



No *Inter Partes* Review Sovereign Immunity For Restasis® Patents

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On February 23, 2018, the Patent Trial and Appeal Board of United State Patent and Trademark Office (“the Board”) denied Saint Regis Mohawk Tribe’s (“the Tribe”) motion to terminate *inter partes* review (“IPR”) proceedings based on the Tribe’s sovereign immunity. See *Mylan Pharma Inc. et al. v. Saint Regis Mohawk Tribe*, Case IPR2016-01127, slip op. (Fed. Cir. Feb. 23, 2018).

In December 2016, the Board instituted IPR proceedings on patents identified in FDA’s Orange Book as covering Allergan’s Restasis® drug product (“the challenged patents”). *Id.* at 2 and 5. On September 8, 2017, Allergan assigned ownership of the challenged patents to the Tribe. See *id.* at 5. On that same day, the Tribe and Allergan also entered into a Patent License Agreement (“License”) granting Allergan “an irrevocable, perpetual, transferable and exclusive license” to the challenged patents “for all FDA-approved uses in the United States.” *Id.* at 6. Two weeks later, on September 22, 2017, the Tribe filed its motion to terminate the IPR based on the doctrine of tribal sovereign immunity. See *id.* at 2-3.

The Board denied the Tribe’s motion to terminate holding that (1) the Tribe failed to establish that it was entitled to assert its tribal immunity in the IPR proceedings; (2) the Tribe’s license agreement with Allergan Inc. (“Allergan”) permitted Allergan to retain “all substantial rights” in the challenged patents; therefore, IPR proceedings may continue with Allergan as the patent owner, and (3) the Tribe was not an indispensable party. See *id.* at 40.

To reach its conclusion that the tribal immunity does not apply to IPR proceedings, the Board first recognized that there is no controlling precedent or statutory basis for the application of tribal immunity in IPR proceedings. See *id.* at 7-10. The Board further explained that Indian tribe’s sovereignty is subject to the superior and plenary control of Congress, and “general Acts of Congress apply to Indians . . . in the absence of a clear expression to the contrary.” *Id.* at 11. The Board looked to congressional intent explaining that “Congress has given the Patent Office statutory authorization both to *grant* a patent limited in scope to patentable claims and to reconsider the patentability of those claims via *inter partes* review.” Thus, the Board held that tribes cannot impose sovereign immunity to bar the federal government from exercising its trust obligations. See *id.* at 11-13. In addition, the Board reasoned that the IPR proceeding is not the type of “suit” to which an Indian tribe would traditionally enjoy immunity under the common law, and the Board would neither restrain the Tribe from acting nor compel it to act in any manner based on IPR decisions. *Id.* at 16. Indeed, reconsideration of the patentability of issued claims via IPR proceedings is appropriate without regard to the identity of the patent owner therefore, tribal immunity does not serve as a basis to terminate these proceedings. *Id.* at 18.

The Board then determined that Allergan is considered to be the effective patent owner because Allergan “has been granted all substantial rights under the patent is considered the owner regardless of how the parties characterize the transaction that conveyed those rights.” *Id.* at 19. In making that determination, the Board explained that under the License (1) Allergan (not the Tribe) primary control over “commercially relevant infringement proceedings;” (2) the Tribe was granted “only contingent, illusory rights to enforce the patents;” (3) Allergan has the exclusive right to make, use, and sell products or services under the patent, and the terms of the License do not allow the Tribe to control Allergan’s (or any other licensee’s) commercial activities with regard to the challenged patents; (4) Allergan retained “all licenses and other rights (*including sublicense rights*



relating to any Generic Equivalent”); (5) Allergan’s rights are “perpetual” and “irrevocable;” (6) Tribe cannot receive a portion of the proceeds from any of Allergan’s commercially relevant litigation or licensing activities; (7) Allergan has the primary right, but not the obligation, to prosecute and maintain the challenged patents, as well as the responsibility for any “Administrative Proceedings” before the PTO; (8) the Tribe cannot freely assign its interests in the challenged patents. *Id.* at 19-34. Accordingly, based on these factors, the Board determined that Allergan remains the effective patent owner, and accordingly the IPR proceedings can continue with Allergan’s participation only, regardless of whether tribal immunity applies to the Tribe. See *id.* at 35.

In addition, the Board held that the Tribe is not an indispensable party. *Id.* at 35. The Board reasoned that the Federal Rules of Civil Procedure (“FRCP”) do not apply to IPR proceedings, and the specific rules for IPR proceedings do not have an analogous requirement for joinder of indispensable parties. *Id.* at 36. In addition, the Board found that, even if FRCP Rule 19(b)(1) applies here, Allergan has at least an identical interest to the Tribe—if not more of an interest as the effective patent owner for the reasons discussed above—to defend the challenged patents. See *id.* at 37. Notably, all evidence and substantive briefing on patentability were complete before the patents were assigned to the Tribe. See *id.* at 38. Thus, for these reasons, the Board held that the Tribe would not be significantly prejudiced if it chooses not to participate. *Id.* at 36-39.

Further, the Board discounted the Tribe’s argument that if the IPR proceedings were terminated, the petitioners had adequate remedy based on the co-pending litigations in the Eastern District of Texas noting that the asserted claims and patents were not the same as those in the IPR proceedings, and that the evidentiary standard for IPRs differs from that of litigations. See *id.* at 39. Notably, Judge Bryson, sitting by designation in the Eastern District of Texas, raised the concern that “Allergan purports to have sold the patents to the Tribe, but in reality it has paid the Tribe to allow Allergan to purchase—or perhaps more precisely, to rent—the Tribe’s sovereign immunity in order to defeat the pending IPR proceedings in the PTO.” *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-CV-1455-WCB, 2017 WL 4619790, at *2 (E.D. Tex. Oct. 16, 2017). Despite this concern, and without holding that the patent assignment to the Tribe was valid, Judge Bryson ordered the joinder of the Tribe in the E.D. Tex. litigation “in order to ensure that any judgment entered in this case will be protected against challenge that the proper parties were not all joined as plaintiffs.” *Id.* at *5. In a separate decision that also issued on October 16, 2017, Judge Bryson found that the asserted claims of the patents-in-suit in the E.D. Tex. litigation were invalid as obvious. See *Allergan, Inc. et al. v. Teva Pharmaceuticals USA, Inc.*, No. 15-CV-1455-WCB, 2017 WL 4803941, at *65 (E.D. Tex. Oct. 16, 2017).

The issue presented to the Board was one of first impression. Thus, the *Mylan* decision marks the first holding that the tribal sovereign immunity doctrine should not apply to IPR Proceedings. The *Mylan* decision makes clear that IPR proceedings may continue with the party that has been granted all substantial rights under the patent as the effective patent owner.

For more information on the matters discussed in this *Locke Lord QuickStudy*, please contact the authors.

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