



Allergan's patent transaction with St. Regis Mohawks could presage more arbitrage patent transactions



By **Steve Brachmann**
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The pharmaceutical treatment Restasis is a medication for patients suffering from chronic dry eye disease marketed by the Irish pharmaceutical multinational Allergan (NYSE:AGN). The drug is an important part of Allergan's corporate portfolio, earning \$336.4 million in net revenues in the U.S. during the second quarter of 2017. Although that was a 9 percent decrease on net revenues for Restasis during 2016's second quarter, that still makes the medication the second-best selling treatment in the Allergan portfolio behind the company's cosmetic treatment Botox. Through

the first half of 2017, U.S. sales of Restasis helped contribute \$645.2 million in net revenues to Allergan.

Allergan's strong position in chronic eye treatments, however, has been under attack since at least last December by the Patent Trial and Appeal Board (PTAB), a tribunal which has proven itself to be an antagonist to patent rights over the five years of its existence. The PTAB decided to institute a series of *inter partes* review (IPR) proceedings against six patents covering

MYLAN - EXHIBIT 1146

Restasis set to expire in 2024 after American pharma rival Mylan Pharmaceuticals (NASDAQ:MYL) petitioned the board to challenge the validity of those patents. Allergan had previously asserted the patents in suits against Mylan and Israeli generic drugmaker Teva Pharmaceuticals (NYSE:TEVA) after those firms filed abbreviated new drug applications (ANDA) with the U.S. Food and Drug Administration (FDA) to produce generic versions of Restasis.

Putting Allergan's feet to the fire, so to speak, by initiating patent validity review trials at the PTAB led that company to develop a brilliant plan to give its intellectual property assets an added layer of protection. On September 8th, a press release issued by Allergan announced that it had partnered with the St. Regis Mohawk Tribe, a sovereign nation located across the border of Canada and New York State, in an attempt to dismiss the IPR proceedings at PTAB. Under the terms of the deal, Allergan transferred ownership each of the Orange Book patents covering Restasis to the St. Regis tribe and has received an exclusive license to those patents from the tribe. The St. Regis tribe receives an upfront payment of \$13.75 million along with annual royalties of \$15 million.

In return for paying this high price to transfer IP assets, Allergan and the tribe get to mount a sovereign immunity defense which could ultimately be successful in getting PTAB to dismiss the IPR proceedings. Such a defense has already worked in a university context. This January, the University of Florida Research Foundation (UFRF) scored a major victory at PTAB when it convinced the PTAB to dismiss three IPRs instituted against its patents on an 11th Amendment defense. The PTAB found in favor of the university's argument that, as a Florida state entity, it could not be the subject of legal proceedings brought by a private party.

Although the St. Regis tribe isn't afforded 11th Amendment protections, as a sovereign nation, the tribe cannot be sued in a venue where it doesn't want to be and can only be sued for compulsory counterclaims. This was a point raised in a call with Michael Shore, partner at Shore Chan DePumpo LLP who is representing the St. Regis tribe in the IPR cases. "If you can avoid IPRs, there's a huge value difference between patents which can be subject to IPRs and patents that are not," Shore said, "a significant enough difference that if you can find a sovereign which is willing to take advantage of that arbitrage, there is money to be made there." The tribe benefits from the upfront payment and licensing fees while Allergan benefits by protecting the Restasis patents behind a sovereign immunity defense. Shore noted that

UFRF's ability to win on its sovereign immunity argument led Medtronic, the infringing party, to immediately take a license with the Florida university foundation.

The benefits to both parties involved with the Restasis patent transaction would seem to defy any legal definition of a sham transaction, although Mylan certainly doesn't find that to be the case. In a telephone hearing on the St. Regis tribe's motion to dismiss the IPRs at the PTAB, counsel representing Mylan called the patent transfer a "sham transaction" on seven occasions. For a transaction to legally be a sham, it would have to be unlawful or illusory in order to serve as a tax shelter or another deceptive device. There's nothing deceptive about the fact that sovereign immunity defenses have proven successful in defending against patent validity challenges at the PTAB, nor are the benefits to either side illusory in nature.

The pharmaceutical world has had a particularly tense relationship with the PTAB, a point acknowledged by Bob Bailey, executive VP and chief legal officer at Allergan. "From a pharmaceutical industry perspective, the IPR process has been a thorn in our side," Bailey said. He explained that the IPR process was not created to give hedge fund managers an easy ability to make money by shorting a stock and then filing a petition for IPR. "We get a call from reverse trolls on a regular basis," he said. "Now we have an alternative."

"We approached a couple of tribes with the idea and they thought we were insane," Shore said. "Then we found the St. Regis Mohawks and their general counsel figured out what we were doing pretty quickly." Dale White, the general counsel for the St. Regis tribe, noted that Allergan worked with the tribe to develop a relationship before entering into the patent agreement. "We are not going to enter into a transaction with just any company," White said, adding that Bailey had come to visit the tribe personally and met face-to-face with tribal leaders to help establish a rapport.

"This is something that we need because our primary source of revenue is the casino, and that can't last forever so we're trying to diversify," White said. Unlike most business deals proposed to the St. Regis tribe in the past, this transaction didn't require the tribe to give up any land or money in entering an agreement that provides a significant upside to the tribal community. White noted that the St. Regis tribe has many needs which can be met through the proceeds of the Restasis patent transaction such as housing, education, healthcare and welfare. According to White, this transaction will go a long way help in helping the St. Regis tribe much more self-sufficient if not completely self-reliant.

“We are hoping that the revenues will continue, but I’m not going to be giving the tribe unrealistic promises of continued revenues,” White said. Although the team believed that the sovereign immunity defense was a strong argument, the tribe was planning on taking a cautious approach to how the money is spent and wait to see the immunity defense play out at the PTAB before using the bulk of the payment. White noted that the tribe plans on investing the money within the community itself instead of making per capita payments to tribal members.

News of the St. Regis patent transaction has sparked interest in others pursuing similar arbitrage arrangements that provide revenue streams to Native American tribes outside of gambling and tobacco. According to Shore, there’s a lot of interest in pursuing such deals in sectors outside of pharmaceuticals. White seemed confident that other tribes would soon pursue their own similar IP deals. “There are 500 tribes in the U.S.,” White said. “There is a lot of media surrounding this and there is a lot of money. There will be other tribes.” Small operating companies have plenty of reason to contemplate such a transaction of their own patents themselves, Shore said. “There may be no IPRs filed yet, but they may be looking to do this preemptively so that when they engage in an enforcement campaign, they have removed the risk of IPR.”

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Mr. V September 19, 2017 12:05 pm

Thank Steve. I’ve read 100 articles about this Licensing deal but found your quotes from the actual parties involved to be most helpful.

Any plans for a follow-up piece on the St. Regis Mohawk-SRC Computers deal?