SOVEREIGN IMMUNITY AND THE INTELLECTUAL PROPERTY SYSTEM

HEARING

BEFORE THE

SUBCOMMITTEE ON
COURTS, INTELLECTUAL PROPERTY,
AND THE INTERNET

OF THE

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CONTENTS

NOVEMBER 7, 2017

OPENING STATEMENTS

WITNESSES

SOVEREIGN IMMUNITY AND THE INTELLECTUAL PROPERTY SYSTEM

TUESDAY, NOVEMBER 7, 2017

HOUSE OF REPRESENTATIVES

SUBCOMMITTEE ON COURTS, INTELLECTUAL PROPERTY AND THE INTERNET

COMMITTEE ON THE JUDICIARY

Washington, DC.

The Subcommittee met, pursuant to call, at 2:00 p.m., in Room 2141, Rayburn House Office Building, Hon. BOB GOODLATTE [Chairman of the Subcommittee] presiding.

Present: Representatives Issa, Goodlatte, Smith, Chabot, Franks, Jordan, Marino, Farenthold, Gaetz, Biggs, Johnson of Georgia, Jeffries, Lieu, Schneider, and Lofgren.

Staff Present: John Lee, Counsel; Carlee Tousman, Clerk; Jason Everett, Minority Chief Counsel; David Greengrass, Minority Counsel; and Rosalind Jackson, Minority Professional Staff.

Mr. ISSA. The Subcommittee on Courts, Intellectual Property, and the Internet will please come to order. Without objection, the chair is authorized to declare recess of the Subcommittee at any time. We welcome everyone here today to a hearing on "Sovereign Immunity and Intellectual Property System." I will now recognize myself for a short opening statement.

The St. Regis Mohawk tribe was invited to testify here today, but they declined, and so, with that, I will place in the record in its entirety, some eight pages plus many other inserts, totaling about 40 pages that came from the St. Regis Mohawk tribe as their position and testimony.

[The information follows:]

COMMITTEE INSERT

Mr. ISSA. I also would place in the record at this time that the following statements of Dale White, general counsel for the tribe. When he was asked whether he would consider doing more sovereign immunity deals, he answered to Bloomberg, "We will probably take as many as Shore law firm can handle." When asked by MSNBC, he said, "Yes. Can you put my phone number in your article?" We will take that in addition to their defense of their current position as they have done these; they want to do more.

[The information follows:]

COMMITTEE INSERT

Mr. ISSA. The IP system only works if it strikes the right balance. We know that we want to, and this Committee is committed to, reward true innovators for their creative works. But the IP system must be protected from several types of wrongful behavior, and I want to make sure that today, because the subject will come up over and above sovereign immunity, that we understand those who have tried to use the PTAB program and try to use it to short funds or essentially, as trolls to coerce money in lieu of a filing have, in fact, been gaming the system every bit as much as we may find today from others.

It is important to understand that under the AIA, the review of patents was intended to end, and in a small way has succeeded, in finding patents which claim claims that belong to someone else. The invalidity of claims overwhelmingly comes from a finding of prior art in which someone else has already owned that invention.

This would be no different than if, in fact, you claim to have rights to land and you put a fence on it and later found out through surveying that somebody else owned four feet of that land. You would be asked to move your fence and nobody would view it as anything other than you get to have the land you truly always had, not the land you may have thought you had without a proper survey.

Speaking of surveys, 99 percent of all patents are not being reviewed under this review process and of that less than one percent that are reviewed, nearly half survive intact. Well, about half have some or all of their claims reviewed or eliminated. In other words, you are dealing with—essentially, a fraction of 1 percent of all patents will be invalidated under this procedure. And again, approximately half of those that are considered actually have that happen.

For that reason, it is important to understand that this is not a large-scale operation, and yet it would, in fact, attract many companies, not just Allergan—who was asked also to be here today and declined, but sent a representative through an association—to put their patents into what I would consider a sham deal.

The word "sham" does not imply illegal. The word "sham" simply says that this was not a good-faith sale of their patent rights, but in fact a sale leaseback for no purpose other than to evade the kind of patent review that is currently in the law and for which Allergan and other pharmaceutical companies regularly find themselves.

One of our challenges here today is that the particular patents that are in this portfolio represent a drug which has been on sale for two decades and for whom the original patents have expired, therefore the companies in this case are not some troll, as I mentioned could occur. The companies that are involved in looking at these patents are ones who want to make what now rightfully would be a generic product. They seek to do so without falling under new patent claims that they could either avoid or that may be invalid.

For this reason, we take particular interest not in Allergan, but in the patents not in suit, so to speak, and in fact, in what I believe is a sham decision.

I want to make one last statement. I have been an advocate, as I am required to do under the Constitution, for constitutional rights, and the right of sovereignty of government and of their lands to Native Americans without a doubt will be protected by this committee and by this Congress.

And one of the groups that has talked to me more than any others are Native American groups concerned that this commercial activity could somehow cause Congress to restrict other commercial activity covered by Native American sovereignty. It is our goal to be very careful in this hearing and in any legislation so that we not diminish in any way the earned and constitutional rights of Native American tribes for their sovereignty, their self-governance, and their own internal commerce.

And with that, I recognize the ranking member of the committee, Mr. Nadler, for his opening statement.

[The prepared statement of Mr. Issa follows:]

COMMITTEE INSERT

Mr. NADLER. Thank you, Mr. Chairman. Mr. Chairman, state sovereign immunity is a well-established concept, enshrined in our Constitution that generally protects States from being sued in federal courts without their consent. Similarly, Federal law generally extends sovereign immunity to Native American tribes as well. For many years Congress and the courts have wrestled with numerous questions concerning the appropriate scope and use of sovereign immunity as it pertains to intellectual property.

For example, is it fair that States can protect their intellectual property from infringement by availing themselves of the legal system, yet they can shield themselves from liability by invoking sovereign immunity if they are sued for the same infringing behavior?

What limitations can be placed on sovereign immunity while staying within constitutional boundaries, and what incentives could we design to encourage States to waive sovereign immunity in IP cases? These are all important questions worthy of careful consideration.

In light of recent events, however, a new set of questions have arisen: Can sovereign immunity be used as a giant loophole for private actors to evade legal scrutiny of their intellectual property and to exploit for their own commercial purposes? And if so, what can Congress do about it? These questions arise because of the recent actions by the pharmaceutical company, Allergan, and its cynical ploy to shield its patents on a lucrative drug from review at the Patent and Trademark Office, by taking advantage of a Native American tribe's sovereign status.

Rather than subject itself to the Patent Office's inter partes review, IPR process, Allergan transferred the patents on its highly successful drug Restasis to the same St. Regis Mohawk Native American tribe, which immediately granted an exclusive license back to Allergan.

Allergan paid the tribe $13.75 million upfront as part of the deal, plus it committed to ongoing royalties of $15 million a year. In exchange, the tribe needed only to agree that it would invoke its sovereign immunity if the patents were challenged in IPR.

According to Allergan, it took this step because it believes IPR is deeply flawed, unfair to patent holders, and disruptive to the balanced process established for generic drug competition under the Hatch-Waxman Act. Moreover, they argue, their patents could still be reviewed in Federal court, just not in IPR. I would note here that if they believe that to be the case their proper recourse is to go to Congress and try to persuade us to change the law, but they did not choose to do that.

It is true that Allergan's gambit did not shield the patents from Federal court review, and in fact, those patents were recently held invalid by a court in the Eastern District of Texas.

However, the Court in that case also made clear that it had "serious concerns about the legitimacy of the tactic that Allergan and the tribe have employed." This deal has been widely condemned, not just because it is seen as thumbing its nose at the legal system, but also because if successful, other drug companies could use the same scheme to protect expensive brand-name drugs from lower priced generic competition.

IPR was created in the 2011 America Invents Act. It is intended to be a relatively quick and inexpensive way for the Patent Office to conduct a second look at an issued patent and to invalidate patents that should never have been issued in the first place.

This administrative process occurs separately from, though often concurrently with, Federal court consideration of the same patent's validity. The IPR process has many critics, not just Allergan, and many questions have been raised about whether it is functioning as intended.

Some stakeholders have complained that it provides competitors with multiple bites at the apple in challenging a patent's validity. Others rightly in my view have argued that it is problematic for IPR proceedings to use a different standard for evaluating patent validity from the one that is used in Federal courts. IPR is also criticized by some as being stacked against the patent holder and as being too likely to find a patent invalid.

The IPR process also has many defenders, however. They argue that the patent system is strengthened by having an efficient system for weeding out invalid patents. They point out that the stockintrade of patent trolls is weak patents that never should have been issued, and they argue that IPR has been invaluable in removing such patents from the market.

They also note that the PTO only institutes an IPR proceeding when there is a reasonable likelihood that the patent is invalid. Thus, they argue, it is to be expected that, once instituted, a significant percentage of proceedings would result in canceling a patent and that statistics should not be read to imply that IPR is unfair to patent holders.

The merits of the IPR process should be debated, and if changes are needed, we should consider them in due course. That is for Congress to decide, with input from relevant stakeholders. It is unacceptable, however, for private actors like Allergan to do an end run around IPR by making use of a third-party sovereign immunity solely for strategic advantage. Such behavior makes a mockery of congressional authority and of the rule of law.

More worrisome is the precedent this transaction sets. Already, other companies are rushing to make similar deals, across various industries. Whatever one thinks of IPR, it is the law of the land, and it is the clear intent of Congress that it be available to anyone who seeks to challenge a patent under its rules.

We should not allow gamesmanship to circumvent Congressional authority. I look forward to hearing from our witnesses today on their thoughts on the appropriate scope of sovereign immunity and intellectual property and what we can do to ensure that it is not abused. I thank the chairman for holding this important hearing and I yield back the balance of my time.

[The prepared statement of Mr. Nadler follows:]

COMMITTEE INSERT

Mr. ISSA. I thank the gentleman. We now welcome our distinguished panel of witnesses here today. And if you would all please rise, and I will issue the oath. I will get to you in just a second, Chairman.

Please raise your right hands. Do you swear that the testimony you are about to give will be the truth, the whole truth, and nothing but the truth? Please be seated.

Let the record reflect that all witnesses answered in the affirmative. And with that, it is my great pleasure and responsibility to introduce the Chairman of the full Committee, Mr. Goodlatte, for his opening statement.

Chairman GOODLATTE. Thank you, Mr. Chairman. I thank you for holding this hearing and for yielding to me. This may be a case of everything that needed to be said has been said by you and the Ranking Member, but not everyone who needs to say it has said it.

Sovereign immunity is a legal doctrine that has existed since the beginning of our Republic. It is a privilege of sovereign entities, such as State governments and Native American tribes, which are responsible for the well-being of those they govern. In recent years, however, it is become apparent that in some circumstances sovereign immunity is being used not on the activities of constituents of State and tribal governments but in a way that harms the intellectual property system all Americans depend on.

There is no doubt that the IP system is vital to the health and competitiveness of the U.S. economy. A strong intellectual property system helps the U.S. maintain its place as the world's leader in technological innovation and creative expression.

The IP system is weakened, however, when some participants of the IP system do not play by the same rules as the rest. I share the concern about the recent instances of private companies paying to rent the sovereign immunity of Native American tribes to protect their intellectual property. Tribal sovereign immunity was never intended to serve the interests of private companies unrelated to the tribes.

If successful, these private companies will be able to enforce their patents against others while exploiting the tribe's sovereign immunity to prevent legitimate challenges to those patents at the Patent and Trademark Office. In effect, these companies will not be playing on a level playing field.

That is similar to the situation before Congress acted to restore fairness to the patent system by passing the America Invents Act, or AIA. This bipartisan measure passed both chambers of Congress by overwhelming margins because of the broad recognition that the patent system had become unbalanced by abusive litigation conduct and low-quality patents issued by an overworked Patent Office.

Inter partes reviews, or IPRs, are a critical part of the AIA's reforms because they provide the Patent Office an opportunity to correct mistakes it made when issuing patents. IPRs allow the Patent Office to weed out low-quality patents that should not have been granted in the first place, leaving in place stronger patents that cover real innovations.

If questionable deals with sovereign entities can extend immunity to artificially protect low-quality patents, the entire IP system is harmed. The facts demonstrate that IPRs and other AIA procedures are effective and accurate.

For example, last year the U.S. Court of Appeals for the Federal Circuit affirmed decisions of the Patent Trial and Appeal Board in AIA cases about three quarters of the time, which was roughly the same affirmance rate as for District Court patent cases.

In 2015, the affirmance rate was even higher at about 85 percent. As a district court recently noted when considering the very issues presented at this hearing, the entire system of AIA post-issuance review may be in peril if the practice of private companies paying for sovereign immunity continues.

I want to thank Chairman Issa for convening this hearing. I want to thank former Chairman Smith for his great, outstanding leadership in getting the America Invents Act passed in the first place. I thank their witnesses for their participation, and I look forward to delving further into this very important and serious issue.

[The prepared statement of Chairman Goodlatte follows:]

COMMITTEE INSERT

Mr. ISSA. Thank you, Mr. Chairman. All Members' opening statements will be placed in the record in written form.

[The information follows:]

COMMITTEE INSERT

Mr. ISSA. It is now my honor to introduce our witnesses, which include Mr. Karl Manheim, professor of law at Loyola—this is why I did not attend Loyola; I cannot do that; I have tried—Law School; Mr. William Jay, partner and cochair, appellate litigation, Goodwin Procter, LLP; Mr. Philip Johnson, principal, Johnson-IP Strategy and Policy Consulting; and Mr. Christopher Mohr, vice president of intellectual property and general counsel at the Software and Information Industries Association.

Before we begin opening statements, I am also going to place in the record a letter we received, Mr. Nadler and I, from Mylan, one of the companies involved in the other side of litigation. And I will just briefly insert that they assert that this has been to them 22 billion doses that would have been available for generic that were not as a result of the activity we are involved in today, and they

put an estimate of $1.5 billion in revenue that was distorted. So, without objection, that will be placed in the record. Mr. Manheim.

[The information follows:]

COMMITTEE INSERT

STATEMENTS OF KARL MANHEIM, PROFESSOR OF LAW LOYOLA LAW SCHOOL; WILLIAM JAY, PARTNER AND CO–CHAIR, APPELLATE LITIGATION, GOODWIN PROCTER, LLP; PHILIP JOHNSON, PRINCIPAL, JOHNSON–IP STRATEGY & POLICY CONSULTING; CHRISTOPHER MOHR, VICE PRESIDENT FOR INTELLECTUAL PROPERTY AND GENERAL COUNSEL, SOFTWARE AND INFORMATION INDUSTRY ASSOCIATION

STATEMENT OF KARL MANHEIM

Mr. MANHEIM. Thank you, Mr. Chairman, Chairman Goodlatte, and Mr. Nadler. I am Karl Manheim, a professor of law at Loyola Law School in Los Angeles, where I teach constitutional law and intellectual property. I had the pleasure of serving the subcommittee as a fellow in 2007 and help with that year's patent reform legislation. It is an honor to be back.

The matter in front of this committee was prompted by Allergan, Incorporated's assignment of its patent for ophthalmic drug to the St. Regis Mohawk tribe. The tribe claims sovereign immunity from suit, thus immunizing the patent from challenge at the Patent Office.

This assignment occurred after two generic manufacturers filed with the FDA an abbreviated new drug application, or ANDA. ANDA is a mechanism created by the Hatch-Waxman Act to encourage the entry of generic competition as a means of lowering drug prices. By law, an ANDA is deemed an infringement of the drug patent.

After Allergan sued for infringement in Federal court, the generics filed the petition for inter partes review at the PTO, pursuant to the America Invents Act. That administrative proceeding was intended by AIA to provide an expeditious and less costly mechanism than litigation to challenge poor-quality patents.

In the Allergan case, the company had assigned its patent to the tribe, making them an indispensable party in any patent challenge. My testimony will focus on the tribe's claim for sovereign immunity, which is still pending before the Patent Office.

As a related matter, States also have sovereign immunity. They are far more active in the patent enterprise through research universities and faculty and other commercial activities. State sovereign immunity, however, is grounded in the 11th Amendment.

Tribal immunity, in contrast, is a product of common law and statutory recognition, thus it is easier for Congress to address abuses of the system in situations like this, where a patent holder assigns its rights to a Native American tribe in order to insulate the patent from challenge. However, solutions do exist for similar abuses by States, and I discuss several of those in my written testimony.

Indian tribes are considered domestic dependent nations. As with other nations, tribes enjoy a degree of sovereignty. The Supreme Court has questioned the wisdom of continuing tribal immunity,

but has yet to overrule it. But because the doctrine is grounded in common law and not in the Constitution, it may be set aside by Federal statute. Doing so, either in general or in specific cases such as patent immunity, raises no constitutional questions, in my opinion.

Senator McCaskill has introduced a bill in the Senate to abrogate tribal immunity in IPR cases. Some rights organizations argue that singling out tribes for adverse treatment discriminates against Native Americans in violation of the equal protection principle in the Fifth Amendment. I do not agree with that argument. Tribes enjoy a privilege that no other entity except States have: immunity from suit. Abrogating and limiting that immunity is not a discriminatory act; rather, its purpose is to restore balance to patent and competition policies.

As the Supreme Court said in Bonito Boats v. Thunder Craft Boats, the patent clause reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the progress of science and the useful arts. That balance is maintained on the one hand by awarding patents to innovative technologies, and on the other hand by facilitating challenges to poor-quality patents. The Hatch-Waxman Act is a prime example of this balance. It encourages generic companies to enter the market and thus to lower drug prices through competition, but they first have to successfully challenge an existing patent. That is made more difficult when the patent holder or assignee has immunity.

Sovereign immunity, whether asserted by a tribe or a State, has the potential of disrupting this finely crafted balance between U.S. innovation and competition policies. I believe Congress has the tools to preserve that balance. On the one hand, it can narrow tribal immunity; on the other, it can condition the grant or assignment of a patent to a sovereign entity by requiring that entity to waive its immunity in patent litigation and IPR proceedings. Those, and other solutions, will likely survive constitutional scrutiny and would benefit the public welfare. Thank you. I will be happy to answer questions later.

[The prepared statement of Mr. Manheim follows:]

INSERT 1

Mr. ISSA. Thank you. Mr. Jay.

STATEMENT OF WILLIAM JAY

Mr. JAY. Thank you, Mr. Chairman. Thank you, Ranking Member Nadler and members of the subcommittee. I would like to thank the subcommittee for its attention to these important issues, and I appreciate the opportunity to participate today.

I am a partner at the law firm Goodwin Proctor, where I litigate constitutional cases and issues of Federal jurisdiction, and also patent cases. I have been asked to testify today on behalf of the Association for Accessible Medicines, which represents companies that develop and bring to market generic and biosimilar medicines. Those products saved the U.S. healthcare system $1.7 billion over the last 10 years, and we are concerned that the rental of sovereign

immunity tactic that Allergan has pioneered will put those savings at risk.

Why is Allergan renting sovereign immunity for tens of millions of dollars a year? It is looking for protection from competition for a product that brings in billions of dollars. And Allergan had a period of patent protection on this product which was coming to an end in 2014, so Allergan went and got a second generation of patents, more patents on the same product, just as its patent monopoly was about to expire. And those new patents do not expire until 2024.

Allergan had reason to be worried that those patents would be subject to challenge under the procedures that Congress created in the Leahy-Smith America Invents Act, so it sought to put its patents beyond the reach of the Patent Office. Effectively, it sought asylum for its patents in Indian country. On the eve of the hearing before the PTO, Allergan did this multimillion-dollar deal with the tribe and within hours the tribe had stepped forward to demand that the PTO stop reviewing these patents and to decide whether these are patents that never should have been issued.

If every company with enough money could use that tribal tactic to block their patents from review, the result will be to leave more bad patents on the books for longer, and that problem is not limited to bad pharmaceutical patents. The St. Regis Mohawk tribe has also apparently already done a deal to rent immunity to a patent troll that is suing Apple. These deals would be bad for the patent system, for competition, and for consumers. And in the healthcare pharmaceutical context, that means patients who need access to medication. It would cut against the very reason why Congress created IPR review in the Leahy-Smith American Vance act just a few years ago.

Now, Congress has set out very clear rules for issuing patents, and one of the clearest is that a patent cannot be issued on something that is just existing knowledge or an obvious variation on existing knowledge. That knowledge might belong to another patent owner, or it might belong to the public because it is out in the public domain. And the authors of the AIA understood all too well that the patent examination process does not always uncover all of the flaws in a patent application, all of the ways in which it duplicates or is just an obvious variation on existing knowledge.

The incredible volume of patent applications makes that an incredibly difficult process for examiners. They often do not even see all of the published papers and other writings that set out what is in the public domain. That is where IPR comes in. IPR is a reform that allows third parties to participate and allows more information to come to light before the Patent Office.

It is one of the most important reforms because it helps to screen out bad patents while bolstering valid ones, and it ensures that poor-quality patents can be weeded out through administrative review rather than costly litigation. It is faster, it is time-limited, it is more efficient, and they just focus on one thing. They focus on whether this is a patent that never should have been issued because it was already in the public domain in the prior art, or it was obvious all along.

Now, IPR co-exists with litigation in court, but it is different, and it is complementary. Now, while some interested parties have criticized IPR as a form of double jeopardy, that is a completely inaccurate criticism. Patent owners get to file multiple lawsuits on the same patent, and it is not surprising that there could be multiple different challenges to the validity of a single patent. But it is important to note that Congress wrote a protection into the AIA that once the PTAB takes up a challenge in an IPR or a similar proceeding and decides on the merits, if the challenger loses, that is it. The challenger cannot relitigate that in court. That is hardly double jeopardy.

But whatever criticisms some people might make of Congress' work in the AIA, what Congress adopted is a set of rules that applies to everybody. Nobody is entitled to a patent on something that is obvious. Since Congress created re-examinations back in 1980 every patent owner has understood that the issuance of the patent does not necessarily mean the last word.

Mistakes can be fixed, but the Allergan strategy of renting sovereign immunity would set up a different set of rules for patent owners with enough money and enough gall to enter into a transaction like this one. That is why we urge Congress to give this problem its close attention and to use its power to regulate the common-law principle of tribal immunity; to restrict that immunity to what its true purpose is: to protect Native American sovereignty, to protect the sanctity of tribal land, to protect the businesses that tribes may run on that land—but not to rent out their sovereign immunity in a way that is going to interfere with not just the patent system but the healthcare system as well.

I thank the subcommittee and I look forward to answering your questions.

[The prepared statement of Mr. Jay follows:]

INSERT 2

Mr. ISSA. Thank you. Mr. Johnson.

STATEMENT OF PHILIP JOHNSON

Mr. JOHNSON. Thank you, Chairman Issa, Ranking Member Nadler——

Mr. ISSA. Would you pull the mic a little closer, please? Would you turn it on, please? Thank you. That helps.

Mr. JOHNSON. Thank you, Mr. Chairman, Ranking Member Nadler, and distinguished Members of the committee. In my written statement I have detailed three issues relating to this topic that should be of concern to the subcommittee: why patent owners now feel it is necessary to assign their patents to sovereigns to aid in their patents enforcements; why sovereigns prefer to have issues relating to their patents adjudicated in the Federal courts rather than in the Patent Office; and what reforms would eliminate any advantage to be gained from assigning patents to sovereigns. All three of these problems are symptoms of the flawed implementation of the inter partes reviews, IPRs, first authorized by the America Invents Act.

Former Chief Judge Michel was right when he testified to you earlier that these IPR proceedings are now doing more harm than

good. Because they were not conformed to the validity and due process standards traditionally used in the courts, they are now fueling a myriad of abuses based on arbitraging the differences in cost and outcomes between IPRs and court proceedings. These include a number of forms of reverse or IPR trolling, as well as disruptions of other time-honored patent challenge frameworks, such as Hatch-Waxman patent proceedings.

Many patent owners now see IPRs is grossly unfair, and therefore prefer to have their patents subjected to challenge in the Federal courts, which they view as more likely to reach just outcomes. While most patent owners can't avoid IPRs, sovereigns may and increasingly are preferring to have all issues relating to their patents, including validity, decided by the courts. Federal court litigation, unlike IPRs, is one-stop shopping.

Federal courts address all issues that could arise concerning the patent's validity and infringement and set the gold standard for fairness, impartiality, and due process. Appellate reviews of district court judgments are also more robust. In appeals from the district court, the Federal Circuit is not usually restricted to a review using only the substantial evidence standard. Especially now that fees are being more routinely shifted to losing parties in district court cases, sovereigns and others are not unreasonable in wanting to have their patent infringement claims assessed there, which is, in the case of the sovereigns, their right to do so.

The solution of these concerns is to remove any meaningful advantage from sovereign patent ownership by revising Patent Office post-grant procedures to conform them to the substance and outcome of the Federal courts, thereby removing any incentive to arbitrage differences between the two, which are now fueling the abuses I mentioned.

What is at stake here is the confidence of investors and their investors in the Constitution's promise that Congress will encourage innovation by securing for limited times to Inventors the exclusive Right to their Discoveries. At present, even fully and fairly litigated court judgments are not being respected as final resolutions. They do not provide quiet title to patents because they may be challenged over and over again by the same or different persons in IPRs, thereby thwarting our Constitution's promise that inventors' patent rights will be secured.

Fortunately, the problems with IPRs are now widely recognized within the IP community and their fixes are well within this subcommittee's purview. But time is of the essence, as the same recognition is now rapidly eroding confidence in our patent system. Since the implementation of IPRs just 5 years ago, the U.S. patent system has dropped in the U.S. Chamber of Commerce's ranking from first to 10th place, due largely to the impact of IPRs on patent reliability.

Moreover, the ability of infringers to invalidate U.S. patents, seemingly at will before the PTAB, is emboldening foreign competitors to copy U.S. technology just when their home countries are strengthening their patent systems for more likely use against U.S.-originated imports. To attract more investment and innovation in this country, enhance our productivity, create more well-paying

U.S. jobs, and increase our GDP, we must act now to strengthen the reliability and enforceability of U.S. patents.

To do this, we must not only provide fair and consistent for determining validity and infringement, but also ensure that patent owners may enjoy quiet title to their patent properties without fear from unfair IPRs. If we are successful in accomplishing these goals, patentees would not need to assign their patents to sovereigns as there would be nothing to be gained by doing so. Thank you, and I look forward to answering any questions you might have.

[The prepared statement of Mr. Johnson follows:]

INSERT 3

Mr. ISSA. Thank you. Mr. Mohr.

STATEMENT OF CHRISTOPHER MOHR

Mr. MOHR. Chairman Issa, Ranking Member Nadler, and Members of the committee, on behalf of the Software and Information Industry Association and its members, thank you for this opportunity to share our views.

SIAA is the principal trade association for the software and information industries and represents over 700 companies that develop and market software and digital content for business, education, and consumers. Our members range from startup firms to some of the largest and most recognizable corporations in the world. SIAA has long viewed assertions of sovereign immunity from suit as out of place in the modern intellectual property system, and we commend the committee for both its past actions on and its continuing interest in this subject.

The doctrine prohibits governments from being sued without their consent, but it is important to understand that it is a procedural, not a substantive, doctrine. It renders the sovereign immune procedurally from being involuntarily hauled into court to answer for its actions without its consent. It does not render the sovereign's actions substantively lawful. And that immunity is necessary when those governments are involved in their core governmental functions. That immunity is out of place when the State participates in a modern and national intellectual property marketplace.

For example, as the committee is well aware, States are active owners and users of intellectual property, engaging in sports broadcasting, merchandising, and a variety of research and licensing activities. In SIAA's view, when they, or any other entity acting as a commercial participant, engage in that federally created sphere the law should require them to play by the same set of rules as anyone else. This committee has historically agreed with that premise.

In 1990, and again in 1992, Congress passed legislation making States liable for damages and intellectual property suits in the same way as other commercial participants. The Supreme Court held the patent version of that legislation constitutionally insufficient to abrogate sovereign immunity. What we face now is different, a situation in which a sovereign has rented out its immunity for the benefit of a private company to avoid inter partes review under the AIA.

There are already patent infringement suits filed by Native American tribes against members of the technology industry, and patent trolls are approaching State universities and tribes, looking to make similar arrangements. Our members are concerned that immunity for hire could undo much of the committee's success in improving patent quality. This committee spent years crafting the AIA and its IPR provisions in response to serious and widespread concerns over the quality of patents issued by PTO, and now IPR is successfully improving patent quality, giving the PTO a chance to reexamine past decisions.

Sovereign immunity should not be used, much less rented, to undermine the committee's hard work and frustrate the Federal scheme. Our members are deeply concerned that this practice will proliferate to impact all industries plagued by bad patents, which certainly includes the software industry. That result should cause concern to everybody concerned about a strong, balanced, and uniform patent system. Even some pharmaceutical companies have publicly stated that they are not supportive of the sovereign immunity argument presented in the Allergan case. Judge Bryson was right to characterize immunity-for-hire transactions as a sham.

The Patent Office, the courts, and, ultimately, you have the ability to prevent this sham. There is no sovereign right to a bad patent, and there is no sovereign right to stop the Patent Office from reconsidering a decision to issue a bad patent. There are good arguments that sovereign immunity should not apply to IPR, which is a procedure by which the Patent Office reconsiders its decision to make a patent grant, albeit with input from the public. IPR does not impose legal liability or determine rights between adverse litigants. Instead, it is a procedure by which PTO reconsiders its decision to grant a public franchise.

Moreover, as I mentioned earlier, the immunity is procedural not substantive. Thus, there are narrow procedural ways for the courts to solve this problem in the context of IPR proceedings that do not involve sovereign immunity at all. For example, as Judge Bryson suggested, it is not at all clear that the assignment necessary to create immunity for hire is legally valid, nor is it clear that the sovereign is a necessary and indispensable party in such cases; thus, even though the sovereign cannot be required to appear in an IPR proceeding, the PTAB may well still be able to conduct its review.

If, of course, the courts permit the subterfuge, or the problem becomes widespread before it reaches a proper resolution, Congress will have to act. The tools available to Congress differ depending on which kind of sovereign it is dealing with. There is a difference between the nature of the immunity afforded to Native American tribes and that afforded to the States. In any event, thank you for considering our views, and I look forward to answering the committee's questions.

[The prepared statement of Mr. Mohr follows:]

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Mr. ISSA. Thank you. I recognize myself for a round of questions. Mr. Mohr, I am going to take your very last statement first. Under the Constitution, the Federal Government does have treaties with

tribes and has the exclusive right to do those. So, when there is a treaty, there is, in fact, a very similar right, a constitutional right, enshrined in the Constitution that would make whatever that was essentially the same as a State. In the famous Andy Jackson Trail of Tears, I think that was well decided that you cannot trump that, if you will. Would that be your understanding?

Mr. MOHR. Well, the question to me is a little bit different, so I am not sure I completely understood.

Mr. ISSA. Well, the idea that on Federal lands——

Mr. MOHR. Yep.

Mr. ISSA [continuing]. That are held in trust for tribes: all their governance and activities are exclusively regulated by the Federal Government, and that under treaties, which essentially that land in trust is part of a treaty process, they have rights that are protected by the Constitution that are every bit as strong as a state. Would not you agree?

Mr. MOHR. Sure, under the treaties, yes.

Mr. ISSA. So, we are really talking not about all of the various sovereign things enshrined in the Constitution. We are limited to the other part of the statement you made, and I am going to come back to you, because you made the best statement of the whole crowd, and they were all good. I am going to come back to you after I asked two simple questions of all the witnesses.

Does anyone see anything wrong with Allergan trying to get additional patents on this drug, making those applications, and initially being granted them? Is there anything wrong that Allergan did by getting those patents?

Hearing no noes, I will take that every inventor, every company, has a basic right to try to write up a new patent with some additional claims, and if the Patent Office gives it to you, good on you.

And would everyone agree that since a court has held that those patents were obvious, they were not new, that in fact there was an inherent process that had to happen somewhere to bring justice to the process of determining whether or not they would be able to further restrict the production of this very profitable drug? Anyone disagree on that? Mr. Johnson, briefly.

Mr. JOHNSON. This is a technicality, but they may have been new, but still been obvious.

Mr. ISSA. Well, but I mean, a court struck down the patents, right?

Mr. JOHNSON. A court has struck down the patents as obvious, but it does not mean that what they had was not new. It meant that——

Mr. ISSA. Right.

Mr. JOHNSON [continuing]. If it were new it did not reach——

Mr. ISSA. Right.

Mr. JOHNSON [continuing]. The standard.

Mr. ISSA. Mr. Johnson, that is the point I want to make, that no wrongdoing was done in asking for the patents and no wrongdoing is implied by the striking down of those patent, as the examiner got it wrong, basically, when it was fully disclosed. And that was not, in fact, the Trade Patent Office doing it, it was an Article III judge, right?

So, the odd thing is we are dealing here with—I think it is five patents in the portfolio—we are dealing with patents that were adjudicated at a high cost in Federal court that could have gone through the other process but were stayed as a result of the claim of sovereign immunity. So, now I am going to go to Mr. MOHR.

You made a point that is so good that I hope we can flesh out here to turn it into legislation and save litigation. The patent, itself, is what is being adjudicated in the Patent Office. Let me ask you a couple of easy questions; hopefully, they are easy. One, did the Indian tribe have to show up at all in this process?

Mr. MOHR. Arguably, no.

Mr. ISSA. Did Allergan have to show up at all?

Mr. MOHR. No.

Mr. ISSA. If this were in an ex parte reexamination, and it went back through the normal Patent Office, does the inventor have to show up, or can they simply allow the ex parte examination to be no party examination, and they can look at it, right?

Mr. MOHR. Right.

Mr. ISSA. So, there is no requirement to produce yourself, whether you are a sovereign entity or the patent holder. In fact, this is an administrative process over the patent. In other words, it is a survey of the property. Right?

Mr. MOHR. That is right.

Mr. ISSA. So, since it is completely optional, if Congress were to through statute make it clear that in fact the jurisdiction, the possession, and the asset lie in the Patent Office, and any adjudication that occurs down the road in Virginia is, in fact, of the patent and not of the people, neither the plaintiffs nor the defendant, even if we allow them to sit submit information. Right?

Mr. MOHR. Congress could do that.

Mr. ISSA. And lastly, in a patent reexamination, and actually, even in an ex parte, if you learn of it, is not it true that anybody in the entire wide world can submit to the Patent Office information to be considered?

Mr. MOHR. I believe that is correct.

Mr. ISSA. So, there is no standing in these cases.

Mr. MOHR. No, there is no—if you mean case for controversy, that is right. No.

Mr. ISSA. So, what we have here is an administrative process going on, no different than the original examination, in which you could send a patent to the Patent Office as an application and never look at it again except to pay the fees as a patent holder and take your chances that the patent holder does not send you back—excuse me—a denial that you then have to discuss with them. Right?

Mr. MOHR. Right.

Mr. ISSA. So, for those who have not seen it, that to me is the essence of what we are discussing here. We are not discussing, I hope, in the long run the question of whether the tribe did something wrong, or whether we need to change sovereign immunity. And one-half of what we are discussing here today it seems to me we can define where the patent is and what is being adjudicated, and I am going to pass this on to the Ranking Member.

My concern, which I will leave to a second round, if we have one, is that when it comes to assigning a plaintiff role in which someone is suing—"heads I win, tails you cannot do anything to me"—we may have to look at that, the active role of when you essentially assign, with the help of a troll, to do lawsuits. And that part will come in the second round. Mr. Nadler.

Mr. NADLER. Thank you. Mr. Jay, the Allergan deal called for by the St. Regis Mohawk tribe called for the St. Regis Mohawk tribe to assert sovereign immunity only in the IPR proceeding. I gather there is no reason that any other patent holders could not transfer their patents to a sovereign on the condition that the patents be shielded from reviewing in both IPR and the Federal courts.

Mr. JAY. That is correct.

Mr. NADLER. Use your mic.

Mr. JAY. That is correct, as we understand the terms of the——

Mr. NADLER. And what would be the impact in generic competition and consumer drug prices if people did that?

Mr. JAY. Often in litigation in district court there is more to the dispute than just whether the patents being asserted by the plaintiff, the brand-name company, are infringed and valid. So, for example, the brand company may try to hold back some patents and not assert them right away as a way of prolonging litigation and deterring generic companies from coming onto the market for an even longer period. One way to combat that right now is that the generic company can file a counterclaim, trying to invalidate all——

Mr. NADLER. And they could not.

Mr. JAY. The concern is that if the plaintiff is a sovereign, that that counterclaim could not be litigated.

Mr. NADLER. It would be a one-way situation, then?

Mr. JAY. Right. And similarly, they could not go into court as a declaratory plaintiff and seek a declaratory judgment of invalidity.

Mr. NADLER. Now, some defenders of this deal argue that Allergan's transference of its patents to the tribe to make use of its sovereign status is no different from cases in which State universities have asserted sovereign immunity in IPR proceedings. I think Mr. Manheim gave his reasons why that was not true. Would you agree that there are differences?

Mr. JAY. There certainly are differences, including both the foundation of the form of immunity which in the case of tribes is a common-law immunity that——

Mr. NADLER. As opposed to——

Mr. JAY [continuing]. Congress has power over. And also, the State cases have involved actual inventions by State universities, State research arms, State employees doing innovation themselves, not taking money to rent out the State's sovereign immunity.

Mr. NADLER. In your testimony you argue that Congress should consider legislation abrogating tribal sovereign immunity in patent proceedings. Aside from the practical difficulties in abrogating State sovereignty, is there any reason to single out the tribes? Do you think there will be a fair result?

Mr. JAY. Well, the constitutional difficulty in abrogating State sovereign immunity obviously is a significant obstacle, and that is why our proposal has focused on——

Mr. NADLER. All right, but given there is a practical obstacle, given the practical obstacle in the one case, but not in the other, do you think abrogating sovereign immunity in the one case but not the other would be a fair result?

Mr. JAY. We do, because Congress has the power to solve the problem before it and to use its power under the Indian Commerce Clause to confine tribal sovereign immunity to its historic function of preserving tribal self-government and preventing it from interfering with the patent system and competition.

Mr. NADLER. Thank you. Mr. Mohr, if agreements like the Allergan deal become the norm, can the IPR process survive, and what impact do you think this would have on the patent troll problem?

Mr. MOHR. I think it is going to get a lot worse.

Mr. ISSA. Microphone, please.

Mr. MOHR. I think the patent troll problem is going to get a lot of worse. From the viewpoint of my members, the IPR system has been an enormous benefit in terms of the ability of our innovative companies to challenge bad patents. The relative ease with which the deal in Allergan could be structured means that, frankly, it could be very easily replicated. Once you know what the terms are and that they have been judicially approved, all you really need is a Xerox machine and you are off and running. So, we are extremely concerned that that, if widespread——

Mr. NADLER. Would destroy the IPR process.

Mr. MOHR. Precisely.

Mr. NADLER. Do you think that Congress should consider limitations of sovereign immunity and IP matters, even when the rights holder developed the property itself rather than acquiring it through an Allergan-type transaction?

Mr. MOHR. Yes.

Mr. NADLER. Because?

Mr. MOHR. Because everyone should play by the same set of rules.

Mr. NADLER. Okay, fair enough. Much of the discussion today has focused on sovereign immunity in the context of patent law, but since the hearing is Title VII Immunity and the Intellectual Property System, can you tell me a little about whether sovereign immunity is concerned for other forms of intellectual property, like copyright?

Mr. MOHR. Sure. Our members, those that are copyright holders, have the same concerns. We used to have an enforcement program, and we would not be able to assert infringement suits against States, and the cornerstone of the problem is the same.

In other words, it is States being able to operate by different sets of rules. The difference between the two statutes, the one that was struck down by the Supreme Court and the one that was invalidated by the Fifth Circuit, is that there is more of a record for copyright infringement, I think, than there was present at the time that the Patent Remedy Clarification Act was enacted. I am still holding out hope that that may pass muster.

Mr. NADLER. Thank you. My last question is to Mr. Manheim. Given the challenges in abrogating sovereign immunity by statute, what incentives can Congress establish to encourage States and

Native American tribes to waive their sovereign immunity in IP cases, short of abolishing the right?

Mr. MANHEIM. Sure. I think we should draw a distinction between existing patents and existing intellectual property rights and those that are yet to be granted, and that could be conditioned upon the waiver of the right to assert sovereign immunity. I think it would be much harder for Congress to require a waiver for existing rights, at least when it comes to States, than for yet-to-be granted rights, because then you are changing the nature of the right that is being awarded.

So, as Chairman Issa was talking earlier about an IPR proceeding, that really the patent holders need not be present, that you are actually challenging the patent as a res, R-E-S; that, I think, is a workable solution going forward. I do not believe it is a solution that would work retroactively.

Now, the distinction between existing patents and prospective patents is an important one when it comes to a statutory remedy for State sovereign immunity. I do not think it is as difficult when we are talking about tribal sovereign immunity, because that really is a creature of statute and common law which Congress has the right to overcome.

Mr. NADLER. I see. I cannot help but observe that you think in that case, the case that you are talking about, that that res is not really res publica.

Mr. MANHEIM. Yes, exactly.

Mr. ISSA. The gentleman yields back. We now go to the gentleman from Pennsylvania, Mr. Marino.

Mr. MARINO. Thank you, Chairman. I would like to start with Mr. Mohr and then move down, or up, however you want to refer to it, if you want to comment on it.

A recent analysis found 263 cases where a district court ruled a patent was valid, only to have the patent subsequently challenged before the PTAB. In 200 of those cases, the PTAB reached a different result and in fact invalidated at least one of those patent claims. How do you explain those disparities between the district court and the PTAB?

Microphone, please. If you want to review your notes, we will go on to Mr. Johnson——

Mr. MOHR. Sure.

Mr. MARINO [continuing]. If you are looking for something specific. Mr. Johnson?

Mr. JOHNSON. Thank you. Well, it is quite simple. The rules that are used in the PTAB are different and much easier to invalidate patents than the rules that are used in the Federal courts.

Mr. MARINO. Can you give me an example of that?

Mr. JOHNSON. Sure. The claims are interpreted using the broadest reasonable interpretation standard before the PTAB instead of the ordinary and customary meaning of the claims, which is known as the Philips standard.

So when these patents which were examined and ended up coming out of the Patent Office with the expectation they would be interpreted using the Philips standard, and then they get to the PTAB, the PTAB broadens the claim so it sweeps in within its coverage prior art that makes them easier to invalidate.

Using the chairman's example, it is as if everyone agreed that the fence was where it was going to be, but when it goes to the PTAB, the PTAB moves the fence out, and lo and behold, instead of just losing the difference between how the fence was moved, they lose the entire property.

And that is why there is rampant invalidation, and what was intended originally by the AIA was that there would be a robust ability to at least amend the claims, to pull them back in if necessary to get them on the right boundaries, but as implemented, the PTAB simply is not allowing those amendments.

Mr. MARINO. All right. Mr. Mohr.

Mr. MOHR. Yeah, I mean, I guess it is unsurprising that I would disagree with that characterization. I think the difference between the two for a couple of reasons.

The first reason is—I mean, again you go back to first principles. Right? The IPR allows the PTO to reconsider its earlier decision to issue a patent, so there is a different standard in Federal court, but that standard reflects deference to the expert agency. There is no reason for the agency to defer to itself.

So you are operating with respect to the broadest reasonable interpretation standard. The PTAB applies the same principles as district court. It is not possible to identify a definitive claim interpretation that every court is going to agree on, so what the PTAB is supposed to do is apply the broadest reasonable interpretation that a court could come up with, and that is the limit on their power.

Mr. MARINO. Mr. Jay.

Mr. JAY. Thank you. Just to build on what Mr. Mohr said, there are safeguards in district court litigation because those are cases being heard by a generalist judge, and often by a lay jury, and the standards for invalidating an issued patent under those circumstances are understandably higher, and Congress has put that in statute.

Congress also put in the statute that, as Mr. Mohr said, when it is the Patent Office, when it is expert adjudicators from the Patent Office doing the adjudication, they do not have the generalist judge problem or the lay jury problem, and as a result, they apply the same standard that the examiner applied when considering whether to issue the patent, because their job is to decide whether the patent should never have issued in the first place.

Mr. MARINO. Professor.

Mr. MANHEIM. I agree with that. The district courts are generalist courts. They hear every variety of Federal claim, and a lot of State claims. There is a presumption of patent validity when a patent gets to district court; there is no presumption of validity in the IPR proceeding, which is heard by a panel of usually people with technical training.

One other thing to say about the district court litigation. There is a very hard reversal rate in district court cases at the Federal Circuit, which is a specialist court. So, this is not to impugn district courts at all. They are doing absolutely the best they can, but this is one explanation for why you would see a different——

Mr. MARINO. Do you think that has some to do with experience? Not so much experience of the repetitiveness of the cases versus district court, or review at the Patent Office.

Mr. MANHEIM. Absolutely. And I have heard that some district court judges are hiring scientific or science students as clerks because their cases are so technically oriented. Now, there is also the patent pilot program in Federal court so that some judges can develop that expertise. I do not have any statistics on that, but—and this is a partial explanation for why you would find different statistical outcomes.

Mr. MARINO. Thank you. My time is expired.

Mr. ISSA. The gentleman yields back. We now go to the gentleman from New York, Mr. Jeffries.

Mr. JEFFRIES. I thank the chairman. I thank the witnesses for your presence here today. Mr. Jay, am I correct that the process for a generic drug company bringing a product to the market is set forth in the Hatch-Waxman act?

Mr. JAY. That is generally correct, yes.

Mr. JEFFRIES. And so, just to make sure I have got this process correct, the generic drug company would file a paragraph for abbreviated new drug application, which would then expedite the potential approval of bringing that generic drug to market. Is that right?

Mr. JAY. Right. The ANDA is a streamlined application that avoids the need to go through clinical trials and so forth, because it builds off of what is already known about the reference drug.

Chairman GOODLATTE. And then the legacy drug company would sue the generic for patent infringement under Hatch-Waxman. Is that right?

Mr. JAY. That is right, if the generic drug company has certified that the patent is either not infringed or is invalid, and that triggers a time limit for the brand company to sue. If the brand company does not sue, the generic can bring a declaratory action to clarify whether the patent is valid or not.

Chairman GOODLATTE. And if the brand company sues, which I believe is the case in the Eastern District of New York where the sovereign immunity issue has arisen, if the brand company sues, then the generic could issue or choose to file a counterclaim in the context of that lawsuit. Is that right?

Mr. JAY. That is correct. It generally does happen that the defendant files a counterclaim alleging that the patent is invalid or unenforceable or both.

Mr. JEFFRIES. Professor Manheim, did you want to comment?

Mr. MANHEIM. I wanted to add to that. We are getting to some areas of technical Federal court jurisdiction, but there is a difference when it comes to sovereign immunity between compulsory and permissive counterclaims.

So, as Mr. Jay said that, if a sovereign entity or assignee is asserting a patent against a defendant or a competitor, they may defend on any ground or assert a counterclaim relating to that patent.

However, recall that the patent system crafts a fine balance between promoting innovation and protecting competition, and so, under a case called Walker Process, if it turns out that the patent was procured by fraud, then the defendant may do more than sim-

ply defend patent infringement, but may also counterclaim for any trust violation.

And that is one way to keep the system in balance, but if the patent holder has sovereign immunity, that counterclaim may not be able to go forward, either in that case or any other case. And so, that is one of the problems I see in sovereign entities being able to resist any form of affirmative litigation or counterclaim or IPR proceeding, as it may upset that balance between innovation and competition. So——

Mr. JEFFRIES. Thank you for that, professor. The judge in the Allergan case ruled or stated that sovereign immunity should not be treated as a monetizable commodity that can be purchased by private entities as part of a scheme to evade their legal responsibilities. I assume you agree with that statement. Is that right, professor?

Mr. MANHEIM. Basically, I do agree with that.

Mr. JEFFRIES. Mr. Jay.

Mr. JAY. Certainly.

Mr. JEFFRIES. Now, I guess the question is, is this an issue that we should allow to resolve itself through the court proceedings? You have got a pending case right now in the Eastern District of Texas. Presumably, whichever way that goes, that will be appealed to the Fifth Circuit; whichever way that goes could potentially be appealed to the United States Supreme Court.

You know, we have three branches of government for a reason, and the courts are endeavoring to tackle what is a complicated legal issue involving a potential sovereign's involvement in a domestic dispute. Or, when is the right moment for Congress to potentially intervene to address what is a complicated challenge here?

Mr. JAY. We do urge that that Congress not wait, and let me explain why these pending cases are not likely to result in solving the problem promptly.

First, the Eastern District of Texas case that you referred to, Congressman, the trial judge in that case, you know, one of our best patent judges, former acting Solicitor General of United States Judge Bryson, decided to let the patent tried into the case permissively, basically to take the sham nature of the transaction off the table as an issue on appeal.

So the Federal Circuit is not going to be considering the sham nature of the transaction in an appeal in that case. Then there is the proceeding going on about the Restasis patents before the Patent Board.

The PTAB recently put out its projected schedule for resolving the case. It has extended the time for a final decision not until next April, April 2018, and there is no way to know what they are going to decide on this motion to dismiss. It could take a long time for the issue to percolate up to the Federal Circuit, from the Federal Circuit to the Supreme Court, and if it comes up in future cases where the Patent Board feels it is unable to even begin in IPR, decisions not to begin an IPR are not appealable at all.

And so, if sovereign immunity starts chilling the board from taking action, that will not be something that can be litigated up to the Court of Appeals.

Mr. JEFFRIES. Thank you. My time is expired. Thank you.

Mr. ISSA. Thank you. I am only going to inquire; the gentleman from Texas is next. Will the gentleman be able to remain? Okay, the gentleman from Texas is recognized.

Mr. FARENTHOLD. Thank you very much. You know, we have had numerous hearings in this committee and other committees in Congress about the high price of prescription drugs, especially in the United States. The patent system is one of the reasons that that is there, but you also see problems once a drug goes into a generic when one company seems to be the only manufacturer of the drugs. And the pharmaceutical industry is taking a big hit in public perception, to the point it is forcing Congress to investigate this and look for solutions.

What we are talking about now, this scheme by which we shield patents from review, seems to me to be another one of the abuses that, you know, non-intellectual property scholars—and I will go to the average American—are just—they just throw up their hands. You know this is what is wrong with the system; this is what is wrong with Washington and they are mad about it.

So, I want to start with Mr. Jay. Could you speak about the balance that is in the system right now with respect to the name-brand pharmaceutical companies and the inventions they do, the link to the patent, and how they go into generic, and how that affects cost, and how this might upset that balance?

Mr. JAY. Absolutely, Congressman. Thank you for the question. Innovation is obviously tremendously important in the pharmaceutical industry, but not every patent that is issued on a pharmaceutical product represents a true innovation.

And so, striking that balance is what the Hatch-Waxman framework is about, and it is what the IPR system is being used for as well, to sift between those patents that represent true innovations and that justify giving a period of market exclusivity to the innovator, and those that are really just an attempt to kind of evergreen the franchise, to make the monopoly last longer through a second-generation patent that does not represent a true innovation.

Mr. FARENTHOLD. And what effect does that have on prices?

Mr. JAY. When there is no competition, of course prices are higher. That is why, for example, the price for Restasis, which is the product we have all been talking about, has more than doubled over 10 years when there is no competition.

Mr. FARENTHOLD. Now, the Federal Circuit judge sitting by designation in district court on the Allergan case said the court "has serious concerns about the legitimacy of the tactic that Allergan and the tribe have employed. What Allergan seeks is the right to continue to enjoy the considerable benefits of the U.S. patent system without accepting the limits that Congress has placed on those benefits through the administrative mechanism for cancelling invalid patents." You are familiar with this case. Do you agree with the judge in that?

Mr. JAY. Absolutely. I——

Mr. FARENTHOLD. Go ahead.

Mr. JAY. Judge Bryson has been around the patent system a long time. As you mentioned, he is primarily an appellate judge. He sits

by designation in Texas a lot. You know, he is a veteran of the system, and we agree with his observation.

Mr. FARENTHOLD. At the risk of opening this up and involving more folks in it, sovereign immunity is also enjoyed by the States and State universities. Is there an unfairness in the system that they are able to, say, be immune from copyright infringement on the software they use for—we will say word processing, just in developing the memos associated with developing whatever they develop.

But yet they can enjoy the patent and copyright system on what they create, but they are not held accountable for their abuses of it. Is there a problem there, too?

Mr. JAY. I would say a couple of things about that. Number one, as I mentioned before, you know, and as I think your question recognizes, often a State university's patent represents innovation that goes on on that campus, you know, by the faculty at that State university, you know, true innovation, not renting out the sovereign immunity. And second, you know, the difference between tribal sovereign immunity and State sovereign immunity is important. It is grounded in the Constitution.

And third, it remains an option for States to agree to waive their sovereign immunity, and you know, a State government has more political accountability, you know, to the customers who buy products in a market that would benefit from competition, you know, than an Indian tribe does.

Mr. FARENTHOLD. I have one final question for Mr. Johnson. At the end of your testimony you said that fixing the IPR system is squarely within this committee's jurisdiction. Give me a couple of things we could do with fixing it, short of throwing it out.

Mr. JOHNSON. You could require that the patent claims be interpreted using the same rules both in the federal courts and in the PTAB proceedings, for one. You could require that the procedures be fair and look at due process issues that are involved between the two.

Right now, many of the protections for patent owners that were written into the America Invents Act have not been implemented, either by regulation or they have been left to individual panels of the PTAB, who basically do not apply them. And a classic abuse of the system is the fact that almost half of the petitions that are filed for IPRs are duplicative of other petitions that were already filed, and some patent owners have received not just one or two or three but a dozen or more petitions, and in one case I have heard over a hundred petitions.

Mr. FARENTHOLD. All right, thank you I know we addressed some of those as well. And my time is out.

Mr. JOHNSON. Suffice it to say, I could go on.

Mr. FARENTHOLD. All right, thank you. I see my time is expired.

Mr. ISSA. We will try to give him time in good time. The gentleman from Georgia, Mr. Johnson.

Mr. JOHNSON of Georgia. Thank you, Mr. Chairman. Mr. Mohr, are assertions of sovereign immunity out of place in a modern intellectual property system?

Mr. MOHR. Yes—oops, sorry about that. Yes.

Mr. JOHNSON of Georgia. Want to explain?

Mr. MOHR. Sure. It goes back to the conversation that we were having earlier.

Mr. JOHNSON of Georgia. Sorry, I missed it. I was getting in.

Mr. MOHR. Oh, apologies. The example I used had to do with the States and how the States are involved in a variety of activities, such as broadcasting sports games and merchandising and research and licensing in which they act really very, very similarly—in fact, identically, in many respects—to private parties, and the idea is when they engage in that federally created marketplace they should play by the same sets of rules. It is a simple fairness question.

Mr. JOHNSON of Georgia. Professor Manheim.

Mr. MANHEIM. I think it is important to have a level playing field across the intellectual property ecosystem, and when one species of participant has an unfair advantage because of immunity it distorts the entire system, whether it is a State or a Native American tribe.

Mr. JOHNSON of Georgia. Mr. Jay.

Mr. JAY. We certainly agree that, especially as the chairman brought up earlier, you know, when the Patent Office has issued a patent, you know, it should be open to the Patent Office to reexamine that patent and to decide whether the Patent Office made a mistake really irrespective of who holds that patent at any given time.

Mr. JOHNSON of Georgia. And Mr. Johnson.

Mr. JOHNSON. We would not have the problem if the rules were being applied the same way both in the Patent Office and in the courts. And by the way, as to administrative review, sovereign immunity does not prevent an ex parte reexamination, even a third party-requested ex parte reexamination, because that is a different type of proceeding to which sovereign immunity does not apply.

So, anyone at any time can go back in and have that patent reexamined by the Patent Office, not by administrative patent judges who really do not have any background in the particular field to which the invention pertains, but by elite patent examiners who actually have experience in understanding the prior art and can do a much better job of reconsidering them.

And those have existed for 40 years, are considered to be fair, have reached resolutions comparable to the Federal courts, and to be an aid which is not susceptible to troll abuse. It is virtually unheard of with respect to ex parte re-examinations.

Mr. JOHNSON of Georgia. Thank you. In light of how Allergan has moved to distort, for lack of a better word, the inter partes review process. Is there a role for Congress to play on this issue? Anybody?

Mr. JAY. I would happily speak to that, Congressman. We think that the issue really is that the assertion of tribal sovereign immunity after a rental transaction like this, you know, threatens to gum up the well-working system, and it threatens to raise prices by allowing some patent owners to escape review when their patents are flawed. We think that there is a role for Congress to play to ensure that sovereign immunity cannot be used to keep bad patents from being subjected to review.

Mr. JOHNSON of Georgia. Yes, sir, Mr. Johnson.

Mr. JOHNSON. In the case of drugs and would-be generic drugs, it is impossible for sovereign immunity to stop that, because under the procedures of the Hatch-Waxman act, after the paragraph four certification is given the patent owner must bring suit in Federal court if they want to stop that generic from coming on the market. And when they bring suit in Federal district court they waive sovereign immunity, so they do not stop anything from coming out unless they sue, and if they sue, sovereign immunity does not apply. There is no known case of a drug being kept off the market because of sovereign immunity.

Mr. JAY. Not yet.

Mr. MANHEIM. Mr. Jeffries asked a similar question and suggested that we might let the courts deal with the problem. However, the Supreme Court has made it pretty clear when it comes to tribal sovereign immunity that it is a matter for Congress to deal with and not for the courts.

Mr. JOHNSON of Georgia. Mr. Mohr.

Mr. MOHR. I think for us there would be no quicker way for me to go from five-eight to five feet than to get out in front of my members. Where we are right now is that we are extremely concerned about the proliferation of this kind of arrangement. We believe it is destructive. We think it is really important because the issue is complicated, particularly if you are concerned about stopping this kind of transaction with States. It is going to require careful study, and we are glad that you are examining this, but we are not in a position to endorse legislation at this time.

Mr. JOHNSON of Georgia. Thank you, and I yield back.

Mr. ISSA. The gentleman yields back. We now go to the very patient gentleman from Florida, Mr. Gaetz.

Mr. GAETZ. Thank you, Mr. Chairman. Mr. Manheim, one of the great threats to creativity in the American economy is the theft of intellectual property, particularly from China. The United States has to maintain some degree of credibility around the world to be able to marshal international efforts to bring China and other violators into compliance with norms.

In recent years, some studies have indicated that the United States has slipped from the leading standard in intellectual property to tied for tenth with Hungary. Is it your assessment that the current construct of this sovereign immunity regime would continue to undermine the United States' credibility on broader issues related to intellectual property?

Mr. MANHEIM. I do not believe so. I agree with your assessment, by the way, and of course, intellectual property is the major engine of the U.S. economy, so we want to do everything to promote innovation and smooth the wheels of progress. But I do not believe that the sovereign immunity issue has a great impact on the direction we have. I think there are other reasons for Congress to examine it, but not necessarily because it is going to affect the U.S.'s competitiveness in the world economy.

Mr. GAETZ. Mr. Mohr, you stated earlier in response to, I believe, Mr. Johnson's question that tribes ought to act like any other private stakeholder in the pursuit of intellectual property. Have I paraphrased you correctly?

Mr. MOHR. Not quite. I think what I said was that sovereign immunity does not have a place in a modern intellectual property system, which is a little different.

Mr. GAETZ. Fair. Are there areas now where tribes are treated differently in the utilization of drugs than perhaps States or other entities?

Mr. MOHR. I think you would have to direct that question to somebody who knows a lot more about Indian tribes than I do. I cannot answer it.

Mr. GAETZ. Sure. In the development of intellectual property, would we agree that there are some circumstances where tribes need to be treated differently than the several states?

Mr. MOHR. It is theoretically possible, sure.

Mr. GAETZ. All right. So, one example that comes to mind for me is cannabis. Right now, tribes are not under the same restrictions that other commercial entities are regarding the cultivation, production, and distribution of cannabis.

Is there a risk if we were to adopt any of the proposals that have been discussed today that we could throw a wet blanket over innovation in the cannabis space if tribes were not treated differently but were instead treated like any other commercial actor?

Mr. MOHR. That is a fair question. I mean, there are two answers. I have two answers to that question. The first is that we have no position on legal marijuana. The second answer to that question is that I think, again, if the tribe—we are looking at two different things. One is that if the tribe were to seek IP protection, specifically patent protection, for whatever they developed, our view would be that they should be subject to IPR to review those patents.

Mr. GAETZ. Mr. Chairman, I would simply say that, as we move forward, there are areas where tribes are treated differently that can create an ecosystem for creativity that might not exist otherwise, and in solving the various challenges that we have seen raised today, I would hate to see us have an unintended consequence of potentially limiting that innovation, particularly in the area of cannabis.

Mr. ISSA. If the gentleman would yield?

Mr. GAETZ. I will.

Mr. ISSA. Being an entrepreneur, but not in that particular field——

Mr. GAETZ. Not yet, Mr. Chairman. You are from California.

Mr. ISSA. This job sometimes drives me to drink. But I agree with the gentleman's premise that nothing we do here should limit sovereign immunity of the States or of Native American tribes in a way that would have any consequences beyond the administrative issue before us, and I think you are exactly right.

Mr. GAETZ. I yield back.

Mr. ISSA. The gentleman yields back, which leaves me and Mr. Nadler. I want to follow up on a couple of things I heard, because I think there are some very important points.

Mr. Johnson, I do not know whether you have got these guys surrounded or they have got you surrounded, but you are doing a really great job. But I want to follow up on some things, because some of the people who, in a broad sense of the word, you may be speak-

ing for today went out of their way to kill Mr. Goodlatte's bill because he would not, I would not, many of us would not do an outright carve-out on the PTAB process for pharma and bio.

And I do not think anyone in this room, including some of my friends from the industry, are going to object to that being said. But one of the reasons was we were not able to find an effective alternative to an outright carve-out, and I think there were a couple of things you said here today that I want to make sure we get into the record.

You know, one of them had to do with the double standard; the other had to do with your assertion particularly that your PTAB judges, and I have one next to me, may or may not be experts in the field, and I will take that point.

And so, what I would like you to do for the record if you are able to do it, individually or as part of a group, is to look at the various off-ramp possibilities that could bring the experts back in.

Currently, it is routine in a PTAB case to stay an ex parte reexamination that may be going on. There may be a question of fairness if the patent holder had become aware of some prior art, submitted that prior art, and reasonably believes that with an examiner knowledgeable in the area would be able to limit their claims, maybe change a dependent claim here or there, and come out with a bona fide as-new patent, and I would like to make sure that even if we can never agree on some things, that we explore the process of amending.

And I say that, particularly, because the one area I am concerned in is when we voted for AIA, we went out of our way to give the court, the administrative court, the ability, actually, to amend claims, and they have used it almost never. And one of the reasons may be your assertion here today, that they lack the expertise, the confidence to do so, or they do not believe, perhaps, that we meant what we said. If you have any comments, and I would go to Mr. Mohr on this part of it.

Mr. JOHNSON. Yes, that was the intention of the AIA to allow amendments, but I think when it came to implementation, in the short timeframe and given the backgrounds and other issues before the APJs, it seemed too unwieldy.

They just, I think, did not know how to get their hands around the examinational aspect and seemed uncomfortable to do what most people would do, which would be to assume that any claim narrower than the originally allowed claim, any amended claim that was narrower, and they were required to be narrower, should be presumed to be valid.

Because if you narrow down, if you have a claim saying you own the whole property, and you say, "Well, at least I own the middle of it," you could presume that was a valid claim. But they seemed reluctant or unwilling to do that, and I think they punted and decided they just would not allow amendments.

Mr. ISSA. For the other witnesses that observe the process—and I know this is slightly outside the one part of the hearing, but it is certainly within the subcommittee's jurisdiction—would you agree that this is one of the areas that could be considered a deficit of this process? Anyone?

Mr. JAY. One development to note on that, Mr. Chairman, is that the Federal Circuit sitting on bond has just recently changed the rules for what has to be shown in order to amend a claim. You know, that literally happened within the past few weeks and has not had a chance really to percolate. That obviously——

Mr. ISSA. It always is interesting to see when the Fed Circuit changes our laws, but having said that, you are right that encouraging a process is part of it. But let me just go back to Mr. Johnson's statement for the other three.

If these judges are not the subject area experts, are we in fact asking a job that these judges are not generalist, but they are also not in specificity the experts that would be assigned within the Patent Office ordinarily to do an examination or reexamination? Mr. Mohr, you have got some experience there. Would you concur with that?

Mr. MOHR. I would say your statements about my experience there are overrated, sir. What I would say is this——

Mr. ISSA. Let's just say that I have had to sit there in the old Crystal City with examiners who knew more about my products than I did, and I was the inventor, so I have been impressed at times with many of the well-read examiners. And I do not necessarily have the same experience other than my Federal court judges at the end of court cases, after they were decided off, often still had questions.

Mr. MOHR. From our perspective, I think our members believe the IPR proceeding is working well, as it is, and we believe that the In re Aqua products decision should be allowed to percolate through the PTO before any consideration of tinkering occurs.

Mr. ISSA. Okay. I have been called a tinkerer at times. I have always taken as a compliment. Mr. Johnson.

Mr. JOHNSON. Yes, I think I am the only one on the panel who is registered to practice before in the Patent Office and has actually written, prosecuted, and appeared before the office——

Mr. ISSA. Well, then we can disallow you altogether.

Mr. JOHNSON. Right, you can. I am guilty of whatever you want to charge me. But I would be happy to submit supplemental testimony on the off-ramp idea. It has received a fair amount of attention, and I believe Chief Judge Michel in his supplemental testimony suggested it was something that should be looked at.

Mr. ISSA. Okay, and I will welcome that. I also would welcome it from organizations that some of you may be involved in. The only question I would ask is when you look at the off-ramp, the most important question that probably would be asked and have to be answered by us is what would be the litigable date on the new, emerging claim? In other words, a normal reexamination you get the benefit that it is a lesser included, and you keep your original litigation date on a new patent.

Especially, if PTAB has determined that you were overly broad, you may lose some of your trailing edge, and those questions, it would be helpful if justifications for all or some to be taken away. Obviously, one of the examples would be when we normally have a Latcha [phonetic] situation of six years. If time has gone by, would we at least limit past damages to six years if something

emerged with a, if you will, new claim, or would we make it upon the day it went into reexamination, on the day it went out?

These questions are important because I am—and I think my ranking member, too—we would like to find ways to take what we have—what Mr. Mohr likes, what Mr. Johnson is more reticent about—and find something that would be agreeable between the parties as even better. And if we can do that, that is certainly a goal of this committee. Mr. Johnson.

Mr. JOHNSON. I would be happy to work on that but suggest that as long as the standards for finding invalidity are lower one place than the other, you are not going to get agreement because the people who see themselves as infringers will want the lower standard; the patent owners will want a higher standard.

So, part and parcel of this will be a need to conform all proceedings so that everybody agrees there is one standard of validity, one standard of non-obviousness, one standard of novelty that is applied everywhere, and then I do believe that, procedurally, you could get where you want to go.

Mr. ISSA. Well, I hope to get there. I will say one thing. I have seen article III judges who know the standard but often consider that the standard is the same, and I think you would probably find that that has been the case.

Certainly, in the case of the Allergan there certainly was a decision that, by clear and convincing evidence, the examiner was just dead wrong, period, and since the examiner did have the prior art, the actual prior patents, and made a decision which was patentable over it, the judge found a way to completely say that he was wrong and not show any deference, if you will, to that since the prior art was fully considered.

Mr. JOHNSON. Since the beginning of the patent system, the courts have always looked at these issues, and when new evidence arises or when the evidence is considered in the full exposure of development to discovery, live testimony heard and determined by the courts, patents have been found invalid, or they have been found valid. And that is always going to continue, and we are not going to stop that.

Mr. ISSA. I look forward to it. Mr. Nadler, do you have anything else?

Hearing no others, I will simply close with an admonishment to all that see the record to look at the 11th Amendment, because in looking at it, the one thing it makes clear is it never limited the Federal Government's decision on its behalf to decide what the States were responsible for.

And I only say that because during the discussion today, so many people seem to think that the 11th Amendment applied, and I think we have to be careful. It certainly applies to if I want to sue my State; it does not seem to apply.

And in legislation that we will be preparing we will make the assumption that if the decision is a decision of the Federal Government, it is binding on the States and on Indian tribes equally as to what the Federal Government's position is, notwithstanding the litigants on either side. And I only say that because we will be writing legislation based on that assumption, and I am happy to have you send me a different view on the 11th Amendment.

Thank you, and we stand adjourned.
[Whereupon, at 3:33 p.m., the subcommittee was adjourned.]

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