UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., AKORN, INC., MYLAN PHARMACEUTICALS INC., MYLAN INC., and INNOPHARMA, INC. Defendants.	Civil Action No. 2:15-cv-1455-WCB (Consolidated) LEAD CASE **REDACTED PUBLIC VERSION**

DEFENDANTS' BRIEF OPPOSING JOINDER OF THE SAINT REGIS MOHAWK TRIBE AS A CO-PLAINTIFF

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The transaction between Allergan and the St. Regis Mohawk Tribe ("the Tribe") is a sham and should be disregarded by the Court. As Allergan's CEO, Brent Saunders, has repeatedly, publicly admitted, the **only** reason for this transaction is to shield its patents from cancellation. Ex. 7 at 1. This transaction was not a genuine purchase of intellectual property by the Tribe. Rather, Allergan paid for the use of the Tribe's sovereign immunity to thwart the parallel *inter partes* reviews ("IPRs") before the Patent Trial and Appeal Board ("PTAB").

Allergan admitted as much in its October 10 filing with the Court conceding that the alleged "consideration" provided by the Tribe was nothing more than the Tribe's promise not to waive its sovereign immunity in the IPR proceedings. Thus, there has been no real change in ownership—just a maneuver to derail the PTAB's ongoing review of Allergan's patents.

The sham nature of the transaction with the Tribe is further underscored by the fact that the Tribe did not pay Allergan a cent for the patents claiming Restasis, which generated $1.4 billion in 2016 sales, or $4 million dollars a day. Instead, *it was Allergan* who paid the Tribe $13.75 million up-front to take faux title to the Restasis patents. Dkt. No. 510, Ex. F at 4; Ex. 8 at 1-2 (the Tribe notifying its members that it "is not investing any money in this business" and "[i]ts only role is to hold the patents"). Thus, Allergan, which has already enjoyed an almost 15 year monopoly, bought up to an additional six years of exclusivity on Restasis for less than 1% of Restasis' annual sales (or approximately four days of Restasis sales). *See* Ex. 9 at 2.

Using this sham transaction, Allergan now wishes to join the Tribe as a co-plaintiff under Federal Rule of Civil Procedure 25(c). Rule 25(c) is discretionary and permits joinder upon a transfer of interest. But there has been no actual transfer of interest. Allergan continues to hold all of the patent rights, [redacted]. The

Tribe lacks any such rights. Further, the illicit purpose of the transaction—to subvert the PTAB's lawful review and not to facilitate this litigation—provides ample reason to deny joinder.

It bears noting in this context that Allergan used the IPR process against a third party's patent that was inconvenient for Allergan's best-selling Botox franchise only one year ago. Allergan even sought a stay of parallel district court proceedings on the ground that the IPR "would save both judicial and party resources, consistent with Congress' intent in passing the America Invents Act." Allergan Memorandum in Support of Motion Stay, No. 1:15-cv-03372, Dkt. No. 40 at 1-2 (N.D. Ill.). It is remarkable that Allergan considered the IPR process a valid, equitable proceeding for challenging patent validity when it filed its own IPR petition just last year—yet, now that the same tribunal is scrutinizing Allergan patents, Allergan and the Tribe consider IPRs "double jeopardy" administered by a "kangaroo court." *See* Ex. 4 at 3. Given its own recent, successful reliance on IPRs, Allergan's attempt to justify its sham assignment by labeling the IPR process inequitable, harmful "double jeopardy" is pure hypocrisy. Ex. 7 at 2; Dkt. No. 510, Ex. J at 2-3.

In any event, even taking the transaction at face value, Allergan retains all substantial rights in the patents. The Tribe cannot be considered the patent owner for purposes of standing and cannot be joined as a co-plaintiff in this suit because it lacks the requisite exclusionary rights. *See generally Azure Networks, LLC v. CSR PLC*, 771 F.3d 1336, 1347 (Fed. Cir. 2014).

I. BACKGROUND

A. The admitted purpose of the transaction is to extend the Tribe's sovereign immunity to Allergan's Restasis patent portfolio to derail the IPRs.

One week before the PTAB was set to hold a hearing in the co-pending IPRs on the patents-in-suit, Allergan purported to assign the patents to the Tribe. One might naturally assume that the Tribe paid Allergan handsomely to acquire the patents covering a drug that generates annual revenues in excess of $1 billion—but that assumption would be wrong. Ex. 2 at 1. Dale White, general counsel for the Tribe, proudly declared: "[T]his transaction didn't require the tribe to give up any land or money in entering an agreement that provides a significant upside to the tribal community." Ex. 1 at 3. In fact, *Allergan paid the Tribe* $13.75 million upfront to hold nominal title to the patents. *See, e.g.*, Dkt. No. 510, Ex. F at 4; Dkt. No. 506, Ex. C at § 4.1; Dkt. No. 511, Ex. K. The Tribe is also eligible to receive a royalty of up to $15 million per year for the life of the patents. *See, e.g.*, Dkt. No. 510, Ex F at 4; Dkt. No. 506, Ex. C at § 4.2.

Allergan and the Tribe have freely admitted the illicit purpose of the transaction in press releases, statements to the media, in communications to the House and Senate, and in filings with this Court. As the same-day joint press release asserts, the purpose of the transaction was "to strengthen the defense of our [Allergan's] RESTASIS® intellectual property" by having the Tribe invoke sovereign immunity to terminate the IPR proceedings. Dkt. No. 481, Ex. 1 at 1; *see also* Dkt. No. 510, Ex. F at 1, 4; Dkt. No. 510, Ex. G at 1-2. The Tribe has separately confirmed the improper purpose of the transaction.[1] Dkt. No. 510, Ex. H at 1-2; Dkt. No. 510, Ex. I at 1-2. And Allergan has admitted in writing to the Senate Judiciary Committee that the purpose of the transaction was to shield its patents from review before the PTAB. Dkt. No. 510, Ex. J at 3-4.

Indeed, even in the context of this litigation, Allergan has freely admitted that the alleged "good and valuable consideration" it received from the Tribe for the assignment was the Tribe's agreement to assert the defense of sovereign immunity in the related IPRs. Dkt. No. 510 at 3-4.

[1] For example, in its own press release, a week after the deal was signed, the Tribe argued that it was only trying to emulate "the same business model and legal positions long employed by public universities and other state sovereigns" who "partner and serve as incubators for start-up companies and large industrial companies to help bring products to market, often with the sovereigns retaining title to the intellectual property." Dkt. No. 510, Ex. H at 1-2. Yet the Tribe fails to note that it played no role in bringing the Restasis product to market; in fact, it played no role at all in this entire litigation, attempting to make an appearance only *after* trial concluded.

The statements of Allergan's Chief Legal Officer, Robert Bailey, and the Tribe's lawyer, Michael Shore of Shore Chan DePumpo LLP ("Shore Chan"), are especially illuminating. For example, Mr. Bailey told *Fortune* magazine that the deal was not Allergan's idea; rather, Shore Chan approached the Tribe and proposed the deal as a way to expand its revenue to include a patent-holding business venture. Ex. 2 at 2. Michael Shore has since admitted to the Wall Street Journal that he came across the Tribe while searching for an Indian tribe willing to take advantage of the "arbitrage opportunity" he perceived as a result of the PTAB's sovereign immunity rulings involving state universities. Ex. 3 at 4.[2] Mr. Shore explained that "[w]e approached a couple of tribes with the idea and they thought we were insane." Ex. 1 at 3.

According to Mr. Shore, after signing the Tribe as a client, his firm scoured the PTAB's docket and identified Allergan "as a company that looked like their needs were acute." Ex. 3 at 4-5. Mr. Shore told the Wall Street Journal that the Tribe proposed a deal in early August and is trying to reach more. *Id.* at 5. Mr. Shore has also unapologetically explained that the purpose of the transaction is to insulate Allergan's Restasis patents from "what has been perceived as a kangaroo-court type atmosphere where all the expectations of patentees that have existed for 150 years are thrown out of the window." Ex. 4 at 3. The hypocrisy of Mr. Shore's assertion is acute when one examines Allergan's own exploitation of post-grant challenges at the PTAB. For

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[2] IPWatchdog also published a quote from Mr. Shore in which he stated: "[I]f you can find a sovereign which is willing to take advantage of that arbitrage, there is money to be made there." Ex. 1 at 2. The "arbitrage" that Mr. Shore is referencing is that the Tribe benefits from the upfront payment and licensing fees while Allergan benefits from protecting the Retasis patents by shielding them behind the tribe's sovereign immunity. *Id.* Mr. Shore said the same thing to a reporter from Intellectual Asset Management who interviewed him alongside the Tribe's general counsel. *See* Ex. 4. Shore stated: "We realized that there's an arbitrage here – there's the value of a non-sovereign patent which is much lower than the value of a sovereign patent." *Id.* at 2.

example, Allergan filed an IPR petition to bolster its Botox franchise, scoring a victory this year against a third-party patent directed to administering botulinum toxin. *See* IPR2016-00102.

In sum, it is apparent from the statements of Allergan, the Tribe, and their counsel that the true purpose of the agreement is to appropriate sovereign immunity in an attempt to shield the Restasis patents from review by the PTAB. The transaction does not represent a bona fide purchase of the patents by the Tribe. The alleged assignment of rights is indeed a sham.

B. The Tribe holds no actual rights; in a simultaneously executed license agreement Allergan took back all substantial and exclusionary rights.

Allergan purports to have assigned its patents to the Tribe in exchange for the allegedly valuable consideration of the Tribe's promise to assert its sovereign immunity in the IPRs. Dkt. No. 510 at 3-4. [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

This is not a mere field of use license as Allergan suggests. *See* Dkt. No. 510 at 4. [redacted]

Allergan has not identified or even suggested another field in which the Tribe has rights.

[redacted]

[redacted]

II. ARGUMENT

A. The assignment to the Tribe should be disregarded as a sham.

The Tribe should not be joined as a co-plaintiff because the assignment is a sham. The assignment lacks economic substance and is an example of the oft-condemned practice of trying to extend tribal sovereign immunity to non-tribal entities as well as the inappropriate practice of assigning legal claims to avoid the proper exercise of jurisdiction.[3] Because there has been no actual transfer of interest, Federal Rule of Civil Procedure 25(c) does not justify joinder.

1. The Tribe has not been assigned any rights; the transaction is like sham arrangements that have been condemned in other contexts.

A notable feature of this purported assignment is that payment went the wrong way: Allergan paid $13.75 million to the Tribe rather than demanding payment in exchange for its patents covering a drug that has demonstrated "substantial commercial success" including "an annual growth rate of 30%, nearly $8 billion dollars in revenue since launch, and net returns well in excess of research and development costs." Dkt. No. 453 at 14-15. Indeed, Restasis accounts for about 10% of Allergan's overall revenue and is Allergan's second-biggest selling product behind Botox. Ex. 3 at 2; Ex. 2 at 1. As Allergan's Chief Legal Officer, Mr. Bailey, told the New York Times in a recent interview: "It's one of our most valuable products . . ." Ex. 5 at 3.

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[3] In the event that the Court finds that the transaction in question is a sham, Defendants reserve the right to assert unenforceability of the patents due to unclean hands. *See, e.g.*, *Gilead Scis., Inc. v. Merck & Co., Inc.*, No. 13-cv-04057-BLF, 2016 WL 3143943, at *1 (N.D. Cal. June 6, 2016) (holding asserted patents unenforceable due to a pattern of misconduct constituting unclean hands); s*ee generally Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 241 (1933) (requiring that "[h]e who comes into equity must come with clean hands.").

So why pay the Tribe to take the patents covering Allergan's "crown jewel"? Aug. 28 PM Trial Tr. 90:2 (Reis). The intent was to create the *appearance* of tribal ownership for purposes of asserting sovereign immunity in the IPRs, while in fact allowing Allergan to retain exclusive and unencumbered rights [redacted]. Thus, no rights were actually transferred; just the assignment of nominal title with the understanding that (in exchange for $13.75 million) the Tribe would assert sovereign immunity in the IPRs.

Sham transactions need not be fraudulent or illegal; they can be merely distortive, evasive, or manipulative, tending in some way to unfairly use the laws to undermine policy aims or goals. *See* Joshua D. Blank & Nancy Staudt, *Corporate Shams*, 87 N.Y.U. L. Rev. 1641, 1643-44 (2012); *see also* Ex. 6 at 5, Simpson et al., *Sham Transactions*, Oxford University Press (2013), Chapter 4 on U.S. at p. 69. The assignment of title to the Tribe and the grant-back of all meaningful rights in the patents to Allergan falls squarely within this definition of a sham. Courts have considered sham transactions in various contexts that aid with understanding this case.

First, Courts have encountered similar transactions in tax cases where parties transfer interests in an attempt to reduce tax liability. Courts look suspiciously at transactions "which do not vary control or change the flow of economic benefits . . ." *Higgins v. Smith*, 308 U.S. 473, 476 (1940). The idea behind the above described "economic substance" doctrine is that tax benefits should not be reaped from sham transactions lacking in economic reality. *See generally Klamath Strategic Inv. Fund ex rel. St. Croix Ventures v. United States*, 568 F.3d 537, 543 (5th Cir. 2009); *see also Coltec Indus., Inc. v. United States*, 454 F.3d 1340, 1353-54 (Fed. Cir. 2006); *Salem Fin., Inc. v. United States*, 786 F.3d 932, 943 (Fed. Cir. 2015). Such transactions are shams and "a lack of economic substance is sufficient to invalidate the transaction regardless of whether the taxpayer has motives other than tax avoidance." *Klamath*, 568 F.3d at 544.

Similarly, the purpose of the transaction between Allergan and the Tribe was to reap the benefit of avoiding scrutiny before the PTAB using a transaction lacking in economic substance. [redacted] the true purpose of the transaction was to transfer nominal title to the Tribe so that the Tribe would assert sovereign immunity in the related IPRs while still allowing Allergan to retain [redacted] rights [redacted] The transaction left Allergan's ability [redacted], entirely intact.

Accordingly, as a matter of economic substance, the transaction did not alter Allergan's rights in the patents; its only purpose was to create the appearance of Tribal ownership.

Second, both federal and state courts have encountered attempts to stretch a tribe's sovereign immunity to non-tribal entities, most notably in the context of "payday" lending, or short-term lending associated with high interest rates. *See* Nathalie Martin & Joshua Schwartz, *The Alliance Between Payday Lenders and Tribes: Are Both Tribal Sovereignty and Consumer Protection at Risk?*, 69 Wash. & Lee L. Rev. 751, 764-67 (2012). Justice Thomas noted this trend and voiced concern in his dissent in *Michigan v. Bay Mills Indian Cmty.*:

> [T]ribal immunity has . . . been exploited in new areas that are often heavily regulated by States. For instance, payday lenders (companies that lend consumers short-term advances on paychecks at interest rates that can reach upwards of 1,000 percent per annum) often arrange to share fees or profits with tribes so they can use tribal immunity as a shield for conduct of questionable legality . . . Indian tribes have also created conflict in certain States by asserting tribal immunity as a defense against violations of state campaign finance laws . . . As long as tribal immunity remains out of sync with this reality, it will continue to invite problems, including *de facto* deregulation of highly regulated activities.

134 S. Ct. 2024, 2052 (2014) (Thomas, J., dissenting). Courts have not hesitated to disregard such schemes as shams. For example, in *People ex rel. Owen v. Miami Nation Enters.*, 2 Cal. 5th

222 (2016) the Supreme Court of California declined to extend tribal sovereign immunity to a tribally owned lender notwithstanding the existence of formal arrangements, whole-tribal ownership, the creation of corporate entities pursuant to tribal law, the express intent to extend tribal immunity to the entity, the seating of tribal members on the board of directors, and some amount of the profits going to support tribal operations. *Id.* at 250-56. Because the tribal entities maintained little control over the lending business (*id*. at 251) and the percentage of the profits going to the tribe appeared to be "very small," what the *Owen* court assumed to be "1 percent of gross revenues from the online lending operations" (*id*. at 232, 255), the court concluded that the arrangement was not one to which tribal sovereign immunity should extend. *Id.* at 251.[4]

Like the payday lending scheme condemned as a sham in *Owen*, Allergan's deal with the Tribe is an attempt to clothe the Restasis patents with sovereign immunity without giving the Tribe [redacted] The license agreement reserves [redacted] While the agreement makes the Tribe eligible to receive a royalty, that royalty represents only a paltry one percent of Allergan's annual Restasis revenues—the same as in the *Owen* case.

As articulated in *Owen*: "[T]ribal immunity is intended to promote the federal policy of tribal self-governance, which includes economic self-sufficiency, cultural autonomy, and the

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[4] *See also Commonwealth of Pennsylvania v. Think Fin., Inc.*, No. 14-cv-7139, 2016 WL 183289, at *5-8 (E.D. Pa. Jan. 14, 2016) (involving "rent-a-tribe" scheme in which tribe acted as "nominal lender" for a payday lending operation managed and controlled by non-Indians; rejecting claim of tribal indispensability under Fed. R. Civ. P. 19(a) on grounds that the tribe and its non-Indian partners shared the "same interest" in defending the legality of the scheme).

tribe's 'ability to govern itself according to its own laws.'" *Id.* at 245 (quoting *Three Affiliated Tribes of Fort Berthold Reservation v. Wold Eng'g*, 476 U.S. 877, 891 (1986)). The question is whether "the dignity that immunity doctrine accords to the tribe by virtue of its sovereign status should extend to the entity by virtue of its status as a tribal affiliate." *Id.* at 245. The present case falls squarely within the zone of exploitation that courts have condemned. Allergan continues to [redacted] profit from its billion-dollar drug franchise while the Tribe asserts rights, unique to its cultural identity, premised on the importance of being able to autonomously self-govern.

Third, courts have found assignments of legal claims to be shams where the assignment is simply a way for one or both parties to defeat the proper exercise of jurisdiction. Litigants may not "manipulat[e]" jurisdiction through assignments that "lack reality and amount to no change in the identity of the party with the real interest in the outcome of the case." *Attorneys Trust v. Videotape Computer Prods., Inc.*, 93 F.3d 593, 597 (9th Cir. 1996); *see also Kramer v. Caribbean Mills, Inc.*, 394 U.S. 823, 827 (1969) (party may not use assignment that is "a mere contrivance, a pretense, the result of a collusive arrangement" to alter jurisdiction) (citations and internal quotes omitted). Among "the classic elements of an assignment which does not affect jurisdiction" are where the purported assignee "had no prior interest" in the matter prior to the assignment; the purported assignor retained significant control and most of the profits; the assignee paid little if any consideration; and there is evidence the "real motive" was to destroy jurisdiction. *Attorneys Trust*, 93 F. 3d at 598-599; s*ee also In re BP p.l.c. Sec. Litig.,* No. 10-md-2185, 2016 WL 29300, at *7-9 (S.D. Tex. Jan. 4, 2016) (holding that an assignment of legal claims that had no articulated business-related justification, where the claimants admitted that the assignments were for the sake of expediency, inappropriately allowed them to "avoid several of the carefully crafted rules of federal procedure and evidence," and thus were inoperable).

Allergan's alleged assignment falls squarely within these elements thus demonstrating that the assignment is a sham. As discussed above in Section I.B., not only does the Tribe [redacted] it also had no prior interest in or connection with this particular litigation. Moreover, the Tribe did not just pay "little if any consideration;" instead, it was the assignor (Allergan) who paid the assignee (the Tribe) to take the patents off its hands for a paltry 1% of Restasis' annual profits.

Finally, Allergan has repeatedly emphasized both to this Court and to the public at large that the real motive—the sole justification for the assignment—was to try to defeat the PTAB's exercise of jurisdiction in the IPRs. In at least this regard, Allergan's alleged assignment to the Tribe mirrors those sham agreements made to defeat jurisdiction. The assignment is an improper attempt to confer the Tribe's sovereign immunity on Allergan's Restasis patents, not a bona fide transfer of patent rights to the Tribe. Thus, the Court should disregard the assignment as a sham.

2. The lack of valid consideration for the assignment confirms that the transaction is a sham that is injurious to the interests of society.

As confirmatory evidence of the sham, Allergan has astonishingly admitted that the only "good and valuable" consideration supporting the assignment of its patents to the Tribe is the Tribe's attempt to confer the benefits of its sovereignty to Allergan to derail the IPRs. Dkt. No. 510 at 3-4. Allergan has not cited any relevant law supporting the assertion that a promise to interfere with a lawful process qualifies as valid consideration sufficient to dignify the contract. While Allergan cites cases that contain a rote mention of "black letter law" or "hornbook law," *id.*, the underlying facts of those cases supply no precedent in support of recognizing the Tribe's promise to invoke its inherent sovereign immunity as valid consideration for a patent assignment.

For a contract to be enforceable, there must be proper consideration. *Hartman v. Harris*, 810 F. Supp. 82, 85 (S.D.N.Y. 1992), *aff'd*, 996 F.2d 301 (2d Cir. 1993). If the consideration requires a party to do that which the party does not have the legal right to do, especially where the transaction is "injurious to the interests of society," then the contract is void. *Alsaedi v. Alsaedi*, 177 Misc. 2d 440, 442 (N.Y. Civ. Ct. 1998) (voiding a contract for the transfer of a lottery license where transfer violated a statute enacted to protect the public health and safety, on grounds such an agreement is "injurious to the interests of society in general, and that the only way to stop the making of such contracts is to refuse to enforce them"). Similarly, consideration consisting of an act or forbearance which is contrary to public policy will render the contract void and unenforceable. *See Village of Upper Nyack v. Christian & Missionary All.*, 143 Misc. 2d 414, 421, 540 N.Y.S.2d 125 (Sup. Ct. 1988). In this context, "[t]he term 'public policy' has been defined as the principle which declares that no one can lawfully do that which has a tendency to be injurious to or against the public good will or welfare." *Id.* (citation omitted).

Here, the alleged consideration requires the Tribe to do something that it has no right to do: extend its sovereign immunity to a non-tribal beneficiary, Allergan, who is indisputably not a tribal sovereign. Dkt. No. 510 at 3-4; Ex. 8 at 1-2 (the Tribe informing its members that its only role will be to "hold the patents"). That is flatly illegal. *Washington v. Confederated Tribes of the Colville Indian Reservation*, 447 U.S. 134, 155 (1980) ("[i]t is painfully apparent that the value marketed by the" tribes, "and what is not available elsewhere, is solely an exemption" from otherwise-applicable law); *Otoe-Missouria Tribe of Indians v. N.Y. Dept. of Fin. Servs*, 769 F.3d 105, 114, 116 (2d Cir. 2014) (tribes may not "profit from leveraging an artificial comparative advantage," and have "*no legitimate interest in selling an opportunity to evade [the] law*") (emphasis added); *Barona Band of Mission Indians v. Yee*, 528 F.3d 1184, 1187, 1190 (9th Cir. 2008) (non-Indians may not paper over the "the economic reality of a transaction" to cloak themselves in tribal sovereignty as a way to "circumvent" the law and "reap a windfall at the public's expense"). For like reasons, transferring nominal title to create the appearance of tribal ownership for the purpose of defeating jurisdiction, while keeping all significant rights with the non-tribal entity, is injurious to the interests of society and the dignity of sovereign immunity.

As observed by members of the Congressional Committee on Oversight and Government Reform: "The implications of Allergan's patent transfer raise questions for Congress as the exchange may impair competition across the pharmaceutical industry and ultimately dissuade companies from pursuing less-costly generic alternatives to brand drugs." Ex. 11 at 2.[5]

The scheme also offends the dignity that immunity doctrine accords to the tribe by virtue of its sovereign status because, in light of the simultaneously executed license, Allergan has taken back the actual rights. *Owen*, 2 Cal. 5th at 245. Over the entirety of the transaction, the Tribe has given its sovereign immunity as consideration for no substantial rights in the patents.

Accordingly, the purported assignment should be disregarded as a sham and as lacking in valid consideration. As recognized by the *Alsaedi* court, the "only way to stop the making of such contracts is to refuse to enforce them." 177 Misc. 2d at 442.

3. Because the transaction is a sham, joinder of the Tribe under Federal Rule of Civil Procedure 25(c) is not appropriate.

Allergan asserts that it seeks to join the Tribe as a co-plaintiff under Federal Rule of Civil Procedure 25(c). *See* Dkt. No. 505 at 2-4. Allergan has not identified any other basis for joining

[5] *See also* Ex. 9 at 1, Letter of the Association for Accessible Medicines (AAM) to Congress (Oct. 10, 2017) ("Allergan's questionable business practice threatens patient access to needed health treatments, threatens the underpinnings of the U.S. patent system and runs afoul of congressional intent in enacting a legal pathway for generic competition."); Ex. 10, *Ars Technica* Policy Post (Oct. 9, 2017) (article reporting that Senator Claire McCaskill has introduced a bill to abrogate sovereign immunity of Indian Tribes as a defense in inter partes review of patents); Ex. 12 at 5-6, Jay et al. (Goodwin Procter LLP), AAM White Paper, *Patent-Assignment Transactions Between Brand-Name Drug Companies and Native American Tribes Will Undermine A Healthy Patent System and Harm Patients* (Oct. 12, 2017) (assessing Allergan's efforts to avoid IPRs).

the Tribe as a party. Rule 25(c) allows permissive joinder of parties based on a "transfer of interest." Fed. R. Civ. P. 25(c) ("If an interest is transferred . . ."). Because the alleged transfer is illusory, and because permissive joinder should be denied in view of the illicit purpose of the purported transfer, Rule 25(c) does not provide an appropriate basis for joining the Tribe.

Rule 25(c) is "wholly permissive." Wright, Miller, & Kane, 7C Fed. Prac. & Proc. Civ. § 1958 (3d ed.). Rule 25(c) allows, but does not require, that a transferee be joined. *Id.* The decision whether to join a transferee under Rule 25(c) is within the sole discretion of the Court based on whether the presence of the transferee "would facilitate his conduct of the litigation." *Television Reception Corp. v. Dunbar*, 426 F.2d 174, 178 (6th Cir. 1970); *accord Matter of Covington Grain Co., Inc.*, 638 F.2d 1362, 1364 (5th Cir. 1981); *Minnesota Min. & Mfg. Co. v. Eco Chem., Inc.*, 757 F.2d 1256, 1263-64 (Fed. Cir. 1985). Allergan has not identified any reason why joining the Tribe would facilitate the conduct of this litigation. Nor can it. [redacted] Moreover, the trial of this case had already been completed by the time the transaction between Allergan and the Tribe occurred, making it impossible for the addition of the Tribe at this late date to facilitate the litigation in any way.

To the contrary, adding the Tribe as a co-plaintiff at this juncture may complicate issues including but not limited to Allergan's prayer for injunctive relief (and scope or basis for any such relief) as well as Allergan's reservation of the right to correct inventorship under 35 U.S.C. § 256 should the Court conclude that the patents do not name the correct inventive entity.

More fundamentally, Rule 25(c) is inapposite because there has been no genuine transfer of patent rights and therefore no actual transfer of interest. Rule 25(c) does not apply when a transfer has not occurred. *See Torres v. Krueger*, 596 F. App'x 319, 322 (5th Cir. 2015) (reciting the conditions under which Rule 25(c) may be applied and declining to join a party on grounds that "[t]here was no such transfer here"). Because the transaction is a sham, admittedly designed to extend tribal sovereign immunity to the Restasis patents rather than a bona fide assignment of the patent rights to the Tribe, the Court can and should disregard it as such. Allergan continues to hold all substantial rights and the Tribe lacks any exclusionary rights to be asserted in this suit. In sum, because the Tribe is not a bona fide transferee, Rule 25(c) by its terms does not apply.

B. Because Allergan retains all substantial rights, the Tribe lacks standing.

Even if one leaves the sham nature of the transaction to one side and takes the agreement at face value, the Tribe cannot be joined as a co-plaintiff because the Tribe has transferred all substantial rights back to Allergan. Allergan, and not the Tribe, is the true patent owner.

The Federal Circuit has long recognized that an exclusive license can function as an effective assignment conveying patent ownership for purposes of standing: "[T]he question is whether the license agreement transferred sufficient rights to the exclusive licensee to make the licensee the owner of the patents in question. If so, the licensee may sue but the licensor may not." *Alfred E. Mann Found. for Sci. Research v. Cochlear Corp.*, 604 F.3d 1354, 1360 (Fed. Cir. 2010). "[A]n exclusive license may be tantamount to an assignment for purposes of creating standing if it conveys to the licensee all substantial rights to the patent at issue." *Aspex Eyewear, Inc. v. Miracle Optics, Inc.*, 434 F.3d 1336, 1340 (Fed. Cir. 2006). When a patentee transfers rights in a patent, the "party that 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." *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1250 (Fed. Cir. 2000). Whichever party holds all, or substantially all, of the rights "*alone* has standing to sue for infringement." *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1340 (Fed. Cir. 2007) (emphasis added).

The Federal Circuit's analysis in *Azure*, 771 F.3d 1336 (Fed. Cir. 2014), is on all fours with this case and illustrates when the nominal title-holder may not join in suit. In *Azure*, a patent holder (Azure) involved local charities in its patent-enforcement activities by partnering with a nonprofit entity and donating all of its patents to the entity (Tri-County). *Id.* at 1340-41. Tri-County then granted Azure an exclusive license, transferring back all substantial rights in the patents and giving Azure control over the enforcement of the patents along with a number of other rights indicative of effective ownership. In *Azure*, the Federal Circuit affirmed the district court's denial of Azure's motion to join Tri-County as a co-plaintiff because it lacked all substantial rights in the patents as well as any exclusionary rights in the patents. *Id.* at 1342-47. In this case, the Tribe retains even fewer rights than the nominal patent owner (Tri-County) in *Azure*. Thus, the Federal Circuit's reasoning in *Azure* prohibits the Tribe from joining suit.

Specifically, to determine whether an exclusive license is tantamount to an assignment, the Court "must ascertain the intention of the parties [to the license agreement] and examine the substance of what was granted." *Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA*, 944 F.2d 870, 874 (Fed. Cir. 1991). Courts generally consider a non-exhaustive list of rights for determining whether a licensor has transferred "all substantial rights" to the licensee, including:

> (1) the nature and scope of the right to bring suit; (2) the exclusive right to make, use, and sell products or services under the patent; (3) the scope of the licensee's right to sublicense; (4) the reversionary rights to the licensor following termination or expiration of the license; (5) the right of the licensor to receive a portion of the proceeds from litigating or licensing the patent; (6) the duration of the license rights; (7) the ability of the licensor to supervise and control the licensee's activities; (8) the obligation of the licensor to continue paying maintenance fees; and (9) any limits on the licensee's right to assign its interests in the patent.

Azure, 771 F.3d at 1342-48. "[T]he nature and scope of the exclusive licensee's purported right to bring suit, together with the nature and scope of any right to sue purportedly retained by the licensor, is the most important consideration." *Mann*, 604 F.3d at 1361; *see also Aspex Eyewear*, 434 F.3d at 1342 (a "key factor has often been where the right to sue for infringement lies").

Where a licensor and its licensee seek to sue jointly on the patents, the inquiry is two-fold: "(1) whether [the licensor] transferred all substantial rights [to the licensee], making [the licensee] the effective owner; and *if so*, (2) whether [the licensor] may nevertheless join in an infringement suit brought by the licensee . . ." *Azure*, 771 F.3d at 1342. Under the second step, parties who "hold less than all substantial rights to the patent and lack exclusionary rights under the patent statutes" lack standing. *Morrow*, 499 F.3d at 1340-41. A party that "does not have any exclusionary rights . . . lacks standing to join the suit as a co-plaintiff." *Azure*, 771 F.3d at 1347. That defect is not cured by the presence of the licensee that holds the exclusionary rights. *Id.*

1. Each of the *Azure* factors precludes joinder of the Tribe; Allergan holds all substantial rights and the Tribe lacks exclusionary rights.

Each of the factors specified in *Azure* demonstrates that Allergan, not the Tribe, holds all substantial rights in the patents. [redacted]

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[6] [redacted]

[redacted]

The restrictions placed on the Tribe also demonstrate that Allergan has retained all of the exploitable patent rights. [redacted]

[redacted]

[redacted]

[redacted]

[redacted] [redacted]

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7 [redacted]

[redacted]

The Federal Circuit has repeatedly held that reserving at least some degree of control over these activities is critical to demonstrating that patents have not been effectively assigned to the exclusive licensee. *See generally Azure*, 771 F.3d at 1343-44; *Propat Int'l Corp. v. RPost, Inc.*, 473 F.3d 1187, 112 (Fed. Cir. 2007) (noting that retention of right to veto, be consulted about, or give consent to litigation decisions weighs in favor of finding a license as opposed to an assignment); *Mann*, 604 F.3d at 1362-63 (noting that right to have joint control over litigation or right to bring suit if licensee refuses to bring suit would also indicate that licensor retained substantial rights); *Speedplay*, 211 F.3d at 1251 (holding that licensor retained no veto rights over licensee's litigation activities and that the licensee's complete control over litigation suggested that licensee obtained all substantial rights); *Vaupel*, 944 F.2d at 875 (holding that patentee's reservation of the right only to be informed about litigation, without reserving a right to dictate or control litigation decisions, suggested an assignment as opposed to a license).

Under the second step of the *Azure* test, the Tribe has not retained any exclusionary rights in this suit. [redacted]

[redacted] Accordingly, the Tribe lacks standing and cannot be joined as a co-plaintiff.

2. Other provisions confirm that Allergan holds all substantial rights; Allergan's rights are not actually limited to a "field of use."

Allegan holds additional rights that are strongly indicative of effective ownership. [redacted] The Federal Circuit has explained that the retention of such rights "is inconsistent with an assignment of the patents." *AsymmetRx, Inc. v. Biocare Med., LLC*, 582 F.3d 1314, 1320 (Fed. Cir. 2009) (highlighting that the party holding all substantial rights had retained a great deal of control over licensed products in the commercial field—a regulated diagnostic use—with respect to FDA filings and prosecution and maintenance of the patents); *see also FlowRider Surf*, 2017 WL 2349031, at *8 (holding controlling patent prosecution and the payment of maintenance fees can "demonstrat[e] . . . the effective owner of the patent . . .").

Stretching to identify a limit on the rights it has reserved for itself, Allergan characterizes the agreement as a "field-limited" license. Dkt. No. 505 at 1, 3. [redacted] While Allergan states that the Tribe has "retained enforcement rights and rights to practice the patents *in all other fields*" Allergan does not identify or even suggest one. Dkt. No. 505 at 3 (emphasis added).

The field-of-use restriction is illusory. Field of use licenses "divide the scope of a patent right by its subject matter." *Int'l Gamco, Inc. v. Multimedia Games, Inc.*, 504 F.3d 1273, 1278 (Fed. Cir. 2007).[8] The rights in question cannot go beyond the scope of the patents. *United States v. Line Material Co.*, 333 U.S. 287, 353 (1948) ("If the limitations in a license reach beyond the scope of the statutory patent rights, then they must be tested by the terms of the Sherman Act.").

[redacted] The patents are directed to therapeutic uses. The patents do not describe or claim non-therapeutic uses. Allergan itself has argued that there are no substantial non-infringing uses because, even though a drug may be prescribed for off-label uses, "[s]uch unauthorized activity does not avoid infringement by a product that is authorized to be sold solely for the infringing use." Dkt. No. 352 at 19 (quoting *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App'x 917, 927 (Fed. Cir. 2011)). [redacted]

[redacted]

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[8] In *A123 Sys., Inc. v. Hydro-Quebec*, cited by Allergan (Dkt. No. 505 at 3), the field-of-use license specified two distinct fields of use: (1) an exclusive license to manufacture, use, sell, import, and offer for sale rechargeable batteries with a *solid* electrolyte, gelled, plasticized or not plasticized, and (2) an exclusive and worldwide license to manufacture and sell lithium iron phosphate in bulk quantities for all applications, including, but not limited to, secondary batteries with polymer or liquid electrolytes. 626 F.3d 1213, 1217 (Fed. Cir. 2010).

[redacted]

In sum, Allergan has not identified, nor does the agreement suggest, any field of use other than the field Allergan has broadly reserved for its exclusive commercial and legal exploitation.

III. CONCLUSION

The Court should not join the Tribe as a co-plaintiff. Allergan's purported transfer of patent rights to the Tribe should be disregarded as a sham. But even if the transaction is taken at face value, Allergan holds all substantial rights in the patents and the Tribe has not retained any exclusionary rights. Therefore, the Tribe lacks standing and cannot be joined as a co-plaintiff.

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Respectfully submitted,

/s/ *Douglas H. Carsten*
Douglas H. Carsten
Wendy Devine
Christina E. Dashe
Alina L. Litoshyk
WILSON SONSINI GOODRICH & ROSATI
12235 El Camino Real, Suite 200
San Diego, CA 92130-3002
Tel: 858-350-2300
Fax: 858-350-2399
dcarsten@wsgr.com
wdevine@wsgr.com
cdashe@wsgr.com
alitoshyk@wsgr.com

Anna G. Phillips
Texas Bar No. 24090329
WILSON SONSINI GOODRICH & ROSATI
900 South Capital of Texas Highway
Las Cimas IV, Fifth Floor
Austin, TX 78746-5546
Tel: 512-338-5400
Fax: 512-338-5499
anphillips@wsgr.com

Melissa Smith
Allen Franklin Gardner
GILLAM & SMITH LLP
303 S. Washington Ave.
Marshall, Texas 75670
Tel: 903-934-8450
Fax: 903-934-9257
melissa@gillamsmithlaw.com
allen@gillamsmithlaw.com

COUNSEL FOR DEFENDANTS MYLAN PHARMACEUTICALS INC. AND MYLAN INC.

/s/ *J.C. Rozendaal*
J.C. Rozendaal (*pro hac vice*)
Michael E. Joffre (*pro hac vice*)
R. Wilson Powers III (*pro hac vice*)
Pauline M. Pelletier (*pro hac vice*)
William H. Milliken (*pro hac vice*)
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Ave. NW, Suite 600
Washington, DC 20005
Tel: 202-371-2600
Fax: 202-371-2540
jcrozendaal@skgf.com
mjoffre@skgf.com
tpowers@skgf.com
ppelletier@skgf.com
wmilliken@skgf.com

COUNSEL FOR DEFENDANT TEVA PHARMACEUTICALS USA, INC.

/s/ *Michael R. Dzwonczyk*
Michael R. Dzwonczyk
Azadeh Kokabi
Mark Boland
Aiyda Ghahramani
SUGHRUE MION PLLC
2100 Pennsylvania Ave NW, Suite 800
Washington, DC 20037
Tel: 202-293-7060
Fax: 202-293-7860
mdzwonczyk@sughrue.com
akokabi@sughrue.com
mboland@sughrue.com
acobb@sughrue.com

Thomas A. Rammer
Sailesh K. Patel
SCHIFF HARDIN LLP
233 S. Wacker Drive, Suite 7100
Chicago, IL 60606
Tel: 312-258-5537
Fax: 312-258-5600
trammer@schiffhardin.com
spatel@schiffhardin.com

John K. Hsu
SCHIFF HARDIN LLP
901 K Street NW, Suite 700
Washington, DC 20001
Tel: 202-778-6467
Fax: 202-778-6460
jhsu@schiffhardin.com

George Chih-Lun Yu
SCHIFF HARDIN LLP
One Market, Spear Street Tower
Suite 3200
San Francisco, CA 94105
Tel: 415-901-8700
gyu@schiffhardin.com

Earl Glenn Thames, Jr.
POTTER MINTON
110 N College Avenue, Suite 500
Tyler, TX 75702
Tel: 903-597-8311
Fax: 903-593-0846
glennthames@potterminton.com

COUNSEL FOR DEFENDANT AKORN, INC.

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was filed electronically in compliance with Local Rule CV-5(a). Therefore, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by e-mail on October 13, 2017.

/s/ *J.C. Rozendaal*
J.C. Rozendaal