

**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 Mark Deem**

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

Consumers will benefit immediately in certain areas. For example, as things stand right now, patents are not available on diagnostic procedures, because after the *Mayo v. Prometheus* decision that is how courts interpreted the language of *Mayo*. This has had a devastating impact on the development of new ways of detecting certain diseases. The case of *Ariosa v. Sequenom* involved the discovery that minute amounts of fetal DNA can be found in the blood of the mother. This discovery obviated the need for drawing amniotic fluid from the womb of the mother to test for genetic defects, such as Down Syndrome. The Federal Circuit, based on their reading of the *Mayo* decision, held the invention was no more than the discovery of a naturally occurring material and was not eligible for patent protection. In *Athena Diagnostics v. Mayo*, the invention was the discovery that the existence of a particular gene in the genome of a patient made it possible to test for myasthenia gravis, an autoimmune disease, for which a subset of about 20% of patients did not respond to traditional testing. Again, the Federal Circuit said that isolating and correlating a particular gene with a disease was not eligible for patent protection. PERA would immediately bring entrepreneurs and venture capital back into diagnostics by restoring the incentives for developing and disclosing similar types of discoveries.

Looking at the longer term, it is clear to me that without the promise of reliable patent coverage, investor interest shifts from the patent intensive areas to more consumer related businesses such as hotels, restaurants, music apps and the like. Obviously, these also benefit consumers at some level.

But on a societal level, those benefits pale in comparison to treatments and cures for debilitating diseases and medical devices that improve and extend the lives of those very consumers who could then go to those hotels, eat at those restaurants, and listen to that music. Reliable and enforceable patents are essential to keep consumers alive and healthy.

**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?**

My response to Question No. 1 identifies one large category of medical technology that currently is largely ineligible for patent coverage and that would become eligible under PERA – medical diagnostics. It also identifies another area – isolating a gene and discovering its precise effect on the human body – that also would be eligible under PERA.

It is important to acknowledge the point that many opponents of PERA have advanced – genes as part of the human body are not eligible and never were. PERA emphasizes that unmodified genes as they exist in the human body will remain ineligible. PERA is intended to override the Supreme Court’s decision in the Myriad Genetics case with respect to genes that have been isolated or otherwise modified by human effort. Stated differently, PERA will allow the eligibility of “genes that have been isolated, purified, enriched or otherwise altered by human activity,” provided they meet the other statutory tests for patentability. Isolating a gene to determine its specific function or the specific types of cell in which the gene expresses its particular protein often requires a lengthy study and extensive experimentation. Patents create incentives to invest time and capital in determining the correlation between a particular gene and a particular disease state, so eligibility is an essential prerequisite.

Beyond that, the judicial proclivity for using eligibility as a gating issue has led to some highly questionable outcomes. In *American Axle v. NEAPCO*, for example, the invention was to place a cardboard insert around a rotating axle in a car or truck to dampen vibrations. Unlike the prior art, the inventor’s design and placement of the insert damped both longitudinal and torsional vibration; as soon as the infringer saw that the invention solved a problem they had been trying to solve for years, they copied it. Two judges on a panel of the Federal Circuit said it was merely a patent on a natural law, even though the patent said nothing about the law in question. There are a number of similar cases reaching a similar conclusion. This type of nonsense will be corrected by PERA.

Another category that will be corrected is the whole field of software. Numerous decisions of the lower courts and Federal Circuit hold that software inventions are ineligible as merely abstract concepts or mathematical algorithms. This is a serious problem, because the vast majority of new technologies in all fields of endeavor rely on software, in many cases because complex problems that have to be solved in real time require the speed of a computer to be useful. PERA will correct this as well.

**3. How has the current state of patent eligibility directly impacted the development of new medical technologies? Can you provide specific examples where patent eligibility issues have hindered innovation?**

There is no question in my mind as to whether the current state of patent eligibility has diminished innovation. I addressed this with specific examples in my answer to Question 1. I also know that there have been significant shifts in the types of invention that attract venture capital and other investors, and I can say unequivocally that weaknesses in the patent system have diminished both the number of entrepreneurs and the number of investors willing to assume the risk of longer term development projects. Creating a new technology requires both dedicated entrepreneurs and dedicated investors, both of whom may be motivated by the

desire of benefitting other people and their nation, but both nevertheless need to be able to justify the expenditure of human resources and capital to support the effort. This in a nutshell is what patents provide, and without it, these entrepreneurs and investors are likely to pursue other activities.

One variable and unknown factor in this discussion is the extent to which the entrepreneurial and investor communities are fully aware of how confused the state of law is and how difficult it may be to prevent large incumbents stealing what they invent. The implication of that question is that the longer it takes to correct the patent system, the worse the shift away from strategically critical industries is likely to become. Given the reality that our nation is not keeping up with some of our competitor nations in innovation, such as China and Germany, the urgency of getting a stronger patent regime is more and more palpable.

**4. How has the Alice/Mayo framework impacted start-up companies, and what would be the expected impact of PERA on those start-up companies?**

A partial answer to Question 4 is found largely in my responses to the foregoing three questions. In addition, however, it is worth noting that PERA addresses only eligibility and not some of the other aspects in which patents have been weakened. Correction of the patent system as a whole is really critical to restoring their intended impact on innovation. The reason for initially correcting PERA alone is that the manner in which the courts and patent office are dealing with eligibility issues are so glaringly hostile to inventors and investors. It is imperative that these be corrected as soon as we can.

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

In my view, neither of the solutions that the High Technology Inventors Alliance proposes would do any more than continue the status quo, except for the "narrow solutions" to specific rulings. This in turn would mean that each time a district court judge finds a bizarre theory on which to posit ineligibility, those of us interested in a rational and protective legal system would have to come back to Congress. The key value of PERA is that it restores clarity surrounding Congressional intent as to what is eligible for patent coverage, leaving to the courts and Patent Office the traditional comparison of an invention with the prior art and determination of adequacy of claims and disclosure.

It is also worth noting that the patent system already requires that inventions reflect “advances in technology.” That is precisely why we look at the prior art to determine whether an invention is just an obvious variation on the prior art. PERA would still demand that the invention rises to the level of being a patentable advance in technology. One of the major problems with the Supreme Court’s jurisprudence as to eligibility is that the court began to conflate eligibility with the other provisions in the patent law. This is precisely what led to the massive confusion that exists today in the lower courts. Exemplary is the American Axle case, where the two-judge panel of the Federal Circuit held that the “claims” did not enable the invention, a requirement of section 112 that does not relate to claims. This bizarre interpretation is nonsense, but is what was wrought by Alice and Mayo.

To put it bluntly: both of the proposals suggested are completely nonsensical. Solution 1 argues that we should wait to see what harm arises before solving for it in a clear way that PERA allows. In some cases years of harm may have arisen by the time one could “empirically prove” that the harm had been done. And who would be motivated to prove it? Nobody. That solution is a fancy sounding poison pill or kill switch.

Solution 2 is addressed above, but if one were to take it one step further and require that the patent office determine the degree of “advance” required, then that would argue that one can read a patent application and foresee the future – as to what impact the subject technology, or its future iterations, will have on society and the economy. It is the job of the patent system to protect novelty and invention. It is not to predict the future.

**Questions from Senator Tillis**  
**for Mark Deem**

**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?

*Far from anything mitigating the problem, the impact of the confusion around Section 101 continues to get worse. More decisions are rendered each year demonstrating how utterly confused the Federal Circuit and lower courts actually are. A couple of recent decisions that were brought to my attention involved patents on a rotating axle and a camera. In both of these cases, a panel of the Federal Circuit held that the patents were directed to a law of nature and therefore ineligible, which to my mind is utter nonsense. Every invention I have ever seen implemented a law of nature or mathematical principle in some way or at some level. From the standpoint of someone who is both an investor and an inventor, this kind of confusion makes it very risky to rely on the expectation that a technology that may require hundreds of millions of dollars in venture investment will receive patent protection that is necessary to seek a return on that investment. If we cannot protect our inventions with patents, we simply will not pursue them and no one will invest in them.*

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?

*For dealing with the Patent Office, I would not think that sequential consideration of issues will matter much. When an application is ready for review by an examiner, a first office action will normally list all the initial reasons the examiner will not issue a patent. In my experience, that is usually helpful even though I may not agree with the examiner, because at least I understand where I have issues to overcome.*

*In District Court, however, judges are sometimes tempted to dismiss a patent infringement case without ever seeing any evidence, and that really fails to give the inventor a fair shot at explaining what the invention actually is or does. Forcing the courts to address initially all the other grounds for rejecting a patent will at least assure that the inventor gets a proper hearing.*

3.

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

*The current state of patent eligibility inhibits the development of next generation technologies in several ways. First, not knowing whether a patent will be struck down arbitrarily by some judge, years after it is issued and following lengthy and expensive litigation, has eroded inventor and investor perception that patents are reliable assets around which to build a business. This is a marked change from a few years ago, when we could be reasonably sure that patents gave innovators and investors the incentive to take outsized risks because they lowered the opportunity for larger companies just to steal a new idea, which is what is now a major problem for startups. Although patent eligibility is a significant part of this problem, it is not the entire problem; numerous other legal issues that surface in patent litigation are also having much the same effect, most prominent among which are the loss of the right to obtain an injunction against infringement and the completely untethered freedom for judges to recreate inventions in hindsight using highly questionable prior art.*

*Second, the growing loss of investor confidence in the integrity and reliability of patents over the last 15 or so years has led to a shift in the types of investments and technologies that entrepreneurs and investors are willing to tackle, with less capital and human resources going into longer term and higher risk development of strategically critical technologies and more going into consumer products and services with quicker exits and less risk. Third, the lack of reliability of patents has forced many companies to look to trade secret protection as their best alternative for protecting their IP, which means that other inventors and the public in general are denied the informational benefit from creative work, which has been one of the primary public benefits of the patent system since it began (but often is not discussed or even recognized).*

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

*The long-term impact of the lack of clarity regarding what is eligible for patent protection in the U.S. is quite dire. As I noted in my testimony, if the top patent officials of the U.S. government, and the judges on the only U.S. court dedicated specifically to hearing patent cases are all confused, imagine the uncertainty and reluctance to invent and invest that this*

*is creating for us, the engineers, researchers and physicians down here doing the inventing, and for the investors that support us.*

*This is costing us cures, treatments, jobs, economic growth, and potentially, lives. We need to be thinking about areas where the U.S. can and must lead like personalized medicine, AI-assisted therapeutic treatments, AI-assisted diagnostics and other major unmet clinical needs that will not be addressed if these innovations cannot be patented. I can tell you with certainty you cannot invest a decade of your life and \$250 million of other people's money on an invention that you cannot protect. That model just doesn't work.*

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

*It is difficult to quantify the economic impact of uncertainty as to patent eligibility and to separate it from the other aspects of the patent system that the courts, Congress, and the federal antitrust agencies have caused. Some aspects of the weakening of patent rights, however, are clearly traceable directly to ineligibility. The Supreme Court's decision in the Mayo v. Prometheus case made it pretty clear most diagnostic innovation was not going to be eligible for patent coverage in the future. This ruling led almost immediately to two terrible decisions from the Federal Circuit – Ariosa Diagnostics v. Sequenom and Athena Diagnostics v. Mayo, both of which held that extremely valuable discoveries were simply based on natural law and therefore not eligible for patent protection. The Athena case made it clear that patents on diagnostic procedures are no longer patent eligible in this country, and as a result, investor funding for developing diagnostics very quickly declined to the vanishing point. A few large companies have continued to invest in lab based diagnostic processes, but only where they can retain trade secret status for the process.*

*Another industry badly affected by the eligibility decisions is the software industry, where nearly every patent that impacts one of the digital technologies is now at risk. Many companies have ceased relying on their patents to protect software and have turned to other methods. A great deal of innovative new software today is being kept in the cloud with limited customer or public access other than to a carefully limited user interface that does not inform anyone how the software is assembled. The source code is a trade secret not available outside of a very small group within the company that owns it.*

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

*I am not the right person to quantify the magnitude of policies that discourage job creation or innovation, but I am reasonably sure that there is some. A recent report from the Kaufmann Foundation showed that startups in the first year or two of their existence are responsible for the bulk of new job creation in this country. The same report shows that young companies as a percentage of the US businesses is declining, as are the number of*

*startups and young companies. This is entirely consistent with the impressions that I stated in response to 3.b.*

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?

*Inventors and investors are well aware that patent eligibility in Europe and Asia is far broader than the scope our own Supreme Court has established for U.S. patents. Moreover, the recently created Unified Patent Court in Europe is getting a lot of attention from startups and entrepreneurs as a far less expensive jurisdiction in which to bring litigation and more likely to end with an injunction if successful. From my perspective, I anticipate that my companies and the entrepreneurs that create them will be looking increasingly to some of the other countries to enforce their patents, particularly the UPC in Europe.*

5. Some have claimed that even under current interpretation of Section 101 there is still a tremendous amount of innovation happening in the U.S. – that we aren't really missing out on anything, and innovation will happen regardless of whether we pass legislation like the Patent Eligibility Restoration Act.

Would you agree with this assessment?

*It is true that there is something called "innovation" found today in many products and services, but it is critically important to differentiate what Clayton Christensen calls "disruptive innovation" from the kind of innovation that simply maintains or improves on existing products or services in order to stay competitive and preserve market share. Many cutting-edge technologies require the kind of disruptive innovation that Professor Christensen describes and that are essential to this nation's ability to maintain its leadership in science and technology. Examples abound – quantum computing, nuclear fusion, artificial intelligence, CRISPR, vaccines, etc. This type of disruptive innovation is far more the province of startups, entrepreneurs and high-risk investors than existing incumbents and large companies.*

*We should acknowledge that large companies are certainly important to our nation's economy, and many large companies perform exceptionally well in terms of organizational efficiencies, cost control, manufacturing, distribution and developing worldwide markets. These organizations invest in R&D largely to improve their legacy products in order to compete with other companies and maintain their market share. What large companies do*



*not do well is to create disruptive new technologies that amount to paradigm shifts. It is nimble entrepreneurs and inventors that are most likely to develop these new technologies that truly disrupt industries and markets and make old technologies obsolete. There are many reasons for this, starting with the level of passion in pursuit of a vision that leads startup founders and their employees to work hundreds of hours each week, sleep on the floor of an office or cubicle, and be single minded about their objectives for months or years. Ideas and dedication for creating genuinely new technologies characterize every startup I have ever worked with, and it is hard for any large company to replicate these qualities with its own employees.*

6. I believe that you have over 250 US patents with your name on them. I think that makes you the only actual inventor on either panel.

As an inventor in the particular area of technology that you are in, can you discuss your views on this issue of patent eligibility in the U.S. and whether Congress should make that more or less clear in statute?

*As both an inventor and an investor, I believe it is critical to our nation that we have clear guidelines for what inventions are eligible. In my view, anyone who wants the current state of confusion to continue is simply voicing undisclosed self-interest. Prior to the current Supreme Court, eligibility was clear. We knew how to get through that first gate and into the rest of the very rigorous process required to prove the worth of our inventions and to demonstrate why they should be protected.*

*It is not clear to me just how and why our country abandoned the belief that anything created by humans through hard work and ingenuity is at least patent eligible, even though not necessarily patentable.*

*What is clear, however, is that we must correct the current state of confusion if we want entrepreneurs and startups to continue attracting sufficient capital to create new companies. Give us back the starting line – we'll do the work to win the race.*