

**Statement of**

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**Before the  
Subcommittee on Intellectual Property**

**Committee on the Judiciary  
United States Senate**

**Hearing on  
The Patent Eligibility Restoration Act –  
Restoring Clarity, Certainty, and  
Predictability to the U.S. Patent System**

**January 23, 2024**

Chairman Coons, Ranking Member Tillis, and members of the Subcommittee, my name is Mark Deem and I am an Operating Partner at Lightstone Ventures, a Menlo Park-based firm that invests in innovative biotech and medtech companies.

I was also a co-founder of The Foundry, one of the most prolific medical device incubators in Silicon Valley, the founder of roughly 20 medical device companies and a named inventor on over 250 issued and pending U.S. patents.

I would venture to guess that many in this room or your immediate family members have benefited from the life-saving technologies that our industry has invented and brought to patients worldwide.

You will hear me mention “patients” a lot during this hearing. I know to some, the number of companies I’ve co-founded, the patents I’ve been granted, the money I’ve raised are perhaps impressive numbers. But what gets me up in the morning, keeps me up late into the night, fuels the passion which I and my colleagues in my industry bring to the job every day, are the patients that we will have a part in helping.

To give you a sense of the work that we do: our team at the Foundry was responsible for the first system to repair leaking mitral valves in the heart via a catheter-based system. Today, those valves can be repaired in a ninety-minute procedure involving a small puncture in the leg, rather than a major surgery requiring opening the chest and stopping the heart. We introduced the first devices that enabled doctors, again through a small puncture in the leg, to fish a tiny wire deep into the brain to capture stroke causing blood clots. Where before, stroke patients who survived often spent many months of rehabilitation to try to regain functionality, today many of those patients leave the hospital within days to resume their normal lives. I have many more examples of the work I and my associates have done to positively impact the lives of patients worldwide.

And none of this innovation, this saving of lives, this restoration towards fuller lives, would be possible without strong patent protection for our work.

It is an honor to testify before you today to share the real-world challenges that inventors, startups and their investors face when presented with the current lack of clarity surrounding patent

eligibility in the U.S. I believe that the bill you are considering, The Patent Eligibility Restoration Act (PERA), is a critical and much-needed piece of legislation and I'm pleased to be here to support it.

### ***The Role of Patents and the Importance of Clarity***

While I appreciate the complexity of patent eligibility law, and I know it rests on years of statutory interpretation that has gone all the way to the Supreme Court, I bring the perspective of an inventor, entrepreneur and investor. One thing that is common when wearing any of those hats is that one is forced to make very difficult decisions that will consume years of your life and often hundreds, or millions of dollars. And these years of our lives and huge capital investments are simply to get to FDA approval, much less to market acceptance and to broad availability to patients worldwide.

Here's how I've done my job for the last three decades: Over the course of a year or so, supported by some seed financing, we start with a blank slate. We look at a wide array of big unmet clinical needs, addressing disease states all over the body. We evaluate a number of inputs when deciding how we will spend the next years of our lives, and millions of our investors' money. We obviously need to know, or be reasonably certain, that the science will work. We need a strong research and leadership team. We need to understand the market we are entering. And, critically, we need to know that our inventions can be protected by strong and enforceable patents.

On this last point, I believe the U.S. is failing many of our most innovative and disruptive inventors and startups. Several witnesses today have noted that all of the active judges on the U.S. Court of Appeals for the Federal Circuit have cited their own confusion regarding patent eligibility. I've also read the statements of the two former USPTO Directors who are testifying today and they have said the state of patent eligibility is in "disarray" and it is leading to "deep uncertainty." And the current USPTO Director, Kathi Vidal, also stated at her confirmation hearing before this Committee in 2021 that either Congress or the courts need to address confusion about patent eligibility under Section 101. I could not agree with them more.

If the top patent officials of the U.S. government, and the judges on the only U.S. court dedicated specifically to hearing patent cases are all confused, imagine the uncertainty and reluctance to

invent and invest that this is creating for us, the engineers, researchers and physicians down here doing the inventing, and for the investors that support us.

I know that this legal uncertainty will be debated here as a relatively abstract concept. Section 101 is a complex provision within a complex statute that has been interpreted in very complex cases by very sophisticated courts.

But I would ask you to look at the reality that this is causing and I would urge you to move quickly to address it. I don't see legal complexity and abstraction, I see specific, game-changing inventions that cannot be patented here in the United States.

And this is costing us cures, treatments, jobs, economic growth, and potentially, lives.

As but one example, there are a number of emerging technologies and companies looking at high resolution eye tracking to diagnose and measure treatment effect and in some cases drug selection and titration for conditions like autism spectrum disorder, traumatic brain injury and treatment resistant depression, among others. I reached out to some of my contacts in that area and received confirmation that just last week one of them received a 101 rejection from the PTO, claiming that this type of eye tracking could be done by a human, and so doing it by the complex camera and computer systems that are subject of the rejected claims are ineligible under the judicial exceptions. I assure that that that is NOT the case.

Personalized medicine holds the promise of more precise patient selection to, for example, weed out potential non-responders before expensive and invasive procedures are done. This can be done by computer-based comparisons of complex physiologic markers. This would not only improve patient care but reduce healthcare costs as well. And these technologies are also at risk for 101 rejection by Alice/Mayo considerations.

While corresponding with the senior, well-respected patent attorney prosecuting the case that received a 101 rejection last week, he commented, and I quote:

*“The worst part is trying to explain to the inventors/engineers at these pioneering tech companies that a patent examiner believes any of these steps can be performed in the human mind. The innovators think the examiners are crazy. The examiners know that*

*they sound crazy but are simply following orders. The patent counselors are stuck in the middle.*

*The fundamental problem is that Congress originally separated the question of “eligibility” (broad category of all processes and machines ... 35 USC 101) from the question of “novelty” (restricting patent protection to only those process and machines that are “novel” over the prior art ... 35 USC 102).*

*It was straightforward since the 1952 Patent Act. The Supreme Court damaged this clarity ... the sloppy wording in the Alice decision and Mayo decision unfortunately and ambiguously injected part of the narrowing novelty limit (35 USC 102) into the broad eligibility category (35 USC 101). It wreaked havoc at the patent office ... where the rubber meets the road”*

Some will say that venture capital is still flowing and innovative companies are still forming in the U.S. despite the concerns we are raising today. I would agree with that to some degree, although I would note that venture investment in the medical device sector where I work has been roughly flat over the past few years and the number of deals reported in 2023 was at a multi-year low<sup>1</sup>.

But that’s not the only way to look at it. My perspective is not to just look at what we ARE doing, but to try to figure out what we CAN do and where the technology is going.

And this is where I think the true concerns lie and this is the problem we are trying to solve for. We need to be thinking about areas where the U.S. can and must lead like personalized medicine, AI-assisted therapeutic treatments, AI-assisted diagnostics and other major unmet clinical needs that will not be addressed if these innovations cannot be patented. I can tell you with certainty you cannot invest a decade of your life and \$250 million of other people’s money on an invention that you cannot protect. That model just doesn’t work. So, I see the Patent Eligibility Restoration Act as not only addressing a current problem, but as a key to unlocking future opportunities.

### **The Current Problem and the Solution Presented by the Patent Eligibility Restoration Act**

It is currently unclear what is and what is not eligible for patenting. As I noted, experts who have led the U.S. Patent and Trademark Office and judges who are entirely focused on hearing patent

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<sup>1</sup> [https://files.pitchbook.com/website/files/pdf/Q3\\_2023\\_Medtech\\_Report\\_Preview.pdf](https://files.pitchbook.com/website/files/pdf/Q3_2023_Medtech_Report_Preview.pdf)

cases cannot reliably predict which patents will be found eligible. This is due to having vague categories of subject matter such as "abstract ideas" held as excluded from patent eligibility.

The Patent Eligibility Restoration Act addresses this uncertainty by eliminating all prior judicial exceptions to eligibility and replacing them with a clearly articulated and limited set of exclusions. Under PERA, U.S. law would draw clear lines regarding what is not patent eligible, this includes: pure mathematical formulas and mental processes, unmodified genes in the human body and unmodified natural material existing in nature. PERA also excludes substantially economic, financial, business, social, cultural, or artistic processes, even when followed by language like "do it on a computer," as long as such processes can be practically performed without the use of a machine.

Beyond that, any useful invention that falls into the four existing statutory categories (machine, manufacture, process or composition of matter) is eligible. No multi-part tests, no nonsensical notions like "post-solution activity."

That framework makes sense to me. Inventors would again have a clear and predictable framework to assess whether their ideas are patent eligible or not. It doesn't mean everything *is* patentable - inventions still need to be novel, non-obvious and described in enough detail so others can implement them. But those are tests we understood clearly prior to decisions such as Alice and Mayo. They are tests we were comfortable applying in making investment decisions.

The net effect of PERA is to strike a decade of judicial tinkering that has needlessly turned the question of patent eligibility into a confusing mess, and harmed us versus our economic competitors. While the U.S. has spent a decade holding back innovations in areas such as fintech, diagnostic solutions and medical devices while trying to figure out whether they are "abstract" or not, our competitors are moving forward and protecting these inventions. China, in particular has leapt well ahead of the U.S. by extending patent protection for a broader range of inventions by focusing on the concrete features of the invention while we spin our wheels arguing about whether something is "abstract" or not.

## **Conclusion**

In conclusion, I would say that I and my colleagues have made it our lives' work to bring innovative new technologies from the minds of inventors to the hands of doctors and ultimately to improve, and sometimes save, the lives of our patients. Along the way we fight every imaginable headwind. We fight complex anatomical and physiological problems which are often poorly understood. We fight technological limitations of the materials and structures which we try to use to treat these disease states. We fight for investment dollars. We fight to design and run complex clinical trials to satisfy FDA, CMS and insurance requirements. Since 1952, we had been fighting a fair fight with clear rules within the United States patent system. But beginning in 2014, with the Alice and Mayo decisions, this fight has become a free for all. Let's make PERA the law of the land, restore more clarity to the patent process, and remove one damaging and unnecessary headwind that stands between inventors, physicians, and patients.