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Final Panelists at Senate 101 Hearing Stress Real-World Effects of Status Quo, Tillis Signals Changes to Draft Text

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Print Article

"Considering where the stresses on the system are today, we're deeply concerned that eligibility law is on a collision course with the future of medicine." – Corey Salsberg, Novartis

After three hearings and 45 witnesses, there were few new fundamental arguments advanced for or against reforming patent eligibility law at today's final Senate IP Subcommittee hearing on the topic, but several key—and some alarming—messages were underscored.

The Draft Will Change

Senator Thom Tillis

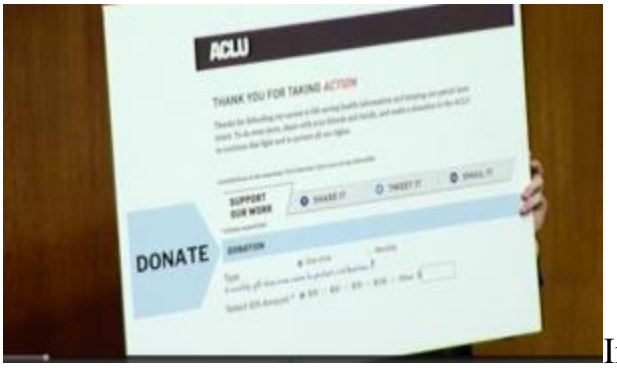
A few takeaways off the bat: there are going to be considerable changes to the working draft. In particular, there were four issues that Senator Thom Tillis (R-NC) noted were raised repeatedly. First, both sides agreed the new proposed definition of "utility," which requires "sufficient and practical utility in any field of technology through human intervention" needs to be further defined; those for reform felt that the language could be too narrowly interpreted, while those against feared it was not definite enough. "Clearly, those terms need better definition or more meat on the bones," Tillis said.

Secondly, everyone was concerned with Section 112(f). Tillis pointed to the practical argument made by inventor Paul Morinville about the impossibility of meeting that requirement in the context of software coding language, for example, while Tillis said the tech companies were afraid the language wasn't strong enough to weed out overbroad software and business method claims that most agree should not be patent eligible.

The third point Tillis noted indicates that there will be a research exemption written into the bill. While Tillis felt that Rick Brandon of the University of Michigan, who testified in the second hearing last week, had sufficiently dispelled the fear that the proposal would preempt broad swaths of fundamental research, he still seemed open to considering an "enhanced experimental use and research exemption."

Finally, the gene patent argument is dead as far as Tillis is concerned, and even one of the anti-reform witnesses testifying today agreed that the continued narrative that the draft legislation would allow for the patenting of a single human gene was not the issue. Dr. Sean George, Chief Executive Officer at Invitae, a genetic testing company that was sued by Myriad Genetics in 2013, explained during the second panel of the day—perhaps more coherently than his allies in the debate—that his concern is with

"method, observation, and association patents that take that genetic information and wrap it up with a disease outcome or an observation that could diagnose a patient or target that patient for a particular therapy." George claimed that pre-2012, his industry suffered due to patent thickets around such inventions, while post-2012, "I believe the data—the actual facts—would show that the industry is currently experiencing a renaissance." George's view was at stark odds with other biotech companies that had testified, however.



In a dig at George's ally in the anti-reform debate, the American Civil Liberties Union (ACLU), Tillis implied that the organization's insistence on framing the issue in what IPWatchdog's Gene Quinn called a "sloppy, unscientific manner" may have more to do with fundraising than substance (see image, right). "We're not gonna touch your genes, ACLU, so problem solved," Tillis said. He also pushed back on the assertion by some that he and Senator Chris Coons (D-DE) had packed the panel with witnesses favorable to reform, saying he felt it had been balanced, and reminding those present that they had specifically invited Apple, Google, Microsoft, Oracle and Dell, who declined to come in favor of being represented by industry associations.

Panelists Paint a Dire Picture

Manny Schecter

Speaking on the first panel, Manny Schecter of IBM responded to a question posed by Tillis about whether Judge Paul Michel was correct in saying that he wouldn't be able to advise a client on Section 101 issues today by agreeing with Michel and indicating that, while it was "a bit of an embarrassment" for him to have to explain the confusion to executives, it was more importantly "a blot on the integrity of the patent system." Schecter pointed Tillis to *ChargePoint Inc. v. SemaConnect, Inc.*, (2018-1739) to illustrate the absurdity of present eligibility law. In *Chargepoint*, the Federal Circuit held an invention relating to distributed networks of charging stations for electric vehicles to be patent ineligible as an abstract idea. "If courts can get that wrong, consider [artificial intelligence] AI, where the purpose is to abstract the functioning of the human brain," Schecter said. He also bolstered arguments made by fellow panelists, Laurie Self of Qualcomm and Byron Holz of Nokia, about the importance of patents to standard setting. Schecter, Holz and Self all stressed that eligibility law was disincentivizing companies from innovating in core technology areas crucial for national security and 

transitioning to 5G and impeding the ability of companies to participate in contributing to standards, since the lack of patents makes parties reluctant to disclose and share information.

Sean Reilly of The Clearing House Payments Company was the sole advocate against reform in the first panel, arguing that there has been an uptick in patent quality for the financial services sector since the *Bilski* and *Alice* cases, and a decline in lawsuits based on dubious patents. Reilly suggested changing the draft language to provide an alternative to 101 that would ensure that companies could still "get out early" when faced with lawsuits and/ or expand the invalidity grounds for review in post grant proceedings at the USPTO.

In the second panel, Laurie Hill of Genentech emphasized what many other panelists did during the hearing—that much of their technology that is ineligible in the United States is eligible in China and Europe. Her fellow panelists, Gonzalo Merino of Regeneron Pharmaceuticals, Peter O'Neill of Cleveland Clinic Innovations, and David Spetzler of Caris Life Sciences, all echoed Hill's sentiments, and stressed the real-world impact. O'Neill said that "the uncertainty has a meaningful impact on our ability to innovate," but still cautioned against drastic reform and advocated for a research exception.

Spetzler's opening statement was troubling, and worth recounting in part. He said that his company, which has spent $400 million to find cures for cancer and has made "unprecedented discoveries" had lots of examples on the company's "long and very painful" road where foreign and domestic companies have continually infringed due to the murkiness of the law. He continued:

It fosters an environment under which we don't share information. It is incentivizing us to keep secrets. The only effective strategy we have is to maintain our position through trade secrets which has a much longer and devastating effect on the advancement of science. Patents give us the ability to share information, broadly disseminate what we've learned and enable more discoveries. It's how we're going to change things. We have to work together – there's no one group that can solve the problem of cancer. So without an effective manner of patenting and protecting our inventions we're going to see a rudderless ship just spinning around.

An equally disquieting testimony was Corey Salsberg's of Novartis, who participated on the final panel. Salsberg drove home with candor what is at stake in this debate. Citing several examples of patent claims Novartis had lost in recent years—including a new digital microscope that was found to be abstract despite having a primary lens coupled with an image sensor; a laser device system applied to a human tissue region in surgery that was also rejected as abstract; claims to a novel pharmaceutical composition to treat arthritis made up of a modified protein that does not exist in nature, which was found to be a natural phenomenon; and several method of treatment claims—he warned that patent law may be on "a collision course with the future of medicine":

The true story of biopharmaceutical innovation is a story about risk-taking, investment, a willingness to fail, and a practical means to keep it all going on a scale that keeps yielding results. The patent system has successfully provided that means since the earliest days of modern medicine, converting daunting set of scientific odds that included a 10 to 15-year development timeline on average and an almost 90% failure rate at the clinical stage into a viable and sustainable business model…. The trajectory is alarming. The future of our industry is that we're moving further into biology, medicine is becoming increasingly personalized as we discover the genetic basis for disease, and we're moving away from pills into these treatments that harness the body's own power to fight disease and finally, software, digital tools and AI are being used for everything from optimizing R&D to virtual medicines. So, considering where the stresses on the system are today, we're deeply concerned that eligibility law is on a collision course with the future of medicine.

Another interesting participant in the last panel was Nicholas Dupont of Cyborg, Inc., a small business specializing in data compression software for Fortune 500 companies, that holds five U.S. patents to date. Dupont founded Cyborg in 2013 as a sophomore in high school. He said that the company has on occasion resorted to trade secret protection over patents and has taken "an exceedingly prudent approach to business development and partnerships, stifling our growth potential."

The Last Word

The 45th panelist in the series of patent eligibility hearings was John Vandenberg of Klarquist Sparkman, LLP. He took a unique approach to the debate and suggested that the senators consider asking some of the companies involved to propose legislation that would overturn *Mayo* but not *Ariad* and *Myriad*, "even if they don't think that's the right way to go." Vandenberg applauded Section 112(f) as proposed, supporting Bob Armitage's analysis of it, but said he would suggest the addition of an amendment requiring the USPTO to identify which claim elements are construed under 112(f). He also urged the senators to consider that the current law equally bars Huawei and other Chinese companies from patenting abstract ideas, while the draft proposal would not. He finished by asserting that "*Alice* is not a mess":

If one handed me 10 patents in the computer space, I would do a much better job predicting the 101 challenge than obviousness, claim construction or 112. I've submitted some data to show that judges are in the same boat. The affirmance rate for 101 decisions is 88% in June 2014- 2017. *Alice* caused angst but it is not unpredictable.

Wrapping up earlier than the previous hearings to make it in time for a floor vote, Senator Tillis emphasized that "there is no pride of authorship" in the draft text and that he was leaving the three days of hearings convinced of the need for "further refinements."

“I want to do this quickly,” Tillis said, adding: “I think we can review the record and make changes, garner consensus, and introduce a final bill sometime after the July 4 recess” in order to take it to the next legislative steps.