



Hearing before the
Senate Committee on the Judiciary
Subcommittee on Intellectual Property

On

“Innovation in America: How Congress can make our patent system STRONGER”

Wednesday, September 11, 2019
Dirksen Senate Office Building, Room 226
2:30 p.m.

Chairman Tillis, Ranking Member Coons and Members of the Subcommittee,

It is an honor to participate, on behalf of the Alliance of U.S. Startups and Inventors (USIJ) for Jobs and the Medical Device Manufacturers Association (MDMA), in this important hearing today focused on specific steps that we can take to strengthen and improve the U.S. patent system.

My name is Eb Bright and I am the President of ExploraMed. ExploraMed is a venture-backed medical device incubator, based in Silicon Valley, that focuses on identifying, creating and developing novel solutions for unmet health needs of patients around the world.

We have launched 8 companies that are improving the quality of life for patients in areas such as chronic sinusitis (which impacts over 35 million Americans a year) and osteoarthritis. We have also pioneered new approaches to urological surgery. Collectively, the companies we have built have received approximately \$680 million in venture funding and have created over 900 direct jobs and thousands of indirect jobs. We have also received over 350 U.S. patents for our inventions and I’ve had the honor to be named as an inventor on 16 of them.

The science we apply is novel and the products we develop are unique, but the process we use to build companies to bring those products to doctors and patients is not. ExploraMed is similar to hundreds of incubators and startups around the country that

create an environment where brilliant researchers, risk-taking entrepreneurs and experienced venture capitalists all collaborate to develop breakthrough technologies to launch the next generation of great American companies. This dynamic is part of the fabric of Silicon Valley, and it is also thriving across the U.S. in places like Research Triangle Park, Delaware Technology Park, Austin's technology incubators, the Silicon Bayou efforts in Louisiana and the Hawaii Innovation Initiative.

Every large, established technology company in America has started this way and we strive to emulate their success and growth. But one area where inventive startups and much larger competitors seem to be on very different sides is their relative reliance on a strong and robust U.S. patent system. For companies such as the ones we have launched at ExploraMed and thousands like them, patents are absolutely critical to every phase of our scientific and business development. Patents are the indispensable currency that drives venture investment in breakthrough startup companies. Patents facilitate the transfer of knowledge whether we are working with a university research partner or another company, they de-risk additional investment when we get deeper into our funding rounds, and help attract top research and executive talent. A strong and defensible patent portfolio is a critical part of nearly every exit strategy of which I have been a part.

Based on my 20-plus years as an inventor and entrepreneur, I can tell you that these aren't just my observations, they are facts that hold true for nearly all startups and young companies that are built on bringing truly innovative and breakthrough products to the market. This rule does not necessarily apply if your business plan is to quickly integrate existing technologies by making incremental improvements to existing products or those that go after what economists call "first mover advantage." But if you are going to build a company that disrupts a marketplace for the better, dramatically improves the level of care for patients, creates an entirely new therapy or leapfrogs an existing technology platform, you need strong patent protection that is consistent, predictable, and reliable.

Unfortunately, we don't have that now in the United States.

This is the result of a series of court cases, the initial implementation of the America Invents Act and the adoption of a business model by many large companies that largely boils down to: infringe now; fight hard if you are sued; and the worst outcome is being forced to pay a royalty at the end of a long, prolonged legal process that most smaller competitors cannot survive. This process has been coined, "*efficient infringement*" by many large incumbent companies. This has resulted in the U.S. patent system being significantly degraded over the past decade, as noted in the [U.S. Chamber of Commerce's annual Global IP Index for 2018](#).

Consider the reality faced by nearly every inventive startup company like the ones ExploraMed has created in the U.S. today.

In the aftermath of the Supreme Court's decision in *eBay v. MercExchange* it has become virtually impossible to enjoin a competitor who is infringing our patents. So, when a startup company is faced with the increasingly common reality of a larger competitor launching a product that infringes on its intellectual property, we are basically told that there is no practical and efficient way to remove that infringing product from the market. We are often told that, in lieu of injunctive relief, pursuing monetary damages in district court should be sufficient. But that is not the case. Patent litigation combined with a seemingly endless Inter Partes review process takes many years – time few startups can ever afford. And for the rare small company that can pursue litigation against a large incumbent using its technology, the Federal Circuit has significantly restricted patent-holders' ability to collect a meaningful damages award. This long and expensive process is also never a substitute for our true objective, which is to see the product we invented and the company we created succeed in the market.

It is important to note what often happens in the actual marketplace if the patent-holding startup decides to pursue this costly and time-consuming legal strategy of seeking limited monetary damages (a pursuit that very few startups can afford and very few venture capitalists are willing to invest in). During the course of litigation, the infringing company maintains or enhances its position in the market, securing revenue, developing customer loyalty, and gaining market share. In the meantime, the infringer is free to open a second front by launching multiple Inter Partes Review challenges at the USPTO and waiting for the smaller company to simply give up or die. Even if the larger infringing company ultimately loses and is forced to pay monetary damages to the patent owner it simply becomes a cost of doing business for them. They have already integrated the startup's IP, captured market share and used their scale to tilt the balance in their direction. All for the cost of *maybe* paying a damages award someday if the startup survives long enough for that to happen.

The debate in Washington is often about how patents work in the context of litigation, and as a patent attorney, I understand how that grabs the headlines. But as the President of a successful life science incubator and an executive of many companies, I can tell you that how our patent system functions in practice below the surface of litigation is far more important to our economy. Litigation is just the tip of the iceberg. Only about 5% of patent-related activity is litigation. The substantial majority of patent-related activity is the rest of the iceberg. The majority of patent activity is related to the transfer of technology, protecting investment, public disclosure to disseminate information, facilitating design-arounds, and promoting technologic advancement. The changes that

have occurred in patent law have eviscerated the ability to enforce a patent at the tip of the iceberg and are magnified on the rest of the iceberg... eroding it away.

You will hear stories of how “patent trolls” are destroying American innovation. You will hear theories about how a restoration of a fair injunctive relief standard will lead to “patent hold up.” And you will hear that allowing serial and coordinated IPR attacks is necessary to eliminate “bad patents.” The practical impact of these narratives has tilted the balance of our patent system to discourage new entrants, drive venture funding away from patent-intensive industries, solidify the position of incumbents and consolidation into a small number of incumbent companies.

It is pretty clear that in the eyes of a few large incumbent corporations, anyone who accuses them of patent infringement is a “troll,” anyone who seeks a license for technology they implement is engaging in “patent hold up,” and any patent that isn’t theirs is probably a “bad patent.”

Thankfully, this Committee has begun to take some steps to call out these false narratives and restore some balance to the patent system for American inventors, entrepreneurs and investors.

Chairman Tillis and Ranking Member Coons, your efforts to address the incredible uncertainty regarding patent eligibility in the U.S as a result of the Supreme Court’s *Alice* and *Mayo* decisions is desperately needed and much appreciated. The combined effect of these cases and their interpretation by lower courts has been to make it largely impossible to gain patent protection for large categories of software and life science inventions. I have seen this first-hand, and I commend your efforts and would welcome the opportunity to work with you as you look to clarify patent eligibility guidelines under Section 101 of the Patent Act.

In addition, the leadership of Director Iancu at the U.S. Patent and Trademark Office has been commendable on several fronts. First, his simple, but much-needed appreciation for the importance of American innovation and a strong patent system has been a breath of fresh air. In addition, he has taken concrete steps to implement new guidelines for patent examiners under Section 101 to provide some additional clarity regarding patent eligibility. He also has worked to address some of the more egregious abuses of the IPR process in which infringers often use serial and collusive tactics to target patent owners who dare to seek licenses or raise infringement claims.

This hearing today on the STRONGER Patents Act is another step in that progression to restore the strength of the U.S. patent system.

I would like to thank Senator Coons for sponsoring this important piece of legislation and also for the support of Senators Durbin, Hirono and Kennedy on this Committee.

The STRONGER Patents Act will make pragmatic and impactful improvements to U.S. patent law that will increase innovation, spur early stage investment and make America more competitive. We see the STRONGER Patents Act restoring balance in two major areas it would address.

First, it would restore the presumption that a permanent injunction will be granted after infringement is proven. In his concurring opinion in the *eBay* case, Chief Justice Roberts noted that in almost all cases, an injunction is appropriate. The restoration of a presumption favoring injunctive relief would go a long way toward addressing the current problems we face.

As a patent attorney, I understand the key argument against this provision, namely, that “patent hold up” will occur if patent owners seek injunctions to create leverage against infringing competitors already active in the marketplace. But that argument ignores the efficient infringement practices that are now commonplace. Besides, it assumes a parity between competitors that does not exist in reality. A venture-backed start-up company cannot kill a large, profitable, incumbent company with patent litigation but that large company can bleed a start-up company to death or even prevent it from coming into existence in the first place.

Here’s how that dynamic might look for an entrepreneur in the medtech field. Imagine you have found a compelling new medical technology at a university and you need to raise significant venture capital to license the technology and attempt to build a company around it. You will probably need 8-12 years to turn the crude prototype and patent application into a product, manufacture it for testing in pre-clinical and clinical studies to prove that it is safe and effective, obtain FDA approval, set-up larger-scale manufacturing, hire sales representatives, teach physicians the clinical data and train them how to use the product, educate health insurance payers about the clinical data and gain their approval to pay for the product and encourage physicians to use it. This will require about \$75-\$100 million along the way. The investment will come in several different rounds of about \$10-\$35 million and there will be no revenue from any products during that time.

That entrepreneur will approach seasoned venture capitalists who will tell you it is not known whether the technology will work for its intended medical purpose and that it is possible that the enterprise may fail at any of those major phases. They will ask, “Well, if you do prove that it works and are successful at all of those phases, then you will have a patent that allows us to get a return on our investment and prevent a pre-existing profitable medical device company from just making and selling their own version of the product after you have proven it works, right?” Currently, the entrepreneur will be forced to say, “not likely.” The potential VCs will know that, in addition to the \$75-\$100 million to get a company to the point of market entry, it will take another \$10-20 million and about 5 years to try to stop any competitors who will be able to challenge the validity

of the patent multiple times in the PTAB, where 75% of the time the PTAB invalidates the patent. Any larger competitor also has more than 20 different ways to try to avoid a ruling of infringement, and even if there is a finding of infringement, it is unlikely that the court will stop them from selling the product.

It makes you wonder ... would you want to start or even invest in starting that company?

There are no known instances of patent hold-up actually preventing the development and distribution of a useful technology. The *theory* of patent hold-up has been allowed to override the reality that without effective opportunity for injunctive relief to remove an infringing product from the marketplace, patent owners, especially startups, are largely powerless to stop their competitors from “efficiently infringing” their inventions. Perhaps that is the objective of some, but I would appeal to the Members of this Committee to use the language of the STRONGER Patents Act as a baseline and seek some sort of compromise that allows patent owners to have a realistic opportunity to discourage infringement in the first place and seek injunctive relief when faced with proven infringement from a competitor. As a country, we should be encouraging innovators to license or design around patents rather than encouraging efficient infringement, which discourages the inventive development of new technology as well as new companies. I do not want to empower abusive legal tactics as they can be used against startup companies as well, but I also do not believe this is a binary situation where the only option is to remove injunctive relief entirely.

It is interesting, and discouraging, to note that the U.S. is somewhat isolated in its move to limit injunctive relief for patent owners. Major industrial nations such as China, Germany and others have a robust injunctive relief mechanism in their law which have led many U.S. companies to seek those venues out to protect their patents.

In addition to restoring a presumption of injunctive relief in cases of proven infringement, the STRONGER Patents Act would enact critical reforms to the Inter Partes Review process at the PTO that was instituted under the America Invents Act.

Perhaps the most significant and needed immediate improvement that the STRONGER Patents Act would make would be to address the dynamic of serial IPR challenges that seem well beyond the scope and intent of the AIA.

As was documented in a 2018 report ***How “One Bite at the Apple” Became Serial Attacks on High Quality Patents at the PTAB*** by the Alliance for Startups and Inventors for Jobs (USIJ):

Congress intended inter partes review (IPR) as an alternative to district court litigation that saves time and money for challenging the validity of the minority of patents that are questionable. It was not intended to become a tool for well-heeled corporations to delay and repeatedly attempt to kill a valid patent in ways not tolerated in district court. Congress recognized the potential for

abuse of PTAB litigation by serial petitions that repeatedly attack an inventor's patent. Throughout the legislative history of the AIA, and as cemented in the enacted legislation, Congress made clear that inventors should not have to endure repeated attacks on their patent claims at the PTAB. Even the best inventions, covered by well-written patents, are prone to be stripped of their protections at the PTAB, precisely because the most valuable inventions draw the most repeated and concerted attacks by so many challengers.

It is this last point that I would like to stress. While the advocates for broad application of the IPR process to allow for unlimited attacks claim this is necessary to weed out “bad patents” the reality in the marketplace is again different from the theories present in those legal arguments. Think about it. Why would companies waste their time and resources only going after “bad patents” that probably have very little value in the marketplace and aren't typically based on the most cutting-edge science and technology? They don't. What is happening now is that IPR petitions are being used strategically and in a coordinated fashion by large companies to target the best patents that are at the core of smaller competitors' most valuable products. It does not take multiple IPRs to take out a “bad patent.” But a good patent (and startup) can be extinguished if they are subjected to endless, coordinated IPRs.

This is exactly an outcome Congress foresaw and sought to avoid. Senator Grassley said this as part of the Senate floor debate on the America Invents Act:

“In addition, the bill (the AIA) would improve the current inter partes administrative process for challenging the validity of a patent.... It would also include a strengthened estoppel standard to prevent petitioners from raising in a subsequent challenge the same patent issues that were raised or reasonably could have been raised in a prior challenge. The bill would significantly reduce the ability to use post-grant procedures for abusive serial challenges to patents.”

Director Iancu has also recognized the real and potential abuse within the IPR process. We applaud him for speaking about it at length, meeting with patent owners and taking steps designed to limit the ability of petitioners to game the system through serial and duplicative IPR filings.

Much more needs to be done however, and the STRONGER Patents Act has several critical provisions to bring balance to the IPR process and end abusive tactics and gaming of the system by large companies and their proxies.

The STRONGER Act's common-sense standing provision would simply apply the same requirement used in federal district court for a petitioner to have a business or financial reason for challenging the validity of a valid U.S. patent. The current lack of a standing requirement has been used as a loophole that has led to some of the most outrageous and abusive tactics imaginable at the PTAB. This has included hedge funds setting up shell entities to challenge companies' patent portfolios after having shorted their stocks. Proxy groups like Unified Patents that collect fees from

“members” and then launch coordinated, serial attacks on patents held by their members’ competitors or any small company whose technology poses a threat. Large companies have threatened startup companies with putting a startup’s entire patent portfolio into IPR reviews if the startup requests the large company take a license to one of its patents. A clear and simple standing requirement will both protect patent owners from abusive behavior like this while still allowing legitimate petitioners to file appropriate challenges to patents they believe were incorrectly granted. That was the whole idea behind IPR in the first place.

STRONGER would also harmonize the standard for claim construction used by the PTAB with the standard used in district court litigation. This would essentially codify a recent USPTO rule change that will significantly limit gamesmanship by petitioners.

In addition, the bill would again harmonize PTAB procedure with district court standards for the burden of proof necessary to invalidate a patent. A District Court requires “clear and convincing” evidence to invalidate a patent. It is manifestly unfair and abusive to apply a lower standard to make a similar invalidity decision simply because the adjudication occurs in an administrative court rather than a district court.

Importantly, STRONGER proposes a package of reforms that would have the combined effect of eliminating the increasing practice of serial and repetitive IPR challenges that data from USIJ has shown come disproportionately from a handful of very large technology companies:

For the top IPR filer, Apple, a whopping 56% of its petitions are duplicative (i.e., multiple petitions filed attacking the same claims). For the next four filers each, over a third of their petitions are duplicative (Samsung (38%), Google (38%), Microsoft (59%), and LG (34%))¹.

The bill contains provisions that would allow PTAB to initiate only one review per claim of a patent, and would allow petitioners to only file one petition to challenge a patent (not file multiple petitions on the same patent as the companies above do routinely).

Finally, STRONGER contains provisions that eliminate the extensive redundancy with district court litigation. It is common if not standard operating procedure for companies to bring the exact same patent validity challenges in both PTAB and district court. This practice places a significant burden on startups as they must fight both in expensive court litigation and in expensive IPR proceedings that are generally tilted against them. STRONGER forces petitioners to simply choose one venue, rather than permit unfair gamesmanship that results from simultaneous access to both.

¹<https://static1.squarespace.com/static/5746149f86db43995675b6bb/t/5bd3757af9619a5ed812cb69/1540584826664/FINAL+USIJ+Serial+IPR+White+Paper+---+Oct+17+20181.pdf>

For the past decade, Congress and U.S. courts have steadily eroded the strength of the U.S. patent system, once the global gold standard. I have no problem trying to solve issues of patent litigation abuse where they exist, but we have gone too far and advocates for large corporations who do not value patents still want to do more damage. They continue to advocate to this Committee that patent protection is too strong in America and that it stands in their way. I have a very clear understanding of why they believe that and why they are fighting legislation to restore balance to the patent system such as the STRONGER Patents Act.

From my perspective as the founder of multiple medical device companies that improve the lives of American patients and that depend heavily on strong U.S. patents, my question is this: when are we going to do something that actually strengthens our patent system to benefit the thousands of entrepreneurs and startups across the country with brilliant ideas and new technologies? We have done enough to tilt the balance of the patent system in favor of large, established corporations. Not every good idea comes from a big company. In fact, the vast majority come from the entrepreneurs and startups that would benefit greatly from the STRONGER Patents Act.