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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 TAKEDA  
PHARMACEUTICAL COMPANY  
LIMITED,  
Plaintiffs,

CAUSE NO. CV-14-50-GF-BMM-RKS

-vs-

VICTOR CONNELLY,  
Defendant.

**PLAINTIFFS' BRIEF IN OPPOSITION TO MOTION TO DISMISS**

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## I. STATEMENT OF THE CASE

Connelly is an enrolled member of the Blackfeet Indian Tribe. The Takeda defendants are non-members, involved in the manufacture and marketing of prescription drugs throughout the United States. Takeda Pharmaceuticals America, Inc. (TPA) and Takeda Pharmaceuticals U.S.A., Inc., F/K/A Takeda Pharmaceuticals North America, Inc. (TPUSA) are Delaware corporations with their principal places of business in Deerfield, Illinois. Takeda Pharmaceutical Company Limited (TPC) is a Japanese corporation with its principal place of business in Osaka, Japan.

Pursuant to approval by the United States Food and Drug Administration (FDA), TPUSA markets and TPA sells, markets, and distributes Actos for prescription by licensed physicians in the United States. TPC is the Japanese parent company of TPUSA, and has manufactured Actos.

On August 1, 2013, Connelly filed a personal injury tort action against Takeda in the Blackfeet Tribal Court, alleging that Actos caused him bladder cancer. Takeda initially filed a Motion to Dismiss and then a Renewed Motion to Dismiss in the tribal court, alleging lack of jurisdiction. To date, the tribal court

has refused to rule on Takeda's Motion, but instead has set the case for trial twice and entered orders compelling off-Reservation discovery.<sup>1</sup>

On July 7, 2014, Takeda filed its Complaint for Injunctive and Declaratory Relief (“Complaint”) in this Court, seeking a declaration that the tribal court lacks jurisdiction over Connelly’s case.

## II. STATEMENT OF THE FACTS

The facts underlying Connelly’s lawsuit in the tribal court are set forth in the Complaint, with record citations. Complaint at 6-14 (Doc. 1). By contrast, Connelly’s factual claims, including his alleged “Jurisdictional Facts,” are unsupported. Connelly’s Brief in Support of Motion to Dismiss (MTD) at 2-6 (Doc. 11).

The IHS is a federal agency within the Department of Health and Human Services, responsible for providing medical care to American Indians and Alaska Natives. The IHS provides medical care to Indians at a hospital and clinic located on the Blackfeet Indian Reservation. *See* Indian Health Service, [http://www.ihs.gov/billings/index.cfm?module=bao\\_su\\_blackfeet](http://www.ihs.gov/billings/index.cfm?module=bao_su_blackfeet). The IHS hospital and clinic are located on reservation land leased to the United States Public Health Service, for operation of IHS facilities. Exhibit 1, December 27,

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<sup>1</sup> Connelly also demanded and obtained an order that Takeda present its General Counsel and Assistant General Counsel for depositions. Doc. 1; Ex. 16 (May 29, 2014 Order).

2013 United States Department of the Interior, Bureau of Indian Affairs, Blackfeet Agency, Response to Freedom of Information Request (FOIA).<sup>2</sup>

Takeda manufactures and sells the diabetes medication, Actos, and had contacts with the IHS about the addition of Actos to the IHS drug formulary. IHS made Actos available to its healthcare facilities for prescription to its patients.

In 2005, Defendant Connelly sought treatment for his diabetes from the IHS facilities, where his doctors prescribed Actos, and he obtained the drug at an IHS pharmacy. Doc. 1; Ex. 4 (Excerpts from the 6/16/14 Deposition of Dr. Richard Odegaard at 9:25 – 10:21, 27:4-7, 27:23 –28:2). Connelly had no communications with Takeda about Actos. Doc. 1; Ex. 5 (Plaintiff’s 12/4/13 Responses to Interrogatories Nos. 17, 19, and 20). In 2008, Connelly was diagnosed with bladder cancer by his IHS physician, *id.* at #21; he sued Takeda in the tribal court on August 1, 2013. Doc. 1; Ex. 1, Connelly Complaint.

As grounds for jurisdiction in the Blackfeet Tribal Court, Connelly alleged that Takeda sold and marketed Actos in the United States and worldwide, and “to pharmacies and physicians located on Blackfeet tribal trust land” through IHS. *Id.* at ¶ 1.2. He alleged that Takeda “came onto the Reservation, through their representatives and agents,” with intent to have IHS doctors and pharmacies make the drug available to Blackfeet tribal members. *Id.* at ¶2.4.

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<sup>2</sup>The redactions and highlighting are on the original letter.



After discovery disproved that Takeda employees entered the reservation, Connelly amended his Complaint to claim that Takeda marketed Actos to the IHS, which then made the drug available for prescription to Blackfoot Indians. Doc. 1; Ex. 11 (Plaintiff's First Amended Original Complaint ("Am. Complaint") at ¶ 2.5. He asserted that Takeda used "marketing tactics" to "drive Actos business in all IHS facilities." *Id.*

Takeda renewed its Motion to Dismiss, because these allegations, even if true, would not confer jurisdiction on the tribal court for Connelly's use of Actos. Doc. 1; Ex. 12 (5/14/14 Takeda's Renewed Motion to Dismiss) at pp. 7-8.

Discovery established that Takeda's marketing to the IHS occurred at the IHS agency offices in Oklahoma City, Oklahoma. Doc. 1; Ex. 8, Excerpts from the 4/24/14 Deposition of Jeffrey McClellan ("McClellan Depo.") at 24:5-11; 26:10-27:4; 35:6-7; 51:4-8; 80:22-23; 128:8-12).

Takeda participated in jurisdictional discovery in the tribal court, and produced a corporate representative to testify about Connelly's allegation that Takeda employees entered the Blackfoot Indian Reservation to market Actos to IHS doctors at that location. Connelly deposed Takeda's corporate representative Jeffrey McClellan, on April 25, 2014. McClellan is Takeda's Elite District Sales Manager for the Pacific Northwest, which included Montana. McClellan's

testimony established that no Takeda employees ever came onto the Blackfeet Indian Reservation for the purpose of selling or promoting Actos:

Q. Did any Takeda sales representative who handled Actos conduct any business, including but not limited to – not limited to any sales activity at the IHS facility hospital, on the Blackfeet Indian Reservation?

A. They did not.

...

Q. Did any Takeda employees who were – who were responsible for Indian Health Services ever conduct any business at the IHS facility on the Blackfeet Indian Reservation?

A. No.

*Id.* at 117:12-118:19). McClellan further testified that Takeda's contacts with IHS regarding the formulary's inclusion of Actos were through the central IHS with its agency headquarters in Oklahoma City. *Id.* at 24:5-11; 26:10-27:4; 35:6-7; 51:4-8; 80:22-23; 128:8-12. Company sales representatives who had territory responsibility for Montana confirmed that they never entered the Blackfeet Indian Reservation to discuss Actos. Doc. 1; Ex. 9 (Declarations of Gretchen Millard, Matt Sheridan, Darrin Branson, Brian Burns, Donna Bishop, Michael Underhill, Leroy Hucke, Brandon Butler, Brian Sherle, John Schroeder, Kelly Moffat, and Clayton Arnold ).

Additionally, seven Takeda employees with responsibility for contacts with the IHS about Actos affirmed that they never went onto the Blackfeet Indian

Reservation. Doc. 1; Ex. 10 (6/9/14 Defendants' Motion for Reconsideration of Order Compelling Depositions and Supplement to Motion to Quash and for Protective Order, Declarations of Christopher Benecchi, William Engro, Charles Kelly, Harry Hayter, Neil McFadden, Andi Moore, and Mark Oldroyd ).

No Takeda representative or employee ever went onto the Blackfeet Indian Reservation for the purpose of selling or promoting Actos; rather, Takeda representatives interacted with the IHS in Oklahoma City, where the IHS – not the Blackfeet Indian Tribe – decided that IHS would include Actos on its federal drug formulary for IHS facilities throughout the United States. Doc. 1; Ex. 10 (Mot. for Reconsideration) at p. 4; Ex. 8 (“McClellan Depo.”) at 24:8-11.

Importantly, Connelly now tacitly concedes the foregoing. Doc. 11; MTD, at pp. 5-7. Contrary to his original allegations in tribal court, Connelly now asserts that the extension of tribal court jurisdiction over Takeda is warranted simply and solely on the basis that he is a “third-party beneficiary” of Takeda’s dealings with an agency of the United States government. Not surprisingly, Connelly points this Court to no authority whatsoever in support of this novel theory, and there is none.

### **III. SUMMARY OF THE ARGUMENT**

Where it is plain that a tribal court lacks jurisdiction to adjudicate a case against a non-consenting non-tribal member, no exhaustion of tribal remedies is required. Such is the case here. No court ever has recognized tribal court

jurisdiction in the circumstances presented by this case. The activity at issue occurred off the reservation, over a thousand miles from the Blackfeet Indian Reservation, and involved Takeda's contacts with the IHS about prescription drugs to include at its facilities. The Blackfeet Indian Tribe lacks the authority to regulate the IHS; thus, its tribal court lacks the authority to adjudicate those matters. There is no plausible basis on which the tribal court can exercise jurisdiction over Connelly's suit in tribal court.

#### **IV. ARGUMENT**

##### **A. No Exhaustion is Required Where it is “Plain” the Tribal Court Lacks Jurisdiction**

There is a well-recognized exception to the requirement to exhaust tribal remedies. In *Nevada v. Hicks*, 533 U.S. 353, 369 (2001), the Supreme Court reiterated the exception to the exhaustion requirement first articulated in *Strate v. A-1 Contractors*, 520 U.S. 438 (1997), that when it is clear that a tribal court lacks jurisdiction, exhaustion is unnecessary: “Since it is clear . . . that tribal courts lack jurisdiction . . . adherence to the tribal exhaustion requirement ‘would serve no purpose other than delay,’ and is therefore unnecessary,” quoting *Strate*, 520 U.S. at 459 n. 14. The Court held that “since the lack of [tribal court] authority is clear, there is no need to exhaust the jurisdictional dispute in tribal court.” 533 U.S. 374.

Just last year, the Ninth Circuit reversed a district court's dismissal of a non-member's declaratory judgment action for lack of exhaustion, where it found tribal

court jurisdiction “plainly lacking.” *Evans v. Shoshone-Bannock Land Use Policy Comm.*, 736 F.3d 1298, 1300, 1302 (9th Cir. 2013) (because “the Tribes plainly lack the power to regulate [the non-member’s] conduct, we reverse [the order dismissing for lack of exhaustion]”). *See also Burlington Northern Railroad Co.v. Red Wolf*, 196 F.3d 1059, 1065-66 (9th Cir. 1999) (holding that “because tribal courts plainly do not have jurisdiction pursuant to *Montana* and *Strate*, the Railroad was not required to exhaust its tribal remedies before proceeding in federal court”). Indeed, Connelly concedes that exhaustion is unnecessary “where it is plain that no federal grant provides for tribal governance of non-member’s conduct . . . .” MTD at 7-8. In sum, Takeda and Connelly agree that a “plain” lack of jurisdiction in the tribal court obviates the need for Takeda to exhaust tribal remedies.

## **B. The Tribal Court Plainly Lacks Jurisdiction Here**

### **1. The tribal court lacks jurisdiction over a non-member for activities off the Reservation**

Neither the Supreme Court, nor the Ninth Circuit, nor any other court in the country Connelly can identify has ever upheld tribal court jurisdiction over a non-member for activities conducted over one thousand miles from the reservation. There is no precedent for tribal court jurisdiction here. Courts have flatly rejected tribal jurisdiction in far less attenuated circumstances.

Tribal courts are not courts of general jurisdiction. *Evans v. Shoshone-Bannock Land Use Policy Comm.*, 736 F.3d 1298, 1302-03 (9th Cir. 2013), quoting *Philip Morris USA, Inc. v. King Mountain Tobacco Co.*, 569 F.3d 932, 939 (9th Cir. 2009). Indian tribal courts have limited jurisdiction over the conduct of nonmembers. *Strate*, 520 U.S. 445; *Montana v. United States*, 450 U.S. 544, 565 (1981). “[A]bsent express authorization by federal statute or treaty, tribal jurisdiction over the conduct of nonmembers exists only in limited circumstances.” *Strate*, 520 U.S. at 445, citing *Oliphant v. Suquamish Indian Tribe*, 435 U.S. 191 (1978) and *Montana*, 450 U.S. at 565.

Indeed, “[t]ribal jurisdiction over non-members is *highly disfavored* and there exists a *presumption against tribal jurisdiction*. *Bugenig v. Hoopa Valley Tribe*, 229 F.3d 1210, 1218 (9th Cir. 2000) (emphasis added) *rev’d on other grounds*, 266 F.3d 1201 (2001); *Strate*, 520 U.S. at 445. There must exist “express authorization” by federal statute of tribal jurisdiction over the conduct of nonmembers; for there to be an express delegation of jurisdiction over non-members, there must be a “clear statement” of express delegation of jurisdiction. *Bugenig*, 229 F.3d at 1218-19.

While Indian tribes “retain inherent sovereign power to exercise some forms of civil jurisdiction over non-Indians *on their reservations*,” *Montana*, 450 U.S. at 565 (emphasis added), the operative phrase is “*on their reservations*.” Neither

*Montana* nor its progeny purport to allow Indian tribes to exercise civil jurisdiction over the activities of non-Indians occurring outside their reservations. See e.g., *Hornell Brewing Co. v. Rosebud Sioux Tribal Court*, 133 F.3d 1087, 1091 (8th Cir. 1998). In *Hornell*, a tribal member sued brewing companies for their manufacture, sale and distribution of an alcoholic beverage, all of which occurred off the reservation. The court rejected the claim of tribal jurisdiction, plainly holding that the tribal court lacked jurisdiction over the breweries' activity *off the reservation*:

[W]e think it plain that the Breweries' conduct outside the [reservation] does not fall within the Tribe's sovereign authority. We deem it clear the tribal court lacks adjudicatory authority over disputes arising from such conduct.

133 F. 3d 1093.

There also is no tribal authority to regulate nonmembers' activities on land "over which the tribe could not assert a landowner's right to occupy and exclude." *Nevada*, 533 U.S. at 359. The federal government, not the tribe, regulates the activities of the IHS at the federal agency's facilities. Thus, the tribe cannot regulate the IHS decisions over what prescription drugs to include on its formulary, or IHS doctors' prescription of medicines in its clinics. Further, any Takeda sales activity of FDA-approved prescription drugs to the IHS is not an activity that the tribal court can legislate or regulate.

**2. The conduct at issue occurred off the Reservation**

It is undisputed that Takeda is a non-tribal member. The conduct at issue here, Takeda's marketing and sale of Actos to the IHS, occurred in Oklahoma, over a thousand miles from the Blackfeet Indian Reservation.

Initially, Connelly based jurisdiction in the tribal court on his claim that Takeda employees entered the Reservation to market Actos to IHS. Doc. 1; Connelly Complaint at 2.4. But the testimony of Takeda's corporate representative Jeffrey McClellan established that Takeda sales personnel did not enter the Reservation to market Actos to the IHS healthcare providers, and Takeda personnel with responsibility for marketing Actos in Montana established that they never entered the Reservation to market Actos. Doc. 1; Ex. 9. Thus, this factual basis for jurisdiction is unsupported.

Connelly next asserted that the tribal court had jurisdiction based upon Takeda's promotion of Actos to the IHS; but this indisputably occurred in Oklahoma. Activity of a non-member occurring over a thousand miles from the reservation cannot subject the non-member to the jurisdiction the Blackfeet Tribal Court. *E.g., Hornell*, 133 F. 3d 1093.

**3. Even conduct at the IHS facilities on the reservation does not give rise to tribal jurisdiction**

Even if Takeda personnel *had* conducted business at the IHS facilities located on the reservation, that activity still would not create tribal court



jurisdiction. The federal government and the IHS are non-members of the Blackfeet Indian Tribe. The Tribe plainly lacks the authority to regulate and control the federal government's IHS. Further, the reservation land on which the IHS operates is leased to the federal government, so the IHS facility is not subject to the control of the Tribe in any event.

A tribal court's adjudicative jurisdiction does not exceed its legislative jurisdiction. *Strate*, 520 U.S. at 453. Thus, if a tribe could not legislate the activity, it cannot exercise jurisdiction over the activity. *Id.* There also is no tribal authority to regulate nonmembers' activities on land "over which the tribe could not assert a landowner's right to occupy and exclude." *Nevada*, 533 U.S. at 359; *Strate*, 520 U.S. 438, 445 (cause of action arose on federal right of way in reservation land; no jurisdiction in tribal court); *Boxx v. Long Warrior*, 2001 U.S. App. LEXIS 24917 (9th Cir. 2001) (cause of action arose on non-Indian fee land within the reservation; no jurisdiction in tribal courts); *Burlington Northern Railroad Co. v. Red Wolf*, 196 F.3d 1059, 1064-65 (9th Cir. 1999), (cause of action arose on railroad right-of-way within the reservation; no jurisdiction in tribal courts); *State of Mont. Dep't of Transp. v. King*, 191 F.3d 1108 (9th Cir. 1999) (cause of action arose on state highway within reservation; no need to exhaust claims in tribal courts); *Wilson v. Marchington*, 127 F.3d 805 (9th Cir. 1997)

(cause of action arose on U.S. highway within reservation; judgment of tribal court not entitled to recognition in U.S. courts).

As the Ninth Circuit just wrote, “[t]he plausibility of tribal court jurisdiction depends on the scope of the Tribe’s regulatory authority as a ‘tribe’s adjudicative jurisdiction does not exceed its legislative jurisdiction.’” *Evans*, 736 F.3d 1298, 1302-04 citing *Plains Commerce Bank v. Long Family Land & Cattle*, 554 U.S. 316, 330 (2008) (quoting *Strate*, 520 U.S. at 453).

The federal government, not the tribe, regulates the activities of the IHS, both in Oklahoma and at the facilities on federally leased land on the Blackfoot Indian Reservation. Moreover, the tribe cannot regulate or exercise authority over Takeda sales activity of FDA-approved prescription drugs to the IHS. Conversely, Connelly points to nothing suggesting that the Blackfoot Indian Tribe can regulate in any fashion the delivery of healthcare by IHS employees at the IHS facilities, regardless of whether those facilities are on fee or leased tribal land. Because the tribe lacks the authority to regulate in these areas, the tribal court cannot exercise adjudicatory jurisdiction over them either.

**4. *Montana*’s general rule and not its exceptions apply**

Connelly contends that *Montana* permits the tribal court to exercise jurisdiction here. Doc. 11; MTD at 9-14. *Montana* held that as a general rule, absent express federal law or treaty, a tribe has no civil regulatory authority over

non-tribal members for activities on reservation land alienated to non-Indians. 450 U.S. at 563-65. The Court recognized limited exceptions to this general rule, but only where the activity in question occurs *on reservation land*, and only to protect tribal self government or control internal tribal relations.

The tribe may regulate the activities of non-members who enter into consensual relationships with the tribe or its members through commercial dealings, and may exercise power over the conduct of non-Indians on fee land when it “threatens or has some direct effect on the political integrity, the economic security, or the health and welfare of the tribe.” *Id.* at 563-566. The “health and safety” exception has been described as requiring a showing that the activity would “*imperil the subsistence of the tribal community*” or be “*catastrophic*” for tribal self-government. *Plains Commerce Bank*, 554 U.S. at 341; *Evans*, 736 F. 3d at 1305-06. Connelly’s attempt to invoke the *Montana* exceptions fails.

**a. *Montana*’s exceptions do not apply where the acts occurred off the reservation.**

First, *Montana*’s exceptions do not apply here; *Montana* addressed the extent of tribal jurisdiction over non-members for activities on non-Indian fee land *located on the reservation*. 450 U.S. 547 (“This case concerns the sources and scope of power of an Indian tribe to regulate hunting and fishing by non-Indians *on lands within its reservation* owned in fee simple by non-Indians.”) *Id.* (Emphasis added.) The activities on which Connelly bases tribal court jurisdiction occurred

over a thousand miles from the reservation, in Oklahoma, where Takeda marketed Actos to the IHS. Doc. 1; Ex. 11 (Am. Complaint) at ¶¶ 2.5-2.6 (alleging Takeda “targeted members of the Blackfeet Tribe through the Indian Health Services formulary some 2.6 MM native Americans” . . . through “marketing tactics to “drive Actos business in all IHS facilities . . .”).

But even if Connelly could establish—despite the undisputed evidence to the contrary—that Takeda personnel went to the IHS facility on the reservation to market Actos to IHS healthcare providers, *Montana*’s exceptions still would not apply here as he contends.

**b. Connelly had no consensual relationship with Takeda.**

Connelly admits that he had no communications with Takeda. So he asserts that the IHS had a voluntary consensual relationship with Takeda based upon the IHS’s provision of medical care and prescription drugs to Blackfeet Indians. Doc. 11 (MTD) at 9-11. He then argues, without citation of authority, that he was the “third party beneficiary” of this relationship, since the IHS provided him medical care, including the prescription for Actos. This, he contends, gives the tribal court jurisdiction over his claim against Takeda. But he offers no authority whatsoever for this radical extension of tribal jurisdiction and the cases he cites do not support any such attenuated jurisdiction.

Both cases on which Connelly relies, *Williams v. Lee*, 358 U.S. 217 (1959) and *Smith v. Salish Kootenai College*, 434 F. 3d 1127 (9th Cir. 2006) dealt with jurisdiction over activities conducted *on the reservation*, for suits arising directly from the business conducted with Indians on the reservation. In *Williams*, the non-members were the owners of an on-reservation general store who filed a debt collection action against the Indian defendants in state court; the state court had no jurisdiction because the general store was on the reservation and the non-members transacted directly with tribal members on the reservation. In *Smith*, the non-member also was a plaintiff in a suit against a tribal entity, who *consented* to tribal court jurisdiction, before withdrawing it after a trial on the merits. *Smith* at 1128-30, 1136. These cases do not support Connelly's arguments; in neither case did the courts hold that a non-consenting, non-member defendant who is not directly conducting business with Indians on the reservation was subject to tribal court jurisdiction, or that a non-member was subject to tribal jurisdiction for a third party's activities.

Connelly's argument that tribal court jurisdiction reaches to the full extent of due process, Doc. 11(MTD) at 11-13, is flatly contrary to Supreme Court and Ninth Circuit authority. He takes *Smith's* discussion of due process wholly out of context. The *Smith* court discussed due process in considering whether a defendant's own actions *in the forum* (*i.e.*, on tribal lands) were such that he might

reasonably anticipate being haled into court there. 434 F. 3d at 1138.

Undercutting Connelly's argument that IHS activity can subject Takeda to jurisdiction is the *Smith* court's recognition that "the unilateral activity" of a third party cannot subject the non-resident to jurisdiction; rather it must be "actions by the defendant himself that create a "substantial connection."” *Id.* [Citations omitted.]

In sum, that Takeda knew the IHS would supply Actos to its facilities that provide medical care to Indians does not give the tribal court jurisdiction over Takeda from Connelly's use of the drug. As set forth above, tribal courts are not courts of general jurisdiction and they have circumscribed power over non-members. *See* Section V.(B).(1.) at 11-13, *supra*.

**c. Connelly's use of Actos does not imperil the tribe.**

Connelly cannot establish, as *Montana*'s exception requires, that his use of Actos or Takeda's FDA-approved Actos to the IHS "impinges on" or is "catastrophic to" the Blackfoot Tribe's self-government. *Plains Commerce Bank*, 554 U.S. at 341; *Evans*, 736 F. 3d at 1305-06. Indeed, the contrary assertion by Connelly now rests on nothing more than the *ipse dixit* of his counsel, even after over 14 months of litigation in the tribal court. The tribal court's exercise of jurisdiction here is not "necessary" to protect the Blackfoot Tribe's self-

government or control its internal relations. Here, as in *Strate*, the claims that Connelly makes are “distinctly non-tribal in nature.” *Strate*, 520 U.S. 457.

**d. Connelly’s use of Actos does affect the tribe’s health and welfare.**

Nor can Connelly show that his use of Actos or Takeda's sale of Actos to the IHS jeopardizes the entire tribe’s “health and welfare,” as required for the application of this exception. Tort injuries to an individual Indian tribal member do not have a “direct effect upon the health or welfare of the tribe,” even where the safety of other tribe members also could be jeopardized. *Strate*, 520 U.S. at 457. In *Strate*, the Supreme Court rejected such a broad interpretation of the *Montana* exception, despite acknowledging that “those who drive carelessly on a reservation endanger all in the vicinity and surely jeopardize the safety of tribal members.” 520 U.S. at 457-458. The Court refused the plaintiff’s broad construction of tribal “health and safety.” *Id.* The Court concluded that the interests of an individual tort plaintiff did not qualify as the “tribal interests” to be protected by *Montana*’s exception; *see also Burlington*, 196 F.3d 1059, 1064-65 (Ninth Circuit rejected tribal plaintiffs’ claim that the deaths of their tribe members on the railroad’s right-of-way across reservation land qualified as a threat to the security, health, and welfare of the tribe under *Montana*’s exception); *County of Lewis v. Allen*, 163 F.3d 509, 515 (9th Cir. 1998) (holding that a tribe's bare interest in the

safety of its members cannot satisfy the second *Montana* exception). Accordingly, Connelly's claimed injury from Actos does not qualify for the *Montana* exception.

**e. Connelly's remaining authority fails to support jurisdiction.**

Connelly relies on *Water Wheel Camp Recreational Area v. Larance*, 643 F.3d 802 (9th Cir. 2011), and *Grand Canyon Skywalk Development LLC v. Sa Nyu Wa Incorporated*, 715 F.3d 1196 (9th Cir. 2013) to argue that the tribe's "inherent right to exclude[] non-Indians from their Reservation and Indian lands provide[s] an independent basis for tribal court jurisdiction." MTD at 15-16. Neither case supports tribal jurisdiction here, and both are distinguishable.

In *Water Wheel*, the Indian tribal entity brought suit in tribal court against the non-nonmember operator of a recreational resort located on the reservation who had leased Indian trust land from the tribe for his business there. The tribe claimed that he had breached his contract and trespassed, once the tribe demanded that he vacate the land at the expiration of the lease. The Ninth Circuit held that the tribal court had jurisdiction of the dispute, because the land at issue belonged to the tribe, and it was subject to their control and regulation. 642 F.3d 816-20.

*Grand Canyon* had similar facts. The tribal entity sued the non-Indian operator of a tourist attraction—a skywalk over the Grand Canyon-- built and operated on tribal land, per a contract with the tribe. The tribe claimed that the operator of the business breached its contract with the tribe. The Ninth Circuit held that the tribal



court had jurisdiction of the dispute “arising when non-Indians chose to do business in Indian Country,” because the tribe both owned and controlled the land on which the skywalk was operated. *Grand Canyon*, 715 F. 3d at 1198.

Neither case supports Connelly’s arguments for jurisdiction here, because 1) Takeda’s marketing of Actos to the IHS occurred in Oklahoma, not on the reservation; 2) Takeda never entered the reservation to market Actos; 3) even if Takeda had entered the reservation to market Actos to the IHS, its facilities and decisions are not subject to the tribe’s control or regulation; and 4) the land on which IHS operates is not subject to tribal control or regulation. Thus, Connelly’s authority is entirely inapposite.

**C. Other Exceptions to Exhaustion Apply, Including the Futility Exception.**

Courts also will not require exhaustion where to do so would be futile. *See, e.g., Johnson v. Gila River Indian Cmty.*, 174 F.3d 1032 (9th Cir. 1999) (two year delay in tribal court review called into question the possibility of tribal court remedies); *Krempel v. Prairie Island Indian Cmty.*, 125 F.3d 621 (8<sup>th</sup> Cir. 1997) (exhaustion not required where there was no functioning tribal court). Here, the status of the Blackfeet tribal court warrants the application of the futility exception.

As set forth in Takeda’s Complaint, the United States Department of the Interior, Bureau of Indian Affairs (“BIA”), recently completed a review of the Blackfeet tribal court system, and found that the courts’ judges and administrator

were hired with invalid tribal resolutions. Doc. 1; Ex. 17 (BIA Report). Thus, at the time this action was filed, the court had no validly appointed judicial officers, in essence a court system without judges. Additionally, the BIA expressed concern that a “political faction” of the Blackfeet Tribal Business Council (“BTBC”) “has significant influence over court activities.”<sup>3</sup> The court appears to be controlled by the BTBC, whose membership currently includes one of Connelly’s attorneys in the tribal court.

“[R]emedies that are inadequate need not be exhausted.” *Coit Independence Joint Venture v. Federal Sav. & Loan Ins. Corp.*, 489 U.S. 561, 587 (1989).

Takeda should not be required to exhaust inadequate tribal court remedies.

Without validly appointed judicial officers, the Blackfeet tribal court system is equivalent to a non-functioning court system. *Krempele*, 125 F.3d at 622.

#### **D. Takeda is Entitled To Injunctive Relief**

Connelly has not moved to dismiss Takeda's request for injunctive relief.

Thus, this request stands unopposed, and the Court should grant it.

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<sup>3</sup>The BIA report states: “It appears the Tribe’s current form of government make it difficult for the court to operate in an independent manner free from external political controversies . . . it is imperative that the Tribe’s Constitution be revised to assure judicial independence . . . [u]ntil constitutional reform can be made, actions must be taken to assure the Court is free from any interference or influence from the Tribal Council.” *Id.*, p. 28.

Takeda has shown that it is entitled to this relief. First, Takeda is likely to prevail on the merits of its arguments that the tribal court lacks jurisdiction over Connelly's case. Second, Takeda is likely to suffer irreparable harm if the tribal court forces this case to trial, because the BIA found that the tribal court lacks the basic procedures to protect confidential information and maintain the confidentiality of Takeda's protected trade secrets that will be disclosed at a trial. *See* Takeda's Complaint, Doc. 1 at 28-33. Takeda thus risks the loss of its valuable trade secrets, which cannot be remedied by any monetary judgment. Courts have recognized that a threatened loss of valuable trade secrets may establish irreparable harm, and that financial harm that cannot practically be remedied is irreparable harm. *Id* at p. 31-33. Third, the balance of equities weighs in Takeda's favor; Connelly has multiple other venues where he could pursue his case in a court with proper jurisdiction. Fourth, there is no public interest served in forcing a party to defend against serious claims in a court that plainly lacks jurisdiction. No court in the nation has ever allowed such a sweeping exercise of tribal court jurisdiction.

### **PRAYER**

Takeda respectfully requests that the Court deny Connelly's Motion to Dismiss, hold that Takeda need not exhaust tribal remedies, and grant the requested injunction.



