

Tribal sovereign immunity in patent cases questioned

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In a creative attempt to shield its patents from invalidity, the pharmaceutical company Allergan, PLC has assigned six patents covering its popular dry-eye drug Restasis to the Saint Regis Mohawk Tribe – a recognised tribal sovereign.

In a lawsuit filed under the Hatch-Waxman Act, Allergan asserted its patents against several companies seeking to develop generic equivalents to the Restasis product, including Teva Pharmaceuticals and Mylan Pharmaceuticals. The defendants filed counterclaims for invalidity of the patents and initiated *inter partes* review proceedings at the US Patent and Trademark Office for all six of the patents. Shortly before an oral hearing in the *inter partes* reviews, Allergan entered into a transaction with the tribe, in which the former:

- assigned the patents to the tribe;
- paid a lump sum of \$13.75 million to the tribe;
- received an exclusive licence to those patents from the tribe; and
- agreed to pay annual royalties of \$15 million to the tribe as long as the patents were not invalidated.

The Restasis products represent about \$1.5 billion in annual revenue to Allergan.

Shortly after the assignment, the tribe filed motions to dismiss in each of the *inter partes* reviews on the basis that it has sovereign immunity. Allergan stated that the *inter partes* review process, which was implemented in 2012 and administered through the Patent Trial and Appeal Board, was "flawed and broken". Allergan further maintained that it had no objection to the validity of the patents being challenged, as long as that challenge takes place only in the federal courts. In their motions to dismiss, the tribe's attorneys held that:

"the Tribe is a sovereign government that cannot be sued unless Congress unequivocally abrogates its immunity or the Tribe expressly waives it. Neither of these exceptions apply here. As Patent Owner, the Tribe is an indispensable party to this proceeding whose interests cannot be protected in its absence."

The tribe's motions to dismiss remain pending and are fully briefed as of this report.

Despite Allergan's efforts to claim sovereign immunity in the *inter partes* review proceedings, Judge William Bryson of the Eastern District of Texas ruled on October 16 2017 that four of the asserted Restasis patents were invalid based on obviousness. In a related order which added the Saint Regis tribe as a plaintiff, the court expressed scepticism about the arrangement:

"Sovereign immunity should not be treated as a monetizable commodity that can be purchased by private entities as part of a scheme to evade their legal responsibilities... If that ploy succeeds, any patentee facing [inter partes review] proceedings would presumably be able to defeat those proceedings by employing the same artifice."

Some members of Congress are concerned that tribal sovereign immunity is being exploited, and a new bill has been introduced which prevents tribes from asserting sovereign immunity in *inter partes* reviews. In her statement to a pharmaceutical group, Senator Claire McCaskill said that "this is one of the most brazen and absurd loopholes I've ever seen, and it should be illegal". McCaskill's bill simply states that "notwithstanding any other provision of law, an Indian tribe may not assert sovereign immunity as a defense in a review that is conducted under chapter 31 of title 35, United States Code".

If such a bill is passed and signed into law, patent holders may question whether sovereign immunity is a viable strategy to avoid invalidation, at least in the context of *inter partes* review proceedings.



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