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. The first set of hearings on patent eligibility were held in 2019, with 45 witnesses over multiple days. In 2024, another hearing was held consisting of 8 witnesses. Since then, there has been guidance from the USPTO and additional court cases.

   Is there a continuing need for Congress to step in with patent eligibility legislation? Please explain.

   No, there is not a need for Congress to pass PERA or otherwise address patent eligibility. The rhetoric of many proponents of PERA or patent eligibility reform does not match the reality. U.S. patent law and patent validity determinations are not in "chaos." The Alice framework for evaluating the patent eligibility is not hard to articulate and district courts have become accustomed to its application. Many tasks assigned to courts under the U.S. patent system require careful application of facts and law according to tests that have been developed through caselaw and the rubric for evaluating patent subject matter eligibility is just one more. Other examples include claim construction, obviousness, and infringement by equivalent. In all cases, there is some uncertainty about the outcome until the court rules, but the process is no less predictable for these other determinations assigned to the court.

   The lack of consensus amongst the Federal Circuit judges on application of the Alice framework in certain instances does not change the fact that the Federal Circuit routinely and predictably applies the current law of patent subject matter eligibility. Their lack of ability to reach a consensus in certain en banc cases does not translate into a need for an overhaul of the law on patent subject matter eligibility.

   It's been twelve years since the Myriad decision and innovation in the life sciences is as robust as ever. Even on the 10th anniversary of that decision, the CEO of Myriad said the Supreme Court ruled correctly. From the use of whole genome sequencing in newborn screening, to novel gene editing treatments for sickle cell disease, and therapies to slow the progression of Alzheimer's disease, the expansion and increased utilization of precision medicine is evident across the lifespan. PERA would create barriers to accessing this innovation by restricting research, requiring expensive licensing fees, and more.

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 is this?

   As noted above, the rhetoric does not match the reality. The current situation is not broken. As with many things, the law could be refined, but it's current status is not an emergency. The courts, the practitioners, and the Patent Office have adapted to the current law.

The current law as articulated in Supreme Court decisions is grounded in concerns about the use of patents to pre-empt access to or exploitation of natural laws, natural materials, and abstract processes without an inventive contribution that goes beyond application of conventional technology to the (possibly) newly discerned natural law, natural material, or abstract process. Protecting access to such ideas and information on a pre-competitive basis so that all may innovate and patent novel technologies for implementing such natural materials and natural laws does more to drive innovation than would passing PERA and allowing the pre-emption of such discoveries through patenting.

Contrary to the pejorative framing of this question, opposition to PERA is based on principled policy preferences and not reflective of any desire to benefit from a "broken status quo."

3. The technologies that the U.S. most needs to develop to compete with China's growth, including advanced computing, AI, and biotechnology, are often those that fall outside current patent eligibility standards.

   How will PERA help the U.S. maintain global leadership in these competitive sectors? What does a failure to enact such legislation mean to our global competitiveness in general?

   First, it is a false premise to suggest that "biotechnology" falls outside the scope of current patent eligibility standards. Current law continues to permit the development of both small molecules and biologics as therapeutics. New drug candidates and new uses (indications) for known drugs continue to be patented. New technologies for detecting biomolecules continue to be invented and brought to market as medical devices. Such new patent eligible inventions may embrace entirely new modalities for detecting certain classes of biomolecules, improved methods of using existing technology, or new reagents for use in diagnostic tests (such as a new antibody used to detect a chosen target molecule).

   PERA will not help the U.S. in terms of its competition with China. While U.S. industrial policy and the desire for global leadership in these fields are worthy topics of interest for Congress, there are many alternatives available to the U.S. for promotion of technological leadership.

4. PERA 2025 has several changes this year compared to PERA from the prior Congress.

   Do you believe that these were good changes to the bill? Why or why not?

   No. PERA is not substantively changed in how it will abrogate over 150 years of case law on patent subject matter eligibility without due consideration for the animating policy concerns behind those court decisions. With respect to its effects on the life sciences, the newest version of PERA does nothing to allay the concerns of the clinical diagnostic community. Moreover the current version has certain "headline" exclusions from patent subject matter eligibility for human genes and natural materials, but those exclusions are vitiated by conditions that return to patent eligibility practically all conceivable ways in which a human gene or natural material could be incorporated into a patent claim.

5. We are all concerned about the cost of prescription medication. Some have argued that the enactment of this bill would lead to higher drug prices for consumers.

   What do you say to that?

   There are much more effective options available for addressing the cost of prescription drugs in the U.S., including the asymmetry in the affordability of drugs in the U.S. and in other industrial nations. That said, there are scenarios where PERA would decrease the affordability of some prescription drugs in the U.S.

   PERA would increase the patent subject matter eligibility of patents directed to the association of certain biomarkers to the patients health status. One type of such a patent could be a so-called companion diagnostic which is used to determine if a patient falls within a certain subgroup (defined the presence of a certain biomarker) that is more likely to benefit from the drug (or less likely to suffer side effects from the drug). A patent on a companion diagnostic could augment a pharmaceutical company's "evergreening" strategy which seeks to maintain patent protection for their drug after the patent on the drug itself has expired. By extending patent protection for a drug after the expiration of the patent on the drug itself (a composition of matter patent), generic entry into the market would be delayed and the costs of the drug would increase compared to what the cost would be with generic competition. Lastly, it is important to note that the ability to obtain a patent on a companion diagnostic is not necessary to provide incentive for the development of the drug in the first place as new drugs are typically protectable under current law by patents on the drug itself and often additional indications or uses of the drug, specific formulations, and/or dosing regimens.

6. Some argue that medical diagnostics will continue to be invented and developed notwithstanding the change in subject matter eligibility from the Supreme Court, because of other factors promoting or protecting innovation – such as the incentives to "publish or perish" in academic, or the ability to protect innovation through other means like trade secrets.

   Do you agree? Why or why not?

   First, as noted above, current law does not prevent the patenting of many innovative developments in the field of medical diagnostics. With respect to the discovery of new biomarkers and their association with health status, current law does not discourage their continued discovery. For example, the identification of new genetic variants and their possible correlation with disease risk or health status is made possible by the low cost of genomic sequencing and mining existing patient data. The cost of identifying a new variant is paltry compared to the enormous costs of developing new therapeutics and consequently, the availability of a 20 year monopoly on such a newly discovered variant is not necessary to incentivize its discovery. Additionally, because the value of such knowledge is greater when validated through publication in reputable databases, many clinical practitioners in the genetic testing field are already motivated to contribute such information to publicly accessible databases.

7. Some critics of PERA claim that restoring patent eligibility to gene-based technologies and diagnostics will impede scientific research, innovation and access to diagnostics. However, 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?

   Europe is a less suitable comparator with the current state of U.S. law on patent subject matter eligibility than was the U.S. prior to 2013 when the law permitted the patenting of genetic diagnostics such as the well-known genetic tests for variants in the BRCA1 and BRCA2 genes that were controlled by Myriad Genetics, Inc. patent-enabled monopoly pricing drove up the cost of testing (e.g. sequencing two genes cost $4000 with a greater than 80% gross profit compared to panels of over 80 genes costing a few hundred dollars today). In that environment patients faced significant cost-driven access barriers to medically necessary testing and researchers paid exorbitant licensing fees.

   As noted above, development of and clinical use of genomic sequencing for patient diagnosis, cancer detection, and cancer treatment monitoring have all blossomed in the U.S. since 2013 with the change in the law. PERA is not needed to foster gene-based technologies in the U.S. and PERA would make the situation worse.

Senator Eric Schmitt
Senate Judiciary 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"
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1. On balance, would PERA make it easier or harder for patent trolls to extort U.S. businesses and companies?

PERA would not ameliorate this problem. On balance, PERA would make it easier for patent applicants, including would-be patent trolls, to obtain patents and then assert them against U.S. companies. Non-practicing entities who obtain patents that are of questionable merit are able to exploit those patents through assertion against multiple entities that find it economically rational to settle for "nuisance-level" payments in lieu of expanding the cost and effort to challenge the patent on the merits. PERA would greatly expand the ability of people who discover (as opposed to invent) a naturally occurring material (e.g., a protein, a nucleic acid sequence, hormone, etc.) or observe a natural phenomenon such as the correlation between a material measurable in the body (e.g., a biomarker in a blood sample) and a clinical condition (e.g., presence of or risk for a disease). A patent on such a correlation would allow the patentee to preempt others from making use of this knowledge without paying a toll for access to this knowledge.

PERA, coupled with modern genetic sequencing technology, would enable the patenting in bulk of such correlations as they are observed for the first time. Would-be patent trolls could amass patents on such correlations and then wait for others to discern which ones are important and then "extort" companies actually trying to functioning diagnostics or therapies to the market and clinical practice.

There is an historical analogue for this problem. Beginning about 30 years ago, with early improvements in DNA sequencing technology, there was an explosion of patent filings on so-called "expressed sequence tags"(ESTs) in a land-rush mentality before their genuine utility was appreciated in the hopes of obtaining a patent before it became apparent that any particular EST might be commercially valuable. Such patents were tailor-made for trolls as they were easy to obtain and they were acquired with the goal of being able to use them against others who might later discern an important use for one as it may relate to a diagnostic or biotherapeutic. The potential problem with EST patents was largely overcome through innovation at the Federal Circuit in developing through caselaw a requirement for more specific utility for such inventions. PERA would relax both eligibility requirements, including as it relates to utility, and increase the ability of patentees to amass large collections of patents solely for the purpose of asserting them against actual innovators who make practical use of the knowledge that is pre-empted by such patents.

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

Patents have conflicting effects on the ability of businesses to implement new and emerging technologies. In principle, the ~20 year monopoly on the use of a patented invention can provide the incentive to invent, develop, and market an application of the patented invention. However, the patent also implies the ability to exclude all others from using that invention and thus businesses seeking to implement that technology can pay the patentee, engage in expensive litigation to challenge the patent, or forego using the patented technology. A proliferation of patents concerning AI processes held by many patentees could make it challenging, expensive and uncertain for businesses to make use of AI processes. This could be particularly the case under PERA with a much greater volume of patents seeking to cover various specific use cases for application of AI that are little more than abstract processes performed at high speed by a computer.

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

PERA would allow patents on laws and products of nature, which currently are not eligible to be patented. If enacted, it would be possible to patent a biomarker (e.g. DNA, RNA, protein, etc.) and its association with health status so long as that association is newly discovered. Even with the human genome fully sequenced and in the public domain, new discoveries are being made daily. For instance, in 2024, the NIH All of Us research program published that it discovered more than 275 million previously unreported genetic variants. This illustrates that new variants are continuously being discerned. Under PERA, one would be able to patent newly discovered variants and their association with health status, and limit further research into the significance of those variants, restrict clinical testing of those variants, and more.

For example, if in a study like the NIH All of US research one identified a list of 100 different mutations (or variants) in several human genes that correlated with a higher risk for colon cancer, a patent claim for a method for analyzing genomic DNA in a human biosample for the presence of absence of such variants would be patent eligible under PERA, but would not be under current law. Because the variants would be newly observed, the claim would be patentable as new and non-obvious.

As another example, if there were a new pandemic caused by a new virus, the first to isolate the virus could patent the genes and proteins characteristic of such virus. For example, the virus could have a protein domain critical for its binding to human cells and causing infection (analogous to the spike protein characteristic of the many variants of SARS coronavirus No. 2). A suitable vaccine would likely include either (i) a killed or inactivated version of the virus, (ii) the protein domain essential for binding, or (iii) nucleic acids encoding such protein domain. Under PERA all of those things, the virus itself (in a purified or isolated form), the protein, or the gene encoding it, would be patent eligible. Because they are new, they would be patentable.

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

Laws and products of nature, while discovered, are not invented and as such, should not be patented. PERA would expand eligibility to include them, which would greatly hamper innovation. Today, researchers are able to invent around those laws and products of nature and obtain patents on innovations based on them. Under PERA, they would be greatly restricted or faced with exorbitant licensing fees just to even study them.

Congress should not expand patent eligibility beyond that of current law as proposed in PERA, because many parties would make new observations about genetic variants of potential clinical interest and obtain patents covering genomic sequencing that answers the question whether such variants are present or absent. (See the first example in my response to Question No.3) All of such patents could be implicated in ordinary patient care in which genomic sequencing is conducted and the patentees could block or inhibit access to this basic knowledge about a patient's health status. It is important to recognize that such observations about correlations between genetic variants and health status are not innovations or inventions. They are instead observations about the natural world and not the creation of inventors. This knowledge should properly be viewed as pre-competitive and available to all and not something that can be pre-empted by the first person to make the observation. Moreover, there is no need to grant 20 year monopolies on such information to incentive its creation or drive its practical exploitation. Such activity as exemplified by the massive All of US research project illustrates that current law in no way inhibits such knowledge creation or sharing.

Congress should not expand patent eligibility beyond that of current law as proposed in PERA, also because PERA would enable the patenting of new pathogens and their features which could allow a single party to control development and distribution of diagnostics and vaccines needed in response to a new pandemic. Furthermore the ability to patent many of the necessary tools for responding to a pandemic would discourage early sharing of information about emerging pathogens.

An illustrative example is the RNA sequence of the SARS-CoV-2 virus. At the outset of the COVID-19 pandemic, the RNA sequence of the virus was posted in the public domain. This led to incredible innovation in a very short period of time. In the U.S. alone, there were nearly 400 FDA emergency use authorized diagnostics, two mRNA vaccines, and therapies such as Paxlovid. Had the entity to first sequence SARS-CoV-2 filed a patent on that RNA sequence, then the presence of such patent applications would have inhibited innovation and the country's response to the pandemic would have been very different. For instance, had one laboratory had a monopoly on testing, the testing capacity, with its very broad access, in the U.S. would have been hindered greatly. Further, if patents were filed on each new variant as the virus mutated, then the diagnostic tests able to distinguish amongst the various permutations of COVID-19 would have been curtailed. The ability to patent in such an instance would be an unearned windfall for one entity and an impediment to rapid and broad-based responses to a pandemic.

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.

The effects of PERA are too broad in the consequences they would have in connection with medical diagnostics and for that reason, PERA should not be adopted. A narrow version of PERA focused just on PERA would not be an improvement as it would still suffer from the flaws related to medical diagnostics as discussed above.

First, it is important to recognize that the current law does not preclude from patent eligibility new methods of detecting biomarkers of interest and thus current law does permit patenting of innovations in medical diagnostics. For example, the field of medical diagnostics is being advanced by multiple companies that have developed improved instruments that can detect the presence of nucleic acids of interest quickly without the need to send samples out to third party laboratories. Patents can and do protect investment in development and commercialization of these kinds of innovations in medical diagnostics. What PERA constrains is the effort to obtain patents that would limit the kinds of questions that one can answer using new or old genetic sequencing technology. Specifically, it would enable patents that cover answering the question whether or not a patient has any of a long list of patented genetic variants relevant to that patient's health status and treatment.

If the goal of Congress were to advance the development of a very specific segment of technology, it is undesirable to establish special patenting rules that only apply to that area of technology. First, the boundary for whether or not the special rule applies would necessarily be imprecise and create uncertainty. Second, there are more direct methods for promoting and rewarding the development of narrow areas of technology other than uses of patents. For example, Congress could create a structure that grants market exclusivity for a short period of time (much less than 20 years) for certain types of new medical diagnostics approved by the FDA if it concluded that such market incentives necessary to promote their development in the U.S.