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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
GREAT FALLS DIVISION**

TAKEDA PHARMACEUTICALS)	
AMERICA, INC.; TAKEDA)	
PHARMACEUTICALS U.S.A, INC.,)	
f/k/a TAKEDA PHARMACEUTICALS)	
NORTH AMERICA, INC.; and)	Case No. CV-14-50-GF-BMM-RKS
TAKEDA PHARACEUTICAL)	
COMPANY, LIMITED,)	
)	
Plaintiffs,)	
)	
v.)	DEFENDANT’S BRIEF IN
)	SUPPORT OF HIS MOTION TO
VICTOR CONNELLY,)	DISMISS FOR LACK
)	OF JURISDICTION
Defendant.)	

COMES NOW the Defendant Victor Connelly, pursuant to *F. R. Civ. Pro.* 12(b)(1) and hereby submits his brief in support of his motion to dismiss the Complaint in this matter for failure to exhaust tribal court remedies.

BACKGROUND

Plaintiffs, Takeda Pharmaceuticals America, Inc., Takeda Pharmaceuticals U.S.A., Inc, F/K/A Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceutical Company Limited (hereinafter referred to as “Takeda”) bring this action seeking an injunction against the Defendant Victor Connelly attempting to prevent him from pursuing his claims in the Blackfeet Tribal Court.

Plaintiffs erroneously characterize Connelly’s tribal court action as an attempt to “legislate or regulate the sale of prescription drugs in the United States”. *ECF Doc. 1*, para. 42. Plaintiffs wrongly assert that their actions which are the subject of the Blackfeet Tribal Court proceeding occurred outside of the Blackfeet Indian Reservation. *ECF Doc. 1*, Para. 39. The Plaintiffs falsely claim that there is no consensual commercial relationship between them and Defendant Connelly.

Based on these erroneous statements, Takeda asks this court to declare that the Blackfeet Tribal Court has no jurisdiction over them. As a part of that argument, Takeda wrongly asserts that it should not be required to exhaust its tribal court remedies before turning to this Court for relief.

The Plaintiffs voluntarily and knowingly distributed and marketed their drug, into the stream of commerce, to doctors, hospitals and in particular the Indian Health Service, knowing and intending that their drug be purchased from them and prescribed to end user individuals including Indian people who receive medical

services from the Indian Health Service. That drug, “Actos” (Pioglitazone), was prescribed to and taken by Victor Connelly and without adequate warning as to the drug’s dangers and side effects, specifically that it creases the risk of bladder cancer, which Mr. Connelly subsequently developed on multiple occasions following the use of the drug.

The drug, Actos (Pioglitazone), was sold into the Blackfeet Indian Reservation, prescribed on the Blackfeet Indian Reservation and ingested within the Blackfeet Indian Reservation by numerous Blackfeet including Mr. Connelly. In this regard all of the Plaintiffs’ actions occurred on Indian trust land within the exterior boundaries of the Blackfeet Indian Reservation. Further, Defendant Connelly was an intended third party beneficiary of the consensual commercial relationship between the Plaintiffs and the Indian Health Service.

For these reasons, applying applicable Federal Indian law principals, the Blackfeet Tribal Court has plausible jurisdiction. Consequently the Plaintiffs must exhaust their tribal court remedies. No exception to the exhaustion requirement exists.

JURISDICTIONAL FACTS

The Defendant herein, Victor Connelly, an enrolled member of the Blackfeet Indian Tribe and resident of the Blackfeet Indian Reservation, brought an action in the Blackfeet Tribal Court against the Takeda Plaintiffs for violations of the

Blackfeet Consumer Sales Practices Act, and various common law torts including strict products liability, negligence, gross negligence, breach of various express and implied warranties, misrepresentation and fraud.

Connelly brought his Blackfeet Tribal court action against Takeda for the resulting and re-occurring bladder cancer sustained as a proximate result of being prescribed and ingesting the defective and unreasonably dangerous drug Actos (pioglitazone).

Actos is a prescription medication used to control blood sugar (glucose) in adults with Type II diabetes.

Connelly was prescribed and ingested Actos from 2005 to early 2012, always on Indian trust lands and within the boundaries of the Blackfeet Indian Reservation.

Connelly's Actos prescriptions were always prescribed and filled on tribal trust lands within the exterior boundaries of the Blackfeet Indian Reservation, and Takeda was the sole manufacturer, seller, and distributor of Actos during this entire time.

Also during this time, Takeda engaged in an aggressive "Marketing Strategy" to "Drive ACTOS business in all IHS facilities" including: Direct mail – letter to pharmacy chiefs, Broadcast E-mail by the Head of the IHS, Partnering opportunities with IHS National Headquarters, Hospital/Sales formulary

announcement leave behinds, Hospital/Sales IHS National Core Formulary Card; and IHS formulary sales verbatim.

Takeda further targeted individual Indian Health Services facilities, including the Indian Health Service Blackfeet Community Hospital serving the Blackfeet Indian Tribe, through aggressive financial incentives that rewarded higher market share at each facility.

Takeda clearly had a consensual commercial relationship with the Indian Health Service for the sale and distribution of its drug Actos. Defendant Connelly was an intended third party beneficiary of this lucrative consensual commercial relationship.

The essence of the Blackfeet Tribal Court complaint is that Takeda knowingly distributed a drug which they knew or should have known was unreasonably dangerous to individuals like Victor Connelly, without adequate warning of the side effects and dangers of the drug. The Blackfeet Tribal Court is not attempting to regulate or legislate the sale of prescription drugs in the United States.

Takeda has challenged the Tribal court's jurisdiction asserting that because they are non-Indians who do not consent to the Tribal court's jurisdiction and whatever took place occurred on non-Indian fee land, the Tribal court lacks

jurisdiction over them. Takeda's motion to dismiss is still pending in the Blackfeet Tribal Court.

LAW AND ARGUMENT

Based on the current prevailing principles of Federal Indian law, Mr. Connelly need only show the Blackfeet Tribal court has a plausible claim to jurisdiction. Plaintiffs must fully exhaust their remedies in the Blackfeet Tribal juridical system including a trial on the merits and appellate proceedings before seeking review by this Court. Based on prevailing federal law principles the Plaintiffs' action herein must be either dismissed or stayed pending the outcome of the Blackfeet Tribal Court proceedings.

a. Exhaustion of Tribal Court Remedies.

The law at this point in time is clear: While non-Indians may bring a federal common law cause of action to challenge a tribal court's jurisdiction, the non-Indian must first exhaust tribal court remedies. *Elliot v. White Mountain Apache Tribal Court*, 566 F.3d 842 (9th Cir. 2008). The exhaustion requirement is rooted in a respect for the principle of comity "and deference to the tribal court as the appropriate court of first impression to determine its jurisdiction." *Grand Canyon Skywalk Development LLC v. Sa Nyu Wa Incorporated*, 715 F.3d 1196, 1199 (9th Cir. 2013), citing *National Farmers Union Ins. Co. v. Crow Tribe of Indians*, 480 U.S. 9, 15-16, *Burlington Northern R.R. Co. v. Crow Tribal Council*,

949 F.2d 1239, 1244-1247 (9th Cir. 1993). Support for this premise was articulated by the United States Supreme Court as: (1) Congress’s commitment to “a policy of supporting tribal self-government and tribal self-determination”; (2) a policy that allows” the forum whose jurisdiction is being challenged the first opportunity to evaluate the factual and legal basis for the challenge”; and (3) judicial economy, which will best be served “by allowing a full record to be developed in the Tribal Court”. *National Farmers*, 473 U.S. at 856.

The exhaustion requirement is not a jurisdictional bar, but rather a prerequisite to a federal court’s exercise of its jurisdiction. *Crow Tribal Council*, 940 F.2d at 1245 n.3. “Therefore under *National Farmers*, the federal court should not even make a ruling on tribal court jurisdiction until tribal remedies are exhausted.” *Stock West, Inc. v. Confederated Tribes of the Colville Reservation*, 873 F.2d 1221, 1228 (9th Cir. 1989).

Consequently the requirement of exhaustion of tribal remedies is not discretionary, it is mandatory. *Crawford v. Genuine Parts Co. Inc.*, 947 F.2d 1405 (9th Cir. 1991).

Exhaustion of tribal court remedies is not mandatory where “an assertion of tribal jurisdiction is motivated by a desire to harass or is conducted in bad faith, or where the action is patently violative of express jurisdictional prohibitions, or where exhaustion would be futile because of the lack of opportunity to challenge

the court's jurisdiction, or where it is plain that no federal grant provides for tribal governance of non-members' conduct on land governed by Montana's main rule. *National Farmers Union v. Crow Tribe*, 471 U.S. 845,856 (1985); *Crawford v. Genuine Parts Co. Inc.*, 947 F.2d 1405, 1415 (9th Cir. 1991); *Grand Canyon Skywalk Development LLC v. Sa Nyu Wa Incorporated*, 715 F.3d 1196 (9th Cir. 2013).

Takeda wrongly asserts that it should not be required to exhaust its tribal court remedies because exceptions to this requirement exist here. Takeda asserts that it should not be required to exhaust tribal court remedies because jurisdiction is plainly lacking, the action is motivated by a desire to harass or is in bad faith, and that exhaustion would be futile. Contrary to the assertions in Takeda's complaint, none of the exceptions to the exhaustion requirement are applicable on the facts of this case.

b. Plausible Tribal Court Jurisdiction.

Takeda first argues that tribal court jurisdiction here is plainly lacking, one of the exceptions to the requirement of exhaustion of tribal remedies rule.

In *Atwood v. Fort Peck Tribal Court Assiniboine*, 513 F.3d 943, 948 (9th Cir. 2008), the court held that where tribal jurisdiction is "plausible", then the exhaustion of tribal court remedies applies. See also *Allstate Indemnity Co. v.*

Stump, 191 F.3d 1071, 1075-76 (9th Cir. 1999). The jurisdiction of the Blackfeet Tribal Court is clearly “plausible” on the facts alleged by Defendant Connelly.

In *Montana v. United States*, 450 U.S. 544, the United States Supreme Court stated: "A tribe may regulate, through taxation, licensing, or other means, the activities of nonmembers who enter consensual relationships with the tribe or its members, through commercial dealing, contracts, leases, or other arrangements. A tribe may also retain inherent power to exercise civil authority over the conduct of non-Indians on fee lands within its reservation when that conduct threatens or has some direct effect on the political integrity, the economic security, or the health or welfare of the tribe." *Id.* at 565-66 (*citations omitted*).

Both prongs of this test have applicability here.

1. Consensual commercial relationship.

The Blackfeet Tribal Court has jurisdiction over this matter because Plaintiffs were in a voluntary consensual commercial relationship with the Indian Health Service, which is the exclusive medical provider for Tribal members within the Blackfeet Indian Reservation, and Plaintiffs sold their product to that exclusive medical provider, under its voluntary and hard-fought sales contract, for which Victor Connelly was an intended third party beneficiary.

It is clear Takeda was engaged in consensual commercial activity within the Blackfeet Indian Reservation over which the Tribe has jurisdiction. At all times

material hereto, Mr. Connelly was being prescribed, and was purchasing and ingesting Takeda's product, all within the Blackfeet Reservation, for which Takeda was receiving a financial profit, at the risk of Mr. Connelly and other Indian People. All of which took place on Indian trust land (not non-Indian fee land) within the Blackfeet Indian Reservation.

Takeda's actions here bring it under the jurisdiction of the Tribal Court pursuant to *Williams v. Lee*, 358 U.S. 217 (1959) and *Smith v. Salish Kootenai College*, 434 F.3d 1127 (9th Cir. 2006)(*en banc*)(applying *Williams v. Lee* to find tribal court jurisdiction). In both *Williams* and *Smith* the courts found that because the non-Indian had voluntarily engaged in consensual contracts with Indians within a reservation, the tribal courts had jurisdiction over them. *Williams* involved a grocery store owner (Lee) doing business within an Indian Reservation. When *Williams* (an Indian) refused to pay, Lee brought suit in the state district court. *Williams* moved to dismiss asserting that the tribal court had exclusive jurisdiction. The Supreme Court agreed, noting that it was "immaterial that respondent was not an Indian. He was on the Reservation and the transaction with an Indian took place there." *William v. Lee*, 358 U.S. at 222,223

In *Smith v. Salish Kootenai College*, 434 F.3d 1127 (9th Cir. 2006), the Ninth Circuit Court of Appeals found that by simply engaging in the act of filing a complaint in the tribal court of the Confederated Salish and Kootenai Tribes,

Smith, a non-Indian, had created enough of a contract to support a plausible assertion of tribal court jurisdiction. *Smith*, 434 F2d. at 1140-1141.

In this instance, Takeda knowingly and voluntarily entered into a consensual commercial relationship with entities who provide services only to Blackfeet Tribal members, with intent that the Indian Health Service purchase their product, prescribe their product to tribal members, and have tribal members ingest that product within the Blackfeet Indian Reservation. They clearly come within the jurisdictional purview of the Tribal Court under both *Williams* and *Smith*.

As the Ninth Circuit Court of Appeals explained in *Smith*:

The Court's "consensual relationship" analysis under *Montana* resembles the Court's Due Process Clause analysis for purposes of personal jurisdiction. "The Due Process Clause protects an individual's liberty interest in not being subject to the binding judgments of a forum with which he has established no meaningful 'contacts, ties, or relations,' "the "constitutional touchstone" being "whether the defendant purposefully established 'minimum contacts' in the forum State." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462,471- 72,474, 105 S.Ct. 2174, 85 L.Ed.2d 528 (1985) (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316, 319, 66 S.Ct. 154, 90 L.Ed. 95 (1945)). Thus, the " 'unilateral activity of those who claim some relationship with a nonresident defendant cannot satisfy the requirement of contact with the forum State;' "rather it must be "actions by the defendant himself that create a 'substantial connection.' " *Id.* at 474, 105 S.Ct. 2174 (quoting *Hanson v. Denckla*, 357 U.S. 235,253, 78 S.Ct. 1228, 2 L.Ed.2d 1283 (1958), and *McGee v. Int'l Life Ins. Co.*, 355 U.S. 220, 223, 78 S.Ct. 199,2 L.Ed.2d 223 (1957)). In its due process analysis, the Court has emphasized the need for "predictability to the legal system" so that the defendant can

"reasonably anticipate being hauled into court." *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297, 100 S.Ct. 559, 62 L.Ed.2d 490 (1980).

Smith v. Salish Kootenai College, 434 F.3d at 1139.

Takeda has clearly met the "constitutional touchstone" requirement of purposefully establishing minimum contacts with tribal members within the Blackfeet Indian Reservation. The Plaintiffs, with the intent of making a profit and of having Blackfeet Tribal members ingest their drug, voluntarily marketed and distributed their drug (Actos) to the Blackfeet Indian Reservation with the intent that the drug be prescribed to and ingested by tribal members, including and in particular Victor Connelly. Takeda in fact sold their drug for profit on the Reservation and Victor Connelly ingested that drug on Indian trust land, thereby suffering serious injury. Finding tribal court jurisdiction on these facts is entirely consistent with prevailing federal Indian law principles.

Takeda's attempts to characterize the tribal court action as being one over activities occurring outside the Blackfeet Indian Reservation are simply wrong. While many of Takeda's marketing strategies and efforts occur outside the Reservation, the clear intent and purpose of those strategies was to secure an exclusive right to sell Actos to all Indian Health Service units across the country including the Blackfeet Community Hospital. To be clear, Indian Health Services did not seek to force Plaintiff to involuntarily sell and distribute Actos. More

importantly, Takeda succeeded in having its drug Actos be the only drug in its class distributed and supplied to Indian Health Service units, including Blackfeet.

The sole purpose of Takeda's efforts were to have Indian patients, like Victor Connelly prescribed Actos. Takeda's ultimate purpose was to have Indian patients become the end-user of its drug and created financial incentives that rewarded the higher market share at each facility through its "ACTOS Special Pricing Terms". That is how Takeda makes a profit – a substantial profit. It is out of this consensual commercial relationship between the Indian Health Service and Takeda that Victor Connelly is the intended beneficiary of Takeda's profit making enterprise.

Takeda's attempt to characterize the tribal court's preliminary assertion of jurisdiction as an impermissible effort to regulate and legislate the sale of pharmaceutical drugs in the United States should also be rejected. Nothing in Victor Connelly's tribal court complaint speaks of regulation or legislation in the area of prescription drugs in the United States. The complaint is, in essence, a products liability case.

2. Demonstrable Impact on Health and Welfare of Tribe.

"A tribe may also retain inherent power to exercise civil authority over the conduct of non-Indians on fee lands within its reservation when that conduct threatens or has some direct effect on the political integrity, the economic security,

or the health or welfare of the tribe." *Montana* 450 U.S. at 565-66 (*citations omitted*). The sale, distribution and ingestion of drugs through the Indian Health Service, which is the sole medical provider for Indians on the Reservation, clearly affects all tribal members and has a demonstrable effect on the health and welfare of the Tribe.

Because they are marketing, selling and promoting the use of their products within the Blackfeet Indian Reservation, the Plaintiffs fall within the adjudicatory authority of the Tribe.

3. Jurisdiction under Water Wheel Camp Recreation Area v. Larance and Grand Canyon Skywalk Development LLC v. SA NYU WA Incorporated.

In two recent cases, the Ninth Circuit Court of Appeals has held that where the underlying transaction did not occur on non-Indian fee land, the Montana test did not apply. In *Water Wheel Camp Recreational Area v. Larance*, 643 F.3d 802 (9th Cir. 2011), and in *Grand Canyon Skywalk Development LLC v. Sa Nyu Wa Incorporated*, 715 F.3d 1196 (9th Cir. 2013) the Ninth Circuit Court of appeals held that where non-Indians had entered into commercial transactions with Indians on Indian land, the Montana test did not apply.

Rather the tribes' inherent right to excluded non-Indians from their Reservation and Indian lands provided an independent basis for tribal court jurisdiction. That is the case here.

Victor Connelly was prescribed the drug Actos on Indian trust land. He ingested that drug on Indian trust land. Agents of Takeda sold the drug on Indian trust land. On these facts, applying the analysis of Water Wheel Camp and Grand Canyon Skywalk, this Court has jurisdiction because the underlying transactions and injuries occurred on Indian trust land and because Takeda voluntarily availed themselves of the Reservation in order to market and distribute their product and make a profit at the expense of Indian people like Victor Connelly.

c. The Tribal Court's preliminary assertion of jurisdiction is not intended to harass or conducted in bad faith.

In its complaint herein, Takeda asserts that it should not be required to exhaust tribal court remedies because Connelly's tribal court action is intended to harass or conducted in bad faith. Takeda misinterprets the "intended to harass or conducted in bad faith" exception to the exhaustion requirement and its claim in this regard should be rejected.

The so-called "bad faith or harassment" exception to exhaustion of tribal court remedies requirement was recently explained in the Grand Canyon Skywalk case. There the Ninth Circuit held, "that where, as here, a tribal court has asserted jurisdiction and is entertaining a suit, the tribal court must have acted in bad faith for exhaustion to be excused. Bad faith by a litigant instituting the tribal court action will not suffice." *Grand Canyon Skywalk*, 715 F.3d 1196, 1201 (9th Cir. 2013). The Ninth Circuit thus concluded that "it must be the Hualapai Tribal Court

that acts in bad faith to avoid the requirement to exhaust tribal court remedies.”

Grand Canyon Skywalk, 715 F.3d at 1202.

As the Ninth Circuit explained:

Additionally, a broader interpretation would unnecessarily deprive tribal courts of jurisdiction and violate the principles of comity that underlie the exhaustion requirement. A party would need only allege bad faith by the opposing party, or a third party, to remove the case to federal court. Comity principles require that we trust our tribal court counterparts can identify and punish bad faith by litigants as readily as we can. GCSD’s proposed reading of the exception would swallow the rule and undermine the Supreme Court’s principle of deference to tribal courts.

Grand Canyon Skywalk, 715 F.3d at 1202.

The Ninth Circuit concluded its discussion of the bad faith requirement by stating that, “[u]ltimately, where a tribe has an established judicial system as here, the interpretation most faithful to National Farmers is that it must be the tribal court that acts in bad faith to exempt the party from exhausting available tribal court remedies”. *Id.*

Applying these principles to Takeda’s bad faith argument mandates that it be rejected and Takeda required to exhaust its remedies in the Blackfeet Tribal Court. Takeda’s erroneous assertion of the bad faith exemption is clearly premised on mischaracterizations of Connelly’s tribal court complaint and on Connelly’s alleged conduct in the tribal court proceedings. *ECF Doc. No. 1*, paras. 62-65. Takeda alleges that Connelly’s decision to file in the Tribal Court as opposed to

filing in some other forum is bad faith, and that Connelly is conducting discovery in bad faith by seeking to depose a Takeda attorney who has already testified at trial and given numerous depositions regarding Takeda's violation of a litigation hold and the destruction of documents in other Actos-bladder cancer litigation across the country.

Takeda makes no allegation that the Tribal Court itself is acting in bad faith as required by the case law. Takeda's approach of bad faith by a litigant was expressly rejected by the Ninth Circuit in the Grand Canyon Skywalk case. It must be rejected here also.

d. Requiring exhaustion of Tribal Court remedies would not be futile.

Takeda's final claim that it should not be required to exhaust its tribal court remedies is that exhaustion would be futile. Once again, Takeda misinterprets the law and its claim must be rejected.

It is correct that the Ninth Circuit has held that where exhaustion would be futile because of the lack of opportunity to challenge a tribal court's jurisdiction, a party is excused from exhausting its claims in the tribal court. *Grand Canyon Skywalk*, 715 F.3d at 1203, citing *Burlington Northern R.R. Co. v. Red Wolf*, 196 F.3d 10590, 1065 (9th Cir. 1999). However, that exception has been narrowly construed to apply to only the most extreme cases. Thus in *Johnson v. Gila River Indian Community*, 174 F.3d 1032, 1036 (9th Cir. 1999), a two year delay in the

tribal appellate court was grounds for a remand to the Federal District Court to determine whether there was a functioning tribal appellate court, and in *Krempel v. Prairie Island Indian Community*, 125 F.3d 621, 622 (8th Cir. 1997, exhaustion was not required where there was no functioning tribal court.

That is not the situation at the Blackfeet Tribal Court and Takeda makes no such allegations in its complaint. Takeda's sole assertion regarding futility is that the Blackfeet Tribal Court has not yet acted on its motion to dismiss for lack of jurisdiction. The case is still in its infancy for procedural purposes and the Tribal Court has merely allowed further discovery to determine all the jurisdictional facts. Moreover, the tribal court's approach is consistent with the underlying principles of comity first articulated by the U.S. Supreme Court.

Those principles include deference to the tribal court as the appropriate court of first impression to determine its jurisdiction", *Grand Canyon Skywalk Development LLC v. Sa Nyu Wa Incorporated*, 715 F.3d 1196, 1199 (9th Cir. 2013), citing *National Farmers Union Ins. Co. v. Crow Tribe of Indians*, 480 U.S. 9, 15-16, *Burlington Northern R.R. Co. v. Crow Tribal Council*, 949 F.2d 1239, 1244-1247 (9th Cir. 1993, and a policy of that allows "the forum whose jurisdiction is being challenged the first opportunity to evaluate the factual and legal basis for the challenge". *National Farmers*, 473 U.S. at 856.

As with its other arguments that it is exempt from the rule requiring exhaustion of tribal court remedies, Takeda's argument regarding futility must also be rejected.

CONCLUSION

Because the Blackfeet Tribal Court has plausible jurisdiction, Takeda must first exhaust its tribal court remedies before seeking review by the Federal District Court. Contrary to Takeda's claims, none of the exceptions to the exhaustion requirement apply here.

This case must therefore be either dismissed or stayed pending a full review in the Blackfeet Tribal Court, including review by the Blackfeet Appellate Court.

DATED this 10th day of September, 2014.

____ss/Joe J. McKay_____
Joe J. McKay, Attorney-at-Law

CERTIFICATION

I hereby certify pursuant to L.R. 7.1(d)(2) that the foregoing Brief in Support of the Defendant's Motion to Dismiss is approximately 3,991 words as determined by Microsoft word, excluding the caption and certificate of compliance.

_____ss/Joe J. McKay_____
Joe J. McKay, Attorney-at-Law