

VIEWPOINT

Selling Patents to Indian Tribes to Delay the Market Entry of Generic Drugs

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Viewpoint

In September 2017, Allergan Plc announced that it had transferred the 6 patents for cyclosporine ophthalmic emulsion (Restasis), its blockbuster drug for chronic dry eye, to the Saint Regis Mohawk Tribe, a federally recognized Indian tribe of about 15 000 members in rural upstate New York with a \$50 million annual budget. The Tribe received \$13.75 million initially and is eligible for \$15 million in annual royalties—a small fraction of the roughly \$1.5 billion in annual US revenues for Restasis. The deal allows the Tribe, as the patents' legal owner, to assert what is known as *sovereign immunity* in a proceeding at the US Patent and Trademark Office (USPTO) where Mylan Pharmaceuticals, a generics manufacturer, is challenging the patents.

Mylan's proceeding before the USPTO is an instance of what is called *inter partes review*. Created in 2012, this novel procedure allows any party to ask the USPTO to reconsider whether it should have granted a patent. Because *inter partes review* gives challengers legal advantages not available in court proceedings, generic manufacturers increasingly rely on it to challenge pharmaceutical patents.¹ Mylan, for instance, is arguing that Allergan's patents are either not novel or obvious in light of earlier work.

But just a week before the USPTO was to begin hearings on the Restasis patents, Allergan announced the patents' transfer to the Tribe and argued that tribal sovereign immunity requires dismissal of the *inter partes review* proceedings. The latest of many efforts by brand-name pharmaceutical manufacturers to delay entry of lower-priced generics,² this legal strategy was the brainchild of the law firm Shore Chan DePumpo LLP. After successfully invoking state sovereign immunity in another USPTO proceeding earlier in 2017, the firm reportedly proposed the patent transfer concept to several tribes before brokering the deal between the Saint Regis Mohawk Tribe and Allergan.³

Further complicating the situation is a separate case in the Eastern District of Texas, where Allergan had previously sued Mylan and other generics manufacturers for patent infringement. The generic companies responded by arguing that the patents are invalid, and in October 2017, the district court ruled in their favor. Although the Saint Regis Mohawk Tribe did not assert its immunity in this proceeding, the judge nonetheless criticized Allergan's deal with the tribe "as part of a scheme" for Allergan "to evade their legal responsibilities."⁴ The decision to invalidate the patents will now be reviewed by the Court of Appeals for the Federal Circuit, and its decision may ultimately make the sovereign immunity question in the USPTO proceeding moot.

The issue of whether sovereign ownership is a viable strategy to protect patents transcends this particu-

lar dispute, however. At the core of this tactic is the legal concept of sovereign immunity, the principle that sovereigns cannot be sued without their consent. This doctrine might strike nonlawyers as bizarre, and is controversial among lawyers and legal academics. Defenders of sovereign immunity argue that the principle preserves each sovereign's dignity and protects public finance by stopping lawsuits seeking damages. Numerous sovereigns enjoy immunity under US law: the federal government, the 50 states (including their state universities) and the US territories, foreign nations, and the 567 federally recognized Indian tribes.

Tribal sovereignty stems from tribes' existence as sovereigns both prior to and after the creation of the United States, and has been recognized by the US Supreme Court since the early 19th century. Although several justices have expressed skepticism about tribal sovereign immunity, the doctrine has survived multiple challenges before the Court. As recently as 2014, the Court upheld the immunity of the Bay Mills Tribe against a suit by Michigan for off-reservation gaming activities.⁵

State sovereign immunity has been used to shield state-owned patents. In 2017, the USPTO dismissed *inter partes review* petitions in 3 cases where the patent owner was a state university.⁶ Two of these involved health-related technologies: a patent on methods for cardiac valve repair owned by the University of Maryland, and a patent on a method of integrating treatment data from multiple bedside machines owned by the University of Florida Research Foundation—the case litigated by Shore Chan DePumpo. If followed by the USPTO, these precedents would seem to similarly bar *inter partes review* of the Restasis patents now owned by the Saint Regis Mohawk Tribe. But these issues of sovereign immunity and patent law are novel legal questions without any guiding decisions from higher courts. The Court of Appeals for the Federal Circuit, which hears all appeals involving US patent law, has yet to review any of the state university sovereign immunity decisions from the USPTO.

One potential resolution involves Congress: both Senate and House members have expressed concern about the deal's potential effect on drug prices, and in October 2017, Senator Claire McCaskill (Democrat from Missouri) introduced legislation that would strip tribes of sovereign immunity in *inter partes review* proceedings.⁷ It seems difficult, however, to justify singling out tribes while permitting other sovereigns such as state universities to invoke immunity.

In our view, a better solution would address sovereign immunity in patent law more generally. Although constitutionally Congress cannot directly alter state sovereign immunity the way it can for tribes,⁸ it can induce states to waive immunity by attaching it as a condition to receive

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federal research funds. Congress already provides considerable research funding to state universities and allows them to profit from resulting patents through the Bayh-Dole Act; Congress could stipulate that states receiving these funds could not block lawsuits that seek to challenge the validity of these patents.

Moreover, any legislative solution should work to address the underlying challenges that have led the Saint Regis Mohawk Tribe and other tribes to pursue such deals. For tribes, economic development and sovereignty are closely linked, especially because federal law substantially limits tribes' powers to tax. American Indians and Alaska Natives have the highest poverty rate of any racial group in the United States.⁹ A small fraction of tribes enjoy large gaming revenues, but most must struggle for funds to supplement chronically underfunded federal programs to provide services for their citizens.

Whether selling patents to Indian tribes or other sovereigns to protect them from inter partes review is a viable strategy remains

highly unsettled, and the situation could shift markedly depending on what Congress, the USPTO, and the Federal Circuit decide in the months ahead. Even the future of inter partes review is itself uncertain: in a pending case, *Oil States Energy Services LLC v Greene's Energy Group LLC*, the Supreme Court is expected to decide whether inter partes review unconstitutionally extinguishes patent rights without a jury.

However the legal issues are decided, the underlying questions will remain—the benefits of early market entry of generic drugs weighed against the provision of incentives for pharmaceutical innovation and the substantial economic, legal, and humanitarian challenges that confront Native American nations. Responding to the Allergan deal requires more than a stopgap narrowly focused on the use of tribal sovereign immunity in inter partes review proceedings challenging drug patents. The underlying questions require longer-term solutions.

ARTICLE INFORMATION

Published Online: January 2, 2018.
doi:10.1001/jamainternmed.2017.7463

Conflict of Interest Disclosures: Dr Ouellette has signed an amicus brief in support of the respondents in *Oil States v Greene's Energy* written by law and economics professors who have no financial interest in the case. She was not compensated. No other disclosures are reported.

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