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 Richard Blaylock

1. What would be a concrete expected outcome for consumers should the *Patent Eligibility Restoration Act* (PERA) become law?

   If PERA were enacted, it would create a patent environment similar to the time before the *Myriad* and *Mayo* decisions and as such, biomarkers (including human genes) and their association with health status would once again be patent eligible. The answer to your question is not hypothetical in that we have a real world test case of what this would mean for consumers and patients, as we saw the consequences pre-2013 and the benefits since then. Specifically, prior to 2013, patient access to genetic testing was greatly limited due to testing monopolies stemming from patents on human genes. I refer you back to my written testimony beginning on page 6 in which I describe at length multiple examples of these consequences for patients.

   To summarize my written testimony, consumers and the broader healthcare system should expect dramatic increases in the cost of testing and concomitant reduced access due to reduced competition. PERA would return us to a pre-Myriad environment with genetic testing monopolists charging high prices for partial results and no provider able to offer comprehensive testing as is offered by multiple genomic testing companies today. These consequences will be particularly felt by lower income patients if they live in states with Medicaid programs that do not cover the only test available due to a monopoly. Further, patients will not have access to tests reflecting the latest scientific advances because just as was the case during the pre-*Myriad* period, providers having a patent on a specific necessary test will lack an adequate business incentive for them to update their tests. Most concerning of all, patients in the United States may find themselves with no access at all to critical, lifesaving genetic information if a patent holder opts not to commercialize a test nor license it, which was the case of long QT syndrome pre-2013.

   For example, if PERA were enacted, a clinician seeking to understand a patient's hereditary cancer risk may need to order genetic tests from multiple laboratories depending on the patent holder of each gene in order to obtain a complete and comprehensive evaluation of genetic risk for each of their patients. This would not only potentially increase the financial costs to patients and payers including Medicare, but also increase the administrative burden on clinicians, delay clinical care as patients wait for multiple test results, contribute to poor patient outcomes, and create unnecessary liability and malpractice risk for clinicians if they fail to order or review all necessary tests. Clearly, if PERA is enacted into law, the broader healthcare system should expect

increasingly impaired access to genetic testing, higher costs, and poorer quality of healthcare.

PERA would also shut down variant sharing data, pivotal to advancing our understanding and interpretation of genomic testing results. After the hearing, I submitted additional written testimony for the record that specifically focused on the federal investment in genomic data sharing, its importance and what the elimination of this would mean for patients. PERA would disincentivize such data sharing which has been a key driver in rapid advancement and broadening of the benefits of genetic testing post-*Myriad*.

2. What specific types of inventions would become newly eligible for a patent under PERA, that are currently not patentable?

   Invitae is concerned that if PERA were enacted, that newly recognized biomarkers and their associations with health status would once again become patent eligible under PERA. Such patents could cover any genetic test (even if using fully conventional, off-the-shelf sequencing techniques) to determine whether or not a patient had such a biomarker. Thus each new patent to another biomarker would be a barrier to conducting a comprehensive screening of a patient's genes for the presence or absence of all biomarkers relevant to their health management.

   As I discussed in my supplemental written testimony, the NIH's ClinVar database is a large and growing database of biomarkers and their association with health status. It's continued growth confirms that Invitae's concern about patenting of new biomarkers remains significant as new biomarkers continue to be identified at a rapid pace and also that the present state of the law is in no way impeding such progress.

3. How does the current state of the law impact smaller innovators and academic research?

   Innovation and medical research in genomics and precision medicine has flourished since the *Myriad* decision in 2013 and I refer you back to my written testimony beginning on page 8 which provides supporting evidence.

4. In your testimony, you asserted that the scope of Section 101 caselaw is clear. Can you explain how you reached this outcome when many of the panelists disagreed?

   Proponents of PERA are not simply trying to clarify the law. They are trying to effect a radical policy change by completely eliminating long-standing Supreme Court jurisprudence that recognized some fundamental limits on the categories of inventions that could be eligible for patenting. Rather than articulate the policy preference they wish to enact by law, advocates for PERA instead try to justify the proposed legislation by claiming that the law is unclear.

   First, the two step analytical process articulated by the Supreme Court in *Mayo* and *Alice* is objectively neither hard to state nor to understand. Many district court judges have applied this standard at an early stage in patent litigation to dismiss patent claims as

invalid for being directed to patent ineligible subject matter. If this standard were hard to understand or apply, district court judges would be much more reluctant to grant motions to dismiss on such grounds.

Second, proponents of PERA and critics of the current Supreme Court jurisprudence on patent subject matter eligibility from time to time quote federal appellate judges in opinions invalidating patent claims where they state that they find the invention at issue to be highly meritorious and bemoan the necessity of invalidating the patent. Where a judge states clearly that he or she would like to rule one way but feels compelled by binding precedent to rule the opposite way, that judge is admitting that the law is clear. If it were not clear, the judge would rule in accordance with his or her views on the law and not decry the requirements of the law.

5. How does the approach to subject matter eligibility in PERA compare with that taken by other countries? Is there research showing a difference in quality and access to innovation for consumers, and ability to compete for innovators here in the U.S., relative to those jurisdictions?

   As a medical genetic testing company, we do not believe there is need for PERA. Beginning on page 8 of our written testimony, there is substantial research and evidence showing improved quality and access to innovation in the United States following the *Mayo* and *Myriad* Supreme Court decisions. If PERA were enacted, we warn that the United States may see the pace of progress in advancement and availability of precision medicine fall dramatically and may even lag behind other countries.

6. I understand that Alice/Mayo and the changes proposed in PERA affect innovation differently depending on many factors, including, among other things, the economic sector, industry, and firm size in question. What economic research or studies should policymakers be aware of in assessing Alice/Mayo's impact on innovation and the expected impact of PERA?

   I refer you back to my written testimony beginning on page 8 which provides market access research and other evidence demonstrating the substantial growth in genomics and precision medicine since 2013.

7. Is there any element or provision of PERA that you believe could positively clarify the issue of patent eligibility? Are there changes that could be made to PERA to address the concerns you've raised? Please explain in as much detail as possible.

   We believe that the current text of PERA is antithetical to the interests of the clinical genetic testing community and therefore do not believe that PERA could be improved by simple changes. If the goal were to codify the law on patent subject matter eligibility, we would recommend that PERA codify existing Supreme Court precedent as it relates to patent subject matter eligibility. This could be accomplished by adding a provision to PERA that requires natural materials and natural phenomena to be deemed prior art. Such an approach captures the animating philosophy behind current supreme court

jurisprudence on patent subject matter eligibility and it would not, as some have glibly asserted, cause the end of patent law as we know it. Rather it would preserve patent law largely as we know it and preserve it from the harms that would follow from enacting PERA.

8. 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?

   Invitae does not see a need for either of Mr. Jones's proposals, but, if the subcommittee were to pursue either or both of them in lieu of PERA, Invitae would welcome the opportunity to advise the subcommittee on how they might be pursued.

Senator Peter Welch
Senate Judiciary Committee
Subcommittee on Intellectual Property
Written Questions for Richard Blaylock
Hearing on "The Patent Eligibility Restoration Act – Restoring Clarity, Certainty, and Predictability to the U.S. Patent System"
January 23, 2024

Section 101(b)(1)(D) of the Patent Eligibility Restoration Act states that "An unmodified human gene, as that gene exists in the human body" is not patentable. However, Section 101(b)(2) creates two exceptions in which the human gene or natural material would not be considered unmodified and therefore patent eligible. These two exceptions are if the gene or natural material is:

- Isolated, purified, enriched, and otherwise enriched by human activity; or
- Employed in a useful invention or discovery.

A gene cannot be studied or tested inside the human body, it must be isolated, purified, sequenced, and amplified, essentially creating a man-made product that can then be used for diagnostics and testing. Under current law because of the *Myriad*[1] decision, the isolation, purification, etc., of a gene is not eligible for a patent. **In your opinion, if PERA became law:**

1. Would the exceptions in section 101(b)(2) of the bill mean that "isolated genes" are now patent eligible?

   Yes, if PERA were enacted, genes isolated from the body would be patent eligible because PERA expressly requires that result.

2. As written would section 101(b)(2) abrogate the *Myriad* decision?

   Yes. The *Myriad* decision stated, "A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated…" Section 101(b)(2) of PERA includes a condition that states a gene or natural material is considered to be modified if it is isolated, purified, enriched, or otherwise altered by human activity. Thus, this section of PERA directly reverses the unanimous decision from the *Myriad* case.
   This is not an accident. Section 2, paragraph (5), part (A) of PERA states that "[a]ll judicial exceptions to patent eligibility are eliminated." Thus, it is the intent of PERA to abrogate Myriad and all other Supreme Court precedent defining patent subject matter eligibility.

[1] Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

3. What practical implications could there be for medical providers and patients seeking genomic testing and diagnosis for diseases such as cancer?

   Patients and medical providers would suffer increasingly from lack of access to comprehensive genomic testing and somatic testing for diagnosis for diseases such as cancer as more and more relevant biomarkers would become inaccessible behind a new patent thicket that would emerge under PERA. PERA would enable highly dispersed ownership of patents on each incremental insight into genetic biomarkers that are relevant for cancer risk, cancer progression, and suitability for specific cancer treatment regimens. For example, if PERA were enacted, a clinician seeking to understand a patient's hereditary cancer risk may need to order genetic tests from multiple laboratories depending on the patent holder of each gene in order to obtain a complete and comprehensive evaluation of genetic risk for each of their patients. This would not only potentially increase the financial costs to patients and payers including Medicare, but also increase the administrative burden on clinicians, delay clinical care as patients wait for multiple test results, contribute to poor patient outcomes, and create unnecessary liability and malpractice risk for clinicians if they fail to order or review all necessary tests. Clearly, if PERA is enacted into law, the broader healthcare system should expect increasingly impaired access to genetic testing, higher costs, and poorer quality of healthcare.

   Dramatic increases in the cost of testing will occur for comprehensive genetic testing or even for access to the evolving standard of care for precision medicine. Prior to the *Myriad* decision in 2013, monopolies on specific genetic tests existed and I refer back to my written testimony beginning on page 6 in which I provide two detailed examples of the consequences of these patents on patient care, including hereditary breast cancer and long QT syndrome. PERA would return us to a pre-Myriad environment with genetic testing monopolists charging high prices for partial results and no provider able to offer comprehensive testing as is offered by multiple genomic testing companies today.

   This challenge will be particularly felt by lower income patients if they live in states with Medicaid programs that do not cover the only test available due to a monopoly. Further, patients will not have access to tests reflecting the latest scientific advances because just as was the case during the pre-*Myriad* period, providers having a patent on a specific necessary test will lack an adequate business incentive for them to update their tests. Most concerning of all, patients in the United States may find themselves with no access at all to critical, lifesaving genetic information if a patent holder opts not to commercialize a test nor license it, which was the case of long QT syndrome pre-2013.

   PERA would also shut down variant sharing data, pivotal to advancing our understanding and interpretation of genomic testing results for clinical care. After the hearing, I submitted additional written testimony for the record that specifically focused on the federal investment in genomic data sharing, its importance and what the elimination of this would mean for patients. PERA would disincentivize such data sharing which has been a key driver in rapid advancement and broadening of the benefits of genetic testing post-*Myriad.*

Questions from Senator Tillis
for Richard Blaylock
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. 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?

   We disagree with that concern as we are not seeing that phenomenon. From our experience, if a medical genetics company were to opt to develop commercially its genetic test overseas in favor of the U.S, there are far more significant drivers for such ex-US efforts such as poor and inconsistent coverage and reimbursement policies by Medicare and Medicaid. We disagree that patent eligibility standards are driving American medical genetic companies to develop innovation overseas.

2.

   a. In your opinion, how has the current state of unpredictability surrounding Section 101 hampered research, development and innovation, particularly in critical industries like life sciences, diagnostics, and artificial intelligence?

   We believe the current state of patent eligibility has helped the genetic testing and broader precision medicine and healthcare industries flourish in the US. I refer you back to my written testimony beginning on page 8 which provides evidence that shows this to be true since the pivotal *Myriad* decision in 2013.

   b. Absent legislative reforms – or some type of clarity from the Supreme Court – do you anticipate America falling behind in not only those key industries but other emerging technologies?

   No, I do not. The commercial and regulatory environment is much more likely to influence the pace of innovation and its implementation in the U.S. in comparison with other countries. Consider the commercial development and launch of new therapeutics. The availability of patent protection for new small molecule drugs is comparable in the U.S. and other advanced economies yet the U.S. remains a world outlier in the approval of and commercial availability of new therapeutics. The distinction arises from differences in our healthcare economy and availability of reimbursement from both private and public insurance and not our patent systems. If there are concerns in Congress about fostering innovation in medical genetics, life sciences or emerging technologies, Invitae would similarly recommend attention could be more profitably directed at the commercial and regulatory environments for those industries as well as levels of government supported research.

3. Some critics of PERA claim that restoring patent eligibility to gene-based technologies and diagnostics will impede scientific research, innovation, and access to diagnostics. But Europe has and continues to allow patents on all of these things, without any of these negative impacts. In fact, academic research in these areas thrives in Europe, and the diagnostics industry there now outcompetes the U.S. If eligibility for these technologies hasn't led to any negative outcomes in Europe, why do you think it would lead to these outcomes here under PERA?

   Invitae questions the assertion that Europe outcompetes the U.S. in clinical genetic diagnostics industry. For example, Invitae suggests that the subcommittee consider the data available in the NIH's Genetic Testing Registry[1], which is a global repository for the listing of genetic tests by providers from around the world. An analysis of the availability of genetic tests listed in the Genetic Testing Registry for the period from 2012 to 2022 showed that fully 49% of all of the listed clinical genetic tests in the world were associated with U.S. laboratories.[2] Since the U.S. is less than 5% of the world population and accounts for about 15% of global GDP, this represents a disproportionate share of the global clinical genetic testing availability and counters the suggestion that Europe is outcompeting the U.S. Notably, the period under study matches very closely the post-Myriad.

   In my supplemental written testimony, I described the NIH's ClinVar database which is the world's leading, authoritative database for clinically interpreted variants (aka genetic biomarkers). Invitae alone has contributed about 40% of the determinations of clinical relevance of variants in the database and U.S. sources collectively comprise well over half of all such contributors. The U.S. continues to lead the world in the clinical genetic testing space and PERA would imperil that reality.

   As I stated in my written and oral testimony, I believe that PERA would lead to negative outcomes in the United States, because we witnessed the consequences of such an approach to the law related to genetic testing in the pre-*Myriad* period and then the benefits of the current caselaw since then. Even the CEO of Myriad Genetics said the Supreme Court got it right on the 10th anniversary of the decision. Specifically, prior to 2013, patient access to genetic testing was greatly limited due to testing monopolies stemming from patents on human genes. I refer you back to my written testimony beginning on page 6 in which I describe at length multiple examples of these consequences for patients.

[1] https://www.ncbi.nlm.nih.gov/gtr/

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10142561/