
# PATENT-ASSIGNMENT TRANSACTIONS BETWEEN BRAND-NAME DRUG COMPANIES AND NATIVE AMERICAN TRIBES WILL UNDERMINE A HEALTHY PATENT SYSTEM AND HARM PATIENTS

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# I. EXECUTIVE SUMMARY

In September 2017, facing the likely invalidation of the remaining patents shielding a multi-billion-dollar drug from generic competition, Allergan Inc. adopted an unprecedented strategy: it paid millions of dollars to rent the sovereign immunity of an Indian Tribe, and now it claims that its patents are beyond the reach of the U.S. Patent and Trademark Office (USPTO). In effect, Allergan's patents are seeking asylum on tribal lands.

Allergan assigned to the Saint Regis Mohawk Tribe all of its remaining patents covering its multi-billion-dollar drug Restasis® without requiring a dime from the Tribe in return; in fact, it was Allergan that agreed to pay the Tribe—$13.75 million up front and $15 million per year for the life of the patents. And Allergan gave up essentially no rights in the patents, because the Tribe agreed to immediately license those same patents right back to Allergan. What Allergan has attempted to get in exchange for the money was a purported "shield" for its patents. The Tribe agreed that once it acquired the patents, it would seek to invoke its sovereign immunity to attempt to force the dismissal of proceedings to review the patents for invalidity (called *inter partes* review, or IPR). Those proceedings, brought by companies seeking to introduce generic competition to Restasis, had been pending before the Patent and Trademark Office's Patent Trial and Appeal Board (PTAB) for more than a year and were close to final resolution when Allergan unveiled its sovereign-immunity gambit.

Allergan's transaction is the first of its kind. If successful, it will likely not be the last. Allergan and the Tribe have suggested that their business transaction is harmless because potential infringers can simply adjudicate patent disputes in federal court. But these types of transactions pose serious potential risks to the health of our patent system. One key part of that system is review of already-issued patents by the experts in the USPTO, to ensure that they comply with the statutory limitations on patent monopolies. USPTO review of issued patents has existed in various forms for nearly 40 years.

Congress created expert administrative review mechanisms because litigation is too slow and expensive a mechanism to clean up invalid patents. Applicants often seek weak patents—patents that do not actually claim a novel, innovative invention, but that allow the applicant to effectively extend the life of its existing patent monopoly. And while the validity of these patents can be attacked in court, patent litigation in court is expensive (with parties each spending millions of dollars per patent infringement lawsuit) and time-consuming, and generalist judges and juries lack the expertise of patent examiners. USPTO review is more streamlined, because it is focused only on specific reasons why a patent may be invalid; it is strictly time-limited; and it is conducted by expert patent judges. This makes valid patents stronger and helps eliminate the incentives to clog the USPTO with invalid patents that impair competition.

If brand-name drug manufacturers know they can make themselves invulnerable to IPRs simply by paying a tribe a small fraction of the amount they receive in revenues each year, this strategy will proliferate. The result will be harm not only to the integrity of the patent system, but to the patients who lose access to competing products as long as invalid patents remain on the books.

Though Allergan and the Tribe have argued that the PTAB "must" dismiss the pending Restasis IPRs, the PTAB's hands are hardly so tied. Recent Supreme Court decisions support the PTAB's concluding that tribal sovereign immunity does not apply in IPR proceedings, which are fundamentally different from civil litigation between private parties. Moreover, even if tribal immunity applies in IPRs, the PTAB is not forbidden by any statute, regulation, or precedent

from continuing to resolve the IPRs that it instituted nearly a year ago when it found that there was a reasonable likelihood that the Restasis patents are invalid. Given Allergan's transparent attempt to avoid the Patent and Trademark Office's review of its patents issuances, the PTAB could readily conclude that fairness and equity warrant in favor of continuing their review of the Restasis patents.

## II. ALLERGAN'S EFFORTS TO AVOID *INTER PARTES* REVIEW

For nearly 15 years, Allergan has enjoyed a market monopoly on cyclosporine, a prescription eye-drop medication for chronic dry eye conditions sold under the brand name Restasis®. Restasis is one of Allergan's largest revenue producers (second only to Botox®), bringing in nearly $1.5 billion in 2016 alone—nearly 10% of the company's annual revenue. Patents that prevented generic drug manufacturers from launching a more cost-effective generic version of Restasis were set to expire in 2014—but just before then, Allergan obtained half a dozen *new* Restasis patents, which do not expire until 2024.

Allergan's new patents have been challenged in court and in IPR proceedings before the Patent Trial and Appeal Board (PTAB), an administrative tribunal within the USPTO. In IPRs and similar proceedings (collectively called "post-grant review"), the PTAB decides whether an already-issued patent is invalid. IPR proceedings therefore allow the agency to take a "second look" at its earlier decision to grant a patent, this time aided by an adversarial presentation, which does not occur during the patent-examination process. And while anyone (even non-competitors) can petition the PTAB to take this second look, the PTAB will "institute" an IPR only where it finds a "reasonable likelihood" that the patent is invalid.[1]

The PTAB agreed to review the current set of Restasis patents and granted IPR petitions separately submitted by Mylan Pharmaceuticals Inc., Teva Pharmaceuticals USA, Inc., and Akorn, Inc. The PTAB consolidated the three instituted IPRs and, after briefing and the submission of evidence by Allergan and the three petitioners, scheduled the final IPR hearing for September 15, 2017, with a final decision expected in early December 2017.

On September 8, 2017, just one week before the scheduled IPR hearing, Allergan entered into an unprecedented transaction: it 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."[2] 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

[1] 35 U.S.C. § 314(a).
[2] 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.

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."[3]

Within the past several weeks, the Tribe has issued "clarifications" regarding its transaction, arguing in a brief before the PTAB and in a public statement that its patent business utilizes the same business model and legal arguments employed by public universities, which engage in technological innovation and license intellectual property to corporations and start-ups. The Tribe pointed out that such universities enjoy sovereign immunity from patent infringement and from challenges to patent validity and stated that it appears that this strategy "is only a concern when a Tribe decides to enter the same business for the benefit its community."[4] But no state university has accepted a sham patent transfer from a corporate patentee to avoid *inter partes* review, much less one on the eve of the PTAB's IPR hearings. Unlike the Tribe, universities actually engage in research and innovation, for which they seek and obtain their own patents. And if there were any question about whether the Tribe's 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).

In short, this case, unlike any other before it, involves a brand-name drug company's attempt to rent tribal immunity for $15 million per year, purely to keep the USPTO from reviewing the patents covering its $1.5 billion-per-year drug.

# III. ALLOWING THE RENTAL OF TRIBAL IMMUNITY COULD HAVE SERIOUS REPERCUSSIONS FOR PATIENTS AND DRUG COMPETITION

Allergan and the Tribe have suggested that their transaction poses no serious concerns because generic drug manufacturers can still challenge patents in federal court. But the potential impacts of this scheme on the patent system are profound, for two reasons: (1) USPTO review is a vital component of a healthy patent system in its own right, and (2) tribal immunity threatens to limit judicial proceedings as well.

## A. USPTO REVIEW IS A VITAL COMPONENT OF A HEALTHY PATENT SYSTEM

Congress has barred the issuance of patents on purported inventions that are not truly novel, or are just obvious variations on existing knowledge. But the USPTO examination process does not always uncover all the flaws in a patent. And 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 did here. The patents protecting Allergan's Restasis monopoly expired in May 2014. But in late 2013 and early 2014, Allergan obtained six new patents that provided Allergan with ten more years of patent exclusivity. These patents attempted to claim essentially the same formulation and methods of treatment Allergan had previously claimed, with a bit more detail about the proportions of ingredients.

[3] 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 (last accessed Oct. 8, 2017).

[4] 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.

Those weak patents were prime candidates for administrative re-examination, and unsurprisingly, the PTAB found a reasonable likelihood that all six are invalid.

For nearly 40 years, the USPTO'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 of vital products such as pharmaceuticals.

Congress created a process for petitioning the USPTO to re-examine issued patents precisely because of concerns that patents were being issued with flaws that render them invalid. The incredible volume of patent applications (more than 600,000 in 2015, with the number of applications rising each year[5]) 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 USPTO 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 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 patents that should never have been issued to begin with.

The initial administrative review processes created by Congress suffered from structural deficiencies that hampered their ability to weed out bad patents. As a result, numerous legislators, including Senators Sessions, Schumer, Leahy, and Whitehouse, expressed concerns that poor-quality patents were still escaping re-examination. Legislators recognized that simple but robust USPTO review would enable inventors and their competition to spend their resources productively, on raising money, commercializing inventions, and 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]

Thus, 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 and other forms of post-grant review, "to ensure that the poor-quality patents can be weeded out through administrative review rather than costly litigation" to "improve patent quality and limit unnecessary and counterproductive litigation costs."[9] Congress provided a greater opportunity for third parties to interact with and present evidence to the PTAB (which is now the first-line adjudicator), as well as limited discovery. The AIA simultaneously provided patent owners with an opportunity to amend their patents during IPR proceedings.

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[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.

[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.

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

[8] H.R. Rep. No. 112-98, at 39 (2011).

[9] 157 Cong. Rec. S5409 (Sept. 8, 2011) (Sen. Schumer); 157 Cong. Rec. S1348 (Mar. 8, 2011) (Sen. Leahy).

To ensure the efficiency of IPRs and other post-grant reviews, the AIA placed strict time limitations on PTAB decisions—no more than 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 sufficiently high threshold for instituting an IPR to "weed out marginal challenges" and to "prevent abuse of these proceedings for purposes of harassment or delay."[11] And to ensure the accuracy of PTAB decisions, the AIA provided that no heightened standard of proof would apply: if a patent is found invalid, it will be canceled.

Transactions like Allergan's threaten to undo this valuable reform of the patent system. If brand-name drug manufacturers can make themselves invulnerable to IPRs simply by paying an Indian Tribe a small fraction of the amount they receive in revenues 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 even a flawed patent 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 using a fraction of the profits that their patents protect, will hurt patients and degrade the patent system. Low-quality patents will once again be roadblocks to innovation and competition, and those who will suffer most are patients who rely on innovation and competition to deliver affordable medicines.

### B. DISTRICT COURT LITIGATION IS NOT A SUBSTITUTE FOR INTER PARTES REVIEW

Allergan and the Tribe contend that their evasion of the PTAB should not be worrisome because if Allergan sues on these patents in district court, the defendant can still argue that the patents are invalid. That ignores that administrative review and patent litigation serve two different but equally vital functions, and Congress intended to make *both systems* available. Pointing to the district court as an alternative forum also obscures the 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. There is no analogue to the PTAB's institution decision, which can streamline the issues. Discovery is much more costly, especially expert discovery. Unlike in IPRs, there is no 18-month time limit in patent litigation; to the contrary, Congress has approximated that a pharmaceutical patent case will take 30 months to resolve in district court, and many take longer. And in district court, even if a patent is shown to be invalid by a preponderance of evidence, the patent survives because of a heightened burden that limits district courts' ability to invalidate patents. In IPR proceedings, by contrast, the expert adjudicators make their decision without any artificially heightened burden, which improves the accuracy of decision-making.

Second, tribal sovereign immunity applies in federal district court proceedings. If transactions like Allergan's are upheld, the tribe renting its immunity to a brand-name manufacturer could potentially invoke that immunity to block generic drug manufacturers from bringing declaratory

[10] 35 U.S.C. § 316(a)(11).
[11] 157 Cong. Reg. S1041 (Mar. 1, 2011) (Sen. Kyl); 157 Cong. Rec. S1374 (Mar. 8, 2011) (Sen. Kyl).

judgment actions or counterclaims to declare a patent invalid.[12] That threatens the well-functioning system for litigating pharmaceutical patent disputes. In the Drug Price Competition and Patent Term Restoration Act, a 1984 statute also known as the Hatch-Waxman Act, Congress created a pathway for faster approval of generic drugs that promotes prompt litigation between brand-name and generic drug manufacturers. Under Hatch-Waxman, if a generic manufacturer applies to market a drug and the brand-name manufacturer does not sue within 45 days, the generic manufacturer can obtain certainty by bringing a civil action for a declaratory judgment that the brand company's patents are invalid or not infringed.[13] Generic drug applicants who are sued on some patents but not others can also file a counterclaim to litigate the validity of the additional patents. But tribal immunity would potentially block declaratory judgment actions and counterclaims.

If brand-name manufacturers can shield themselves from generic applicants' declaratory judgment actions by renting tribal immunity, they can effectively delay generic drug launch by holding some of their patents in reserve and waiting until after FDA approval of a generic to file or threaten suit. Generic drug applicants 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—because the damages sought for "at risk launch" are potentially quite significant, and often greater than the profits that the generic applicant could hope to earn. For a blockbuster drug like Restasis, 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.

If transactions like Allergan's are upheld, 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. And while generic drug defendants could defend their own alleged infringement by arguing that any "asserted claims" (patent claims that the patent owner alleges are infringed) are invalid, 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.[14] Furthermore, these consequences will only increase uncertainty, which damages incentives for investment in generic drug competition.

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[12] *A123 Sys., Inc. v. Hydro-Quebec*, 626 F.3d 1213, 1217 (Fed. Cir. 2010); *Quinault Indian Nation v. Pearson for Estate of Comenout*, __ F.3d __, 2017 WL 3707898, at *4 (9th Cir. Aug. 29, 2017).

[13] 35 U.S.C. § 271(e)(5).

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

# IV. THE PTAB CAN AND SHOULD RESOLVE INSTITUTED IPRS IF A PRIVATE PATENT HOLDER ATTEMPTS TO HIDE BEHIND RENTED TRIBAL IMMUNITY

The PTAB has at least two options for reaching the merits of instituted IPRs should patentholders engage in a tribal immunity rental transaction: it could conclude that tribal immunity does not apply in administrative "second look" proceedings, or it could conclude that even if tribal immunity does apply and has not been waived, it should continue to exercise its Congressionally granted authority to review the patents issued by the USPTO even without the Tribe's participation.

## A. TRIBAL IMMUNITY DOES NOT APPLY IN IPR PROCEEDINGS

Sovereign immunity, including tribal sovereign immunity, unquestionably applies in judicial proceedings between private parties. But it does not apply in administrative proceedings in which the federal government is "exercising its superior sovereign powers."[15] As the Supreme Court held in *Federal Maritime Commission v. South Carolina State Ports Authority*, it is only where an administrative proceeding bears "a remarkably strong resemblance to civil litigation in federal courts" and where a sovereign would "be required to answer the complaints of private parties" that sovereign immunity shields a sovereign from participating in those proceedings.[16]

There are fundamental differences between adversarial civil litigation and *inter partes* review that could lead the PTAB to conclude that tribal immunity simply does not apply to IPR proceedings. Many of these differences were discussed by the Supreme Court just a year ago in *Cuozzo Speed Technologies, LLC v. Lee*, in which the Court rejected the argument that *inter partes* review is "a 'surrogate' for court proceedings" and instead stated that in many ways "inter partes review is less like a judicial proceeding and more like a specialized agency proceeding."[17]

First, and perhaps most fundamentally, the purpose of an IPR is different from the purpose of district court litigation. An IPR does not adjudicate a controversy between private parties as civil litigation does; rather, it offers the USPTO "a second look at an earlier administrative grant of a patent."[18] That is why the patent owner can sometimes amend the patent during the IPR proceeding. Because the purpose of an IPR is for the USPTO to reexamine its own earlier agency decision, the PTAB also offers a lower burden of proof than civil patent litigation. If the PTAB finds by a preponderance of the evidence that the patent is invalid, it will be cancelled.

Second, the universe of potential IPR petitioners is broader. A patent owner chooses whom to sue in district court. IPR petitions, however, can be filed by anyone who is not the owner of the patent, whether or not they have been sued or threatened with suit on the challenged patent.[19]

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[15] *Quileute Indian Tribe v. Babbitt*, 18 F.3d 1456, 1459 (9th Cir. 1994).
[16] 535 U.S. 743, 757, 760 (2002).
[17] 136 S. Ct. 2131, 2143 (2016).
[18] *Id.* at 2144.
[19] 35 U.S.C. § 311.

Third, unlike a district court, the PTAB may continue to conduct IPRs even after a petitioning party and patent holder have settled. Once the patent is being scrutinized by the PTAB, the patent owner can no longer insulate its flaws from review by settling with the petitioner.

Fourth, a key rationale of the Supreme Court in holding that sovereign immunity applies in Federal Maritime Commission adjudications of alleged Shipping Act violations was that the Commission lacked discretion to refuse to adjudicate complaints brought by private parties, and thus sovereigns were truly being "coerced" by private parties into answering private disputes. The Court took great care to note that sovereign immunity did not preclude the government from investigating and prosecuting "alleged violations of the Shipping Act, either upon its own initiative or upon information supplied by a private party, and to institute its own administrative proceeding against a state-run port."[20] It further stated that notwithstanding tribal immunity, "private parties remain perfectly free to complain to the Federal Government about unlawful state activity and the Federal Government [remains] to take subsequent legal action."[21] This is precisely the nature of IPR proceedings: private parties supply information to the USPTO regarding patentability in the form of IPR petitions, and the PTAB has complete and unreviewable discretion about whether or not "to institute its own administrative proceeding." Thus, under the Supreme Court's reasoning, sovereign immunity poses no barrier to the PTAB's resolution of the IPRs it decided to institute.

PTAB panels have on three occasions concluded that sovereign immunity applies in IPR proceedings. Those decisions, however, addressed the issue of *state* sovereign immunity, which has a constitutional foundation, whereas tribal sovereign immunity is a common-law concept that Congress is free to abrogate. Furthermore, regardless of that distinction, those earlier panel decisions are not binding on future panels, including the *Allergan* panel, and do not take proper account of the Supreme Court's analyses in the *Federal Maritime Commission* and *Cuozzo* cases.

Thus, there is no barrier to the PTAB's concluding that tribal immunity is inapplicable in the Restasis IPRs, or any IPRs involving attempts to assign patent rights to tribes in order to thwart the PTAB proceedings. The PTAB may also conclude that particular conduct by a tribe constitutes a waiver of any claimed immunity.

### B. INSTITUTED IPRs SHOULD NOT BE DISMISSED WHERE A PATENT HOLDER TRANSFERS ITS PATENTS TO A SOVEREIGN TO AVOID AN ADVERSE IPR DECISION

Even if tribal immunity does apply in IPR proceedings, and even if immunity-renting commercial transactions like the Saint Regis Mohawk Tribe's do not constitute a waiver of that immunity, the USPTO should complete its review of the agency's 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. Nothing in the America Invents Act or the USPTO's rules or regulations precludes the PTAB from resolving instituted IPRs in this situation, just as the inability to include a relevant party in litigation does not negate a federal court's authority to adjudicate disputes between the parties who have been joined.[22] Indeed, PTAB rules expressly permit IPRs to continue even with *no* parties—even when a petitioner abandons its petition following settlement

[20] 535 U.S. at 768 (citations omitted).
[21] *Id.* at 768 n.19 (quotation marks omitted and alteration in original).
[22] Fed. R. Civ. P. 19 advisory committee note (1966).

with the patent holder, "the Board . . . may independently determine any question of . . . patentability."[23]

Furthermore, in past IPRs involving sovereign state entities, the PTAB has allowed an IPR to continue where there is a remaining party that can adequately represent the patent owner's interest.[24] That is certainly true in Allergan's case: Allergan has been involved in these IPRs for more than a year, and in a September 11, 2017 telephone conference with the Board following Allergan's assignment and license-back agreements, Allergan stated that it fully intends to continue participating in the IPRs. In an attempt to obtain dismissal of the IPRs, the Tribe has recently argued that Allergan cannot adequately represent the Tribe's interests, but most observers would likely find this argument to be contrived and not compelling. Allergan has an enormous financial stake in the patented product and continues to litigate the same patents in district court. If the Tribe really believed that Allergan could not adequately represent its interests with respect to the Restasis patents, then it would have already joined the pending district court litigation. But the Tribe has not joined those proceedings, which recently caused the presiding judge to order the parties to file briefs by October 13, 2017, addressing "whether the assignment of the patents to the Tribe should be regarded as a sham."[25]

Finally, the PTAB has sometimes looked for guidance to some of the factors in Federal Rule of Civil Procedure 19(b), which addresses when an action should be dismissed if a person considered necessary to the dispute is unable to be joined. Rule 19(b) is expressly premised on "equity and good conscience," and courts can consider any "considerations which may be applicable in particular situations," in addition to enumerated factors.[26] Faced with a patent holder's assignment of its patent rights to a sovereign entity following IPR institution for the express purpose of avoiding the PTAB's final decision, the PTAB could easily find that "equity and good conscience" weigh heavily in favor of continuing the IPRs, with or without the sovereign's participation.

In short, there is no statute, rule, or precedent that requires the PTAB to dismiss instituted IPRs if a patent holder assigns its patents to a Native American tribe and licenses those patents back for the express purpose of avoiding a final IPR decision. To maintain the integrity of the patent system and discourage the large-scale use of these types of sham patent transfers, the PTAB can and should continue to exercise its authority to take a "second look" at prior USPTO patent decisions.

# V. CONCLUSION

For more than four decades, USPTO review of issued patents has been considered a vital component of a healthy patent system, and Congress has worked to improve that review system to systematically 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 same abuses: 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 competition. The PTAB's hands are far from tied, however. By concluding that sovereign immunity does not apply in IPR proceedings under the Supreme Court's *Federal Maritime Commission* and

[23] 37 C.F.R. § 42.74(a).
[24] *See Reactive Surfaces Ltd., LLP v. Toyota Motor Corp.*, No. IPR2016-01914, 2017 WL 2992429, at *6 (July 13, 2017).
[25] *Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 15-cv-01455 (E.D. Tex. Oct. 6, 2017), ECF No. 503.
[26] Fed. R. Civ. P. 19(b); Fed. R. Civ. P. 19 advisory committee note (1966).

*Cuozzo* decisions, or by concluding that it can finish its "second look" at the Restasis patents given the equities of the tribal immunity rental transactions, the PTAB can ensure Allergan's transaction does not start a trend.