Answers To Questions For The Record from Senator Tillis
for Courtenay C. Brinckerhoff,[1]
Witness for Senate Committee on the Judiciary, Subcommittee on Intellectual Property,
January 23, 2024 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?*

   I agree with this concern. Anecdotally, I have clients in the diagnostics space who are no longer filing patent applications in the U.S. (because diagnostic methods as such are considered to be not eligible for patenting under *Mayo*), but continue to seek and obtain patents in Europe, where they will develop their products and spend their further research and development resources.

   While many U.S. companies continue to innovate in the diagnostic space, many doing so are maintaining their discoveries as trade secrets. This will not have the same impact on driving innovation as patent protection would, because the discoveries are not being made known to others who might improve upon them or build new innovations on them. In his written and live testimony, Mr. Blaylock argued that PERA would undesirably "permit the privatization of natural phenomena in the form of knowledge of new biomarkers and their clinical relevance," but it is the current state of Section 101 that incentives innovators to keep their discoveries to themselves. Mr. Blaylock's position forgets that patent rights come with the cost of public disclosure, and only last for a limited time. Without PERA, innovators have little reason to share what they learn about newly discovered disease biomarkers and personalized medicine, and more reason to develop their technologies in-house while keeping the underlying methodology a trade secret. It is the trade secret paradigm, not the patent system, that rewards "privatization" of knowledge.

   I am aware of an empirical study reported in 2022 in the Washington and Lee Law Review[2] that determined that, "in the four years following *Mayo*, investment in disease diagnostic technologies was nearly $9.3 billion dollars lower than it would have been absent *Mayo*." The study focused on venture capital investment in the United States, in particular. While it did not consider whether money was invested in other countries instead, it at least indicates reduced investment in specific U.S. industries impacted by *Mayo*, which is of grave concern.

[1] I am a partner at Foley & Lardner LLP, but my testimony is based on my personal opinions, and should not be understood to reflect the views of Foley & Lardner LLP, its partners, or its clients.

[2] Hoyt, *The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies*, WLULR 79(1): 397-452, available at https://scholarlycommons.law.wlu.edu/wlulr/vol79/iss1/8/ (accessed Feb. 19, 2024).

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?*

In my opinion, the current state of unpredictability surrounding Section 101 undermines confidence in investing in technologies impacted by the Supreme Court decisions (and subsequent Federal Circuit and district court decisions that have expanded their reach), including diagnostics and pharmaceutical and other industries that may exploit unique properties of isolated natural products (such as chemicals isolated from plants and isolated microorganisms). The ever-changing contours of the "judicially-created exceptions" under Section 101 adds another level of unpredictability to industries that already face a high level of risk due to long development timelines and risk of failure for technical reasons. When the "judicial exceptions" are applied in an unpredictable manner, the validity of a patent and the value of associated technologies also are unpredictable. Section 101 issues are considered in potential deals, and unpredictability can be a drag on valuation and impact investment decisions.

The risks associated with Section 101 are all the more acute because patent challenges are most likely to come *after* a product has been commercialized and attracted competitors—e.g., after the technical hurdles have been overcome and significant investment has been made in the technology. Overall, this means funding may be more difficult to secure and/or valuations may be decreased due to the diminished scope of patent protection and risk that patents will be invalidated under Section 101 after significant investments have been made. This in turn acts as a drag on innovation and hampers robust economic development in impacted fields.

(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?

I have concerns about the relative disadvantage caused by the current state of patent eligibility in the U.S. Since its inception, the U.S. patent system has encouraged investment in innovation, spawning new technologies and entirely new industries and helping propel the U.S. to its preeminent status. Patent rights are even more important today, where U.S. companies compete on a global stage in a global economy, and against entities supported by foreign governments, including China. U.S. innovation is driven by private capital that must be backed by the rewards of the patent system—the right to exclude others *for a limited time*. But, since *Mayo*, *Myriad*, and *Alice*, there are important inventions in critical technologies that cannot be patented in the U.S. that can still be patented in other countries, including Europe, Japan, and China. This puts U.S. innovators at a disadvantage, and undermines the potential rewards of investing in U.S. innovation. The size of the U.S. market will always make it important, but for industries with long, expensive, and risky development timelines, the cost-benefit analysis is skewed when patent protection is uncertain or unavailable, especially when it is available with certainty in other countries.

3. *In your experience, does the state of Section 101 have a greater impact on smaller or larger companies and why?*

   In my experience, sole inventors and smaller companies are more impacted by the uncertainty, for several reasons. First, innovators may not realize the current state of the law, and may invest in their technologies before learning the technology cannot be patented. Many of the lines drawn are counter-intuitive, and do not make sense to scientists or engineers. Additionally, sole inventors and smaller companies do not have the resources to spread the risks or hedge their bets, and do not have the infrastructure or market position to commercialize their technologies without patent protection. While larger companies may be able to bring (non-pharmaceutical) products to market without a patent, smaller companies need patents to attract investors or for acquisition deals. Without patents, the technology may be shelved and companies shut down. Additionally, the expanding applications of the "judicial exceptions" can particularly impact sole inventors and small business, who may invest everything in technology protected by a patent, only to have it unexpectedly wiped out as a judicial exception.

4. *In your experience, does the state of Section 101 have a greater impact on clients in specific technology areas?*

   In my experience, the way the "judicial exceptions" to Section 101 are being applied is picking winners and losers in technology areas in a manner that does not make sense from a scientific standpoint or market perspective. Diagnostics are the biggest losers, as court decisions leave little room for eligibility whenever the invention touches on diagnosing a disease or condition, determining which treatment is likely to be most effective in a given patient, etc. No matter how many details are added to the claims, unless they involve *a new laboratory technique* they are likely to be found ineligible. In contrast, computer-related technologies may be found eligible if they embody an "improvement in an existing technology"—which does not have to be the computer hardware. Yet, diagnostics and personalized medicine are at the forefront of medical innovation. Shouldn't our patent system encourage investment in these fields that are so critical to well-being?

   In other life sciences areas, the current state of Section 101 favors development of synthetic chemical products or modified versions of naturally-occurring products, even if the naturally-occurring product would be just as useful. This doesn't make sense to innovators, who understand that discovering a new substance and determining its usefulness can make a more significant contribution to the state of the art than modifying an existing one. The constraints of the current state of Section 101 are skewing incentives to innovate and invest in a direction that technology and other market forces might not favor, and that are not necessarily beneficial to the public in general or consumers in particular.

5. *How could the requirements for patentability, under Sections 102, 103, and 112, address concerns that have been addressed under Section 101?*

   Section 101 has been invoked when there is question whether the subject matter is *deserving* of a patent, but the other statutory requirements for a patent provide limitations on a case-by-

case basis that can address these concerns without preventing patents from being granted across entire fields of technology. For example, products of nature that already have been identified are barred from patenting by Section 102, methods that make only incremental contributions over the prior art may be barred from patenting by Section 103, and claims that reach beyond what the inventor has described and enabled in the patent are invalid under Section 112. In that regard, many patent claims that have been invalidated under the "abstract idea" judicial exception could have been challenged under Section 112. Thus, it is important to keep in mind that patent eligibility under Section 101 is just a threshold requirement. The subject matter still must satisfy the other statutory requirements for a patent set forth in Sections 102, 103, and 112 before a patent will be granted or upheld.

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

   If PERA becomes law, U.S. consumers will continue to benefit from the robust economy and high quality of life that has been engendered, fostered, and incentivized by having a robust patent system. With regard to the life sciences industry, most if not all products on the market today stem from inventions made *before* the Supreme Court decisions that upended U.S. patent eligibility law as we knew it, and certainly before the U.S. Patent and Trademark Office (USPTO) issued its 2019 Patent Eligibility Guidance to examiners that applied the *Myriad* decision to subject matter other than isolated genes and applied the *Mayo* decision to new diagnostic markers. Thus, consumers have not yet felt the brunt of these decisions. As such, of greater concern is the outcome for consumers if PERA does *not* become law, because consumers will be missing out on innovations that will not be developed (or not marketed in the U.S.) because patent rights are not available to protect investments in the nascent technologies.

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

   Court decisions that have invalidated patents under *Mayo*, *Myriad*, and *Alice*, provide clear indications of types of inventions that would once again be eligible for a patent again under PERA. These include important and "ground-breaking" diagnostic methods, such as the subject matter at issue in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.,*[4] which permitted diagnosis of certain fetal characteristics via maternal blood tests instead of invasive and dangerous amniocentesis procedures, the subject matter at issue in *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC,* [5] which permitted diagnosis of neurological disorders such as myasthenia gravis based on a novel biomarker that could identify patients missed by prior state-of-the-art testing, and the subject matter at issue in *Roche Molecular Sys., Inc. v. Cepheid*, [6] which permitted rapid detection of bacteria associated with tuberculosis where the prior state-of-the-art test was less informative and required weeks.

   PERA also would provide clarity that pharmaceutical formulations of "natural products" can be patented. Court decisions after *Myriad* have gone both ways, invalidating some

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[4] 788 F.3d 1371 (Fed. Cir. 2015).

[5] 927 F.3d 1333, 1335-36 (Fed. Cir. 2019).

[6] 905 F.3d 1363 (Fed. Cir. 2018).

formulation patents (including a patent on a formulation having a certain minimum ratio of "omega-6 and omega-3 fatty acids" and "contained in one or more complementing casings providing controlled delivery of the formulation to a subject") [7] and upholding others (such as a "dietary supplement" with "beta-alanine in a unit dosage of between about 0.4 grams to 16 grams").[8] This inconsistency leaves innovators and competitors in the formulation space with no clear guidance on what is and is not eligible for patenting, and that uncertainty hampers both innovation and competition. PERA provide clarity that pharmaceutical formulations of "natural products" are eligible for patenting.

PERA would restore the patent eligibility of new and useful "isolated" natural products, including isolated natural products that may be useful as medications, diagnostic agents, vaccines, antibiotics, or in industrial applications, such as bacteria used in brewing, baking, cheese- and yogurt-making, oil- and plastic-degrading bacteria used for environmental remediation, and carbon-fixing microbes used to address CO_2 emissions.

For all of these reasons, PERA would restore patent eligibility to what was eligible for patenting before the 2012-2014 Supreme Court decisions in *Mayo*, *Myriad,* and *Alice.* As I understanding it, PERA would *not* make subject matter "newly eligible" that was not eligible previously.

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?*

   I believe the cases outlined above address this question, and highlight my concerns regarding the lack of patent eligibility for ground-breaking diagnostic innovations, and the uncertainty surrounding how Section 101 will be applied to natural products (such as the inconsistent treatment of formulation patents noted above).

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

   I believe the current state of the law has an outsized impact on smaller innovators who require private investment and/or collaborations to take their inventions from the laboratory to the marketplace. Likewise, while academic research may be partially funded by institutional or government grants at the start, they ultimately require private investment or collaborations for commercialization. The availability and existence of valid and enforceable patent rights are essential for attracting investors and securing deals. When innovators and researchers cannot patent their inventions, their ability to take their technology to the marketplace is severely limited, because third parties do not want to risk investing in technology that others will be permitted to freely copy. Additionally, sole inventors and smaller companies do not have the resources to spread the risks or hedge their bets, and do not have the infrastructure or market position to commercialize their technologies without patent protection. While larger companies may be able to bring (non-pharmaceutical)

[7] *In re Bhagat*, No. 2016-2525 (Fed. Cir. Mar. 16, 2018) (unpublished).

[8] *Nat. Alts. Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338 (Fed. Cir. 2019).

products to market without a patent, smaller companies need patents to attract investors or for acquisition deals. Without patents, the technology may be shelved and companies shut down. The empirical study reported in 2022 in the Washington and Lee Law Review[9] determined that, "in the four years following *Mayo*, investment in disease diagnostic technologies was nearly $9.3 billion dollars lower than it would have been absent *Mayo*." This study indicates that the current state of Section 101 is having a concrete, negative impact on investment in innovations impacted by the "judicial exceptions."

5. *The Courts and the U.S. Patent Office have had 10 years to develop the Alice/Mayo caselaw and guidance for the innovation ecosystem. 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?*

   As I noted above, for life sciences technologies such as diagnostics and isolated natural products, PERA would *restore* patent eligibility to what was eligible for patenting before the 2012-2014 Supreme Court decisions in *Mayo*, *Myriad,* and *Alice.* Thus, rather than signify a new paradigm, it would restore the status quo prior to *Mayo*. Additionally, the current draft of PERA itself provides specific examples that will inform its interpretation and application.

   When considering this issue, I think it is important to keep in mind that even though *Mayo*, *Myriad,* and *Alice* were decided 10 years ago, still today there is no certainty or predictability in how a court will apply the "judicial exceptions" to Section 101. As one example, in my written testimony I discussed the Federal Circuit decisions in *Yu v. Apple Inc.*[10] (invalidating claims to a digital camera) and *Cardionet, LLC v. Infobionic, Inc.*[11] (upholding claims to a medical device) as emblematic of this unpredictability, which seems especially acute for applications of the "abstract idea" exception.[12] Additionally, although the U.S. Patent Office has issued guidance for examiners, courts are not bound by that guidance, and have expressly declined to follow that guidance.[13] This undermines confidence in the validity of patents granted today, since they still could be challenged under a new extrapolation of *Mayo*, *Myriad,* or *Alice.*

   Thus, rather than supporting a cautious approach to PERA, the case law that has developed over the past 10 years and that continues to expand the "judicial exceptions" underscores the urgent need for legislative action.

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[9] Hoyt, *The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies*, WLULR 79(1): 397-452, available at https://scholarlycommons.law.wlu.edu/wlulr/vol79/iss1/8/ (accessed Feb. 19, 2024).

[10] 1 F.4th 1040 (Fed. Cir. 2021).

[11] 955 F.3d 1358 (Fed. Cir. 2020).

[12] *See e.g., Am. Axle & Mfg. v. Neapco Holdings, 967 F.3d 1285* (Fed. Cir. 2020).

[13] *See, e.g., Cleveland Clinic Found. v. True Health Diagnostics LLC,* 760 F. App'x 1013 (Fed. Cir. 2019).

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?*

In my written testimony, I highlighted how the current state of U.S. patent eligibility is at odds with what is considered patentable subject matter in other jurisdictions, including Europe, Australia, China, Japan, and Korea. PERA would address the current international divide in what types of inventions can be patented.

PERA's approach to subject matter eligibility is analogous in several ways to that taken in other countries. For example, like PERA, the European Patent Office ("EPO") excludes specific subject matter (like scientific theories), but permits patenting of isolated genes and gene fragments as long as the patent's description "indicate[s] the way in which the invention is capable of exploitation in industry."[14] Similarly, under PERA, an isolated gene would be *eligible* for patenting as long as it is "useful," where "useful" is defined as having "a specific and practical utility from the perspective of a person of ordinary skill in the art to which the invention or discovery pertains."

The EPO's commentary on the patent eligibility of certain "discoveries" in Europe is consistent with my understanding of what types of "isolated" natural products would be restored to eligibility under PERA. This EPO commentary states:

> An example of such a case is that of a substance occurring in nature which is found to have an antibiotic effect. In addition, if a microorganism is discovered to exist in nature and to produce an antibiotic, the microorganism itself may also be patentable as one aspect of the invention. Similarly, a gene which is discovered to exist in nature may be patentable if a technical effect is revealed, e.g. its use in making a certain polypeptide or in gene therapy.[15]

Indeed, the fact that the other patent offices who are part of the "IP5" (the forum of the five largest intellectual property offices in the world), have seen the changes in U.S. patent law under *Mayo*, *Myriad,* and *Alice* and decided *not* to follow the U.S.'s "lead," is a sign that they have determined that restricting patent eligibility as the U.S. has done would not be beneficial to their economies.

As noted above, the 2022 Washington and Lee Law Review article cited above determined that, "in the four years following *Mayo*, [U.S.] investment in disease diagnostic technologies was nearly $9.3 billion dollars lower than it would have been absent *Mayo*." Similarly, David

[14] European Patent Office, "Guidelines for Examination in the European Patent Office," Part G (Patentability), Chapter III (Industrial application), part 4 (Sequences and partial sequences of genes), https://www.epo.org/en/legal/guidelines-epc/2023/g_iii_4.html (accessed Jan. 13, 2024).

[15] European Patent Office, "Guidelines for Examination in the European Patent Office," Part G (Patentability), Chapter II (Inventions), part 3.1 (Discoveries), https://www.epo.org/en/legal/guidelines-epc/2023/g_ii_3_1.html (accessed Feb. 19, 2024).

Taylor concluded from a survey of investors reported in the Cardozo Law Review in 2019[16] that investors held an "overwhelming belief that patent eligibility is an important consideration in investment decision-making, and that reduced patent eligibility makes it less likely their firms will invest in companies developing technology." While these studies focus on innovators' access to investment, a decrease in investments today will lead to decreased consumer access to innovations tomorrow.

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. 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 to the studies cited above, but note that this is outside my field of expertise.

8. *How has Alice/Mayo impacted patent litigation and how would PERA impact patent litigation?*

   My practice does not focus on patent litigation, but I understand that *Alice* and *Mayo* have impacted patent litigation by permitting patent challengers to invalidate patents at an early stage of litigation, such as at the motion to dismiss stage, on a record with very little or no evidence other than the patent document itself. Moreover, the uncertainty surrounding the scope of the "judicial exceptions" and the willingness of courts to invalidate seemingly concrete inventions as "abstract ideas," has incentivized challenges based on patent eligibility. PERA would reign in the use of Section 101 as a blunt instrument against patents, and would require patent eligibility determinations to be made on a more precise basis.

9. *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?*

   At the outset, I disagree with Mr. Jones's position that the U.S. Patent Office and courts are applying the "judicial exceptions" to Section 101 in a predictable manner. The only predictability in the life sciences space is that diagnostic methods as such are *not* eligible for patenting, but certainty in what cannot be patented does not incentivize innovation. The

[16] Taylor, *Patent Eligibility and Investment*, 41 Cardozo Law Review 2019-116, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3340937 (accessed Feb. 19, 2024).

contrasts provided by the formulation and device cases cited above are just two examples of ongoing, problematic uncertainty.

I also disagree that any consistency in how the U.S. Patent Office applies Section 101 should weigh against the need for legislative reform. The U.S. Patent Office has issued guidelines for examiners to follow, but those guidelines are not binding on (or followed by) the courts, and always lag behind the most recent court decisions. As I noted in my written testimony, the U.S. Patent Office *2016* Patent Eligibility Guidance was inconsistent with the Federal Circuit's *2015* decision in *Sequenom*, because it took until later in 2016 for the Federal Circuit decision to become final (*e.g.*, the Supreme Court did not deny *certiorari* in *Sequenom* until June 2016, after the USPTO's May 2016 guidance was promulgated). The years that pass between a district court's expansive application of a "judicial exception" and a final determination of whether that holding will stand represent years of uncertainty not only for the parties to the litigation, but to all innovators and competitors potentially impacted by a similar decision.

Turning to Mr. Jones's approaches, I understand alternative (1) to be a backward-looking approach that would only attempt to remedy harm after it had occurred. I do not understand how such an approach could promote investment in innovation. Once R&D investment has not occurred in a given area of technology, it will be too late to incentivize innovation in that space. The fallacy of this approach is underscored by the fact that the technologies addressed by PERA can be patented in other countries. Thus, even today innovators in other countries are still incentivized to invest in R&D, and publish and patent their inventions in these areas, leaving U.S. innovators out in the cold.

Furthermore, it seems likely that alternative (1) ultimately would create additional unpredictability and inconsistency. It already is difficult to pin down which industries would qualify as "areas of technology for which the current jurisprudence has created significant and empirically demonstrable impediments," and this difficulty will be exacerbated as lines between various "areas of technology" continue to blur. For example, methods of treatment are still eligible for patenting under the current judicial exceptions, but as the industry continues to shift towards reliance on big data, artificial intelligence, and personalization, there is a risk that certain types of treatments will be deemed ineligible under the "abstract idea" or "natural phenomenon" paradigms. If this occurs, there could be a divide across the health care industry, with some treatment modalities eligible for patenting and some that would experience "significant and empirically demonstrable impediments" and not be brought to market due to lack of availability of patent protection.

In general, we are seeing technology become more complex and interconnected, and many inventions do not fall neatly within well-defined categories. As such, the retrospective approach of alternative (1) seems not only insufficient to address current problems, but also likely to create even more uncertainty that will further hinder investment in innovations that do fit squarely under current paradigms.

With regard to alternative (2), if PERA is considered in the context of the Patent Act as a whole, it already may achieve the objective of tying "patentability" to "inventions that

embody an advance in technology." Patent eligibility under Section 101 is just a threshold requirement. The subject matter still must satisfy the other statutory requirements for a patent set forth in Sections 102, 103, and 112 before a patent will be granted or upheld, which include requirements of novelty and non-obviousness. Moreover, the current draft of PERA retains the "useful" requirement of Section 101, and defines "useful" as having "a specific and practical utility from the perspective of a person of ordinary skill in the art to which the invention or discovery pertains."

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In my written testimony, I proposed a change to the current draft language of PERA to signal and make clear that diagnostic methods are being addressed, but mis-cited the specific subsection at issue. That proposal is for PERA § 101(c)(1)(B)(ii), and is that "natural phenomenon" be added to the list of things that should not be considered. With the proposal, PERA § 101(c)(1)(B)(ii) would read:

> (ii) whether a claim element is known, conventional, routine, or naturally occurring or a natural phenomenon;

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