

3 Places The Allergan Tribal Deal May Face Pushback

By **Matthew Bultman**

Law360, New York (October 12, 2017, 7:14 PM EDT) -- Allergan PLC's controversial attempt to shield patents for dry-eye drug Restasis from review at the Patent Trial and Appeal Board by making a deal with a Native American tribe has drawn intense scrutiny, amid concerns from groups including lawmakers and generic-drug companies. Here are three places where the deal will be closely examined.

Congress

It's been a little more than four weeks since Allergan announced it would transfer six patents for Restasis to the St. Regis Mohawk tribe, and then license them back. It believes that the tribe, as a sovereign nation, is immune to patent challenges in inter partes review at the PTAB.

The agreement has created quite a stir on Capitol Hill.

Sen. Claire McCaskill, D-Mo., called it "one of the most brazen and absurd loopholes I've ever seen." Some of her Senate colleagues said it was "blatantly anti-competitive" and called for a committee investigation.

Meanwhile, members of the House Oversight and Government Reform Committee have asked Allergan to turn over various documents relating the deal after expressing concern that other drugmakers might adopt the approach and impede the entry of lower-priced generic drugs to the market.

"The implications of Allergan's patent transfer raise questions for Congress as the exchange may impair competition across the pharmaceutical industry and ultimately dissuade companies from pursuing less-costly generic alternatives to brand drugs," committee members wrote Oct. 3 to Allergan CEO Brenton Saunders.

And the calls for more investigations keep coming.

Earlier this week, groups including America's Health Insurance Plans, the American Hospital Association and the Association for Accessible Medicines sent a letter to congressional leaders asking them to take a close look at Allergan's arrangement, CNBC reported.

Chad Landmon, the chair of Axinn Veltrop & Harkrider LLP's intellectual property and Food and Drug Administration practice groups, said the amount of attention the strategy has gotten in Washington isn't

all that surprising. In fact, he expects there could be more scrutiny to come.

“If this is a successful strategy, if they are able to have the IPRs dismissed, I would expect a lot more attention to be brought to bear on this, both from Congress and from people like the [Federal Trade Commission] and the antitrust plaintiffs that are out there,” he said.

District Court

Perhaps the most pressing concern for Allergan isn't in the nation's capital but more than 1,100 miles away, in the Eastern District of Texas, where the deal seems to have piqued the interest of one federal judge.

Senior Federal Circuit Judge William Bryson, who is overseeing infringement suits Allergan brought against various generics makers, has ordered briefs addressing whether the tribe should be added as a co-plaintiff or whether “the assignment of the patents to the tribe should be disregarded as a sham.”

The judge is expected to decide by Friday whether a hearing is needed.

What Judge Bryson determines likely won't impact his ultimate conclusion about whether the patents are valid or infringed, which was the subject of an earlier bench trial. But it could affect reviews at the PTAB — the proceedings Allergan has said all along it is looking to escape.

Some have speculated that St. Regis will lose the ability to argue sovereign immunity at the board if it is named a co-plaintiff in the district court litigation. But legal experts said that remains an open question, noting that Federal Circuit precedent seems to suggest otherwise.

What could be problematic for Allergan, they said, is if Judge Bryson decides the transaction is indeed a sham and St. Regis does not have to be added to as a co-plaintiff. The judge's opinion, even if it's not binding on the PTAB, could carry some weight at the board.

“If Judge Bryson is comfortable concluding that he does not need to add the St. Regis tribe to his proceeding, I wouldn't be surprised if the patent office felt comfortable proceeding with the IPRs absent St. Regis,” said Brian Nolan, a partner at Mayer Brown LLP.

The PTAB

While all of this is going on, the PTAB is still considering a motion that St. Regis filed last month seeking to dismiss the IPRs that Mylan and other generics makers brought against the Restasis patents, based on sovereign immunity.

Mylan, which must file its response to the motion by Friday, has already suggested the deal is a sham and argued the tribe waived its immunity by offering what the drugmaker said amounted to a “protective service.”

The PTAB has not decided one way or the other whether tribal sovereign immunity applies to IPRs, though experts have said it would appear that it does, given previous rulings that patents owned by state universities are shielded from board review by similar state protections.

But even if tribal sovereign immunity does apply, and it's decided the licensing deal is not a sham, some

believe there are still questions about whether Allergan gave up enough rights in its patents to require that the tribe be included in any review.

Allergan appears to have structured the licensing deal similar to one that was involved in an earlier PTAB case involving NeoChord Inc. and the University of Maryland.

NeoChord in that case argued that Harpoon Medical, which had a license to use the university's patents, should be considered the "effective patentee." But the PTAB said the university held onto enough rights that the IPR couldn't go ahead without it.

Allergan is looking for a similar result here, but there are no guarantees.

"It's still an open question whether or not that's going to be sufficient to pass muster to be able to assert immunity," Zachary Silbersher, a partner at Kroub Silbersher & Kolmykov PLLC, told Law360 last month.

--Editing by Brian Baresch and Mark Lebetkin.