**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 Andrei Iancu

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

RESPONSE TO QUESTION 1: Consumers should expect to have greater access to products based on the latest developments in computer-implemented technologies and medical advances. Whereas the Supreme Court's recent decisions in *Bilski*, *Mayo*, *Myriad*, and *Alice*, and their progeny, have called into question the ability to patent our inventions in these areas of technology—and for medical diagnostics, have made it clear that they are largely not patent eligible—under PERA, there would be clarity that these areas of innovation deserve patent protection (assuming the innovation meets the other statutory requirements for a patent). With that protection, we should expect to see more rapid innovation in addition to more breakthrough advances, which often come from smaller companies that need patents to secure capital and compete against entrenched incumbents. In addition, the incentives provided by patents can lead to decreased prices for consumers by encouraging competition in the same product space by multiple companies.

In addition to these consumer benefits, Americans would benefit from greater access to high-paying jobs. The U.S. Patent and Trademark Office's ongoing study of patent-intensive industries has consistently found that this segment of the economy has a significant wage premium, standing at 97% for 2019 in the latest report.[1] Providing clear rules around patent eligibility is one more way to make the United States an attractive location for these companies, and in turn, for the jobs they will bring.

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

RESPONSE TO QUESTION 2: PERA would eliminate the Supreme Court's confusing judicial exceptions—abstract ideas, laws of nature, and natural phenomena—and their further interpretations by the lower courts, and replace them with the longstanding statutory language allowing a patent for "any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof,"[2] followed by clearly-articulated categories that are not

[1] Andrew Toole et al., *Intellectual Property and the U.S. Economy: Third Edition*, U.S. PATENT AND TRADEMARK OFFICE 10 (2022), https://www.uspto.gov/sites/default/files/documents/uspto-ip-us-economy-third-edition.pdf.
[2] Proposed new 35 U.S.C. § 101(a). PERA § 3(a)(2) (note that the proposed language omits "new" from the current statutory text of § 101 while otherwise reciting "process, machine, manufacture, or composition of matter" in an

considered to be patentable inventions on their own.[3] The bill further provides guidance for when there is enough practical application of such matter for it to become patent eligible.

To illustrate:

(1) Claims that rely on concrete, physical descriptions of technical inventions would almost always be patent eligible (though not necessarily patentable), in contrast to the status quo where the judicial exceptions can be read so expansively that it would be nearly impossible for an applicant to know, when drafting the claim language, if claims would hold up before the examiner or later before a court.

A good example of a case that might come out the other way under PERA and ameliorate this type of confusion is *American Axle & Manufacturing* v. *Neapco Holdings*, 967 F.3d 1285 (Fed. Cir. 2020). In that case, a two-judge majority on the Federal Circuit held a patent claim (claim 22) to a method of making "propshafts" for automobiles to be ineligible under § 101 because they concluded that the claim was "directed to" the judicial exception of "a law of nature," Hooke's law.[4] The claim, however, makes no explicit reference to this law and instead describes the method with reference to the required physical attributes of the different components of the propshaft.[5] This claim reads:

> 22. A method for manufacturing a shaft assembly of a driveline system, the driveline system further including a first driveline component and a second driveline component, the shaft assembly being adapted to transmit torque between the first driveline component and the second driveline component, the method comprising:
>
> providing a hollow shaft member;
> tuning a mass and a stiffness of at least one liner, and
> inserting the at least one liner into the shaft member;
> wherein the at least one liner is a tuned resistive absorber for attenuating shell mod vibrations and wherein the at least one liner is a tuned reactive absorber for attenuating bending mode vibrations.[6]

Under PERA, this claim would easily satisfy new § 101(a) by being a "method." It also would not be identified as ineligible under any of the subparagraphs of § 102(b)(1). For example, it does not claim a mathematical formula "as such," which would lead to exclusion under § 102(b)(1)(A). Notably, although this claim would be patent eligible under the new § 101, it

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effort to clarify that questions of newness should be considered under the novelty analysis of § 102 rather than the eligibility analysis of § 101).

[3] Proposed new 35 U.S.C. § 101(b)(1)(A)-(E). PERA § 3(a)(2).

[4] *American Axle*, 967 F.3d at 1291 ("We conclude that independent claim 22 of the '911 patent is patent ineligible under section 101 because it simply requires the application of Hooke's law to tune a propshaft liner to dampen certain vibrations.").

[5] *See id.* at 1319 ("I cannot fathom the confusion that will be caused by declaring that claims are ineligible as directed to a natural law, when it is clear to all involved that this patent does not recite any particular natural law. Every mechanical invention must apply the laws of physics—that does not render them all ineligible, or maybe it does now.") (Moore, J., dissenting).

[6] *Id.* at 1290.

still might not satisfy the rest of the patentability criteria. As the dissent in *American Axle* wrote, the concerns that led the majority to find the patent ineligible under § 101—whether the patent had enough disclosure to teach a skilled artisan to make and use the full scope of the claimed invention—would more properly be addressed under the "enablement" prong of § 112.[7]

(2) Many claims to diagnostic methods would again become patent eligible, fixing the confusion caused by the Supreme Court's *Mayo* case in particular. This change would restore the stability needed in the patent system to justify significant investments to develop and validate diagnostics, including obtaining regulatory approval where needed.

One such case that might come out differently under PERA is *Athena Diagnostics* v. *Mayo Collaborative Services*,[8] which I discuss in my written testimony. In that case, the patent claimed a method of detecting a rare neurological disorder through the use of assays designed to test for the presence of certain antibodies. Under current Supreme Court case law, these claims were found patent ineligible as directed to a natural law—namely, the correlation between the presence of the antibodies and the neurological disorder—using conventional techniques.[9] PERA would likely allow such claims to be patent eligible, recognizing the investment of resources and ingenuity it takes to uncover these correlations and their value to patient well-being. As the dissenting judge wrote in *Athena*, "[u]ntil discovery of the diagnostic method described in [the patent-at-issue], some 20% of patients suffering from the neurological disorder *Myasthenia Gravis* were not capable of being diagnosed."[10]

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?

RESPONSE TO QUESTION 3: Please see the response above to Question 2.

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

RESPONSE TO QUESTION 4: The current state of the law hurts small innovators in at least two ways: first, it impedes their ability to attract capital investment. Venture capitalists and others are more likely to feel comfortable investing in research-intensive startups and small businesses that have patents to secure their rights. If patent protection is unavailable or uncertain in specific areas of technology, it will be harder for those startups and small businesses to receive funding.[11] If those businesses start disappearing from the U.S. or never get started in the first place, or are started in other countries with stronger patent systems, America's role as a global technology leader will suffer. Second, small innovators who lack access to robust, reliable

[7] *Id.* at 1317 ("The majority states the claim 'must identify "how" that functional result is achieved by limiting the claim scope to structures specified at some level of concreteness.' . . . this is a question of enablement, not eligibility.") (Moore, J., dissenting).
[8] 915 F. 3d 743 (Fed. Cir. 2019).
[9] *Id.* at 746.
[10] *Id.* at 757 (Newman, J., dissenting).
[11] *See, e.g.*, David Taylor, *Patent Eligibility and Investment*, 41 CARDOZO L. REV. 2019 (2020) (reporting on the reluctance of venture capitalists who are aware of the § 101 case law to invest in areas of uncertain protection).

patent protection will be less able to defend themselves against competitors, especially large, established competitors, who might copy successful products. Also, because the established competitor did not have to incur the research and development costs to create that successful product, it will be easier for them to undercut the smaller innovator on price. Even if the smaller innovator has a patent, if it is in a technological area falling within the uncertainty created by the Supreme Court's line of § 101 cases, the established company can bet that it will have at least a reasonable chance of invalidating the patent if it is sued for infringement, possibly quite early in the litigation without that company incurring many litigation expenses.

Academic researchers in areas with uncertain or unavailable patent protection also will face similar difficulties if they make discoveries with great potential for becoming consumer products because they will have trouble finding private sector partners and investors. For example, research that could lead to a new diagnostic tool will typically take significant investment beyond the initial laboratory success, including the expenses involved in FDA approval in many cases. Without patent protection to deter would-be copiers, the private sector will take its investment dollars elsewhere and the academic research will remain merely academic.

5. The Courts and the U.S. Patent Office have had 10 years to develop the Alice/Mayo caselaw and offer guidance to the innovation ecosystem about the scope of Section 101. PERA introduces new terms and standards that would have to be newly interpreted by the Courts. How long do you think it would take the Courts and the Patent Office to bring certainty to the application of the new Section 101 should PERA become law? Can you explain why a potential new period of uncertainty would be more attractive than the current status quo?

RESPONSE TO QUESTION 5: Once Congress finalizes the contours of PERA and passes it into law, it will bring an immediate amount of certainty to Section 101. It will do this by eliminating the judicial exceptions, which have proven to be unworkable over the past decade, and replacing them with a clear articulation of what is a patent-eligible invention and what is not. This structure of defined matter that is not an invention, such as "mathematical formulas," is much more amenable to judicial interpretation than amorphous terms like "abstract idea." While there will always be litigation at the outer edge of any term's meaning, the language of PERA starts off by being much more concrete. Importantly, this will not only help examiners and judges, but it will help inventors who do not have law degrees or experience in case law research understand whether they are operating within a patent-eligible field just by reading the statute. Any lay person now just reading the statute would probably not even realize that significant judicial exception exists to the plain text of Section 101.

I base my answer in part on the success we saw after introducing a new, comprehensive Section 101 guidance at the USPTO when I was Director. The guidance clarified, among other things, that the "abstract idea" judicial exception could be grouped into various categories. A study conducted through the USPTO's Office of the Chief Economist found that the introduction of this guidance significantly decreased the variability in decision-making between examiners

within only a year.[12] PERA, by making similar changes to the statute as the guidance, should help to reduce variability among examiners and judges in a similarly speedy period of time.

6. 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?

RESPONSE TO QUESTION 6: After the recent U.S. Supreme Court cases on patent eligibility, the patent systems of the United States's economic counterparts currently allow for the patenting of a broader range of innovation; academic scholarship has confirmed this assessment with a survey of patent applications that have been granted in the EU and China but not in the United States.[13] These trends are mirrored by shifts in capital investment from the United States to these other regions.[14]

Collectively, this data provides a concerning, early-stage warning of a shift in technological leadership to these other countries—companies are most likely to want to be located where they can secure returns on their investments in research and development, and venture capital is most likely to want to invest in those geographic locations as well. As new technology hubs are created, they are naturally the destinations for the next generation of innovators and entrepreneurs. While the U.S. has established technology hubs already that may obscure the beginning of this shift elsewhere, it will take the U.S. a long time to recover if the next generation of technologies are based on innovation centers in other countries.

7. 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. Mr. Blaylock's and your testimony reached different conclusions about the state of investment in R&D in the life sciences. What

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[12] Andrew A. Toole & Nicholas A. Pairolero, *Adjusting to Alice: USPTO Patent Examination Outcomes After Alice Corp. v. CLS Bank Internationa*l, U.S. PATENT AND TRADEMARK OFFICE (2020), https://www.uspto.gov/sites/default/files/documents/OCE-DH_AdjustingtoAlice.pdf.

[13] Kevin Madigan & Adam Mossoff, *Five Years Later, the U.S. Patent System is Still Turning Gold to Lead*, IPWATCHDOG (Dec. 15, 2019), https://www.ipwatchdog.com/2019/12/15/five-years-later-the-us-patent-system-is-still-turning-gold-to-lead/id=116984/; Kevin Madigan & Adam Mossoff, *Turning Gold to Lead: How Patent Eligibility Doctrine is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939 (2017); *The State of Patent Eligibility in America: Part III: Hearing Before the S. Subcomm. on Intellectual Property of the S. Comm. of the Judiciary*, 116th Cong. (2019) [hereinafter, "*2019 Patent Eligibility Hearing Part III*"] (written testimony of Gonzalo Merino, Vice President and Chief Intellectual Property Counsel, Regeneron Pharmaceuticals) ("The disparity in subject matter eligibility requirements between the US and other countries is stunning. Indeed, our applications that were rejected in the US have not been rejected elsewhere, including Europe and China.").

[14] Preetika Rana, *Your Cancer Drugs May Soon Be Discovered in China*, WALL STREET JOURNAL (Apr. 11, 2017), https://www.wsj.com/articles/china-emerges-as-powerhouse-for-biotech-drugs-1491816607; Jackie Snow, *China's AI Startups Scored More Funding Than America's Last Year*, MIT TECHNOLOGY REVIEW (2018), https://www.technologyreview.com/2018/02/14/145616/chinas-ai-startups-scored-more-funding-than-americas-last-year/; *see also* Elizabeth Chien-Hale, *A New Era for Software Patents in China*, LAW360 (May 25, 2017), https://www.law360.com/articles/924934/a-new-era-for-software-patents-in-china.

economic research or studies should policymakers be aware of in assessing Alice/Mayo's impact on innovation and the expected impact of PERA?

RESPONSE TO QUESTION 7: A variety of sources suggest that some research opportunities are being abandoned in the life sciences due to the inability to obtain patent protection under the current Supreme Court case law. For example, a number of witnesses previously testified before this subcommittee about their own organizations' inability to commit resources or obtain further funding where patent protection has become uncertain or unavailable.[15] Research has also shown a disparity in small companies being able to obtain patent protection in fields impacted by the Supreme Court's *Myriad* decision, in comparison to large companies—a concern given the role that smaller companies often play in advancing disruptive innovation.[16] Other research shows a shift in venture capital investments away from the U.S. and into other countries.[17] Finally, there is also literature directly showing a likely deficit in U.S. life sciences investment attributable to the decrease in patent protection available in the life sciences.[18]

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

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[15] *2019 Patent Eligibility Hearing Part III*, *supra* note 13 (written testimony of Peter O'Neill, Executive Director, Cleveland Clinic Innovations) ("Financial supporters of new products put significant weight on intellectual property rights, including patents, when issuing support. Those financial supporters are following federal court cases like ours, and weighing whether a patent is likely to withstand a court challenge. The absence of that financial backing can make it nearly impossible to bring products to market."); *id.* (response to question for the record of Sen. Tillis by Corey Salsberg, Vice President and Global Head Intellectual Property Affairs, Novartis) ("We and our peers across the world's innovative industries have long relied on America's leadership in innovation policy to fuel the work that we do, one of the primary reasons why we have made the United States home to our global R&D headquarters / . . . The strength and predictability of the United States patent system is a significant factor in making these types of investment decisions."); *see also The State of Patent Eligibility in America: Part I: Hearing Before the S. Subcomm. on Intellectual Property of the S. Comm. of the Judiciary*, 116th Cong. 7 (2019) (written testimony of Sherry M. Knowles, Principal, Knowles Intellectual Property Strategies, LLC) ("Nonlimiting examples of life-saving or disease curative drugs that are naturally occurring and would not be patentable, and thus would likely not have been developed under the Supreme Court case of *AMP v. Myriad Genetics* include penicillin, amoxil, tetracycline, cyclosporin, cephalosporin, streptomycin, chloramphenicol, insulin, Taxol, doxorubicin, vincristine, vinblastine, and many others."); *2019 Patent Eligibility Hearing Part III*, *supra* note 13 (written testimony of Laurie Hill, Vice President, Genentech, Inc.) (§ 101 rejections in patent applications include "cancer medicine using proteins from the patient's body and curated bacteria isolated from the patient's microbiome for treatment of Irritable Bowel Syndrome").

[16] Mateo Aboy et al., Myriad's *Impact on Gene Patents*, NATURE BIOTECHNOLOGY (2016).

[17] *See, e.g.*, Rana, *supra* note 14.

[18] A. Sasha Hoyt, *The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies*, 79 WASH. & LEE L. REV. 397 (2022), https://scholarlycommons.law.wlu.edu/wlulr/vol79/iss1/8.

inventions that embody an advance in technology." What are your views on these proposals?

RESPONSE TO QUESTION 8: Mr. Jones's proposals would not solve the problems created by the Supreme Court's patent eligibility jurisprudence, but rather would put America even further behind in global technological leadership. The first proposal would necessarily make the United States lag behind other countries—it calls for patent eligibility to expand based on already-proven success. Given the delay between breakthrough ideas and proof of commercial success, by the time a new technology is empirically proven to be "worthy" of patent protection under Mr. Jones's proposal, it would presumably already be produced somewhere else. Alternatively, companies might have already turned to trade secret protection in these new areas, and there would not necessarily be any need for them to embrace patent protection even if it subsequently became available. Under this scenario, the public would lose the benefit of patent disclosures, impeding further research and development and leading to silos of advances in technology. This model of innovation also tends to favor bigger, more established companies that can use their internal silos of knowledge, to the disadvantage of startups and small businesses—normally the primary drivers of disruptive innovation in our economy.

The second proposal presupposes that policymakers—or indeed anyone—can foresee what is going to be an "advance" in technology that merits protection. Innovation has continually shown itself to be unpredictable, which is why innovators are celebrated and often considered unconventional revolutionaries.

In addition, this proposal threatens to double-down on a problematic aspect of the Supreme Court's current patent eligibility jurisprudence: the conflation of "eligibility" with newness or "novelty" through its reliance on the concept of "advances" in technology. While not all new ideas are advances (some new ideas can be worse than the status quo), advances are necessarily new. Eligibility should be a separate inquiry.

**Senator Peter Welch**
**Senate Judiciary Committee**
**Subcommittee on Intellectual Property**
**Written Questions for The Honorable Andrei Iancu**
**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?
2. As written would section 101(b)(2) abrogate the *Myriad* decision?
3. What practical implications could there be for medical providers and patients seeking genomic testing and diagnosis for diseases such as cancer?

RESPONSE TO QUESTIONS 1 & 2: In *Association for Molecular Pathology* v. *Myriad*, the Supreme Court held that a claim to an isolated human gene, which is identical to the gene as found in a human, except for the chemical changes needed to separate it from the rest of the genetic material and work done to purify it, was not patent eligible under 35 U.S.C. § 101, but that laboratory-made complementary DNA (cDNA), which corresponds only to the segments of the gene that encode for a protein sequence, are patent eligible.[2] PERA, in line with longstanding precedent before *Myriad*, would likely allow for the patenting of both the isolated DNA corresponding to the gene and the cDNA corresponding to the coding sequences of the gene.[3] The bill would accordingly overrule-in-part and affirm-in-part the Supreme Court's *Myriad* holding.

Although an isolated human gene would again be patent eligible, it would not automatically pass the other statutory requirements for being awarded a patent (novelty, non-obviousness, and the

[1] *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, 569 U.S. 576, 133 S. Ct. 2107 (2013).
[2] *Id.* at 2119-2120.
[3] *See, e.g.*, *Parke-Davis & Co.* v. *H.K. Mulford Co.*, 189 F. 95 (C.C.S.D.N.Y. 1911) (holding isolated adrenaline to be patent eligible) (Hand, J).

disclosure requirements of 35 U.S.C. § 112). In particular, the complete sequencing of the human genome is now known and publicly available.

RESPONSE TO QUESTION 3: The practical application for patients seeking genomic testing would be the future availability of better, more precise testing with robust reproducibility. Restoring patent protection for the field of medical diagnostics generally (including diagnostics predicated on genomic testing) will restore the incentives for companies to invest the resources necessary to develop testing that can pass regulatory scrutiny—itself a very expensive process. Without the ability to recoup investments, companies are going to be less willing to commercialize correlations discovered in the laboratory. Even if these correlations are still published, they may never have the benefit of receiving widespread validation and testing to assess how generalizable the correlation is across entire populations, or to have the test-in-question scrutinized by a regulatory agency. In sum, patients are likely to see a decrease in new diagnostics going forward, absent a restoration of certain, predictable patent rights. PERA would likely *increase* the availability of effective genome tests and improve diagnostic ability for diseases, such as cancer.

**Questions from Senator Tillis**
**for Andrei Iancu**
**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?

RESPONSE TO QUESTION 1: Yes, I agree with that concern. After the recent U.S. Supreme Court cases on patent eligibility, the patent systems of the United States's economic counterparts currently allow for the patenting of a broader range of innovation. Academic scholarship has confirmed this assessment with a survey of patent applications that have been granted in the EU and China but not in the United States.[1] These trends are mirrored by shifts in capital investment from the United States to these other regions.[2]

Collectively, this data provides a concerning early-stage warning of a shift in technological leadership to these other countries—companies are most likely to want to be located where they can secure returns on their investments in research and development, and venture capital is most likely to want to invest in those geographic locations as well. As new technology hubs are created, they are naturally the destinations for the next generation of innovators and entrepreneurs. While the U.S. has established technology hubs already that may obscure the beginning of this shift elsewhere, it will take the U.S. a long time to recover if the next generation of technologies are based on innovation centers in other countries.

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[1] Kevin Madigan & Adam Mossoff, *Five Years Later, the U.S. Patent System is Still Turning Gold to Lead*, IPWATCHDOG (Dec. 15, 2019), https://www.ipwatchdog.com/2019/12/15/five-years-later-the-us-patent-system-is-still-turning-gold-to-lead/id=116984/; Kevin Madigan & Adam Mossoff, *Turning Gold to Lead: How Patent Eligibility Doctrine is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939 (2017); *The State of Patent Eligibility in America: Part III: Hearing Before the S. Subcomm. on Intellectual Property of the S. Comm. of the Judiciary*, 116th Cong. (2019) [hereinafter, "*2019 Patent Eligibility Hearing Part III*"] (written testimony of Gonzalo Merino, Vice President and Chief Intellectual Property Counsel, Regeneron Pharmaceuticals) ("The disparity in subject matter eligibility requirements between the US and other countries is stunning. Indeed, our applications that were rejected in the US have not been rejected elsewhere, including Europe and China.").

[2] Preetika Rana, *Your Cancer Drugs May Soon Be Discovered in China*, WALL STREET JOURNAL (Apr. 11, 2017), https://www.wsj.com/articles/china-emerges-as-powerhouse-for-biotech-drugs-1491816607; Jackie Snow, *China's AI Startups Scored More Funding Than America's Last Year*, MIT TECHNOLOGY REVIEW (2018), https://www.technologyreview.com/2018/02/14/145616/chinas-ai-startups-scored-more-funding-than-americas-last-year/; *see also* Elizabeth Chien-Hale, *A New Era for Software Patents in China*, LAW360 (May 25, 2017), https://www.law360.com/articles/924934/a-new-era-for-software-patents-in-china.

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?

RESPONSE TO QUESTION 2.a. The current state of unpredictability of patent eligibility (or unavailability in the life sciences) has compounded the risks that investors must consider before funding promising technology-driven companies. Not only are there the many other reasons a company might fail—inability to develop a successful product, personnel issues, failure of commercial success—but if a company is successful and loses its patent protection (or never has it in the first place), there will be virtually nothing to stop a competitor from copying and selling the product.

For the life sciences, a variety of sources suggest that research opportunities are being abandoned due to the inability to obtain patent protection under the current Supreme Court case law. For example, a number of witnesses previously testified before this subcommittee about their own organizations' inability to commit resources or obtain further funding where patent protection has become uncertain or unavailable.[3] Research has also shown a disparity in small companies being able to obtain patent protection in fields impacted by the Supreme Court's *Myriad* decision, in comparison to large companies—a concern given the role that smaller companies often play in advancing disruptive innovation.[4] Other research shows a shift in venture capital investments away from the U.S. and into other countries.[5] Finally, there is also literature directly showing a likely deficit in U.S. life sciences investment attributable to the decrease in patent protection available in the life sciences.[6]

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[3] *2019 Patent Eligibility Hearing Part III*, *supra* note 1 (written testimony of Peter O'Neill, Executive Director, Cleveland Clinic Innovations) ("Financial supporters of new products put significant weight on intellectual property rights, including patents, when issuing support. Those financial supporters are following federal court cases like ours, and weighing whether a patent is likely to withstand a court challenge. The absence of that financial backing can make it nearly impossible to bring products to market."); *id.* (response to question for the record of Sen. Tillis by Corey Salsberg, Vice President and Global Head Intellectual Property Affairs, Novartis) ("We and our peers across the world's innovative industries have long relied on America's leadership in innovation policy to fuel the work that we do, one of the primary reasons why we have made the United States home to our global R&D headquarters / . . . The strength and predictability of the United States patent system is a significant factor in making these types of investment decisions."); *see also The State of Patent Eligibility in America: Part I: Hearing Before the S. Subcomm. on Intellectual Property of the S. Comm. of the Judiciary*, 116th Cong. 7 (2019) (written testimony of Sherry M. Knowles, Principal, Knowles Intellectual Property Strategies, LLC) ("Nonlimiting examples of life-saving or disease curative drugs that are naturally occurring and would not be patentable, and thus would likely not have been developed under the Supreme Court case of *AMP v. Myriad Genetics* include penicillin, amoxil, tetracycline, cyclosporin, cephalosporin, streptomycin, chloramphenicol, insulin, Taxol, doxorubicin, vincristine, vinblastine, and many others."); *2019 Patent Eligibility Hearing Part III*, *supra* note 1 (written testimony of Laurie Hill, Vice President, Genentech, Inc.) (§ 101 rejections in patent applications include "cancer medicine using proteins from the patient's body and curated bacteria isolated from the patient's microbiome for treatment of Irritable Bowel Syndrome").

[4] Mateo Aboy et al., Myriad's *Impact on Gene Patents*, NATURE BIOTECHNOLOGY (2016).

[5] *See, e.g.*, Rana, *supra* note 2.

[6] A. Sasha Hoyt, *The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies*, 79 WASH. & LEE L. REV. 397 (2022), https://scholarlycommons.law.wlu.edu/wlulr/vol79/iss1/8.

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?

RESPONSE TO QUESTION 2.b. Yes, the U.S. risks falling behind not only in the key industries you have listed, but in other emerging areas of innovation, too. The trend we are already seeing in the areas we know about gives reason to be concerned that the U.S. is falling behind in general in its leadership of innovation. If that trend continues, the locus of intellectual activity will be located in hotspots other than Silicon Valley or North Carolina's Research Triangle, and this includes areas of innovation that are yet to be invented.

3. During your time at the USPTO, you issued guidance to clarify the state of Section 101 law. This guidance did a lot of good, but even you have stated that this guidance is not enough.

   As someone who has been on the forefront of IP policy in our country, why do you think Congress needs to legislate today?

RESPONSE TO QUESTION 3: Congress needs to legislate today to ensure that the U.S. does not fall behind in the world's leadership of innovation.

The guidance that the USPTO put in place while I was Director has helped provide more certainty and clarity for examiners and patent applicants, but it necessarily had to operate within the bounds of the Supreme Court and Federal Circuit's case law.[7] It is ultimately this case law that needs to be addressed, and in my opinion, fixed, by Congress through legislation such as PERA. In addition, the courts are not bound by USPTO guidance, and legislation is the only way to reverse the confusion caused by these decisions.

4. Ensuring that America can compete economically on the global stage is a primary goal of mine.

   A predictable patent system is key to this goal. Inventors need to be incentivized to dream up new inventions and creations. Investors need to be incentivized to fund our inventors. A predictable patent system provides such incentivizes because inventors will be assured that their works are protected, and investors will be able to see returns on their investments because competitors will not be able to steal inventions.

   I am concerned that the state of Section 101 law is hurting American competitiveness.

   Do you think that's true? Do you think other countries are providing more predictability in their patent systems than we are?

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[7] *See* Andrew A. Toole & Nicholas A. Pairolero, *Adjusting to Alice: USPTO Patent Examination Outcomes After Alice Corp. v. CLS Bank Internationa*l, U.S. PATENT AND TRADEMARK OFFICE (2020), https://www.uspto.gov/sites/default/files/documents/OCE-DH_AdjustingtoAlice.pdf.

RESPONSE TO QUESTION 4: Yes, I do think that other, national patent systems currently are providing more predictability on eligibility than the United States, and that this is affecting American competitiveness as I have described in my responses to questions 1 and 2. The Supreme Court's jurisprudence, particularly on what constitutes an "abstract idea" as one of the judicial exceptions to § 101, lends itself to uncertainty. Lower courts have struggled to make sense of the boundaries of this exception, and have applied it to cases where the patent claims are directed to physical embodiments of mechanical products—it is hard to see how anyone could predict that descriptions of concrete machines could be considered abstract, and this inability to predict hampers inventors, small businesses, and those who want to fund them. PERA addresses this problem by providing a clear list of what is and what is not eligible for patent. If enacted, this bill should provide significantly more certainty to the patent system going forward.

5. As Justice Thomas and others have said, all inventions essentially build off of laws of nature, natural phenomena, or abstract ideas.

   In drafting PERA, I thought it was important to make sure that our legislative exceptions do not constitute per se rules in which inventions that have certain elements that fall under these exceptions are automatically deemed unpatentable. You agreed with me in your testimony.

   Why is it important that we do not have per se rules and can you give examples of technologies that might contain certain elements that fall under these exceptions, but should not be excluded from patentability?

RESPONSE TO QUESTION 5: It is important to delineate not only what is not an eligible invention on its own, but also how an invention that has one element that might not be eligible on its own—such as a mathematical formula—is integrated enough with eligible matter into a practical application that renders the combination eligible for a patent. To stay with the example of a mathematical formula, physics is replete with mathematical formulas corresponding to how materials interact in the world. If a machine is developed that uses one of these formulas as part of how it operates, it quite likely should be patent eligible as a machine, and granted as a patent provided that the invention meets the rest of the conditions for patentability (novelty, non-obviousness, and sufficient disclosure).