Questions for the Record from Senator Alex Padilla
Senate Judiciary Committee
"The Patent Eligibility Restoration Act – Restoring Clarity, Certainty, and Predictability
to the U.S. Patent System"
Tuesday, January 23, 2024

Questions for the Honorable David J. Kappos

1. What would be a concrete expected outcome for consumers should PERA become law?

   Answer: With investment incentives restored under PERA, consumers should expect new breakthroughs and increased access to lifesaving and novel technologies. Improvements in technology tomorrow also leads to lower prices and further access to today's technologies. Overall, fixing the patent system will lead to a strong and vibrant U.S. innovation economy, providing health, prosperity and security for all Americans.

2. What specific types of inventions would become newly eligible for a patent under PERA, that are currently not patentable? Can you provide an example of a patent denied under the Alice/Mayo framework that best illustrates the concerns you've raised about the existing patent system?

   Answer: One significant type of invention that PERA would deem eligible would be an innovation that cannot be meaningfully performed without the use of a computer or article of manufacture yet under the current regime could be misconstrued as "directed to" an "abstract idea." For example, a claim like the one found ineligible in *Interactive Wearables*[1] (for a "wearable content player") should clearly be eligible, and would be under PERA.

3. Can you provide an example of a patent denied under the Alice/Mayo framework that best illustrates the concerns you've raised about the existing patent system?

   [See answer to #2 above.]

4. Mr. Jones's testimony included proposed alternative approaches to addressing concerns with the state of Section 101. He proposed the two possible alternative approaches: (1) "[] a narrow solution that is targeted specifically and exclusively at any areas of technology for which the current jurisprudence has created significant and empirically demonstrable impediments to obtaining patent protection to the extent that such impediments can be shown to have resulted in clearly insufficient levels of R&D investment."; (2) "a broader legislative solution that tethers patentability to its underlying policy purpose by explicitly limiting the availability of patent protection to only those

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[1] *Interactive Wearables, LLC v. Polar Electro Oy*, No. 2021-1491, 2021 WL 4783803 (Fed. Cir. Oct. 14, 2021).

inventions that embody an advance in technology." What are your views on these proposals as compared to the approach of PERA?

> **Answer**: Neither of these approaches comes close to the simple, balanced regime that PERA would provide. Option (1) explicitly acknowledges a broken system, and proposes a patchwork-type fix that would purportedly address the areas that "can be shown to have resulted in clearly insufficient levels of R&D investment". The proposal does not describe what the fix would be, but as a threshold matter, it would be very difficult to clearly identify specific areas affected more than others. Moreover, such a deficiency would only be identified after decades of neglect, long after the battle is already lost. Option (2) is no better, and suggests a "broader" solution that limits "patent protection to only those inventions that embody an advance in technology". While this approach may be aligned with the ideals of PERA, it is an ill-defined and impossible-to administer standard that would not be a meaningful threshold test for entry to the patent system.

5. How did Alice/Mayo impact patent litigation and how would PERA impact patent litigation?

> **Answer**: The vagueness and randomness of the *Alice*/*Mayo* framework have enabled patent infringers to exploit Section 101 as a litigation weapon exacting unnecessary burdens and costs on good-faith patent holders and the courts, further disincentivizing investment and innovation. Patent infringers now routinely raise Section 101 as a defense, often merely as a strategy to complicate and prolong litigation, rather than as a good-faith defense. One analysis found that from 2012 to 2014 (when *Alice* was decided), Section 101 was raised in just *two* Rule 12(b)(6) motions across the country each year. In the year after *Alice*, that number rose to 36 motions, and by 2019, accused infringers were filing nearly 100 such motions each year. PERA would restore clarity and balance to Section 101 and ensure that it can only be used in the limited situations where it is appropriate.

Questions from Senator Tillis
for David Kappos
Witness for the Senate Committee on the Judiciary Subcommittee on Intellectual Property
Hearing "The Patent Eligibility Restoration Act – Restoring Clarity, Certainty, and
Predictability to the U.S. Patent System"

1. In 2018 judges on the Federal Circuit issued a concurring opinion to the court's denial of *en banc* rehearing in *Berkheimer v. HP Inc.*, in which they stated that "the law needs clarification by higher authority, perhaps by Congress, to work its way out of what so many in the innovation field consider are [Section] 101 problems."

    Has anything changed in your opinion since 2018 that would mitigate the concerns raised by these judges or have things actually gotten worse?

    > **Answer**: Nothing has changed since 2018 to improve the situation. If anything, things have gotten worse. Courts continue to operate in the Alice/Mayo echo chamber where the safest route is to issue and affirm Section 101 ineligibility decisions. And our international competitors such as China are taking advantage of the situation and continue to attract an increasing share of R&D investment with their far more favorable patent eligibility standards.

2. In response to a March 2021 letter from myself and Senator Cotton, the USPTO launched the "Deferred Subject Matter Eligibility Response Pilot Program," which invited selected patent applicants to defer consideration of subject–matter eligibility issues until other patentability issues are resolved.

    What are your thoughts on deferring consideration of subject–matter eligibility issues during patent examination?

    > **Answer**: Deferring consideration of subject matter eligibility questions until after the other patentability hurdles are resolved is a step in the right direction, but falls far short of the complete overhaul Section 101 needs. Deferring eligibility questions helps reduce time spent quibbling with the patent office when there are more fixable issues with the claims, like amending around the prior art, that can be sorted first— and once the other issues are sorted, the claims are less susceptible to 101 rejection. But this does not address the fundamental problem, which is that Section 101 has been judicially expanded into a fuzzy all-encompassing test when it should be no more than a gatekeeper with a very low threshold to exclude only those ideas that are clearly unsuitable for any access to the patent system.

3.
    a. How has the current state of patent eligibility inhibited the development of next generation technologies?

    > **Answer**: Innovators and creators are, and have always been, incentivized by intellectual property rights, including the grant of exclusive patent rights. The

Founders knew this, and we know this today. Patent rights encourage inventors to invent, and investors to invest. Consequently, the current lack of clarity and predictability in the patent system due to Section 101 jurisprudence has caused reduced investment and reduced innovation in key fields of technology, including medical diagnostics, biotechnology, software and artificial intelligence (AI).

b.   What is the long-term technological and economic impact of the current eligibility jurisprudence?

Answer: Reduced investment is stunting investment of resources into development of cutting edge technologies. More directly, there are many examples of lifesaving technologies (e.g., in biotech) whose programs were abandoned due to Section 101 impediments. If Section 101 is not fixed, the U.S. will continue to slow down. All the while, our international rivals are actively seeking to make it *easier* to patent new technologies and therefore present an attractive alternative for investment and R&D activity.

c.   Can you quantify, in easy to understand terms, the economic impact of the current state of patent eligibility?

[See answer to "d" below.]

d.   In other words, how much is the current uncertainty costing our economy in terms of jobs, innovation, and development?

Answer: Numerous studies have shown that the Supreme Court's changes to subject matter eligibility law through *Myriad, Mayo* and *Alice* have decreased confidence in the U.S. patent system, decreased private investment in key areas of technology that rely on patents, decreased commercialization of innovations in these areas, and created threats to America's economic, social and national security interests. One 2022 empirical study concluded that in the four years following *Mayo*, venture capital investment in disease-diagnostic technologies was nearly $9.3 billion lower than it would have been without that verdict. A 2020 study similarly concluded that almost one-third of venture capital and private equity investors who knew about at least one of the Supreme Court's eligibility decisions indicated that these cases caused their firms to either invest less in affected areas, or shift investments out of biotechnology, medical device, pharmaceutical and software and internet industries into other areas. Meanwhile, 62% of investors "agreed that their firms are less likely to invest" in companies developing patent-ineligible technologies "given the unavailability of patents."

4. One of the key concerns from innovators is that, absent additional clarity in this space, we're going to start seeing American companies start developing their inventions overseas in jurisdictions which have broader standards of patent eligibility.

Do you agree with that concern and, if you do, what evidence have you seen to suggest that technological inversion is already occurring?

> **Answer**: I absolutely agree with that concern, and the data confirms it. For example, one study shows that from 2016 to 2020, the market capitalization of Chinese biopharma companies increased exponentially in value, from $1 billion to over $200 billion, and China saw over $28 billion invested in its life sciences sector in 2020, double the previous year's amount. Another study states "it should be a warning to our law and policy makers that Chinese AI start-ups are now receiving more funding than American AI start-ups. According to a review published in 2018 by MIT Technology Review, of the $15.2 billion invested in AI startups globally in 2017, 48 percent went to China and just 38 percent to America. The U.S. is starting to lose out in capital investments in key industries, such as artificial intelligence which has interconnections to newly emerging medical diagnostic technologies, highlighted by the fact that while the U.S. accounted for 77 percent of such investment before the *Alice* decision, that investment fell to 50 percent three years after the *Alice* decision."

5. In your opinion, when did problems begin with Section 101, and what factors led to the problematic state that we are in today?

> **Answer**: The *Bilski* case in 2010 laid the framework for what was to come, but the trouble began with the *Myriad* and *Mayo* decisions in 2012 and 2013 and came to a head in 2014 with *Alice* decision, which established an unduly constrictive, un-administrable 2-prong test we have been struggling with based on highly subjective standards like claims being "directed to" ineligible concepts like "abstractness."

6. Late last year an article was published claiming that the problems with Section 101 have been overstated.

How would you respond?

> **Answer**: That same article actually acknowledged that "[t]oo many critics to count—including academics, practitioners, legislators, and judges—have lambasted the patent eligibility framework as an unpredictable morass of confusion." What that article relied on to counter this overwhelming consensus was a single point—evidence of a high affirmance rate on Section 101 decisions. What that evidence actually shows, however, is that due to the uncertainty, innovators are avoiding investment in costly eligibility disputes in all but the most clear-cut cases, that lower courts are erring on the side of ineligibility in line with the signals coming out of the higher courts, and that the CAFC is deferring to the decisions of the lower courts because the CAFC does not have clear standards to rely on to overturn ineligibility decisions of the lower courts. If anything, this is further evidence that nothing is working with Section 101.

7. Do you think the legislation protects against eligibility for ineligible claims that have phrases like "do it on a computer" added to them?

Answer: It certainly does. While PERA moves away from the nebulous, expansive, constrictive judicial exceptions, and makes eligible any invention or discovery that can be claimed as a useful process, machine, manufacture or composition of matter, or any useful improvement thereof, it provides explicit exceptions that are clearly defined and easy to apply, such as pure mathematical formulas and mental processes, unmodified genes in the human body and unmodified natural material existing in nature, substantially economic, financial, business, social, cultural or artistic processes, even when followed by language like "do it on a computer", as long as such processes can be practically performed without the use of a machine or manufacture. This is a balanced approach that is clear, fair and administrable.

8. Can you illustrate with an example of a claim that would be eligible under PERA (although ineligible under the current regime), compared to a claim that even PERA would find ineligible?

    Answer: To put this in the context of recent Supreme Court cases, a claim like the one in *Alice*, involving financial machinations performed in real time and tied closely to its computer implementation, would likely survive the PERA threshold and proceed to be tested against 102, 103 and 112. In contrast, a claim like the one in *Bilski*, for which it was explicitly stipulated by the parties that the invention could be performed without a computer, would likely be ineligible under PERA's standards.

9. Despite how broken the current situation is, is it in the interest of some parties to maintain the broken status quo?

    Answer: As discussed, fixing the broken Section 101 will increase investment and development in critical technological areas. This may, of course, come at a necessary cost in some instances, such as a potential natural price premium for certain new products to help defray the cost of investment and development efforts. But to focus on that is short sighted and wrong, as the cost of not having the new technologies in the first place due to lack of investment incentives is infinitely higher. And it goes without saying that parties aligned with the interests of our foreign competitors would also be happy to maintain the status quo.

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<u>**QUESTION FROM SENATOR BLACKBURN**</u>

1. **In this era of artificial intelligence (AI) and machine learning—but also more generally— the question of whether an algorithm is patentable is particularly relevant. Likewise, even where an algorithm is ineligible for a patent under existing law, it may be copyrightable. In your view, is there a need to clarify in federal law when an AI or machine learning algorithm is patentable or copyrightable?**

> **Answer**: Focusing on patent law, the optimal first line of IP defense for technological innovations, there is definitely a need for legislative clarity to counteract the current state of confusion revolving around patent eligibility for computer-implemented inventions. These issues are especially acute when it comes to AI and machine learning, which inherently involve using computers to handle "abstract" tasks (like language recognition, responding to queries, decision making, etc.) typically performed by humans. PERA provides this much needed clarity, and restores predictability which is crucial to further development in these sectors.