

**UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA,  
INC., and AKORN INC.,  
Petitioners,

v.

ALLERGAN, INC.,  
Patent Owner.

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Case IPR2016-01127 (8,685,930 B2)

Case IPR2016-01128 (8,629,111 B2)

Case IPR2016-01129 (8,642,556 B2)

Case IPR2016-01130 (8,633,162 B2)

Case IPR2016-01131 (8,648,048 B2)

Case IPR2016-01132 (9,248,191 B2)

***AMICUS CURIAE* BRIEF OF JAMES R. MAJOR, D.PHIL.  
IN SUPPORT OF PETITIONERS' OPPOSITION TO  
ST. REGIS MOHAWK TRIBE'S MOTION TO DISMISS**

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*Amicus Curiae* James R. Major, D.Phil. (“Amicus”) hereby submits this brief in support of Petitioners’ Opposition to St. Regis Mohawk Tribe’s Motion to Dismiss (Paper 87) to Corrected Patent Owner’s Motion to Dismiss for Lack of Jurisdiction Based on Tribal Sovereign Immunity (Paper 81) (the “Motion”).

Amicus takes no position as to the applicability, if any, of tribal sovereign immunity in *inter partes* review proceedings and is submitting this brief to provide arguments that may assist the Board in deciding the Motion. The arguments herein do not necessarily reflect the views of: (i) Major IP Law PLLC or its clients; (ii) Lucas & Mercanti, LLP or its clients; or (iii) any associations of which Amicus is a member. Amicus has no direct financial or controlling interests in any of the parties to the above-identified proceedings.

## **ARGUMENT**

### **I) The Express Rights that the Tribe Retains Are Illusory**

Under the Patent License Agreement between Saint Regis Mohawk Tribe and Allergan, Inc. Dated as of September 8, 2017 (the “Agreement”), Saint Regis Mohawk Tribe (the “Tribe”) “retains all rights under the Licensed Patents not expressly granted hereunder . . . .” Agreement (Ex. 2087) ¶ 2.4. The expressly-retained rights “includ[e] the right to use and practice the Licensed Patents for research, scholarly use, teaching, education, patient care incidental to the foregoing, sponsored research for itself and in collaborations with

Non-Commercial Organizations (‘Non-Commercial Uses’) . . . .” *Id.*

At first blush, the Tribe has apparently retained the right to practice, for example, the method of claim 1 of U.S. Patent No. 8,633,162 B2 (the “’162 Patent”) in caring for patients incidental to a research study. *See* ’162 Patent cl. 1 (“A method of treating dry eye disease . . . comprising topically administering to the eye of a human in need thereof an emulsion . . . .”) *and* Agreement, Schedule 1.32(a) (listing the ’162 Patent as a “Licensed Patent[.]”). However, if taken at its word, the Tribe *already had* the right to practice the Licensed Patents. This is because, as the Tribe urges, the Tribe has “inherent sovereign immunity.” Paper 81, 8. Even when Allergan, Inc. (“Allergan”) was the assignee of the Licensed Patents, the Tribe could, if taken at its word, assert sovereign immunity to defeat *any* suit of Allergan’s alleging infringement of the Licensed Patents.

Of course, the patent laws do not exist in a vacuum and there may be other laws and regulations that prevent the Tribe from practicing the Licensed Patents. Allergan assigned to the Tribe all rights in the Licensed Patents by way of a Patent Assignment Agreement dated September 8, 2017. Ex. 2086. However, Allergan *could not* exempt the Tribe from any law or regulation at least on the principle of *nemo dat quod non habet*: a party cannot give what it does not have.

Because the Tribe already had the express rights that the Tribe purportedly “retained” in the Agreement, the express rights that the Tribe retains are illusory.

## **II) The Right of the Tribe to Enforce the Licensed Patents in Infringement Suits Unrelated to a Generic Equivalent Is Nugatory**

“With regard to any Infringement that does not relate to a Generic Equivalent, as between the Parties, [the Tribe] shall have the first right, but not the obligation, to control and prosecute any past, present or future Infringement with respect to the Licensed Patents . . . .” Agreement ¶ 5.2.3. Therefore, “the Tribe has the first right to enforce the [Licensed Patents] for all infringement unrelated to generic equivalents of Restasis®.” Patent Owner’s Reply to Opp’n to Mot. to Dismiss for Lack of Jurisdiction Based on Tribal Sovereign Immunity (Paper 93), 2. While these rights appear important, they are nominal on closer inspection.

While the Tribe purportedly retains some rights under the Agreement, the Tribe has agreed “not [to] directly or indirectly develop, market or license any Competing Product or engage in or license activities that would and/or are intended to result in a Competing Product.” Agreement ¶ 2.4. A “‘Competing Product’ means any Generic Equivalent or any product other than a Licensed Product that is developed or approved by the FDA for any indication that includes or is the same as any indication for which any Licensed Product is approved by the FDA.” Agreement ¶ 1.10 (emphasis in original omitted). Written slightly differently, a Competing Product “means ~~any Generic Equivalent or any product other than a Licensed Product~~ that is developed or approved by the FDA for any

indication that includes or is the same as any indication for which any Licensed Product is approved by the FDA.” An example of one such Competing Product would be a compounded, non-FDA-approved product for an indication for which the FDA has approved a Licensed Product such as Restasis<sup>®</sup> (cyclosporine ophthalmic emulsion). *See* Paper 93, 2. However, the Tribe has agreed to refrain from activities that would result in such a product. And this would doom any possible suit against the producer of a Competing Product.

Remedies for infringement of a patent include injunctions, lost profits, or damages no less than a reasonable royalty. *See* 35 U.S.C. §§ 283-84 (2012). However, the Tribe could not successfully seek any of these remedies.

Lost profits would be unavailable because the Tribe has agreed to refrain from activities that would result in a Competing Product. Additionally, the reasonable royalty would be zero. “[I]t seems unlikely that a willing licensor and willing licensee would agree to a zero royalty payment in a hypothetical negotiation, where both infringement and validity are assumed.” *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1328 (Fed. Cir. 2014). However, this is one such case. Shorn of any ability to license activities that would result in a Competing Product, the Tribe would not be a “licensor” in the hypothetical negotiation and no rational licensee would seek a license when none was available. *See Apple*, 757 F.3d at 1330 (citing 7 DONALD S. CHISUM, CHISUM ON PATENTS § 20.07[3][a]

(2011) (“The premise of the reasonable royalty measure is that a holder of a valid and infringed patent has inherently suffered legal damage *at least to the extent of a lost license royalty opportunity.*”) (emphasis added)).

To obtain a permanent injunction:

A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

*eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). However, the Tribe would have suffered no injury in equity because the *eBay* Court rejected the proposition that infringement of a valid patent was injury *per se*. *eBay*, 547 U.S. at 393-94. The Tribe would have also suffered no monetary damages as described above, and the balance of the hardships would certainly favor an alleged infringer for the same reasons. Finally, the public interest would certainly not be served by enjoining the alleged infringer without good reason.

In sum, any infringement suit that the Tribe has the first right to bring would fail. Therefore, the right of the Tribe to enforce the Licensed Patents in infringement suits unrelated to a Generic Equivalent is nugatory.



### **III) The Rights that the Tribe Do Retain Are Insufficient to Support a Holding that the Tribe Retains All Substantial Rights in the Licensed Patents**

Despite the arguments above, the Tribe does retain some rights, such as the right to enforce the Licensed Patents in connection with Generic Equivalents if Allergan does not do so. Agreement ¶ 5.2.2. However, that right is *contingent*. In any event, there would be no remedy in light of the Tribe's agreement to refrain from activities that would result in a Competing Product. *See infra* § II. Another right is to provide written consent to Allergan before Allergan can settle an infringement suit related to a Generic Equivalent. Agreement ¶ 5.2.2. But that consent is all but meaningless, given that the Tribe would receive no financial benefit from any such settlement. *See* Agreement ¶¶ 4.1 and 4.2 (providing for payments of flat fees). Merely holding title to the Licensed Patents and having a mixture of other, inconsequential rights is insufficient to support a holding that the Tribe retains all substantial rights in the Licensed Patents.

## **CONCLUSION**

Because the Agreement has stripped the Tribe of any meaningful rights in the Licensed Patents, the Board should hold that Allergan is the true owner of the Licensed Patents and deny the Motion.

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Respectfully submitted,

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## **CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. §§ 42.6(3)(4) and 42.205(b), the undersigned certifies that on December 1, 2017, a complete entire copy of the *Amicus Curiae* Brief of James R. Major, D.Phil. in Support of Petitioners' Opposition to St. Regis Mohawk Tribe's Motion to Dismiss was provided, via electronic service, to the persons named below at their address of record, viz:

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