



LAW

## < Partnership Between Drug Giant And Native American Tribe May Affect Patent Challenges

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ARI SHAPIRO, HOST:

Now a story of strange bedfellows. One is drug giant Allergan, maker of Botox and other hugely popular medicines. The other is a small Native American tribe in upstate New York. As David Sommerstein of North Country Public Radio and our Planet Money team reports, the partnership could make it harder to challenge drug patents.

DAVID SOMMERSTEIN, BYLINE: Allergan's drug for dry eyes, Restasis is a blockbuster - 1 and a half billion dollars in sales last year. So the company wants to protect its patent for the drug as long as it can, until it expires in 2024. Now, it used to be a lot easier to protect patents. A generic drug maker would say, hey, Allergan, your Restasis drug isn't new and novel enough to deserve patent protection; we should be able to make it, too, and sell it cheaper. But Allergan could tie up the whole thing in expensive lawsuits for years. It often worked out in the patent holder's favor. But in 2011, Congress wanted a change. Bob Stoll was a commissioner for the U.S. Patent and Trademark Office who helped streamline the process.

BOB STOLL: An effective and less-costly manner than spending millions of dollars going to court.

SOMMERSTEIN: Now instead of a lawsuit, there was a simpler process - a review board. And you know what? It worked. The board had its own problems - patent trolls, multiple challenges. But the pendulum swung from the patent holder to the patent challenger.

MICHAEL SHORE: It's pretty well known as the patent death squad. It's a kangaroo court in my opinion.

SOMMERSTEIN: Michael Shore is a patent lawyer in Dallas. He represents big companies like Allergan and also public universities. This new review board made his job harder. But in January he found a workaround. He was representing the University of Florida, and he successfully argued his client's patent couldn't be challenged at the review board because it's a state university, part of the government of Florida, a sovereign entity. So Michael Shore, sitting at his desk, savoring his victory, had a thought. How can I do this for all my clients? He needed more sovereign entities.

SHORE: Actually I think I did a Google search on sovereigns, and Indian tribes came

SOMMERSTEIN: So Shore started calling Indian tribes, and eventually he ended up on the phone with Dale White, general counsel for the 13,000-member Saint Regis Mohawk Tribe. And they came up with a plan. The Mohawks called Allergan and said, hey, give us your Restasis patent, \$14 million and some royalties. We'll lease the patent back to you so you can make the drug, and we'll protect the patent at the review board.

I mean this must be really crazy to just have this plop out of the sky in your lap really.

SHORE: (Laughter) Yeah, it's - we're all kind of shaking our heads a little bit.

SOMMERSTEIN: The Mohawks have a modest casino. But like most Native tribes, there's a lot of poverty on the reservation.

SHORE: So having the ability or opportunity that might come along with this business venture is life-changing for the tribe.

SOMMERSTEIN: When the deal was announced, there was a lot of blowback. Critics called it sleazy, a hornet's nest. David Mitchell is founder of a new not-for-profit called Patients For Affordable Drugs. He says he has nothing against the Mohawks. But he says the deal keeps generics out of the market, and that means higher prices for people who need medicines.

DAVID MITCHELL: Allergan is gaming that system, thwarting the will of Congress, finding a way to abrogate the law and thereby hurting patients. And it's flat out wrong.

SOMMERSTEIN: If this sovereignty protection stands up, Indian tribes could end up with lots of patents and a substantial revenue stream, and the pendulum would swing back in favor of the patent holder. For NPR News, I'm David Sommerstein.

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