorney in private practice and co-author of Unconstitutional Application of 35 U.S.C. § 101 by the U.S. Supreme Court, 18 J. Marshall Rev. Intell. Prop. L. 144 (2018), made the most poignant case regarding the powers granted in the Constitution, and that a "four page handwritten document" is being ignored. She explained that Congress has the whole power to define the metes and bounds of subject matter eligibility by statute, and that the Supreme Court is bound to statutory interpretation. Rather than relying on the plain language of the statute, the Supreme Court is referring back to its own cases, and providing an inconsistent test that brings us back to the time before the 1952 statute. She cautioned that if Congress does not take some action, Congress will continue to lose its constitutionally granted power to the Supreme Court. Ms. Knowles made a powerful case for the eligibility of natural products isolated from nature, noting her own battle over breast cancer and the natural product, Adriamycin, that helped cure her. She hoped that the bill would overturn Myriad, and that "the highest public interest is life itself." She also suggested that the amendments to section 112(f) need further discussion.

Ms. Alex Moss, Staff Attorney at Electronic Frontier Foundation supports the current Supreme Court precedent. She stated that "software after *Alice* is thriving." She disagreed with the notion that the current state of section 101 was "a mess" or "confusing." She told anecdotes of individual inventors who were subject to what she termed "abusive litigation and licensing." Ms. Moss stated investment should be in innovation rather than litigation, and that the holding in Alice empowers district courts to dismiss cases at an earlier stage. In response to Ms. Moss's statements, Senator Coons noted that it is rare that you have areas of law where judges are asking for congressional intervention.

Professor Mark Lemley, Professor of Law and Director, Program in Law, Science and Technology at Stanford University School of Law agreed with the characterization of the current status of section 101 as "frustrating," "a mess," and "uncertain." He noted that different fields of invention had been affected to different extents, medical diagnostics being one of the hardest hit, but that patent trolls had caused a different problem in the software industry. He believed the bill would be helpful to weed out abusive

claims, but that it would be subject to interpretation, particularly with respect to "human intervention" and "field of technology." Senator Coons asked the Professor if he had thoughts on how to draft technology-specific legislation without running afoul of TRIPS. Senator Coons also wondered if the bill would provide for AI growth, and suggested that perhaps other types of IP protection (e.g., copyright) would be a "better fit." Professor Lemley expressed his concern that, although Senator Coons clarified that the proposed bill was not intended to overrule *Myriad*, the bill could currently be read as doing so. He also noted the need to replace or resolve the issue of, for example, existing judicial tests that would be overruled by the proposed bill.

Mr. Michael Rosen, Adjunct Fellow at American Enterprise Institute noted that two-thirds of biotech applications were being rejected under section 101. He agreed with the elimination of the word "new" from the proposed bill, and believed that limitations that were "well understood, routine and conventional" should be weeded out under section 103. He believed the consideration of "practical application" as to section 101 would accommodate future innovation.

Professor Paul Gugliuzza, Professor of Law at Boston University School of Law argued that gene patents hinder the development of diagnostics. He believed the state of patent law has improved with the AIA, and agreed with the assertions of Ms. Moss that the current state of the law on section 101 allowed issues to be decided early and saves litigation costs. He also pushed back on the contention that the Supreme Court was incapable of addressing the issue. Professor Gugliuzza cited two pending certiorari petitions in the Vanda and Berkheimer cases, and the fact that the Supreme Court has called for the solicitor general's views. He believed the Committee's interest in patent eligibility could spur the Supreme Court to address previous precedent. Professor Gugliuzza specifically emphasized the benefit of the system until now to the development of information technology.

Professor Joshua Sarnoff, Professor of Law at DePaul University referred to the 101 problem as a separation of powers issue. He believes that the problem is resulting in patents going to foreign entities. He emphasized the need for legislative clarity. Professor Sarnoff suggested that one option would be to mandate that the Federal Circuit accept en banc hearings. He also suggested that specialized judges be used, and that juries should not be necessary if sections 101, 102, 103 and 112 were considered questions of law with subsidiary questions of fact. Professor Sarnoff asserted (possibly in response to Professor Gugliuzza and others) that the focus should not be on how claims are litigated, but on having certainty from the beginning on whether claims are valid or not.

Mr. Patrick Kilbride, Senior Vice President, Global Innovation Policy Center at the U.S. Chamber of Commerce noted that the goal should be to allocate resources, and that patents help that allocation by creating private property rights. He further noted that investment transactions only occur when there is that patent property right, and that we should return to such core principals. Mr. Kilbride acknowledged that the PTO has tried to help with guidance, but that the international IP index indicates that there has been an erosion of predictability. He also contrasted the current U.S. situation to that of China, where they invest in the mechanics of IP.

Professor Adam Mossoff, Professor of Law, Antonin Scalia Law School at George Mason University also spoke of patents as property rights that cause economic growth. He provided statistics demonstrating the extreme over-application of the Alice-Mayo test, and noted the Supreme Court's unwillingness to fix the issue. He agreed that Congress should amend section 101 to abrogate Alice and Mayo. Professor Mossoff also stressed that patents were being allowed in Europe and China that were not being allowed in the U.S. Like various other witnesses, he described section 101 as a "rough general filter" that should be followed by the analyses under 102, 103 and 112, and that there is no requirement for a "flash of genius." Finally, he stated that "you can have something quick, and you can have something right, but you can't have both," meaning that an earlier end to litigation does not mean the court gets it right. Professor Mossoff asserted that the patents previously denied in the U.S. but accepted in Europe and China would at least meet patent-eligibility under the proposed bill.

The subcommittee will hear further testimony from another 30 witnesses over the course of the second hearing, which took place yesterday on June 5th, and the final hearing, which will take place on Tuesday, June 11th in 226 Dirksen Senate Office Building. Both will be available by webcast here.

The list of witnesses and their written statements for the first hearing can be found here.