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IP FRONTIERS

Allergan and New York Native American tribe partner to protect drug patents

The St. Regis Mohawk Tribe, whose Akwesasne territory straddles the U.S.-Canadian border in Franklin County, New York, and the provincial border between Ontario and Quebec, recently parlayed its sovereign immunity into several valuable pharmaceutical patents and a significant revenue stream.

Allergan PLC, a leading global pharmaceutical company headquartered in Dublin, Ireland, transferred six patents covering its top-selling dry eye drug Restasis to the St. Regis Mohawk Tribe. Under their agreement with Allergan, the St. Regis Mohawk Tribe receives a \$13.75 million initial payment and \$15 million in annual royalties, starting next year, until the Restasis patents expire in 2024 or are no longer valid (yes, you read that correctly—Allergan paid the St. Regis Mohawk Tribe millions of dollars to take ownership of the Restasis patents). Allergan retains the rest of the revenue from the sales of Restasis, the company's second-biggest seller after Botox, which had \$1.4 billion in sales last year.

In a unified statement about the agreement with Allergan, the Saint Regis Mohawk Tribal Council said, "This is a viable and sound opportunity for the Saint Regis Mohawk Tribe to enter into the patent, technology and research sector as part of our overall economic diversification strategy. We realize that we cannot depend solely on casino revenues and, in order for us to be self-reliant, we must enter into diverse business sectors to address the chronically unmet needs of the Akwesasne community; such as housing, employment, education, healthcare, cultural and language preservation." Before the Allergan deal, the St. Regis Mohawk Tribe's annual budget was



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reportedly about \$50 million.

The St. Regis Mohawk Tribe's sovereign immunity is worth millions of dollars to Allergan to protect the Restasis patents from generic competition. Generic drug manufacturers Akorn Inc., Mylan NV and Teva Pharmaceutical Industries Ltd.

have challenged the validity of the Restasis patents in an inter partes review proceeding at the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office.

"The Saint Regis Mohawk Tribe and its counsel approached Allergan with a sophisticated opportunity to strengthen the defense of our Restasis intellectual property in the upcoming inter partes review proceedings before the Patent Trial and Appeal Board," Allergan Chief Legal Officer Bob Bailey said in a statement.

An inter partes review is a form of patent review that was introduced as part of the America Invents Act in 2011, which allows third parties to challenge the validity of patents based on patents or printed publications that existed before the filing of the patent application. Inter partes reviews at the Patent Trial and Appeal Board have significantly changed the patent landscape. While invalidating a patent in federal court typically costs millions of dollars, invalidating a patent via an inter partes review can cost a few hundred thousand dollars—a relative bargain.

Critics of inter partes reviews and similar patent challenges available through the Pat-

ent Trial and Appeal Board, such as many pharmaceutical and high-tech companies, argue that these proceedings have been exploited by so-called patent trolls, hedge funds and others. The Supreme Court is currently weighing the constitutionality of the Patent Trial and Appeal Board challenge processes in several cases.

The Restasis patents are also being challenged in a separate review of the patents in federal court in Texas. The federal court decision is expected within the next few months, according to Allergan's chief legal officer. Allergan admits that their motivation to attempt to avoid the inter partes review proceedings via St. Regis Mohawk Tribe's sovereign immunity is the "double jeopardy" that occurred when their Restasis patents were challenged on the same issues in both federal court and in the inter partes review.

In an interview, Allergan CEO Brent Saunders said, "We did this to really make sure that we can defend these patents in only one forum," and "We are completely open to having these patents adjudicated in the federal courts. But we don't think, going through that, we should be subject to a second review" at the Patent Trial and Appeal Board.

Teva, one of the challengers in the Restasis inter partes review, said it would keep pursuing the inter partes challenges and criticized Allergan's tactic as a "new and unusual way for a company to try to delay access to high-quality and affordable generic alternatives." However, based on legal precedent, St. Regis Mohawk Tribe's sovereign immunity will likely be effective in preventing the Restasis patents from being challenged in the inter partes reviews at the Patent Trial and

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Appeal Board. Recently, the board dropped cases against the University of Florida and the University of Maryland, citing their sovereign immunity as state institutions. St. Regis Mohawk Tribe's sovereign immunity, which bars lawsuits against certain types of government entities, is treated very similarly to governmental immunity.

Sovereign immunity is a legal concept that predates the American republic; it stems from the idea that a sovereign or state cannot commit a legal wrong and therefore is immune from civil suit or criminal prosecution. Sovereign immunity is codified in the 11th Amendment to the U.S. Constitution, and provides that the "judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another state, or by citizens or subjects for any foreign State."

The Supreme Court has interpreted the 11th Amendment as a grant of immunity to the states against certain adjudicative proceedings brought against them by private parties. The broader doctrine of sovereign immunity is rooted in common law and likewise prohibits actions against foreign states in federal courts and administrative tribunals. Although somewhat murky, the Supreme Court has held as recently as 2014 that Native American tribes retain inherent sovereign authority and tribal immunity as "domestic dependent nations" that extends beyond reservation land and to commercial cases.

After the University of Florida ruling, the law firm representing the university began looking for a Native American tribe that was interested in taking ad-

vantage of the "arbitrage opportunity." The St. Regis Mohawk Tribe signed on as a client of the firm and approached Allergan, who was identified "as a company that looked like their needs were acute," with the sophisticated opportunity to strengthen the defense of the Restasis inter partes review. The tribe is purportedly trying to enter into similar agreements with other pharmaceutical companies.

Allergan's legal maneuvering is a new twist in pharmaceutical and technology companies' longtime fight to protect their lucrative products from lower priced versions, whose introduction usually cuts into and then largely eliminates sales of the brand-name products within months. And there's worry the matter could go beyond just stopping reviews at the Patent Trial and Appeal Board: While Allergan has indicated that it will only use the St. Regis Mohawk Tribe's sovereign immunity to escape the inter partes review, tribal immunity has been successfully applied in federal court in other situations.

If Allergan's groundbreaking deal is effective in avoiding the reviews at the Patent Trial and Appeal Board, other pharmaceutical companies will likely follow suit, and generic drug companies will lose access to the attractive Patent Trial and Appeal Board forum. But at least one of the challengers in the Restasis inter partes review, Mylan NV, is fighting the application of St. Regis Mohawk Tribe's sovereign immunity to the inter partes review. "The tribe here has not been dragged into this proceeding against its will. ... It

has deliberately by its own admission targeted these proceedings for exactly this kind of revenue-generating opportunity," a Mylan attorney said during a recent hearing before three judges from the board.

In addition to arguing that the tribe has waived immunity, it has been reported that the generic manufacturers plan to rely on cases in which payday lenders have partnered with tribes to circumvent state laws barring high interest rates. Some courts have ruled that such lenders were not entitled to sovereign immunity because they were not arms of the tribe.

If the generic drug companies are unsuccessful in preventing the application of St. Regis Mohawk Tribe's immunity, patent owners have found a new method to insulate themselves—at a relatively low cost—from challenges at the Patent Trial and Appeal Board. Given the potential power of this tactic, there's little doubt that other industries or patent "trolls" with very valuable patents will be next in line to make a deal with a Native American for their sovereign immunity.

In fact, at least one technology patent-holder has already done so. A lawyer for the St. Regis Mohawk Tribe told The New York Times that even before the Allergan deal, the tribe agreed to hold patents for a "technology company," which he declined to name.

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