

STATEMENT OF JOE KIANI
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BEFORE THE SUBCOMMITTEE ON INTELLECTUAL PROPERTY
COMMITTEE ON THE JUDICIARY UNITED STATES SENATE
“Reforming the Patent Trial and Appeal Board –
The PREVAIL Act and Proposals to Promote U.S. Innovation Leadership”
November 8, 2023

Introduction

Chairman Coons, Ranking Member Tillis, Chairman Durbin, Ranking Member Graham, and Members of the Subcommittee: Thank you for this opportunity to testify.

It is great to be back before the Judiciary Committee. Twenty years ago, I testified before the Senate Judiciary Committee Antitrust Subcommittee in support of Congressional oversight and competition in the marketplace to ensure that patients and caregivers have access to the innovative medical technologies they deserve.

My message is unchanged; innovation saves lives. The very foundation of sustained innovation lies in strong and predictable intellectual property (IP) rights. Life-saving technologies can reach consumers only if innovators can protect their IP rights through a reliable patent system.

There’s no monopoly on who can be inventive. It’s just a matter of throwing yourself at the problem, working on it and then all of a sudden one day you feel like gods are speaking to you, they’re putting some idea in your head, and there you go. There’s your invention.

I will explain why this is true through the story of my own company, Masimo.

Masimo Story:

In 1989, I started Masimo when I was 24. I had a small condo and took out a loan against it to start Masimo out of my garage. Money was tight and I still remember giving a friend many shares in Masimo, just to use his desktop publishing computer to write out my business plan. My partner Mohamed and I worked day and night and my sister helped with research and everyday business.

At the time, pulse oximetry was known as a “fair weather friend.” It failed just when you needed it most and was shockingly unreliable. It falsely alarmed so much on very fragile babies that the alarms created a “crying wolf” syndrome where the caretaker simply ignored them. Another consequence of the prior technology was that the caretakers would increase the supplement oxygen to the baby because conventional pulse oximeters would give a falsely low measurement. This increase in oxygen is actually toxic, and for babies, causes retinopathy of prematurity. This was the leading cause of blindness.

We set out to solve what others in the industry had concluded was unsolvable: making pulse oximetry work on the patients who need it most, including patients who are moving or have a weak pulse, such as the most vulnerable babies in the NICU.¹ We developed a pulse oximeter that enabled accurate measurement despite motion and low blood flow. We didn’t stop there; we invented rainbow Pulse CO-Oximetry. Our Pulse CO-Oximeter shined not just 2 wavelengths as with pulse oximetry, but 12 wavelengths of light through tissue using advanced signal processing, very tiny signals are pulled out in

order to determine hemoglobin levels (the amount of protein in red blood cells that transports oxygen from the lungs), and other variables such as the level of carbon monoxide in the blood. Today most firefighters use our technology, not only to identify fire victims that need to be treated for carboxyhemoglobin poisoning, but their own testing to make sure they can go back into the fire without disorientation that is caused by CO poisoning. Also, our hemoglobin monitor has dramatically reduced unnecessary blood transfusions and identified those who need it sooner.

Our technology was groundbreaking. It was revolutionary. Unfortunately, our technology was so innovative that other companies decided to steal it.

Patent Infringement and Litigation – The First Round:

When we started Masimo in 1989, patents were revered. The strength of our patents, consistency of court's enforcing those patents, and the uniqueness of our ideas allowed us to raise absolutely critical funding.

By 1991, we started meeting with venture capitalists. These venture capitalists hired lawyers to look at our patent applications, which had not yet published or issued, to see if we were likely to be able to protect our innovation from others and therefore have a chance at breaking into the market. Over time, I had to raise nearly \$100 million from private investors. In each round of financing, the investors moved forward only after concluding that we could protect our innovations with patents.

However, that did not stop the infringers. When Nellcor, a huge med-tech company that had about 90% market share learned about our technology and recognized it was orders of magnitude better than its own, they met with us. We were excited to tell them about what we had developed. We were so proud that our hard work had gotten the attention of such a powerful company. However, our excitement was short lived. We soon learned that this company systematically copied our technology. In fact, the leadership of that company told me they would "squash" Masimo "like a bug."

After more than 5 years of litigation, including appeals, that the well-funded infringer made as expensive as possible, we were able to enforce our patents and obtain an order that the infringing technology would be enjoined.²

In another litigation against Philips, a large multinational, the District Court, after a full jury trial stated, "the undisputed damages evidence was that an entire industry—other than Philips and one Chinese company—took licenses from Masimo for innovative technology that saved thousands of lives and billions of dollars in healthcare costs."³

No patent was held invalid by the courts or the patent office even after the extremely rigorous review throughout the process. None.

This was before the PTAB.

Patent Infringement and Litigation – Apple:

I never planned on competing with Apple. They seemed focused on making gadgets for our everyday lives. But Apple called me in 2013. They had researched my company and concluded that Masimo was the "platinum" in noninvasive monitoring. Apple asked to "dig deep" into our technology and asked how

we saw the future of healthcare involving Apple's devices. They asked how we could integrate Masimo technology into Apple products.

I, some might say naively, provided this information to Apple. I was thrilled that the world's largest company had taken an interest in healthcare, and particularly in our revolutionary medical grade pulse oximetry technology. I saw this as a path to improve healthcare on a very large scale, by bringing medical monitoring directly to consumers. This was something I had planned and developed for over 25 years.

Unfortunately, instead of working with us, Apple decided to hire Masimo's Chief Medical Officer and the Chief Technical Officer from a Masimo spin-off. They then decided to and did hire what Apple called "the next level down" of Masimo employees. They ultimately hired over 20 of our team members, despite Masimo paying its team members at the top of the market. A company working closely with Apple then hired most of another team from our spin-off.

Indeed, Steve Jobs is famously known to have quoted Picasso as follows: "Good artists copy. Great artists steal. And we have always been shameless about stealing great ideas." More recently, the head of engineering at Apple reaffirmed that statement, trying to spin it as a positive practice at Apple.

Masimo now has litigation against Apple in three different forums. We started litigation in California and asked the International Trade Commission (ITC) to investigate, which they did. Apple then retaliated by bringing suit against us in Delaware.

After two years, in October, the ITC issued a decision in our favor.

I will not get into the details of the litigation but note that numerous articles and reports have written about our story. Those articles include at least the following: (1) the Wall Street Journal, "When Apple Comes Calling, 'It's the Kiss of Death,'"⁴ (2) the L.A. Times: "An Orange County entrepreneur's \$60-million legal battle to stop Apple from steamrolling startups,"⁵ (3) The Heritage Foundation Report: "Big Tech's Abuse of Patent Owners in the PTAB Must End,"⁶ (4) The Hill: "Apple's anti-competitive tactics must be stopped,"⁷ and "Big Tech's 'patent troll' attacks are a smokescreen — don't let them fool you,"⁸ (5) New York Times: "The Patent Fight That Could Take Apple Watches Off the Market,"⁹ (6) LA Times: "A Big Victory for an Orange County Entrepreneur in his legal fight against Apple,"¹⁰ (7) Forbes: "International Trade Commission Issues Ruling Potentially Banning Apple Watches From Being Imported To U.S.,"¹¹ and "Some Apple Watches Are About To Be Banned In The U.S. What Happens Next?"¹²

Enter The PTAB:

Prior to the PTAB, Masimo patents withstood every challenge in Court and the USPTO. Those challenges were extensive, by well-funded large companies such as Nellcor, now part of Medtronic, and Philips Medical. Thus, Masimo's patents were subjected to intense scrutiny from millions of dollars of attacks by very competent, well-paid lawyers. Yet, Masimo's patents survived **all** of those attacks.

Compare that with what happened at the PTAB with Apple. Apple filed 33 inter-partes review (IPR) petitions on 22 Masimo patents. Apple challenged 473 claims, of which 343 were held invalid by the PTAB. The judges that invalidated hundreds of property rights previously granted by the U.S. Government had no particular background in pulse oximetry. Yet they decided that the primary examiner with almost 3 decades of expertise in the field of the invention and the pre-existing technology, had

gotten it wrong about 80% of the time. This is the same examiner that issued other Masimo patents that withstood rigorous legal challenges in Federal Courts.

We spent over \$13 million defending our patents in these IPRs filed by Apple. How many companies could afford such an expense?

We have no doubt that these patents struck down by the PTAB would have been upheld before an Article III judge and jury and normal patent validity challenges at the patent office, just as all Masimo patents in the past.

But we were not in a Federal Court before an Article III judge vetted by Congress. We were at the PTAB before Administrative Patent Judges with a track record of invalidating patents that the USPTO's experienced examiners issued.

This surely was not the intent when the America Invents Act (AIA) was passed. The intent was to offer companies that wanted to challenge the validity of patents a more efficient alternative to the court system. The intent was to give inventors quiet title – a period of time where the patent could have a second look, but after that second look everyone would know where they stood. Then the inventors could go back to doing what they do best: working hard in the lab to develop the next life-saving technology.

However, the PTAB has not lived up to the stated goal. Defendants reflexively file an IPR, and often numerous IPRs, against each patent in the litigation. This has enabled opportunistic large corporations to use the PTAB to attack, often invalidate their property rights, and at times eliminate, smaller competitors. Apple is the largest customer of the PTAB.

The Need for PTAB Reform

I say with great confidence that Masimo would not be here today if the current PTAB had been in place 30 years ago. Masimo would have lost important property rights upon which the company was built and investors had trusted, and would not have had the financial resources to defend itself. Because Masimo would not exist, neither would countless innovations that have saved so many thousands or millions of lives, saved billions of dollars, and improved health outcomes.

Hernando de Soto, a famous economist, has long been credited for his understanding that strong protection of property rights drives economic growth. However, the PTAB kills over 80% of property rights once an IPR is instituted. Smaller innovators then learn that a valuable property right granted by the U.S. Government and on which they relied is now worthless, and the company built on that property right might also be worthless. This is like the government confirming you own a piece of land, your building a home on that land, then the government taking it away because someone found the land grant invalid based on the opinions of a highly paid "expert" hired by your neighbor who wants to live in your house. The standard applied at the PTAB is low, and the review standard at the appellate court is high, resulting in the massive loss of property rights upon which companies were built. I personally know of companies that this has put them out of business. This is the opposite effect that what is desired for economies to flourish.

Large well-established entities, such as Big Tech companies, flood the PTAB with duplicative filings. The fact that defendants that have been sued for patent infringement reflexively file IPRs, in spite of the

estoppel effect, shows that the PTAB is known to be a one-sided forum, not the efficient and equitable system that Big Tech argued it would become.

In the words of Judge Paul Michel:¹³

The PTAB has proved extraordinarily useful to patent challengers. The board has invalidated as many as 84% of the patents, partially or entirely, that it has fully adjudicated. That figure suggests that either the USPTO is really bad at its job of deciding whether to issue a patent in the first place—spoiler alert: it isn't—or there's a thumb on the scale.

That thumb belongs to Big Tech.

Support for the PREVAIL Act:

We need to support strong and predictable property rights in innovation. In the new world of AI everywhere, rewarding creativity and inventiveness will continue to be a key to progress. The PREVAIL Act takes a good step in reforming this broken system. It recalibrates and makes the PTAB process better, and I thank Senators Coons and Tillis for their leadership.

The PREVAIL Act's clear and convincing evidence standard promotes a better system that should move in the right direction to helping incentivize innovation. It should reduce the extensive abuse of large companies with market power and should enable U.S. innovators and their investors to have more certainty in which to invest.

Conclusion:

Today, Masimo technology monitors over 200 million patients around the world each year.¹⁴ We have approximately 10,000 employees and we continue to innovate.

Our many inventions revolutionized the industry, and our technology has saved countless lives around the world. With our innovation and commitment to improving outcomes for even the youngest and most fragile of patients, Masimo technology has helped virtually eliminate blindness in the NICU due to severe retinopathy of prematurity.¹⁵ It has also been proven to reduce deaths on the general care floor¹⁶ and reduce mortality after surgery.¹⁷

We are excited about the new innovations and devices that we have developed and continue to develop. Masimo's new advanced technologies will increase patient safety, improve life all while saving money, by automating hospitals, protecting people at home from the dangers of opioids, enabling parents to monitor their baby's wellness and room conditions, bringing groundbreaking personalized hearables to consumers, and helping doctors continuously monitor their patients in their homes.

The future of innovation and economic prosperity are dependent on strong patent protections. To protect our global leadership in innovation and continue to save lives with breakthrough medical technologies, we must stop the ability of companies with tremendous market power to so easily wipe away property rights granted by the U.S. Government, and guaranteed by the Constitution, and upon which an entire company may have been built in reliance.

We need to take the long view when it comes to IP, we should err on the side of protecting innovation. Without strong intellectual property protections and a fair arbiter of those rights, the United States will continue to cede technological supremacy to China.

I want to again thank Senators Coons and Tillis for their leadership in PTAB reform and thank Committee members and staff for your efforts to protect innovation and intellectual property rights.

I look forward to working with you in support of this important legislation and answering your questions.

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- ¹ <https://www.masimostork.com/en-us/our-masimo-story.html>.
- ² *Mallinckrodt, Inc. v. Masimo Corp.*, 147 Fed. App'x 158, 176-77 (Fed. Cir. 2005).
- ³ *Masimo Corp. v. Philips Elec. N. Am. Corp.*, 2015 WL 2379485, at *19 (D. Del. May 18, 2015).
- ⁴ Tilley, Aaron, "When Apple Comes Calling, 'It's the Kiss of Death,'" Wall Stret Journal; April 20, 2023 <https://www.wsj.com/articles/apple-watch-patents-5b52cda0>.
- ⁵ Merchant, Brian, "An Orange County entrepreneur's \$60-million legal battle to stop Apple from steamrolling startups," Los Angeles Times. October 5, 2023. <https://www.latimes.com/business/technology/story/2023-10-05/column-joe-kiani-masimo-apple-watch-pulse-oximeter-lawsuit>.
- ⁶ Mossoff, Adam, "Big Tech's Abuse of Patent Owners in the PTAB Must End," The Heritage Foundation Edwin Meese III Center for Legan & Judicial Studies Legal Memorandum No. 336. June 29, 2023. <https://www.heritage.org/sites/default/files/2023-06/LM336.pdf>.
- ⁷ Cooper, Mark, Opinion Contributor, "Apple's anti-competitive tactics must be stopped," The Hill, 08/19/23. <https://thehill.com/opinion/technology/4158989-apples-anti-competitive-tactics-must-be-stopped/>.
- ⁸ Mossoff, Adam, Opinion Contributor, "Big Tech's 'patent troll' attacks are a smokescreen — don't let them fool you," The Hill. 08/18/23. <https://thehill.com/opinion/technology/4157340-big-techs-patent-troll-attacks-are-a-smokescreen-dont-let-them-fool-you/>.
- ⁹ [nytimes.com/2023/10/30/opinion/apple-watch-masimo.html](https://www.nytimes.com/2023/10/30/opinion/apple-watch-masimo.html)
- ¹⁰ [latimes.com/business/technology/story/2023-10-27/apple-watches-violate-patents-held-by-orange-county-tech-company-us-international-trade-commission-finds](https://www.latimes.com/business/technology/story/2023-10-27/apple-watches-violate-patents-held-by-orange-county-tech-company-us-international-trade-commission-finds)
- ¹¹ [forbes.com/sites/mollybohannon/2023/10/26/international-trade-commission-issues-ruling-potentially-banning-apple-watches-from-being-imported-to-us/?sh=4d1279b45dde](https://www.forbes.com/sites/mollybohannon/2023/10/26/international-trade-commission-issues-ruling-potentially-banning-apple-watches-from-being-imported-to-us/?sh=4d1279b45dde)
- ¹² [forbes.com/sites/katiejennings/2023/10/31/some-apple-watches-are-about-to-be-banned-in-the-us-what-happens-next/?sh=16f61537d1cc](https://www.forbes.com/sites/katiejennings/2023/10/31/some-apple-watches-are-about-to-be-banned-in-the-us-what-happens-next/?sh=16f61537d1cc)
- ¹³ Michel, Paul R., Chief Judge, Ret., Federal Circuit and Chris Israel, "Don't Let Big Tech Sabotage U.S. Innovators' Protections," Bloomberg Law; April 22, 2022. <https://news.bloomberglaw.com/ip-law/dont-let-big-tech-sabotage-u-s-innovators-protections>.
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