SAINT REGIS MOHAWK TRIBE v. MYLAN PHARMACEUTICALS, INC., Appeal Nos. 2018-1638 to -1643 (Fed. Cir. July 20, 2018). Before Dyk, Moore, and Reyna. Appealed from the Patent Trial and Appeal Board.

Background:

Allergan was involved in an ongoing dispute with several generic drug manufacturers over its patents relating to dry eye treatment. In 2015, Allergan sued the generic drug manufacturers in the Eastern District of Texas, alleging infringement. The manufacturers then petitioned the PTAB for *inter partes* review (IPR) of the patents. The Board instituted IPR and scheduled a consolidated oral hearing. Before the hearing, Allergan transferred title of its patents to the Saint Regis Mohawk Tribe. The Tribe then moved to terminate the IPRs, asserting tribal sovereign immunity, and Allergan moved to withdraw. The Board denied both motions.

Issue/Holding:

Did the PTAB err in finding tribal sovereign immunity does not apply in IPRs?
No, affirmed.

Discussion:

Indian tribes are generally entitled to sovereign immunity. Derived from common law, the immunity protects the dignity of the sovereign tribes by precluding private parties from haling tribes before a tribunal. However, this immunity does not extend to actions brought by the federal government. Whether a federal agency proceeding is considered to be an "action brought by the federal government" depends on whether the proceeding is more like an agency enforcement action, or a civil suit brought by private parties. Fed. Maritime Comm'n v. S.C. State Ports Auth., 535 U.S. 743 (2002) ("*FMC*").

The Tribe contended that tribal sovereign immunity applies in IPRs under *FMC* because IPRs are adjudicatory proceedings between private parties in which the petitioner, and not the USPTO, defines the contours of the proceeding. In contrast, the manufacturers argued that IPRs are more like traditional agency actions, where the Board is reconsidering a grant of a government franchise.

The Federal Circuit acknowledged that an IPR is a "hybrid proceeding" with both adjudicatory characteristics and characteristics of a specialized agency proceeding. It looked to the following four factors in determining IPRs are more like agency enforcement actions than civil suits brought by private parties: (1) the Director has broad discretion to institute IPRs; (2) once an IPR is initiated, the Board may continue review regardless of party involvement; (3) IPR procedural rules are substantially different from those used in court proceedings; and (4) IPRs are not that different from reexaminations (in which the Tribe conceded sovereign immunity would not apply). Thus, the Federal Circuit held that tribal sovereign immunity does not apply in IPRs.

Judge Dyk concurred, providing a detailed history of IPRs and stating that while IPRs have some features similar to civil litigation, IPRs remain at their core more like an agency reconsideration of a patent grant. For example, IPRs do not require adjudication of infringement or the exercise of personal jurisdiction, a characteristic which itself suggests sovereign immunity does not apply.