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SOVEREIGN IMMUNITY AND THE INTELLECTUAL PROPERTY SYSTEM

HOUSE JUDICIARY COMMITTEE

**SUBCOMMITTEE ON COURTS, INTELLECTUAL PROPERTY
AND THE INTERNET**

NOVEMBER 7, 2017

Good afternoon, Chairman Issa, Ranking Member Nadler, and Members of the Subcommittee. I would like to thank the Subcommittee for its attention to the important issues you'll be examining today, and I appreciate the opportunity to participate in this hearing.

I am a partner at the law firm of Goodwin Procter LLP. 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.

My law practice focuses on constitutional and appellate litigation, including in intellectual-property matters. I have worked on issues of sovereign immunity, including Indian tribal sovereignty, for many years—in private law practice, in government service, and as a law clerk to the late Justice Antonin Scalia. In particular, during five years in the Office of the Solicitor General at the U.S. Department of Justice, serving in both Republican and Democratic administrations, I regularly confronted questions of sovereign immunity—federal, state, and tribal—and of Congress's power to waive or abrogate it.

In addition, I regularly work on intellectual-property cases like the ones that the Allergan transaction would block. I have briefed and argued many pharmaceutical patent cases, in trial court, on appeal, and in the Supreme Court. I have also handled a number of cases arising from the Patent Trial and Appeal Board, including *inter partes* reviews (IPRs) like the one Allergan and the Saint Regis Mohawk Tribe are seeking to have dismissed. My work on these cases has not been one-sided: I have represented brand-name as well as generic pharmaceutical

companies, and I have worked on IPRs for patent owners as well as for companies challenging patents.

I hope that my experience can prove helpful to the Subcommittee as it considers these important issues.

Introduction

I would like to start by providing some background on how these sovereign immunity issues arose in the patent arena.

In September 2017, Allergan Inc. (a brand-name drug company) was facing the likely invalidation of the remaining patents for its chronic dry eye medication cyclosporine ophthalmic emulsion, sold under the brand name Restasis®. Restasis is one of Allergan's largest revenue producers—second only to Botox®. Restasis brought in nearly \$1.5 billion for Allergan in 2016 alone, or nearly 10% of the company's annual revenue. Since 2003, Allergan has been the only drug company to sell a cyclosporine ophthalmic emulsion, because the drug was protected by patents that were set to expire in 2014. But just before the patents expired, Allergan obtained half a dozen *new* Restasis patents, which do not expire until 2024.

Now, just because a patent is issued by the Patent and Trademark Office does not mean that it claims something genuinely new and inventive. That's why so many patents are challenged after issuance. Allergan's new patents were no exception: they attempt to claim essentially the same formulation and methods of treatment Allergan had previously claimed in its expiring patents, but with a bit more detail about the proportions of ingredients in Restasis.

Allergan used its new patents to sue generic drug companies that were seeking FDA approval to market generic versions of Restasis. Allergan asked a federal court in East Texas to enjoin generic drug companies from marketing and selling their generic Restasis products—and thus put any price competition on hold—until the new Restasis patents expired in 2024. The generic drug companies defended against Allergan’s lawsuit by contending that Allergan’s new patents were invalid because they did not represent genuine innovation.

Some of the generic drug companies asked the Patent and Trademark Office (PTO) to take another look at whether these patents were truly inventive, by filing a petition for *inter partes* review (IPR). Congress created IPR six years ago as part of the America Invents Act. The IPR procedure allows the Patent and Trademark Office (PTO) to take a second look at the validity of patents it previously issued, but only on two specific grounds. The ground at issue here is whether the patents were issued on purported inventions that are just obvious variations on existing knowledge. If so, then the PTO never should have issued the patents in the first place.

Inter partes review is not automatic: the PTO has discretion about whether to grant (or “institute”) *inter partes* review, but it cannot do so unless it finds a “reasonable likelihood” that the patent is invalid. That is exactly what happened here—in late 2016 and early 2017, the PTAB instituted IPRs to review all of the unexpired Restasis patents. Allergan and three generic drug companies participated in the IPRs—Mylan Pharmaceuticals, Teva Pharmaceuticals USA, Inc., and Akorn Inc. After briefing and the submission of evidence by Allergan and the three petitioners, the PTAB scheduled the final IPR hearing for September 15, 2017, with a final decision expected in early December 2017.

Just seven days before the scheduled IPR hearing, facing the likely invalidation of the remaining patents shielding its multi-billion-dollar drug from generic competition, Allergan adopted an unprecedented strategy: it paid millions of dollars to, essentially, rent the tribal sovereign immunity of a Native American tribe. Allergan paid the Saint Regis Mohawk Tribe \$13.75 million up front, plus \$15 million annually, for the Tribe to take ownership of the Restasis patents, immediately license those same patents back to Allergan, and then move to dismiss the IPRs on the basis of tribal sovereign immunity, which the Tribe did within two hours of signing the assignment and licensing agreements.

Allergan and the Tribe were remarkably candid about the reason for the transaction. Allergan’s Chief Legal Officer stated that the transaction represented an “opportunity to strengthen the defense of our RESTASIS® intellectual property in the upcoming *inter partes* review proceedings before the Patent Trial and Appeal Board.”¹ The Tribe was even more transparent in a “Frequently Asked Questions” document about its newly-established “Office of Technology, Research and Patents.” The Tribe stated that it “is not investing any money in this business” and that companies like Allergan will “pay the tribe for holding the patents and protecting them” from being invalidated during IPR proceedings, which are “very unfair to companies with valid patents and allow[] . . . infringers to void valid patents.”²

In the weeks that followed, the Tribe issued “clarifications” regarding its transaction, arguing in a brief before the PTAB and in a public statement that it is

¹ Press Release, Allergan, Allergan and Saint Regis Mohawk Tribe Announce Agreements Regarding RESTASIS® Patents (Sept. 8, 2017), <https://www.allergan.com/news/news/thomson-reuters/allergan-and-saint-regis-mohawk-tribe-announce-agr>.

² Frequently Asked Questions About New Research and Technology (Patent) Business, Saint Regis Mohawk Tribe, https://www.srmt-nsn.gov/_uploads/site_files/Office-of-Technology-Research-and-Patents-FAQ.pdf.

doing the same thing that some state universities do. The Tribe pointed out that some such universities enjoy sovereign immunity, such as when they are sued for patent infringement.³ But no state university has accepted a sham patent transfer from a corporate patentee to avoid *inter partes* review. Unlike the Tribe, universities actually engage in research and innovation that leads to scientific, medical, and pharmaceutical discoveries, for which they seek and obtain their own patents. And if there were any question about whether this transaction is unconventional, one need only look at the flow of money—from the assignor, Allergan, to the assignee, the Tribe, which received the patent portfolio covering a multi-billion-dollar product without having to pay a dime. It would be like me *paying you* a massive lump sum to take title to my house, and then continuing to pay you huge amounts of money each year to rent my house back to me. Something is plainly not right here.

In short, Allergan attempted to rent tribal immunity from the Saint Regis Mohawk Tribe for about \$15 million per year, to shield its patents from the PTO's review in the hopes that Allergan could avoid competition for its \$1.5 billion-per-year drug. Or to put a finer point on it, Allergan is seeking asylum for its patents on tribal lands.

Allergan's transaction is the first of its kind, but it will likely not be the last. Indeed, the Tribe has already announced that it reached a similar agreement with a company that holds computer technology patents.⁴ Allergan and the Tribe have suggested that their transaction poses no serious concerns because generic drug manufacturers can still challenge patents when they get sued in federal court. But

³ Tribe Provides Clarification on Allergan Agreement, Saint Regis Mohawk Tribe, Sept. 14, 2017, <https://www.srmt-nsn.gov/news/2017/tribe-provides-clarification-on-allergan-agreement>.

⁴ Frequently Asked Questions About New Research and Technology (Patent) Business, Saint Regis Mohawk Tribe, https://www.srmt-nsn.gov/_uploads/site_files/Office-of-Technology-Research-and-Patents-FAQ.pdf.

if this type of transaction is successful, it would have serious repercussions for patients and drug competition, for at least two reasons that I will discuss: (1) PTO review is an important component of a healthy patent system in its own right, and (2) tribal immunity threatens to limit judicial proceedings as well. This type of transaction is antithetical to the goals of the America Invents Act. And in the context of pharmaceutical products, it threatens the well-functioning system for litigating pharmaceutical patent disputes that Congress created in the 1984 Hatch-Waxman Amendments, which created a pathway for faster approval of generic drugs in order to accelerate price competition from new FDA-approved generic medicines. One key feature of the Hatch-Waxman Amendments is that they promote prompt litigation between brand-name and generic drug manufacturers.

PTO Review Of Patents Is A Vital Component Of A Healthy Patent System

Congress has barred the PTO from issuing patents on purported inventions that are not truly novel, or are just obvious variations on existing knowledge. But the PTO's generally brief examination process does not always uncover all the flaws in a patent. The incredible volume of patent applications (more than 600,000 in 2015, with the number of applications rising each year⁵) and limited staffing at the USPTO leave patent examiners constrained in their ability to accurately assess patentability. And the patent examination process is an interaction between the patent applicant and the PTO with little (if any) opportunity for third parties to provide evidence or arguments relevant to patentability. Indeed, researchers have found that patent examiners spend an average of just nineteen hours on each patent application, which includes the time spent reading the application, searching for "prior art" that would render the proposed patent invalid, interviewing the

⁵ U.S. Patent Statistics Chart Calendar Years 1963-2015, U.S. Patent & Trademark Office, https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm.

applicant's counsel, responding to the applicant's arguments, and rendering a decision.⁶ Given these circumstances, it is no surprise that patent applicants are frequently able to obtain weak, non-innovative patents that would never have been issued if the examiner had access to all the relevant literature and knowledge.

Moreover, patent owners have incredibly powerful incentives to seek and obtain as many patents as possible, even dubious ones: each new patent can extend the life of an existing monopoly, and even a weak patent can be a powerful deterrent to competition. Indeed, that is exactly what Allergan has attempted to do here.

Nearly 40 years ago, Congress created a process for petitioning the USPTO to re-examine issued patents, precisely because Congress was concerned that patents were being issued with flaws that render them invalid, and that full-blown litigation in court was not a sufficiently workable way to weed out these flawed patents. Since then, the PTO's ability to reconsider and cancel patents that never should have issued has been an important part of the patent system. That process, as improved by Congress over time, is necessary to ensure that patents merit full confidence and certainty and that they do not unjustifiably restrict competition in the markets for vital products such as pharmaceuticals.

The initial administrative review processes created by Congress suffered from structural deficiencies that hampered their ability to weed out bad patents.

Members of the House and the Senate recognized that creating a simple but robust form of PTO review would enable inventors and their competition to spend their resources productively, on raising money, commercializing inventions, and

⁶ Melissa D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-Level Application Data*, Nat'l Bureau of Econ. Research (July 2014), <http://www.nber.org/papers/w20337.pdf>.

manufacturing products for patients, rather than spending millions of dollars per lawsuit litigating weak patents. It could also provide “additional access to the expertise of the Patent Office on questions of patentability”—something that was not possible in district court litigation.⁷

As a result, Congress reformed the system for re-examining issued patents as part of the America Invents Act (AIA) passed in 2011.⁸ The AIA created new procedures, including *inter partes* review, “to ensure that the poor-quality patents can be weeded out through administrative review rather than costly litigation” to “help screen out bad patents while bolstering valid ones.”⁹ These proceedings are heard by the PTAB as the first-line adjudicator, generally by three “administrative patent judges” who are experts in patent law and often familiar with the technological subject matter. The AIA provided a greater opportunity for third parties, such as generic competitors, to interact with and present evidence to the PTAB. Discovery is available, though less onerous and therefore less expensive than in court. And a person or company that is worried about getting sued on an invalid patent can petition for an IPR or similar AIA proceeding without waiting to be sued by the patent owner in a place of the patent owner’s choosing.

To ensure the efficiency of IPRs, the AIA placed strict time limitations on PTAB decisions—no more one year to resolve an instituted IPR absent good cause to extend that deadline for no more than six additional months.¹⁰ These time limits ensure that those results are reached quickly, compared with the years it often takes to resolve patent litigation in federal court. The AIA also established a substantial threshold for instituting an IPR to “weed out marginal challenges” to issued patents

⁷ 157 Cong. Rec. S1352 (Mar. 8, 2011) (Sen. Udall).

⁸ H.R. Rep. No. 112-98, at 39 (2011).

⁹ 157 Cong. Rec. S5409 (Sept. 8, 2011) (Sen. Schumer); 157 Cong. Rec. H4420 (June 22, 2011) (Rep. Goodlatte).

¹⁰ 35 U.S.C. § 316(a)(11).

and to “prevent abuse of these proceedings for purposes of harassment or delay.”¹¹ And if a petitioner litigates an IPR unsuccessfully, it cannot re-litigate in district court “any ground that the petitioner raised or reasonably could have raised during that [IPR].”¹²

Transactions like Allergan’s threaten to undo this valuable reform of the patent system. If brand-name drug manufacturers can shield themselves from IPRs simply by paying an Indian Tribe a small fraction of the revenues they receive each year, the cost of eliminating flawed patents from our patent system will skyrocket. And if flawed patents are harder to eliminate, companies will have greater incentives to pursue weak patents, like Allergan’s Restasis patents, as a means of extending a monopoly.

Inter partes review is not simply an alternative venue for patent litigation; it serves a crucial role in a healthy patent system. Allowing brand-name drug companies to immunize their flawed, improperly granted patents from IPR proceedings by renting tribal immunity will hurt patients by blocking access to more affordable generic medicines. Low-quality patents will once again be roadblocks to competition and genuine innovation, and those who will suffer most are patients who rely on competition to deliver affordable medicines.

District Court Patent Litigation Is Not A Substitute For *Inter Partes* Review

Allergan and the Tribe have argued that their efforts to evade the PTO’s review of the Restasis patents should not be worrisome because potential infringers can still argue *in court* that the patents are invalid, once they are sued for infringement. This argument ignores that administrative review and patent litigation serve two

¹¹ 157 Cong. Reg. S1041 (Mar. 1, 2011) (Sen. Kyl); 157 Cong. Rec. S1374 (Mar. 8, 2011) (Sen. Kyl).

¹² 35 U.S.C. § 315(e).

different but equally vital functions, and Congress intended to make *both systems* available. It also obscures the significant impact that tribal sovereign immunity could have on district court proceedings.

First, a district court case generally takes much longer than an IPR proceeding and costs much more. The parties have to litigate infringement as well as the invalidity of the patents. And while the PTAB can streamline the issues in IPRs by instituting IPRs only on specific patents and specific grounds of invalidity, federal courts have no similar mechanism to narrow the issues in patent litigation.

Discovery is much more costly, especially expert discovery. Unlike in IPRs, there is no 18-month time limit in patent litigation; to the contrary, the Hatch-Waxman Amendments reflect Congress's assessment that an average pharmaceutical patent case will take about 30 months to resolve in district court. That is why FDA approval decisions are automatically stayed for 30 months if a brand-name drug company initiates patent litigation shortly after a generic drug company seeks FDA approval of a new generic drug. Many Hatch-Waxman patent cases take longer than 30 months.

Second, while it is still an open question whether tribal sovereign immunity applies in IPR proceedings at all, there is no dispute that tribal immunity applies in federal court. Unless a court finds that transactions like Allergan's are sham transactions that should be ignored, as the U.S. District Court for the Eastern District of Texas did a few weeks ago, a tribe renting its immunity to a brand-name manufacturer could potentially block generic drug manufacturers from bringing their own lawsuits to declare a patent invalid, or even from asserting invalidity counterclaims when they are sued on patents owned by a tribe.¹³ That threatens the well-

¹³ *A123 Sys., Inc. v. Hydro-Quebec*, 626 F.3d 1213, 1217 (Fed. Cir. 2010); *Quinault Indian Nation v. Pearson for Estate of Comenout*, 868 F.3d 1093, 1098-99 (9th Cir. 2017).

functioning system for litigating pharmaceutical patent disputes that Congress crafted. In the Hatch-Waxman Amendments, Congress created a pathway for faster approval of generic drugs that promotes prompt litigation between brand-name and generic drug manufacturers *before* a generic launch, so that generic manufacturers are not dissuaded from exploring new, competitive products by the threat of money damages. If a generic manufacturer seeks FDA approval of a generic drug and the brand-name manufacturer does not sue within 45 days, the generic drug company can bring a civil action for a declaratory judgment (a judicial declaration) that the brand company’s patents are invalid or not infringed.¹⁴ Some patents (those not listed in FDA’s Orange Book) are eligible for a declaratory-judgment lawsuit even earlier in the process. Generic drug companies who are sued on some patents but not others can also file a counterclaim to whether the remaining patents are invalid. These tools allow generic drug companies to make plans to enter the market with the benefit of certainty about what patent rights are implicated. But tribal immunity would potentially block declaratory judgment actions and counterclaims.

If brand-name manufacturers can shield themselves from efficient review of their patents by renting tribal immunity, they can effectively delay generic drug launch by holding some of their patents in reserve and waiting until FDA approves a generic before the brand-name manufacturer filings or threatens a patent lawsuit. Generic drug companies are typically reluctant to launch their products “at risk”—until they have “patent certainty” that the brand-name manufacturer’s patents are not infringed or are invalid. This is because the damages sought for “at risk launch” are potentially quite significant, and often greater than the profits that the generic manufacturer could hope to earn. For a blockbuster drug like Restasis,

¹⁴ 35 U.S.C. § 271(e)(5).

which brought in an average of \$4 million *per day* in 2016, the prospect of even delaying (if not preventing) launch is worth the relatively marginal cost of renting tribal immunity.

Thus, rental of tribal sovereign immunity can prevent the Hatch-Waxman procedure from working as designed. This tactic can allow the brand name drug company to hold on to wrongly-issued patents for far too long, significantly delaying generic drug competition. The result is higher drug prices for Americans.

Tribal immunity could also preclude generic drug companies from asserting invalidity counterclaims to challenge patents covering brand-name drugs even if tribes *sue them* for infringement. Brand-name manufacturers have historically attempted to keep multiple and late-listed patents in reserve, unasserted until the last minute, to scare generics away from launching upon receiving approval. With tribal immunity potentially blocking counterclaims challenging unasserted patent claims, and generic manufacturers' reticence to launch products at risk, brand-name drug companies can again delay generic drug launch for the minimal cost of renting tribal immunity.

A tribal immunity rental scheme thus poses serious consequences for federal court litigation and, ultimately, patients taking brand-name drugs at brand-name drug prices—upwards of five times the cost of a generic alternative.¹⁵ Furthermore, these consequences will only increase uncertainty, which damages incentives for investment in generic drug competition. In short, if brand name pharmaceutical companies are able to rent tribal sovereign immunity and use it to evade the efficient review of their patents through IPR or the federal courts, patients and our

¹⁵ Generic Drug Facts, U.S. Food & Drug Admin., <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm167991.htm> (last updated Oct. 6, 2017).

economy will be hurt and drug prices will remain unnecessarily high due to the lack of generic drug competition.

Congress Should Pass Legislation Expressly Abrogating Tribal Sovereign Immunity In PTO Post-Grant Patent Review Proceedings.

There are good arguments that under Supreme Court precedent, including *Federal Maritime Commission v. South Carolina State Ports Authority* and *Cuozzo Speed Technologies, LLC v. Lee*, tribal sovereign immunity does not apply in IPR proceedings. An IPR is not exactly like a contested court case between two parties. Nobody is being haled into court and threatened with money damages; instead, the PTO is reconsidering a patent that someone voluntarily asked it to issue. And even if tribal sovereign immunity *does* apply in IPR proceedings, AAM believes that the PTO is not barred from taking a second look at its earlier decision to grant a patent where a patent owner transfers its patents to a sovereign entity for the express purpose of avoiding a final IPR decision.

But the applicability of tribal sovereign immunity in IPR proceedings is an open question that will not be finally resolved until the PTAB, the Federal Circuit, and potentially the Supreme Court weigh in on this issue, which will take years. In the meantime, brand-name drug companies that have non-innovative patents protecting lucrative products will likely follow in Allergan's footsteps, in the hopes of avoiding *inter partes* review and delaying, as long as possible, the invalidation of their patents and the introduction of generic drug competition.

Congress should consider legislation abrogating tribal sovereign immunity, to the extent it might otherwise apply, in PTO post-grant patent review proceedings like *inter partes* review and patent challenges in federal court.

Conclusion

For nearly four decades, PTO review of issued patents has been considered a vital component of a healthy patent system, and Congress has worked to improve that system to eliminate invalid, competition-killing patents. The rental of sovereign immunity is a transparent attempt to thwart this process. If successful, these transactions would bring back the very abuses that drove Congress to create patent re-examination in the first place: a proliferation of weak patents, a lack of public confidence in patents, a lack of certainty in the validity of issued patents, and a lack of generic drug competition for patients. Congress should take up legislation that ensures that when companies like Allergan seek to obtain the benefits of the patent system, they may not exclude themselves from the legal methods for reviewing their patents, including the IPR system that Congress created for all patents. No one has the right to hold on to a patent that isn't innovative; certainly no one should be able to shield such a patent from review while using it to preserve a monopoly and charge higher prices to patients and the public.