

A Native American Tribe, a Drugmaker and an Unusual Patent Plan

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- Saint Regis Mohawk Tribe will get payment, annual royalties
 - Agreement may put drug out of reach of some patent challenges
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Allergan Plc <<https://www.bloomberg.com/quote/AGN:US>> has found an unusual way to shield one of its blockbuster drugs from generic competition.

The drug giant, which is defending its intellectual property on multiple fronts, said it will transfer the rights to Restasis to the Saint Regis Mohawk Tribe, in a move designed to quash challenges filed at the U.S. patent office by rival drugmakers. The medication, a treatment for chronic dry eye, brought in \$1.49 billion in sales last year.

The pact, which will entitle the upstate New York tribe to a one-time \$13.75 million payment and \$15 million a year in royalties, could open up a new way for drugmakers to head off challenges to patents backing billions of dollars a year in sales.

Several top drugmakers have recently reported slowing sales and shrinking profits due to the loss of exclusivity for top-selling medications, and the Trump administration has said it wants to drive down drug prices. At the same time, attacks on drug patents have been made easier under the patent office's recently created fast-track legal review process.

By moving key patents to a sovereign Native American group, Allergan says it may be able to protect itself.

"I would expect it creates a playbook for other cases down the road both for us and for others," said Bob Bailey, Allergan's chief legal officer.

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Shares of Allergan, which is based in the U.S., rose 1.8 percent to \$232.13 at 2:24 p.m. in New York.

A Novel Idea

Allergan said it had been approached by the tribe with what it called a “sophisticated opportunity to strengthen the defense” of Restatis’s patents, which have been challenged under a process called inter partes review, or IPR.

The tribe, which is a sovereign government entity, says that it is shielded from civil legal challenges over patents. State and foreign governments can’t be sued or subjected to federal government action except in certain circumstances.

“We are impressed with the tribe’s thoughtful and enterprising approach, which will allow them to achieve their goals of self-reliance and help them address the most urgent needs in their community,” Bailey said in a statement.

Mylan NV has filed petitions with the patent office to challenge Allergan’s patents under the IPR process. The agency previously determined that Mylan has established a “reasonable likelihood” of winning its arguments that the patents are invalid, though a hearing on the case is scheduled for next week in Alexandria, Virginia.

Drugmakers have long railed against the IPR process, which enables challenges before the Patent Trial and Appeal Board, because it means they have to defend their patents against assaults in two different forums. They have to win in both the court and before the agency.

Strategy Skeptics

Some legal experts were skeptical that the accord would withstand scrutiny.

“It seems highly suspicious. They’ll have to tread a very careful line with that one,” said Brad Wright, a patent lawyer with Banner & Witcoff in Washington who specializes in cases before the agency.

The patent board recently ruled in two cases that state-university-owned patents aren’t subject to the review process because states have sovereign immunity. In those cases, the university was the original owner of the patents.

The board will have to take a close look at the agreement with the tribe. It may decide that Allergan retains enough control over the patents, such as its ability to use them in district court, that the transfer is a “sham transfer of assets,” Wright said.

Mike Fuller, chair of the biotechnology practice group at law firm Knobbe Martens, said that patent officials could find that the tribe can't step into the middle of an ongoing review.

"I don't know that it's going to work, honestly," he said.

Patent Strategy

By transferring ownership to the tribe, Allergan can try to limit its legal battle to the courts, where it's harder to invalidate patents because of a more stringent legal standard.

"The way I think about this is what we're doing here today is to really allow Allergan to focus the defense of the Retstasis patent in the federal court system and avoid the double jeopardy of the IPR system," Allergan Chief Executive Officer Brent Saunders said in an interview.

Last week, a trial was held in a federal court dispute where Allergan is seeking to prevent generic drugmakers from selling their copycat drugs until the company's patents expire. The judge in that case has ordered additional legal arguments to be submitted by Sept. 20.

Success for Allergan's deal with the Saint Regis Mohawk Tribe would open a whole host of questions for the patent-review process, which was set up under a 2011 law. Tech companies are the biggest users of the system, intended as a lower-cost way to resolve patent disputes.

"If they can do it, other drugmakers can do it, and not just other drugmakers but other companies," said Wright, the patent lawyer. "It's a massive loophole and you could drive a Mack truck through that."