Responses to Questions from Senator Tillis

By Steven P. Caltrider, 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. **Is there a continuing need for Congress to step in with patent eligibility legislation?**

Yes - "making do" should not be confused with sound IP policy or misinterpreted as the problem has been solved for several reasons:

- USPTO guidance is a positive step toward consistency before the USPTO, but it lacks the force of law. Even with the guidance, patent-worthy innovation is being rejected at USPTO. Claims directed to medical diagnostics, gene or cellular therapy, antisense oligonucleotides (ASO), and RNA-based therapies continue to face eligibility rejections and challenges.
- Courts continue to strike down meritorious inventions. Every member of the Federal Circuit—absent the newest members who have not written on the point—has called on Congress to address eligibility (See *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333 (Fed. Cir. 2019).*
- Investment is impacted. I see this almost daily at Dana-Farber, especially in diagnostics and more recently in DNA/RNA based treatment modalities.

The exceptions to patent eligibility remain judge-made law and unique to the United States. Despite the origins in the judiciary, the Supreme Court has declined to correct the law. Therefore, only Congress can restore patent eligibility to provide the clarity, certainty, and predictability needed for investment.

2. **Despite how broken the current situation is regarding patent eligibility, is it in the interest of some parties to maintain the broken status quo? Why?**

Yes, the status quo benefits those seeking a "quick kill" in litigating a patent, including patents protecting meritorious inventions. Some of these inventions represent significant advances – breakthroughs in science.

- Patent eligibility is a threshold issue of law – that is, the issue is considered by the court early in the litigation. This allows a challenger to raise patent eligibility and, if successful, resolve the case at less expense.
- Some believe a judge's eligibility ruling is more likely against the patentee than a jury on §§ 102, 103, and 112, especially where the perceived equities may favor the patentee.

3. **How will PERA help the U.S. maintain global leadership in competitive sectors like AI and biotechnology? What does failure to enact such legislation mean?**

Patent eligibility is judge-made law unique to the United States. Others have carried out economic analysis showing a negative impact on U.S. investment. See, e.g., 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). The reduction in investment is consistent with my observations of investment at Dana-Farber.

US competitiveness with China is a multifactorial policy issue – including education and fiscal policy. IP policy is a significant factor. Ironically, over the same period that the US patent system is becoming less reliable and certain, China has been amending its laws to be more supportive of innovation, particularly for multinational corporations. In other words, China recognizes a strong IP system is foundational to a competitive advantage. PERA will strengthen the IP system by providing the needed certainty for investment in these highly competitive sectors.

A failure to enact legislation will continue the downward slide (absent the Supreme Court fixing the problem). Unfortunately, only in hindsight, will historians assess whether a failure to enact this needed reform was the tipping point to America losing its global leadership in innovation.

4. **PERA 2025 has several changes compared to prior drafts. Are these good changes? Why or why not?**

These changes are acceptable if they enable the compromise necessary to advance the bill into law. The change of interest to Dana-Farber is expressly providing that an "unmodified human gene, as that gene exists in the human body," "unmodified human gene that is isolated from the human body, but otherwise the same as that gene exists in the human body" and "an unmodified natural material as that material exists in nature" are not patent eligible subject matter.

Candidly, the eligibility of human genes is a red herring. Advances in science and the state of the art have rendered the issue largely moot. Naturally occurring human genes will not be patentable with or without this provision because of § 102 (novelty).

If they help advance the bill, these changes are acceptable as a belt-and-suspenders approach. The "cost" is a degree of uncertainty that judges may broadly construe the language to impinge on burgeoning technologies such as gene therapy and cell-based therapy. Such modalities may include a human gene (e.g., a correct copy of a gene to augment or replace a missing or mutated gene) delivered to the cell via a delivery system, commonly a vector. A claim directed to a method of treatment that includes a gene, even if identical in whole or in part to the naturally occurring human gene, incorporated into a delivery system should be eligible subject matter, and the delivery vector, including the gene, as a composition of matter. Congress should make clear—either in the text or legislative history—that the exclusion covers human genes as they exist in nature and does not reach human-made, engineered, or materially modified nucleic acids, vectors, viral capsids, or cells used in gene and cell therapy. That is, the word "unmodified" should be construed to include modifications upstream or downstream of the native gene sequence or natural material and unnatural combinations of naturally occurring DNA or RNA.

5. **We are all concerned about the cost of prescription medication. Some argue PERA would raise drug prices. What do you say?**

PERA will have no impact on the cost of prescription medicine. To state the obvious, when a patent expires the price of a medicine drops dramatically due to competition. Without a patent, there is no new medicine. PERA does not extend patent terms or alter FDA exclusivities.

The argument that PERA will raise drug prices has two parts: (1) without PERA, so-called "bad" patents will be easier to knock out, thereby lowering prices; and (2) PERA will allow patents on genes and other products of nature, thereby driving higher costs. Neither has merit.

Patent quality is a real concern, but PERA is not the answer to quality—and § 101 was never the right tool to address patent quality. A "bad" patent is a patent that should not have issued under §§ 102, 103, and/or 112. Improvements in law, regulations, and USPTO practice are needed to improve patent quality. In addition, the executive branch should appoint, and the Senate should confirm, judges with a deep understanding of patent law and its role in supporting innovation and the role of the court to apply, not create law. Most of the uncertainty in patent law, including patent eligibility, is judge-made law.

Concerns about claims to genes and other natural products are similarly misplaced. If a claim is drafted to read on a natural substance in its native state, it should fail for lack of novelty. If a claim is drafted so broadly that it blocks entire fields of research or so ambiguously that it is unclear what is claimed, it should fail under § 112.

In sum, a meritorious invention denied a patent due to eligibility does not lead to lower prices; it leads to no medicine or diagnostic at all.

6. **Some argue diagnostics will be invented anyway due to publish-or-perish or trade secrets. Do you agree?**

Basic academic research will continue and will be published. But, basic research is not a medical diagnostic or new treatment. To transition from basic research to applied research that develops a new medical diagnostic or treatment, substantial investment is needed. That investment must be supported by patent protection. Furthermore, such academic, basic research often spurs the formation of new companies and such companies by virtue of their high risk - high reward approach are often the source of transformative or break-through innovation. These new companies are heavily reliant on IP for investment.

A second issue with this argument is even basic research suffers. Basic research at Dana-Farber is funded by four sources – Federal grants, private grants, income from royalties on previous innovation, and private charitable donations. Without the prospect of the translational investment necessary for the basic research to reach patients, private grants and donations go down and royalty income driven by medical diagnostics declines. The virtuous cycle of investment that drives innovation reaching patients is not driven by the "publish or perish" mindset but by sound IP policy.

Responses to Questions from Senator Schmitt

By Steven P. Caltrider, 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. **On balance, would PERA make it easier or harder for patent trolls to extort U.S. businesses and companies?**

The best answer is neither harder nor easier. PERA will have virtually no impact on so-called "patent trolls and their ability "to extort US businesses and companies." PERA will provide needed certainty in the patent law, which will support investment and innovation. This certainty makes it harder for a patent holder to bring a dubious claim that could "extort" a business. However, the impact of PERA in view of other considerations is not likely to be material to the so-called "patent troll" issues. A dubious patent claim would be invalid under Sections 102, 103, and/or 112.

2. **How would expanding patent eligibility for AI processes under PERA impact the ability of businesses to implement those technologies?**

AI is vital to innovation, including life science innovation, and overall American competitiveness. Patent eligibility of AI related innovation is critical to support this innovation. Patents enable inventors and small to medium size businesses -- businesses who cannot compete based on size -- to contribute to this wave of transformative innovation.

The patent issues associated with AI are complex in all areas – inventorship (§101), novelty (§102), obviousness (§103), enablement (§112), written description (§112), and definiteness (§112). The application of settled law to this new technology is best developed – at least at this stage – through the courts (not for the court to make new law but for the court to apply settled law to new facts). U.S. leadership in biotechnology is an example of this approach. In the early days of biotechnology, there were calls for regulation and changes to patent law. While some regulations were promulgated, the settled law was applied such that one patent owner/business/company could not overclaim and dominate an entire field of research (see *Amgen v. Sanofi,* which prohibits a claim to more than what is invented, described, and enabled). Similarly, the confines of what AI-related innovation is patentable under sections 102, 103, and 112, i.e., how this settled law should apply to this new technology, should evolve through cases, not by prohibitions of eligibility, which would stifle this important innovation. Sections 102, 103 and 112 are sufficient to prevent overbreadth and indefinite claims that could have a chilling effect on businesses.

3. **What are examples of the types of medical innovations that are ineligible under current law but would be eligible under PERA?**

Dana-Farber has experienced significant challenges in securing patents on medical diagnostics and more recently DNA or RNA-based therapy, including gene therapy, cellular therapy, siRNA-based therapies. These technologies artificially (i.e., through human intervention) seek to leverage endogenous biological pathways to treat a disease or condition. These critically important diagnostic and treatment modalities are at risk of being ineligible without PERA and with PERA would be eligible.

The challenges do not end with USPTO examination or allegations that a claims lacks eligibility, however. Investment by potential licensees, which are critical for the basic research at Dana-Farber to be clinically developed to reach patients, is challenging under current law due to the uncertainty of the IP. And, without the prospect of commercial investment to fund clinical development, funding through private grants and donations in medical diagnostics is also challenging. PERA would make these important, life-saving technologies unquestionably eligible

4. **Why should Congress—or why should Congress not—expand eligibility to such medical innovations?**

PERA returns eligibility to the pre- *Alice* / *Mayo* understanding of patent eligibility and to Congress' intent, which was that "anything under the sun made by man" was patent eligible (citing the language used in the legislative history of the 1952 patent act). No one should be satisfied with the current standard of care in cancer or other vexing diseases and conditions. The proven method of fostering innovation – across all technologies – is strong intellectual property protection. PERA will remove the uncertainty that is threatening patent eligibility for medical diagnostics and new treatment modalities. Congress should enact PERA because patients are waiting for new cures.

5. **Critics of PERA have advocated a more narrowly tailored approach to expanding eligibility for specific innovation areas like medical diagnostics, arguing PERA is too broad. Are those concerns founded or unfounded? Please explain why.**

A more tailored approach is a slippery slope. Innovation in the United States has driven the U.S. to be a global leader on IP policy over the last century or more. A hallmark of IP policy over this era has been neutrality in relation to the underlying technology. The U.S. has championed neutrality as well through treaties and bilaterial agreements. Neutrality – rather than a tailored or bespoke law for each technology sector remains the best policy for three primary reasons:

(1) Tailored rules for medical diagnostics will almost inevitably miss the mark. Tailoring is in hindsight – in view of today's technology. Science is unpredictable. No one would have anticipated the developments in gene therapy, cellular therapy and DNA/RNA based treatments. It would be tragic that certain "product of nature" related patent claims are eligible under a tailored exception for medical diagnostics but not treatment modalities. In other words, technology used in medical diagnostics today may be the basis for a new treatment modality in the future. Rather than a tailored carve out for medical diagnostics, PERA returns patent eligibility to these important technologies by eliminating the "product of nature" judicial exception, but for the statutory exceptions in section 5(D).
(2) Subject matter not subject to the tailored approach remains under the *Alice*/*Mayo* cloud of uncertainty. Other critical technologies, including AI-related innovation, rely on patent protection and would benefit from PERA.
(3) The U.S. would lose its leadership position in advocating sound, harmonized IP policy. If the U.S., can put in place tailored IP laws, it arguably will legitimize other countries tailoring their laws to favor or disfavor certain industries or technologies. The strong voice of U.S. leadership on IP is important for American global competitiveness.