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IP HOT TOPIC

THE DRAFT SUBJECT MATTER ELIGIBILITY BILL: A WORK IN PROGRESS

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On May 22, 2019, U.S. Senators Thom Tillis (R-NC) and Chris Coons (D-DE), Chair and Ranking Member of the Senate Judiciary Subcommittee on Intellectual Property, and Representative Doug Collins (R-GA-9), Ranking Member of the House Judiciary Committee, Hank Johnson (D-GA-4), Chairman of the House Judiciary Subcommittee on Intellectual Property and the Courts, and Steve Stivers (R-OH-15) released a bipartisan, bicameral draft bill that would reform §101 of the Patent Act. The draft bill text comes after the Senate Judiciary Subcommittee received feedback from stakeholders, industry representatives, and individual inventors after releasing its §101 reform framework back in April.

Earlier this week, the subcommittee concluded its third and final hearing regarding the state of patent eligibility in the United States. According to the Subcommittee's press release, the purpose of these three hearings is to "solicit additional stakeholder feedback and to hear from a diverse set of witnesses on the problems different industries are facing with our nation's patent eligibility laws." Each hearing featured three panels of five witnesses each, for a total of forty-five witnesses. In addition to §101, the bill also included proposals to amend §100(k) and §112(f). The witness testimonials to date have included stakeholders and stakeholder representatives, industry leaders, and small businesses across a wide array of technology spectrum. Of the forty-five panelists that testified, the majority were in favor of the draft bill but most noted that further refinement was needed.

Proponents' Arguments

Those in favor of congressional action included Paul R. Michel (former Chief Judge-US Court of Appeals for the Federal Circuit); Q. Todd Dickenson (former Director of the USPTO); and David J. Kappos (former Director of the USPTO). Judge Michel delivered the most resounding endorsement of the bill when he stated that, after spending 22 years on the Federal Circuit and nine years since dealing with patent cases, he "cannot predict in a given case whether eligibility will be found or not found." He followed by saying that "if I can't do it, how can bankers, venture capitalists, business executives, and all the other players in the system make reliable predictions and sensible decisions?" Both Directors applauded the USPTO's 2019 revised §101 guidance, but both noted the need for congressional action to change the law as an administrative agency like the USPTO cannot change the law or impact court decisions.

Critics' Arguments

The camp against the bill raised concerns that (1) broadening eligibility will increase the issuance of bad patents, and therefore, will increase frivolous litigation; (2) small entities have benefited from the *Alice* decision (which the current draft law would abrogate) because courts have been able to invalidate patent claims and dismiss cases before the expensive discovery and expert witness phases; (3) the proposed language of §112(f) may place an undue burden on inventors to describe every single structure in a given invention; and (4) the draft bill would allow for the patenting of genes due to the abrogation of the *Myriad* case.

The Supreme Court's *Myriad* decision dominated panel discussions relating to biotechnology and pharmaceutical industries. Senators Tillis, Coons, and other proponents of the bill refuted the allegations that the bill will allow the patenting of genes. However, as best summarized by Sean George, CEO of Invitae, critics of the bill noted that the "golden age of precision medicine ushered in by the unanimous [*Myriad*], [*Alice*], and [*Mayo*] decisions has just begun. Patient care has improved and innovation in genetics has thrived because of the lack of patents on DNA, not in spite of it." He further noted that enabling patents on genetic information threatens that progress, and that the threat extends to other aspects of molecular diagnostics, beyond simply avoiding patents on the genes themselves, which would allow the return of patent thickets. The critics also urged the Subcommittee to preserve what they deemed currently beneficial to innovators instead of indiscriminately "sweeping away 150 years of case law".

§112(f) Proposal

Moreover, with regard to §112(f), most panelists noted that they are still taking the provisions under consideration. On the other hand, Paul Morinville, president of U.S. Inventor and a vocal opponent of the provision, noted that the objective of a patent application is to communicate to those skilled in the art and not to lay persons. As such, the provisions limiting the use of functional language would unduly require inventors to describe each and every structure, "leading to an exhaustive and costly effort to catalog each and every structure that can achieve every function employed in the invention."

§101 Proposed Provisions

As for §101, the draft bill includes three legislative provisions that require further deliberation as they appear to have the most significant impact, if enacted in their current form. Initially, the first legislative provision states that the "provisions of section 101 shall be construed in favor of patentability." This signals a potential return to what many referred to as the original interpretation of §101—a gate keeper threshold of what types of inventions are patent eligible and what types are not. Accordingly, this appears to reflect the committee's intent to refocus §101 as an *eligibility* threshold and not a standard for determining *patentability*.

The second provision states that all cases establishing or interpreting the judicially created exceptions to subject matter eligibility are "hereby abrogated." Moreover, the provision states that "no implicit or other judicially created exceptions to subject matter including "abstract ideas," "laws of nature," or "natural phenomena," shall be used to determine patent eligibility. This is by far the most sweeping reform proposed in this bill. Essentially, this proposal would eliminate a decade's worth of Supreme Court precedent and it is not yet clear what will replace it. For example, it is not currently clear if the bill will relegate §101 to simply be a patent eligibility threshold, or whether it will be revised to include the closed list of exclusive categories of statutory subject matter that would *not* be eligible for patent protection, as previously proposed in the Subcommittee's draft outline of §101 reform.

In his closing remarks of the third hearing session, Senator Tillis indicated that some language that further defines what is not patent eligible may make it back into the draft bill. However, as we noted in a previous article (linked **here**), such language (e.g. the proposed exclusive statutory categories) is vague and subjective. For example, the categories of fundamental scientific principles, products that exist solely and exclusively in nature, pure mathematical formulas, economic or commercial principles, and mental activities are not entirely clear, and may end up requiring further judicial interpretation, hence returning this entire effort back to square one. It is important that Congress recognize the confusion that this language presents, and ensure that any statutory exclusion more clearly defines the bounds of the exclusion. Similarly, Congress would need to clearly define the bounds of any statutory inclusion.

Lastly, the draft bill proposes that the eligibility of a claimed invention under §101 shall be determined "without regard to: the manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional or routine; the state of the art at the time of the invention; or any other considerations relating to sections 102, 103, or 112 of this article." This is further evidence that the Subcommittee intends for §101 to be a mere eligibility threshold and not a final arbiter on patentability. This explicit delineation removes the controversial "well known, conventional, or routine" standard of §101 analysis, and places such determination solely within §102, 103 and 112. This should reduce the conflation between eligibility and patentability standards currently applied by the USPTO and the Federal Courts.

Ramifications for Stakeholders and Moving Forward

The current §101 rules have proven to be advantageous for some industries (e.g. large software companies) and disadvantageous to others (e.g. biotechnology, medical diagnostics). There's no doubt, however, that more work lies ahead of Congress if this bill is to be beneficial to a wide array of stakeholders across the technology spectrum. For example, proponents of the bill have argued that the current narrow eligibility threshold stifles innovation because companies cannot risk investments into new technologies without adequate protection for those investments. On the other hand, critics of the bill have argued that the bill's broadening of the eligibility threshold will increase the number of granted patents, leading to an increase in assertions and litigation, leaving innovators to always be preoccupied with litigation rather than innovation.

In his concluding remarks, Senator Tillis also stated that he wants to "do this quickly" and that the Subcommittee can "review the record and make changes, garner consensus, and introduce a final bill sometime after the July 4 recess."

Given the Subcommittee's goals to simplify and clarify the standard, some predictions can be made irrespective of what the final version will look like. Initially, it is likely that the bill will relegate §101 to a gatekeeper standard for eligibility, and rely on other sections of the law to determine patentability. This may provide a welcomed change for many stakeholders, including the USPTO Examiner corps, who commonly grapple with constantly changing and convoluted eligibility standards. Moreover, while it is currently not clear whether this law, if passed, would apply retroactively, patent owners prosecuting patent applications in adversely affected technologies may consider keeping their current patent applications pending before the USPTO in anticipation of a simpler standard that is construed "in favor of eligibility." An unintended consequence of the law change may make proposed §112(f) the next battle ground of patent litigation, as it does not sufficiently define the claim interpretation mechanisms. As such, patent owners may wish to consider fortifying currently in-draft applications against any changes to §112(f) by including alternative structural equivalents in their disclosure.

Lastly, with regard to patent assertions, patent owners fearful of asserting their patents because of eligibility challenges may feel more confident that their patents can withstand such challenges in view of this bill. This means that a potential increase in assertions is likely in the short term, pending any provisions that the bill may provide to preserve the above-noted post-*Alice* reduction in assertions.

Congress's draft bill will have to strike a surgical balance between sufficiently broadening the eligibility standard while ensuring that the post *Alice* reductions in litigation are preserved to avoid any unintended adverse consequences. As Senator Coons said, "more work needs to be done."

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