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Insights: Alert

Tribal Immunity Cannot Shield Patents from IPR

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The Federal Circuit determined in an opinion last week that tribal sovereign immunity does not apply in an inter partes review (IPR) challenge to patent validity. *Saint Regis Mohawk Tribe v. Mylan Pharmaceuticals Inc.* (July 20, 2018). The dispute began when Allergan asserted patents related to RESTASIS® treatment for dry eye against a number of generic drug companies. Several of the defendants responded by filing IPR petitions challenging the validity of Allergan's asserted patents. After institution of the IPRs, Allergan assigned the challenged patents to the Saint Regis Mohawk Tribe, which then moved to terminate the IPRs on the basis of sovereign immunity. The Patent Trial and Appeal Board (PTAB) denied the Tribe's motion, and the Tribe appealed.

The Federal Circuit noted that Native American tribes, as domestic dependent nations, are generally immune from suits, absent a clear waiver or abrogation by Congress. However, the Court held such immunity does not apply where a federal agency "engages in an investigative action or pursues an adjudicatory agency action." The Tribe had argued that IPRs are contested, adjudicatory proceedings, distinguishable from an agency action because petitioners, not the agency, define the contours of the proceedings. The generic drug companies countered that an IPR is merely a reconsideration of a government agency grant. The Federal Circuit acknowledged that IPRs are hybrids of agency and contested, adjudicatory proceedings but reasoned that several factors weigh in favor of deeming IPRs an agency action. The government enjoys broad discretion in whether to institute an IPR and can proceed with an instituted IPR even in the absence of petitioner participation. Further, rules of procedure in federal courts and the PTAB are significantly different.

In ruling that tribal sovereign immunity does not bar IPRs, the Federal Circuit notably declined to determine whether state sovereign immunity would be treated differently. The PTAB has held previously that state sovereign immunity can bar an IPR but that, when a state entity asserts the patents in federal court, the entity waives sovereign immunity. In February, the Regents of the University of Minnesota (Minnesota) appealed a decision by the PTAB denying Minnesota's motion to dismiss an IPR Thus, the Federal Circuit will soon have an opportunity to address applicability and waiver of state sovereign immunity.

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