

Do American Indian Tribal Deals Shield Patent Owners from Inter Partes Review?

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Allergan's assignment of the patents on one of its blockbuster drugs to an American Indian tribe in an attempt to dismiss a USPTO inter partes review (IPR) proceeding on "tribal sovereign immunity" grounds has shaken up the patent bar - with some dismissing this as, at most, a temporary loophole and others saying "why didn't I think of that?" Allergan's move comes on the heels of a series of challenges to IPRs, including an attack on their constitutionality in the *Oji States* case pending at the Supreme Court. In this, our inaugural post, we provide an update on the Allergan play, its potential outcomes and their ramifications.

Tribal Sovereign Immunity

With no time to see if *Oji States* strikes down IPRs, Allergan recently assigned six patents on its highly-successful Restasis® dry-eye treatment to the Saint Regis Mohawk Tribe, an American Indian tribe located in upstate New York, in an attempt to dismiss the pending IPR on tribal sovereign immunity grounds. Under the deal, Saint Regis receives a one-time payment of \$13.75 million and \$15 million in annual royalties for taking ownership of the patents and, in return, Allergan retains an exclusive license.

Allergan announced the deal on September 8, on the eve of the scheduled final hearing in the IPR, which was brought by Mylan and other generic manufacturers challenging the validity of its patents covering its Restasis® product. The USPTO's Patent Trial and Appeal Board ("PTAB") postponed the hearing to allow Saint Regis to file a motion to dismiss on tribal immunity grounds.

In its motion to dismiss, Saint Regis argues that as a federally recognized, sovereign American Indian tribe, it has inherent sovereign immunity. According to Saint Regis, tribal immunity has long been upheld by the Supreme Court, albeit it has apparently never been invoked to avoid an IPR.

The generic challengers argue in their opposition to the motion that the Allergan assignment is a "sham" that did not transfer substantial rights in the patents to the tribe such that Allergan remains the true patent owner, but even if the Tribe could be considered the patent owner its interests are adequately represented in the IPR by Allergan.

The stakes are high for Allergan. It recently lost its co-pending federal district court case with Mylan over the same patents at issue in the IPR. In the district court, after voicing "serious concerns about the legitimacy of the tactic" employed by Allergan, Senior Judge Bryson (sitting by designation from the Federal Circuit) found all of the asserted patent claims invalid for obviousness. If Allergan can reverse that decision on appeal, and if Saint Regis prevails on its immunity argument in the IPR, that would be a total win for Allergan. If, however, the Saint Regis immunity argument is rejected, Mylan and the other generic makers would have a second bite at the apple in the IPR, if need be, with a lower burden of proof than in federal court (in an IPR invalidity must be proven by a preponderance of the evidence, whereas in federal court, invalidity must be proven by clear and convincing evidence).

State Sovereign Immunity Origins

While Allergan's deal took many by surprise, it is not entirely without precedent. Earlier this year, the PTAB dismissed two IPRs filed against state universities on state sovereign immunity grounds. In those cases, the PTAB found that the Eleventh Amendment bars the institution of an IPR against an unconsenting state that has not waived its sovereign immunity. While there are some differences between state sovereign immunity and tribal sovereign immunity, the PTAB's dismissal of the two state university IPRs put tribal sovereign immunity in play.

Unlike state sovereign immunity, tribal sovereign immunity can be taken away by Congress and, almost immediately after Allergan's deal was announced, some members of Congress sought an investigation into the deal and its implications on competition. Another member of Congress has introduced legislation to close the so-called "loophole" and abrogate sovereign immunity of American Indian tribes as a defense in IPRs.

Potential Outcomes and Ramifications

Initially dismissed as a novelty, Allergan's play is now being taken seriously as the understanding of tribal sovereign immunity has grown and the potential power of such deals is appreciated. And interest is not limited to the pharmaceutical sector. Earlier this year, Saint Regis took assignment of about 40 patents on computer technology previously owned by SRC Labs, and has now asserted some of them against Amazon and Microsoft. And another patentee who is suing Apple on its iPad assigned its patent to a patent holding company affiliated with a different American Indian tribe.

Whether this emerging trend has legs depends on the final outcome of the Saint Regis motion to dismiss. A final decision granting the motion would send shock waves and have patentees scurrying to quickly tie up tribal deals. But even a decision denying the Saint Regis motion would not necessarily see an end to such deals. The PTAB could, for example, deny the motion in a way that limits the decision to the specifics of the Allergan deal, focusing on the extent of rights retained by Allergan. Other patentees would then likely test the limits of that decision by structuring tribal patent assignments in new and creative ways.

Alternatively, the PTAB could dodge the ultimate question and find that Saint Regis took ownership of the patents too late, and that suit can continue against the original party, Allergan. Such an outcome would merely encourage patentees now watching from the sidelines to execute tribal deals earlier, prior to receiving an IPR petition.

Even a decision finding American Indian tribal immunity does not apply would not necessarily negate the application of state sovereign immunity, pushing patentees towards finding an academic partner to hold its patents.

A decision on the motion to dismiss is expected any day. The deadline for the PTAB's decision in the IPR is December 6, 2017, unless that deadline is extended for "good cause".