PERA 2025 Debated in Senate IP Subcommittee Hearing, with Business Methods, Diagnostics in Focus

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"The law isn't settling down, it continues to be hopelessly confused." – David Kappos

Eight witnesses across two panels testified today during a hearing of the Senate Subcommittee on Intellectual Property to discuss perspectives on the latest version of the Patent Eligibility Restoration Act (PERA), which its key sponsor, Senator Thom Tillis (R-NC) expressed urgency about passing before he retires from congress in 452 days.

Titled, "The Patent Eligibility Restoration Act – Restoring Clarity, Certainty, and Predictability to the U.S. Patent System," the hearing's first panel included three pro-PERA witnesses and one who was against passage. Two former U.S. Patent and Trademark Office (USPTO) Directors, Andrei Iancu and David Kappos, along with Mark Cohen of the University of Akron Law School, weighed in for PERA, while Mike Lemon of the National Retail Federation warned that passing the bill will return the retail industry to the days of "patent trolls" abusively targeting retailers will low quality patents.

PERA 2025 Recap

PERA 2025 would reset the law of patent eligibility in the United States to where it was before the U.S. Supreme Court's rulings in *Mayo Collaborative Services v. Prometheus Labs., Inc.*, 566 U.S. 66

(2012) and *Alice Corp. v. CLS Bank Int'l,* 573 U.S. 208 (2014). Earlier versions of PERA would have also directly overruled the Supreme Court decision in *Assoc. for Molecular Pathology v. Myriad Genetics*, 569 U.S. 576 (2013), which held that isolated DNA is not patent eligible. However, PERA 2025 is slightly different than the bill introduced in 2023, at least relating to human genes. PERA 2025 still says that unmodified human genes as they exist in the human body are not patent eligible, but prior versions of the bill said that isolation of genes was considered a modification. PERA 2025, however, leaves out the world "isolated" and says that "a human gene shall not be considered to be unmodified if that human gene is purified, enriched, or otherwise altered by human activity; or otherwise employed in a useful invention or discovery."

However, PERA 2025 still dismantles current judicial exceptions to eligibility by explicitly stating that eligibility for any useful process, machine, manufacture or composition of matter is "subject only to the exclusions in sub-section (b) and to the further conditions and requirements of this title." The four exclusions contained in sub-section (b) are limited to:

1. A mathematical formula that is not part of a claimed invention.
2. A process that is substantially economic, financial, business, social, cultural or artistic, even though at least 1 step in the process refers to a machine or manufacture.
3. A mental process performed solely in the human mind, or which occurs in nature wholly independent of any human activity.
4. An unmodified human gene, as the gene exists in the human body.
5. An unmodified natural material, as the material exists in nature.

While isolation of human genes does not appear to be enough to qualify as modification for purposes of conferring patent eligibility, PERA 2025 would specifically consider isolation of a "natural material" to be sufficient. Specifically, the bill says that a natural material would be considered modified and patent eligible if it is "isolated, purified, enriched, or otherwise altered by human activity; or otherwise employed in a useful invention or discovery."

A new Section 4(b) also states that "pre- or post-solution activity by a computer (or other machine or manufacture) in claim language shall not be sufficient to confer patent eligibility on the claim if that computer (or other machine or manufacture) is not necessary to practically perform the invention."

Thus, claims that merely add a computer as window dressing to the invention will be insufficient to confer patent eligibility,

Business Method Concerns

Lemon took issue with the idea that PERA would continue to exclude business methods, however, arguing that the bill would return the patent system fully to the pre-*Alice* world. "On the practical impact side…I haven't spoken

to a single company in any of the sectors repped by [United for Patent Reform] that agrees with the interpretation that this will keep business method patents out," Lemon said. "The bill does provide specific exclusion for rote language, but what happens when you craft it in a way that doesn't use rote language and instead just applies technical jargon around the process they're describing? That's what *Alice* said; you cannot put technical jargon around an abstract idea and make it patent eligible."

But Kappos disagreed with Lemon's opening statement that asserted the current law has actually *resolved* the confusion that existed prior to *Alice*, pointing to recent, conflicting U.S. Court of Appeals for the Federal Circuit (CAFC) opinions in cases such as *Yu v Apple* and *Contour IP Holdings*:

"The case law's not working fine at all," said Kappos. "Two cases, both about identical concepts—use of dual sensors in cameras in order to improve acuity of photography—the first one, *Yu v. Apple*, goes to one panel of the Federal Circuit that finds the claims to be abstract and ineligible; the second one, *Contour Holdings*, goes to a different panel…that finds the claims to be technological and perfectly eligible. So, the law isn't settling down, it continues to be hopelessly confused."

Iancu agreed, and further agreed with Lemon that "we don't want vague patents," but said the other statutes, like Sections 102, 103 and 112, should address such claims while Section 101 remains a coarse filter. "The problem we have had over the past several years is that courts have conflated these various statutory schemes," Iancu said.

However, Lemon dismissed the notion that this would help with the business method problem and refuted the point made by Iancu and other panelists that other sections of the Patent Act should "do the heavy lifting" when it comes to patentability and invalidating patents. According to Lemon, they weren't doing that before the America invents Act (AIA) and *Alice* and they would not do it this time either, were PERA to pass.

Cohen's key concern was with the United States ceding its competitive edge to China, which has amended its patent law four times since it was first introduced in 1984 and has "continuously adapted it to new technological challenges," he noted. China also "aggressively curates" its case law and has become increasingly less transparent over the years, "so it's hard to tell how Americans fare before the courts in China," Cohen said. But chiefly, "China believes in IP," while many in the United States and Congress do not, and China has "taken steps to aggressively improve their system in their own interests."

Senator Chris Coons (D-DE) asked Iancu how he and Kappos came to agree on the issue of eligibility coming from two very different presidential administrations and parties. Iancu replied that patent law is one of the last—or maybe the only—areas of the law that is still nonpartisan or bipartisan and not driven by partisan politics. "We've both, I believe, seen the same things," Iancu said, adding that, as a litigator, he also regularly witnesses the problems that the unpredictability causes both parties:

"When lawyers have a difficult time telling their clients with reasonable certainty what the likely outcome is more likely than not to be that increases the likelihood of litigation, in lengthens the likely

span of a lawsuit, and makes it more difficult to reach a settlement," particularly "given that for every Section 101 decision out there there's an equal and opposite Section 101 decision."

Diagnosing the Diagnostics Problem

The second panel also included three pro-PERA witnesses and one opponent of the bill. Richard Blaylock of Pillsbury Winthrop Shaw & Pittman said that PERA threatens U.S. leadership in personalized medicine innovation, while Steven Caltrider of the Dana-Farber Cancer Institute, Sue Peschin of the Alliance for Aging Research and Corey Salsberg of Novartis spoke in favor of PERA.

Blaylock argued that PERA will allow for the patenting of biomarkers that would be detrimental to the industry and that the revised language regarding human genes in the latest version of the bill fails to address the concerns because additional exclusions in the bill hollow them out. Blaylock also rejected the suggestion that diagnostics are not currently patentable in the United States, which the first panel touched on, calling it "categorically false."

Squires patent on diagnostics – nothing about the current law that prevents the patenting of new diagnostics. Many new point of care diagnostic testing platforms are being

Caltrider, however, called the situation "a crisis" and said that PERA will not be a barrier to patient access. "The ultimate barrier to patient access is a medicine or a diagnostic never being discovered, developed or commercialized," he said. "The fact innovators are adapting as best they can does not mean the crisis is solved."

Peschin had a similar view of the diagnostics landscape and said that diagnostics are being left on the shelves. She and others pointed to the fact that all of the CAFC judges have asked congress to step in and solve the problem.

Salsberg was particularly worried about a case just argued at the Federal Circuit in which a panel is considering an appeal from a district court decision concerning patents on genetically engineered host cells in which the court found the patents to be patent ineligible products of nature. Salsberg said the case has "dire consequences" for the industry and that the implications "should worry everyone."

Senator Mazie Hirono (D-HI) asked whether the new language in the bill makes Blaylock feel any better about the bill, but he replied that he would still "delete the entire draft" because the current law is superior, thought he did agree to address the language with the committee going forward. Essentially, Blaylock said that the bill leaves all of the genomes to future pathogens, for example, open to being patented and that the language allowing a natural material to be considered modified and patent eligible if it is "isolated, purified, enriched, or otherwise altered by human activity; or otherwise employed in a useful invention or discovery," makes the exclusion on unmodified genes moot.

Tillis concluded the hearing by promising he intends to do everything he can to move the bill forward and to get a markup, and that those who are still concerned should provide feedback.

The Council for Innovation Promotion (C4IP), for which both Kappos and Iancu serve as Co-Chairs of the Board, sent a letter to congress on the PERA hearing, urging continued forward motion on the bill.