

DJIA	22,890.88	NASDAQ	6,610.54	S&P 500	2,555.79	Oil	51.06
+49.87		+19.03		+4.86		+0.46	
+0.22%		+0.29%		+0.19%		+0.91%	

Allergan Partners With Indian Tribe to Protect Drug Patents -- 3rd Update

By Jonathan D. Rockoff | Published September 08, 2017 | [Features](#) | Dow Jones Newswires

Allergan PLC has taken a novel step to protect top-selling drug Restasis from generic competition: the company has sold the drug's patents to an Indian tribe in upstate New York to block rivals from challenging the patents at the U.S. Patent and Trademark Office.

The St. Regis Mohawk Tribe, which operates a casino on its reservation near the Canadian border, asked the patent office on Friday to drop patent challenges filed by Akorn Inc., Mylan NV and Teva Pharmaceutical Industries Ltd. due to the tribe's special legal status as a sovereign government, which the tribe says gives it immunity from patent-office review.

If its moves succeed, Allergan will be able to avoid a pending hearing before a patent-office panel on the patents for its Restasis dry-eye drug, a key product for the company. A separate review of the Restasis patents, by a federal court in Texas, will continue.

"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 office, Allergan CEO Brent Saunders said in an interview.

Teva said it would keep pursuing its patent challenges, while criticizing Allergan's tactic as "new and unusual way for a company to try to delay access to high quality and affordable generic alternatives."

Akorn and Mylan didn't respond immediately to requests for comment.

The agreement entitles the tribe to a \$13.75 million initial payment and \$15 million in annual royalties, starting next year, until the Restasis patents expire or are no longer valid. Allergan retains the rest of the revenue from Restasis, Allergan's second-biggest seller after Botox with \$1.4 billion in sales last year.

Dale White, general counsel for the 13,000-member tribe, said it would use the proceeds to diversify revenue beyond its casino and address "unmet needs" in areas such as housing, health care and education.

"Even though the casino has been good for us, we can't rely on it long term. We have to diversify," he said.

The legal maneuvering is a new twist on drug companies' longtime fight to protect their lucrative products from lower-priced generics, whose introduction usually cuts into and then largely eliminates sales of the brand-name drug within months.

Allergan has been trying to shield the drug from competition on many fronts, including from a new dry-eye drug, called Xiidra, from rival Shire PLC. Allergan also is fending off lower-price generics, suing potential manufacturers in the federal court in Texas for patent infringement.

The federal court in Texas held a trial on the claims last week, and Allergan expects a decision within the next few months, according to Bob Bailey, the company's chief legal officer.

Allergan took out the Restasis patents in 2013 as the company began facing generic threats. The company says the Restasis patents don't expire until 2024, while generic rivals argue the patents shouldn't have been granted in the first place and should be ruled invalid.

To invalidate the patents, Akorn, Mylan and Teva asked the U.S. Patent and Trademark Office under a process known as inter partes review.

The IPR process was established six years ago as a quicker, cheaper path to determine the validity of patents, compared with the process in federal courts. But critics, including drug companies, say it has been exploited by so-called patent trolls, hedge funds and others.

The Supreme Court is weighing the constitutionality of the patent-office challenge process.

Allergan still faces a potential loss in the case it initiated in federal court. It is unclear if tribal sovereign immunity could protect drug patents in federal court.

But patent-law experts say Allergan seems to have found a way -- under a web of court and patent-office decisions -- to at least avoid the risk of setback at the patent office.

"Barring some radical change in the law, it looks like Allergan just checkmated everybody," said Jacob Sherkow, an associate professor at New York Law School's Innovation Center for Law and Technology.

Michael Carrier, an intellectual-property specialist at Rutgers University Law School, said such an outcome would remove a valuable tool for keeping down drug costs. "This is an ominous development because there will be a lot of cases, unlike this case, that will only be challenged through IPR" because the cumbersome federal court process may deter generic-drug makers from challenging the patents for some expensive drugs, Mr. Carrier said.

There is precedent for sovereign immunity in patent-office cases. In January, the Patent Trial and Appeal Board, the patent-office panel that hears intellectual-property challenges, dropped a case against the University of Florida citing its sovereign immunity as a state institution.

After that ruling, Michael Shore, a lawyer at Shore Chan DePumpo LLP in Dallas that represented the university, said the firm began looking for an Indian tribe that was interested in taking advantage of the "arbitrage opportunity."

After signing on the St. Regis Mohawk Tribe as a client, Mr. Shore said, they pored over patent-office cases and identified Allergan "as a company that looked like their needs were acute." The tribe proposed the deal in early August and is trying to reach more, he said.

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