Case No. 15-35403

IN THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

TAKEDA PHARACEUTICALS AMERICA, INC., et al.

Plaintiffs/Appellants,

vs.

VICTOR CONNELLY

Defendant/Appellee

On Appeal from the United States District Court
For the District of Montana, Great Falls Division
Honorable Brian Morris
Case No. 4:14-cv-00050-BMM

APPELLEE'S BRIEF

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the undersigned counsel of record for the Appellee certifies that the Appellee Victor Connelly is not a corporation and that no corporate party is related to his claim and that he is an individual person.

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JURISDICTIONAL STATEMENT

Appellee Connelly agrees with and adopts the Jurisdictional Statement of the Appellants.

INTRODUCTION

Victor Connelly, Appellee, (hereinafter "Connelly") is an enrolled member of the Blackfeet Indian Tribe and resident of the Blackfeet Indian Reservation in Montana.

Appellants 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") are non-Indians and non-residents of the Blackfeet Indian Reservation.

Takeda manufacturers and distributes Actos (pioglitazone), which is a prescription medication used to control blood sugar (glucose) in adults with Type II diabetes. Takeda was the sole manufacturer, seller, and distributor of Actos at all times relevant to this case.

Connelly was prescribed ACTOS by physicians at the Blackfeet Community Hospital (an Indian Health Service facility) 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 at the IHS clinic on tribal trust lands within the exterior boundaries of the Blackfeet Indian Reservation. Connelly developed bladder cancer and subsequently brought suit in the Blackfeet Tribal Court against Takeda alleging various product liability torts including negligence based on a failure to warn.

Takeda originally brought this action in the district court seeking an injunction against the Victor Connelly attempting to prevent him from pursuing his claims in the Blackfeet Tribal Court. Connelly moved to dismiss on the grounds that Takeda had failed to exhaust their tribal court remedies. Takeda asserted that it was exempt from exhaustion because tribal court jurisdiction was plainly lacking.

Applying applicable Federal Indian law principals, the District Court found that the Blackfeet Tribal Court has plausible or colorable jurisdiction over Connelly's claims against Takeda. Because Takeda's activities had a predictable, and intended end result (prescription of and ingestion of ACTOS to Indians), and because that result occurred on Indian trust land within the Blackfeet Reservation, the Tribe retains a landowners gatekeeping authority, which in turn supports the

Tribe's assertion of jurisdiction. The District Court's conclusion was correct and should be affirmed by this Court.

STATEMENT OF THE ISSUE

Whether the District Court correctly held that a tribal court had "plausible" or "colorable" jurisdiction over a product liability claim brought by a tribal member against a non-member prescription drug manufacturer whose drug was prescribed and ingested by the tribal member on Indian trust land within the reservation, including at an Indian Health Service clinic located on land owned by the tribe and leased to the federal government and on the tribal member's own Indian trust land, where the drug manufacturer intentionally targeted sales and distribution of its drug to reservation Indians to take advantage of the epidemic of diabetes among Indian people?

STATEMENT OF THE CASE

Appellee Connelly accepts the Statement of the Case presented by the Appellants.

STANDARD OF REVIEW

Appellee Connelly accepts the Appellants statement of the Standard of Review in this case.

SUMMARY OF THE ARGUMENT

The District Court correctly concluded that the Blackfeet Tribal Court has plausible jurisdiction over the tort claim of Blackfeet Tribal member Victor Connelly for activities occurring on Indian land within the Blackfeet Indian Reservation. In so doing, the District Court properly relied upon the aggressive marketing activities of Takeda to drive its diabetes drug ACTOS in all Indian Health Service facilities and pharmacies under IHS control with the intent that the drug be prescribed to and ingested by Indian people like Victor Connelly in finding that Takeda had sufficient Reservation based activity to subject it to tribal court jurisdiction. The District Court implicitly rejected Takeda's specious claim that it should be able to aggressively market its drug(s) to the Indian Health Service with the intent that those drugs be ingested by Indian people in Indian Country and that when those drugs are ingested by and do cause injury to Indian people within Indian Country that they (Takeda) are not engaging in Reservation activities.

The District Court also correctly concluded that the act of leasing Tribal land to the United States Public Health Service Indian Health Division did not deprive the Blackfeet Tribe of the landowner's right to occupy and exclude and that this inherent sovereign power was a sufficient basis to support a preliminary finding of

"plausible" Tribal Court jurisdiction. The applicable lease itself does not state that the Tribe is surrendering ownership rights. To the contrary, the lease obligates the lessee to obey all laws, sets out a reservation of rights to the lessor (including oil and gas leasing, rights-of-way, and other legal grants). Additionally the Tribe has significant operational authority over the Indian Health Service unit that is located on the lease pursuant to the applicable Federal statute. Finally, the lease specifically states that the land remains in trust status subject to supervision by the Secretary of the Interior.

Because the Blackfeet Tribe clearly retains a landowners right to occupy and exclude with respect to the Tribal land on which the Blackfeet Community, Indian Health Service Hospital is located and because Takeda was engaged in activities with an intended end result on Indian land within the Blackfeet Indian Reservation, the District Court correctly concluded that the Blackfeet Tribal Court has plausible jurisdiction over Connelly's tort claim against Takeda and that Tribal Court remedies must therefore be fully exhausted.

LAW AND ARGUMENT

It is now an axiom of Federal Indian Law that Indian Tribes are unique aggregates retaining some aspects of their inherent sovereignty over their land and their territory. While Indian tribes no longer possess absolute sovereignty over non-Indians or non-Indian land within their reservations, in certain instances Tribes

may still exercise some form of jurisdiction where non-Indians and non-Indian land is involved. Where the activities of non-Indians occurs within an Indian reservation on tribally owned land and there are no competing or overriding state interests, the authority of a tribe to regulate this conduct by adjudication, regulation or otherwise is at its high point.

Because the conduct of the Appellant Takeda which is the subject of this lawsuit occurred on land owned by the Blackfeet Indian Tribe and Victor Connelly in trust within the Blackfeet Indian Reservation, the Tribe's inherent power to exclude and set conditions upon entry onto its land, is a plausible or colorable basis for regulation of Takeda's conduct though a tort claim in the Blackfeet Tribal Court. Takeda must therefore fully exhaust its remedies in the Blackfeet tribal court. Tribal court jurisdiction is not plainly lacking.

1. EXHAUSTION OF TRIBAL REMEDIES.

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 F2d 1221, 1228 (9th Cir. 1989). That includes full review by the tribe's appellate court if one exists. *Iowa Mutual Ins. Co. v. LaPlante*, 480 U.S. 9, 19 (1987) (holding that until appellate review is complete, the Blackfeet Tribal Courts have not had a full opportunity to evaluate the claim and federal courts should not intervene). *Iowa Mutual*, 480 U.S. at 16-17.

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).

There are recognized exceptions to this general rule. Exhaustion of tribal court remedies is not mandatory where tribal court jurisdiction is plainly lacking. *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).

Because tribal courts are competent law-applying bodies, the tribal court's determination of its own jurisdiction is entitled to some deference. *FMC v. Shoshone-Bannock Tribes*, 905 F.2d 1311, 1313 (citing *Santa Clara Pueblo v. Martinez,* 436 U.S. 49, 65-66 (1978)). When considering questions of tribal jurisdiction, the Court should be mindful of the "federal policy of deference to tribal courts" and that "[t]he federal policy f promoting tribal self-government encompasses the development of the entire tribal court system, including appellate courts". *Water Wheel Camp Recreation Area v. LaRance*, 642 F.3d 802 (9th Cir. 2011), citing *Iowa Mut. Ins. Co. v. LaPlante*, 480 U..S. 9, 16-17 (1987); *United States v. Wheeler*, 435 U.S. 313, 332 (1978) (recognizing that tribal courts are important mechanisms for protecting significant trial interests).

Takeda incorrectly asserts that it should not be required to exhaust tribal court remedies because jurisdiction is plainly lacking. Contrary to Takeda's assertions, on the limited facts of this case, the Blackfeet Tribal Court does not plainly lack jurisdiction. Based upon the Tribe's ownership of the land (and Connelly's ownership of his own land where he occasionally ingested ACTOS), the Blackfeet Tribal Court has a plausible or colorable claim to jurisdiction over Connelly's tort claims against Takeda.

2. TRIBAL JURISDICTON.

The District Court found that the Blackfeet Tribal Court has plausible jurisdiction over Connelly's tribal court action based on Takeda's alleged conduct on tribal trust land within the Blackfeet Indian Reservation. (ER 008-015). Relying on United States Supreme Court precedent (*Nevada v. Hicks*, 533 U.S. 353 (2001); *Strate v. A-1 Contractors* , 520 U.S. 438 (1997); and *Montana v. United States*, 450 U.S. 544 (1081)), the District Court determined that ownership status of the land was an important factor in determining tribal jurisdiction. *Id*. Applying the decisions of the Ninth Circuit Court of Appeals in *McDonald v. Means*, 309 F.3d 350 (9th Cir. 2002), *Water Wheel Camp Recreation Area v. LaRance,* 642 F.3d 802 (9th Cir. 2011), and *Grand Canyon Skywalk Development, LLC v. SA NYU WA Inc.*, 715 F.3d 1196 (9th Cir. 2013), the District Court found that the land upon which the Indian Health Service hospital is located (and where

Connelly was prescribed ACTOS), was land over which the Blackfeet Tribe maintained a landowner's right to regulate entry and exclude. *Id*. In so doing the District Court found that there were no competing state interests and rejected Takeda's claim that because the land was leased by the Tribe to the Indian Health Service, the land was the equivalent of non-Indian fee land.

As it did in the lower court, Takeda reasserts its claims that by leasing land for a community hospital to the Indian Health Service, the Blackfeet Tribe lost its right to regulate conduct on that land and that the land is, in essence, the equivalent of non-Indian fee land. Appellant's Opening Brief DE 7-1, pgs 22-28. Takeda further argues that none of its conduct occurred within the Reservation and that it is otherwise not liable for the actions of the Indian Health Service in placing ACTOS on its formulary for Indian hospitals, for the actions of the prescribing doctor or for the alleged injury to Connelly who ingested the drug on Indian trust land within the Reservation; all outcomes which Takeda actively sought and were reasonably foreseeable. DE 7-1, pgs. 11-22. Both assertions are wrong.

a. Status of the land.

Before turning to Takeda's conduct, Appellee Connelly will first address the issue of the status of the land upon which the Blackfeet Community Hospital is located and is where Connelly was prescribed the drug. It should be immediately noted however, that Takeda does not dispute that Connelly ingested ACTOS on

the Blackfeet Reservation. (ER 010). Or that he alleged that he ingested the drug at his home and work, on Indian trust land within the Blackfeet Reservation. *Id*.

It has been long recognized that Indian Tribes are distinct political entities who still possess limited powers of self-government. *Worcester v. Georgia*, 6 Pet. 545, 559 (1882); *United States v. Wheeler*, 435 U.S. 313, 322-323 (1978). The sovereignty of Indian tribes is of a unique and limited character, *Wheeler*, 435 U.S. at 323, and centers on land owned by the Tribe and on tribal members within the Reservation. *United States v. Mazurie*, 419 U.S. 544, 557 (1975) (tribes retain authority to govern both their members and their territory, subject only to Congressional limitation); *Nevada v. Hicks*, 533 U.S. 353, 392 (2001)(tribes retain sovereign interests in activities occurring on land owned by the Tribe)(O'Conner J., concurring in part and concurring in judgment)

As part of this retained sovereignty, tribes have authority to exclude outsiders from entering tribal land. *Duro v. Rena*, 495 U.S. 676, 696-697 (1990); *New Mexico v. Mescalero Apache Tribe*, 462 U.S. 324, 333(1983) ("A tribe's power to exclude non-members entirely or to condition their presence on the reservation is well established"). Importantly, the power to exclude exists independent of a tribe's general jurisdictional authority. *Duro,* 450 U.S. at 696-697. From a tribe's inherent sovereign power to exclude flow lesser powers, including the power to regulate non-Indians on tribal land. *South Dakota v.*

Bourland, 508 U.S. 679, 689 (1993) (recognizing that a tribe's power to exclude includes the incidental power to regulate).

The authority to exclude non-Indians from tribal land necessarily includes the lesser power to set conditions upon their entry through regulation. *Water Wheel Camp Recreation Area v. LaRance*, 642 F.3d 802, 808 (citations omitted). "Regulatory authority goes hand in hand with the power to exclude". *South Dakota v. Bourland*, 508 U.S. at 691 n. 11.

Nevertheless, the U.S. Supreme Court has also held in more modern times that generally, tribes lack civil jurisdiction over the activities of non-Indians on non-Indian land within a reservation. *Montana v. U.S.* 450 U.S at 565. In the "path-marking" case, see *Strate*, 520 U.S. 4459 (referring to *Montana*), *Montana* v. *United States,* 450 U.S. 544, while setting out the general rule related to lack of tribal jurisdiction over non-Indians on non-Indian land within the Reservation, the United States Supreme Court set out exceptions to that general rule: "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).* By its terms, the Montana rule applies only to non-Indian conduct on non-Indian land.

It is now recognized that the U.S. Supreme Court's decision in *Montana* limited the Tribe's ability to exercise its power to exclude only as applied to the regulation of non-Indians on non-Indian land, not on tribal land. *Water Wheel Camp Recreation Area v. LaRance,* 642 F.3d 802, 814. (citations omitted). The general rule, as now recognized by the U.S. Supreme Court and the Ninth Circuit Court of Appeals is that the U.S. Supreme Court's decision in *Montana* does not affect the general principle that tribes retain inherent power to regulate the conduct of non-Indians on Indian land. *Id*. (citations omitted). Having found that the tribe in that case had regulatory jurisdiction, the Ninth Circuit went on to hold that it also had adjudicatory jurisdiction. *Water Wheel Camp*, 642 F.3d at 814-817.

It is against this backdrop of sovereignty and the undisputed fact that Connelly was prescribed, obtained and ingested ACTOS on tribal land within the Blackfeet Indian Reservation, that Takeda incorrectly asserts that because the tribe's land is leased to the Indian Health Service, the land is now akin to non-Indian fee land over which the Tribe has no control.

Just as the District Court rejected that argument, so too should this court. First, Takeda has pointed to no case or other authority which holds that when a tribe leases its land to a non-Indian, the tribe is deprived of all sovereign power

over activities of non-Indians occurring on that land and that the leased land becomes in essence, non-Indian fee land. No court has ever made such a dramatic reduction in the inherent sovereignty of a tribe based on a lease of tribal trust land. This Court should refuse Takeda's invitation to do so.

Takeda's basic challenge to the District Court's conclusion that the Blackfeet Tribe retained a landowners right to occupy and exclude regarding the parcel leased to the Indian Health Service for a hospital, is Takeda's mistaken view that "the fundamental premise of the district court's holding was that the **IHS clinic activities** were subject to the control of the Blackfeet Tribe, thus subjecting its activities to tribal adjudication." Takeda Brief, DE 7-1, pg. 24. (emphasis supplied). And, that "[s]imply put, in leasing reservation land to the federal government to operate the IHS facility the tribe failed to retain any right to control **the activities that occurred there while the clinic was in operation**. Thus, contrary to the district court's conclusion the tribe retained no such right, divesting the tribal court of jurisdiction over **the activities occurring within the IHS clinic**." Id. , pg. 28 (emphasis supplied). Takeda is clearly trying to falsely imply that the Blackfeet Tribe is attempting to regulate the manner in which health care is provided at the IHS hospital, particularly the approval of drugs. That is not the case.

What is happening with Connelly's tribal court action is that the Tribe is "regulating" through adjudication, the consequences of Takeda's activities as those consequences relate to the tort claims set out in Connelly's tribal court complaint. Connelly alleges that Takeda had knowledge that ACTOS could cause bladder cancer and that it therefore had a duty to warn all physicians, subscribers and providers. He further alleges that ACTOS caused him to develop bladder cancer and that Takeda's failure to warn violated various common law torts. ER 010. That would seem to be nothing new in the world of tort product liability for drug manufacturers like Takeda. Indeed what is taking place in the Blackfeet Tribal Court is nothing different than routinely takes place in state district courts around this Country. See e.g, *Stevens v. Novartis Pharmaceuticals Corporation,* 2010 MT 282, 358 Mont. 474, 247 P.3d 244 (2010) (negligence action against manufacturer Novartis for failure to properly warn of possible negative side effects of drug).

Contrary to Takeda's claims, taking into consideration the BIA's role and regulations regarding the lease, the purpose of the lease, and the retained authority of the Blackfeet Tribe, the district court found that the, "PHS lease does not appear to diminish the Blackfeet Tribe's landowner status to the point of negating Connelly's claim of Blackfeet Tribal Court jurisdiction. At a minimum, the IHS [sic] allotment does not qualify as non-Indian fee land that prohibits tribal court jurisdiction." ER 16.

The District Court was correct in its analysis. First, it is undisputed that the Blackfeet Tribe owns the land on which the Blackfeet Service Unit (known locally as "the Blackfeet Community Hospital") is located. ER 3-4. The Tribe leases the land to the United States of America for $1.00, for the use by the Public Health Service, Division of Indian Health, Department of Health, Education and Welfare, for a Public Health Facility. ER 186-189. The Indian Health Service is a federal agency whose primary role is fulfilling the United States trust responsibility to Indians. The lease is subject to all regulations of the Bureau of Indian Affairs as set out in Title 25 of the Code of Federal Regulations, Part 162. The Blackfeet Tribe retains the authority, pursuant to Title 25, Section 450 of the United States Code, Public law 93-638, to contract for complete administration of the underlying lease between it and the United States regarding the hospital and the Tribe has the authority under the same statute to contract for the entire operation of the Blackfeet Community Hospital.

The lease from the Tribe is a grant of rights from the Tribe to the lessee; it is not a transfer in fee simple. In granting the right to use tribal land, the Tribe reserves all rights not expressly granted. This reservation of rights may be express or implied. In this instance, the lease is for a critical purpose to the Blackfeet People, the operation of a health care facility. The Tribe is not making money on the lease. Indeed, the lease rental fee is $1.00 for a term of 25 years;

that is just one dollar for the whole 25 years, not even $1.00 per year or $25.00. ER 186-187. The lease has a clause expressly reserving to the Tribe the right to make oil and gas leases on the leased land, to grant rights of way across the leased land, and "such other legal grants", subject only to the provision of damages to the United States. ER 187.

It is a long accept general rule of Indian law "that statutes passed for the benefit of the dependent Indian tribes or communities are to be liberally construed, doubtful expressions being resolved in favor of the Indians." *Alaska Pacific Fisheries Co. v. United States*, 28 U.S. 78, 79 (1918). Tribes lease their lands pursuant to the authority contained in Title 25 Section 415 of the United States Code. That is a statute for the benefit of Indians. It stretches the imagination to believe that the consequence of leasing tribal land to any non-member would be loss of tribal authority. That is not in the best interests of tribes or their judicial systems.

The District Court compared the lease of the Blackfeet land to the United States for a hospital for its People, to the grant of right-of-way to the BIA for a reservation road system in *McDonald v. Means*, 309 F.3d 530 (9th Cir. 2002). Means, a member of the Northern Cheyenne Tribe was seriously injured when his vehicle hit a horse owned by McDonald, a non-Indian, on BIA Rt. 5 on the Northern Cheyenne Indian Reservation. Reversing the District Court, the Ninth

Circuit Court of Appeals found that even though BIA Rt. 5 was a road which anyone could use, considering the applicable BIA regulations which granted authority to the Tribe and the BIA's trust responsibility to maintain a reservation road system, the road in that case was not the equivalent of non-Indian fee land under the Montana test, but rather a "tribal road" or "BIA road". It is important to note that in *McDonald v. Means*, the land at issue was a right of way granted to the BIA by the Tribe in which no specific reservation of rights was made.

The same is true here. The lease is given to the Federal government for the purpose of fulfilling the government's trust responsibility to provide health care to Indians. The Tribe retains significant authority to manage the actual lease through federal statute, and the Tribe has significant authority to contract or compact to operate the health care facility located on the lease and which is the very purpose of the lease. Finally, the lease is a limited grant of rights to the lessee in the first instance (as opposed to a right of way) and the Tribe expressly reserved various rights.

On these facts, as the District Court correctly concluded, the land upon which the Indian Health care facility sits in Browning, Montana, on the Blackfeet Indian Reservation where Connelly was prescribed and filled his prescription for ACTOS, was located on land owned by the Tribe over which the Tribe still retained a sufficient gatekeeping right as to premise adjudicatory jurisdiction over

Connelly's claim in tribal court. Certainly, as the District Court more precisely concluded, for the purposes of the challenge in this case, the land does not qualify as non-Indian fee land that precludes tribal court jurisdiction.

Takeda's efforts to characterize Connelly's underlying tribal court lawsuit as one attempting to regulate the conduct of the Federal Government or the Indian Health Service itself is grossly misplaced. Connelly has never made a claim against the Federal government arising out of his bladder cancer and Takeda can point to no such claim. Takeda manufactured and marketed ACTOS. Takeda became aware of information that ACTOS could cause bladder cancer. Under common law product liability principles, Takeda had a duty to warn providers, prescribers and caregivers administering the drug of its potential danger. Connelly alleges that Takeda failed to give proper warning, that he ingested ACTOS and it caused his bladder cancer. That has nothing to do with the Indian Health Service or the Federal government.

Lastly, Takeda's reliance on the various jurisdictional right-of-way cases is equally misplaced. DE 7-1, pgs 26-30. All of the cases relied upon by Takeda for the proposition that Indian trust land became the equivalent of non-Indian fee land involved rights-of-way granted under state and/or federal law (state highway, federal/U.S. highway, railroad right-of-way). *Id.* Indeed, the Ninth Circuit has held that even on a reservation right-of-way open to the general public, if the road

can be characterized as a "tribal road" or a "BIA road", then it does not meet the *Strate* test of being equal to non-Indian fee land for jurisdictional purposes. See *McDonald v. Means*, 309 F.3d 530 (9th Cir. 2002) and *Allstate v. Stump,* 191 F.3d 1071, 1072 (9th Cir. 1999).

Takeda has offered no case where this line of authority has been applied to a lease of tribally owned land. Extending the *Strate* rule to leases of tribal land (or even to leases of individually owned Indian land) would be a detriment to Indian Tribes and would probably result in a decline of leases to non-Indians thereby potentially adversely affecting reservation economies.

Importantly, Takeda makes no effort to challenge Connelly's claim that he ingested the drug ACTOS at his home and at his work, all on Indian trust land within the Reservation. So even if the District Court was wrong in its conclusion regarding the status of the leased land, there was still conduct on tribal trust land which could be the basis for tribal authority as a landowner. In this sense, Takeda's claims regarding the jurisdictional status of the leased land are simply meaningless. Takeda engaged in activity on Indian trust land, both individual Indian land and Tribal trust land, which gives rise in and of itself, to a colorable claim to tribal court jurisdiction.

The District Court correctly held that a lease of tribally owned land to the Indian Health Service for the purposes of establishing a public health facility did

not result a diminishment of the landowner's right to occupy and exclude so as to preclude an exercise of tribal court adjudicatory jurisdiction over a product liability case involving drugs dispensed at the facility. This Court should affirm that holding.

b. Takeda's conduct.

Throughout the proceedings in the tribal and federal courts, including this Court, Takeda has loudly claimed that it had no contact with the Blackfeet Indian Reservation, that its agents did not enter the Reservation (particularly the Indian Health Service Hospital) and that its only activities took place in Oklahoma City, Oklahoma far removed from the Blackfeet Indian Reservation. Relying on general Indian law principles articulated by the U.S. Supreme Court, Takeda therefore erroneously summarily concludes that because, according to Takeda, all of its activities took place outside of the Blackfeet Indian Reservation, tribal court jurisdiction over it is plainly lacking. See *Montana v. United States*, 450 U.S. 544; *Strate v. A-1 Contractors*, 520 U.S. 438, and *Nevada v. Hicks*, 533 U.S. 353.

As noted by Takeda, this Court has addressed possible tribal court jurisdiction over conduct similar to that described here (aggressively marketing its product to Indian consumers on a reservation) on two separate occasions. First in *Crawford v. Genuine Parts Co. Inc.*, 947 F.2d 1405, *rev'd. on other grounds* (9th Cir. 1991), this Court addressed whether the Blackfeet tribal court had plausible

jurisdiction over an action brought in the Blackfeet Tribal Court against Genuine Parts Co., a company located outside of the State of Montana, for the improper manufacturing and installation of brakes on a ford bronco. Genuine Auto Parts had sued in Federal court alleging that the Tribal Court lacked jurisdiction arguing in part that the case was not sufficiently tied to reservation interests. *Id*. at 1407-1408. Genuine Parts asserted that there was significant "off-reservation activity", that state courts would have at least concurrent jurisdiction and the principles of comity set out in *National Farmers Union v. Crow Tribe* and *Iowa Mutual v. LaPlante* simply did not apply. *Id*.

Rejecting that argument, this Court stated: "Lawsuits springing from on-reservation automobile accidents have often been considered to arise on the reservation, at least when members of the tribe are involved in the litigation. *Id.* citing *Iowa Mutual v. Laplante* and *National Farmers Union*. "Such disputes clearly "arise" on the reservation, given the situs of the harm on the reservation and the presence of Indian parties." citing *Stock West Corp. v. Taylor*, 942 F.2d 655, 662 (9th Cir. 1987).

In *Crawford*, this Court had no trouble basing tribal court jurisdiction on the fact that the situs of the harm was on the Blackfeet Reservation and the plaintiffs were Indians. *Crawford* was no longer good law as it related to the location of the accident post-*Strate*, because it occurred on a U.S. Highway traversing the

Blackfeet Reservation. However the Court's analysis regarding the situs of the harm and the parties is still relevant. Especially considering that Takeda's conduct in this case was comparable to Genuine Parts' conduct in Crawford, and in this case that conduct did occur on tribal and individual Indian trust land within the Blackfeet Reservation.

Similarly, in *Phillip Morris USA v. King Mountain Tobacco Co*., 552 F.3d 1098 (9th Cir. 2009), this Court addressed the scope of tribal court jurisdiction over a claim by an Indian business related to federal copyright law against Phillip Morris USA for its sales of cigarettes outside of the Yakima Indian Reservation and over the internet. In holding that the Yakima tribal court lacked jurisdiction over Phillip Morris' off-reservation and internet claims against King Mountain, this Court opined that, "Phillip Morris complaint does not allege claims based on King Mountain's sales of its cigarettes on the Yakima Reservation, ... To the extent that Phillip Morris challenges King Mountain's sales activities to stores on the reservation, tribal court exhaustion would be appropriate as to those claims, as there would be a colorable claim that Phillip Morris's voluntary decision to sell its cigarettes within the Reservation supplies the requisite voluntary commercial relationship to meet Montana's first exception with respect to claims arising in that market." *Phillip Morris USA,* 552 F.3d at 1110, nt. 3. Thus it would seem that, consistent with the analysis in *Crawford v. Genuine Auto Parts*, this Court would

find plausible tribal court jurisdiction over Phillip Morris' on-Reservation activity and claims arising in the reservation market. In that instance, like Takeda here, Phillip Morris would be intentionally marketing its product into the Reservation whether for reservation retailers or reservation purchasers.

In this case, Takeda's conduct consisted of engaging in an aggressive marketing plan specifically targeting the Indian Health Service with the intent that the drug ACTOS be prescribed at all Indian Health Service facilities to Indians including Victor Connelly. *Takeda Marketing Strategy/ "Pull Through" Strategy*. (filed under seal separately).

Takeda's efforts targeted all individual IHS facilities, including IHS's Blackfeet Hospital, through aggressive financial incentives that rewarded higher market share at each facility through its "ACTOS Special Pricing Terms." (filed under seal).

The Indian Health Service was created for the purpose of meeting the U.S. Government's trust responsibility to members of Federally recognized Indian tribes pursuant to the U.S. Constitution, treaties, Executive Orders , federal laws and U.S. Supreme Court decisions. "hhtp://www.ihs.gov/aboutihs/". The Actos which Connelly was prescribed and ingested was paid for by the Indian Health Service in fulfillment of its trust responsibility to Connelly as a member of the Blackfeet Indian Tribe.

While no Takeda employees apparently promoted or sold Actos directly on the Blackfeet Indian Reservation, since at least 2005 Takeda engaged in an aggressive marketing plan specifically targeting the Indian Health Service with the intent that the drug be prescribed at all Indian Health Service facilities to Indians including Victor Connelly. (filed under seal separately).

Takeda's Managed Markets group was primarily responsible for contacts with the IHS regarding the IHS's inclusion of Actos on the IHS's formulary.

Takeda's Managed Markets employee contacts with the IHS regarding the inclusion of Actos on the IHS prescription drug formulary occurred primarily through the IHS agency offices in Oklahoma City.

Some individual Takeda sales representatives have indicated that they never made direct contact with the Blackfeet Community Hospital. However none of these individuals had responsibility for the area serving the Blackfeet Hospital, and those who were responsible have never been deposed. . And Connelly believes that at least one Takeda sales representative did visit the Blackfeet Community Hospital, but was told that the hospital was being serviced by the Marketing group.

ACTOS is intended to treat Type II diabetes. Diabetes is epidemic among American Indians and Alaskan natives in the United States. *Special Diabetes Program for Indians (SDPI), 2007 Report to Congress: On the Path to A*

Healthier Future; SDPI 2001 Report to Congress: Making Progress Toward a Healthier Future, http:www.ihs.gov/ MedicalPrograms/Diabetes/ . . .module=programsSDPI. Diabetes occurs in these populations in a rate higher than any other ethnic group in America, causing serious demonstrable economic and health and welfare impacts on American Indian Tribes. *Id*. For these reasons, Congress has enacted special legislation to address this serious health care epidemic among Indian people. See *Indian Health Care Improvement Act*, 25 U.S. C. Sec. 1601 et seq.; *Special Diabetes Program for American Indians*, Pl. 105-33, Section 4922, augmented by Pl. 106-554, Sec. 931.

Importantly, it was with this knowledge that the Takeda Plaintiffs targeted the Indian Health Service for distribution of their drug ACTOS, with the intent that it be prescribed to and taken by Indian people within their reservations throughout America.

Takeda has argued that because their conduct occurred in Oklahoma, it was not on-reservation conduct for jurisdictional purposes. Takeda then goes on to assert that its marketing activities took place with the Indian Health Service offices in Oklahoma City, Oklahoma and that it had no connection to the Blackfeet Indian Reservation. That approach simply ignores that Takeda's specific purpose was to get the Indian Health Service to list ACTOS on the IHS drug formulary so that it would be distributed to all IHS facilities, including on Indian Reservations.

Takeda knew that this was the intended result of its activity and it was foreseeable that any issues arising out of the drug's use would occur within Indian reservations where the drug was being prescribed to and ingested by reservation Indians.

In this case, Takeda was essentially using the Indian Health Service as a governmental distributor of its drug, knowing that the drug would then be distributed to Indian Health Service clinics/pharmacies located on Indian reservations where it would be prescribed to Indian people for their consumption. First there is a marketing effort to the IHS headquarters for the drug formulary. Then the drug is distributed to local Indian Health Service clinics and pharmacies to be prescribed by local IHS doctors to Indian people within a reservation. Takeda is not engaged in this effort out of altruistic motivation. The motivation is simple: profit. The only difference here is that the Indian Health Service, out of its trust responsibility to Indians arising from treaties and other agreements, is paying for the drug, rather thnt the end-user having to pay out of their own pocket.

Applying the rationale of *Crawford* and *Phillip Morris* regarding the conduct of a manufacturer who sells products into the stream of commerce knowing and intending that the product will be used and could cause injury in the site of ultimate end use, the District Court concluded that Takeda was engaged in sufficient on-reservation conduct to warrant a finding of plausible tribal court jurisdiction. Indeed in this case, Takeda is not just selling its product into the

general stream of commerce, it was specifically targeting a finite and extremely vulnerable population of society to take advantage of a Congressionally recognized epidemic – Diabetes. That it could be held accountable for the consequences for the use of its product was foreseeable. For Takeda to now claim that it should not be held liable in the forum where it intended its drug be used by the people who it intended to use the drug, is nothing short of unconscionable.

Takeda's reliance on *Hornell Brewing Co. v. Rosebud Sioux Tribal Court*, 133 F.3d 1087 (8th Cir. 1998) is wrong. That case involved a tribal court action against the brewer for alleged defamation based on sales of the beer outside of the reservation. There were no allegations of sale on the reservation or distribution on the reservation intentionally to Indian people. The case has no application here.

3. PLAUSIBLE JURISDICTION UNDER "MONTANA" EXCEPTIONS.

After finding plausible tribal court jurisdiction pursuant to the Blackfeet Tribe's inherent authority as a landowner with a landowner's right to exclude, the District Court stated that its "determination precludes analysis at this point as to whether either *Montana* exception provides a colorable basis for tribal court jurisdiction." citing *Admiral Insurance Company v. Blue Lake Rancheria Tribal Court*, 2012 WL 1144331 (N.D. Cal. 2012).

However, Appellant Takeda has addressed the issue of application of Montana in this case. And, while Connelly believes it premature to address the

issue where the District Court did not discuss or rely on that line of reasoning, Connelly will address those issues none-the-less.

a. Notwithstanding its general rule, tribal court jurisdiction is plausible under both *Montana* exceptions.

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. See also Crawford v. Genuine Parts and Phillipe Morris USA.

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 "garden variety" products liability case.

2. Nexus between the voluntary commercial relationship and Connelly's claims.

The precedent further requires that there be some nexus between the commercial relationship and the underlying claims. See *Phillip Morris U.S.A. v. King Mountain Tobacco Co.* , 569 F.3d 932, ___ (9th Cir. 2009) *citing Atkinson Trading Co. v. Shirley*, 532 U.S. 645, 656 (2001).

In this case, based on the allegations, there is clearly an nexus between the voluntary commercial distribution by Takeda of the drug ACTOS and Victor Connelly's development of bladder cancer. Once again, Takeda intentionally and voluntarily marketed its drug to the Indian Health Service knowing and intending that the drug be prescribed to Indians at IHS facilities, in particular the Blackfeet Community hospital.

Takeda accepted the economic benefit of its commercial relationship with the Indian Health Service. Connelly now seeks to hold Takeda liable for the alleged failure to warn everyone (the IHS, the prescribing physician and Victor Connelly) about the danger of the drug ACTOS and that the drug could cause bladder cancer. In this case, the Tribe is protecting, through its tribal court, all of its members from the consequences of a bad drug. The fact that the regulation of the Takeda Plaintiffs' conduct takes the form of a tort action in the Blackfeet Tribal Court does not diminish the Tribe's jurisdiction or inherent sovereignty. See. *Dolegencorp, Inc. and Dollar General Corp. v. The Mississippi Band of*

Choctaw Indians, et al., 732 F.3d 409 (5th Cir. 2013) , revised opinion 3/14/2014 case no. 12-60668.

Importantly Indian Tribes have a vested interest in protecting the health of their members when it comes to diabetes. Diabetes is epidemic in American Indians and Alaskan Natives who suffer from the disease at rates higher than any other ethnic group in America. SDPI, 2007 and 2011 Reports to Congress, http:www.ihs.gov/ MedicalPrograms/Diabetes/ . . .module=programsSDPI. For this reason, "[a]ddressing this disease and its consequences for tribal communities is an important health priority for our nation." *SDPI, 2007 Report to Congress: "On a Path to a Healthier Future"*, pg. 29, http:www.ihs.gov/ MedicalPrograms/Diabetes/ . . .module=programsSDPI..

3. Takeda's conduct imperils the health and welfare of the Tribe.

Considering the epidemic nature of diabetes in Indian County, Takeda callously asserts that its intentional distribution of the diabetes drug ACTOS has no demonstrable impact on the health or welfare of the Blackfeet Tribe.

Contrary to this position is the fact that the United States Congress has recognized that diabetes is epidemic in American Indians who suffer the highest incidence of the disease in America. Moreover, the Special Diabetes Program for Indians expressly recognizes the economic impact of the disease in American Indians not only for Tribes, but for the nation as a whole. SDPI, Id.

"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*). While it is correct that the Supreme Court has further modified this standard to require that the challenged conduct imperil the subsistence of the Tribe be catastrophic to the Tribe, that standard is met here. See *Plains Commerce Bank v. Long Family Land & Cattle Co*., 554 U.S 316, 341 (200); *Evans v. Shoshone Bannock Land Use Policy Comm.*, 736 F.3d 1298, 1305-1306 (9th Cir. 2013.

Like the land use in *Brendale v. Confederated Yakima Tribes and Bands of the Yakima Indian Reservation*, 492 U.S. 408 (1989), the activity of Takeda, in the context of the extreme health crises represented by diabetes in Indian Country, clearly imperils the health and welfare of the Blackfeet Tribe and has the potential to be catastrophic to the Blackfeet Tribe.

CONCLUSION

For the reasons set forth herein, this Court should affirm the District Court's holding that on the limited facts of this case, the Blackfeet Tribal Court has plausible jurisdiction over the product liability claims of Connelly against Takeda.

STATEMENT OF RELATED CASES

Appellee Connelly is unaware of any other cases pending in this Court that are related to this appeal.

DATED this 28th day of October, 2015.

___s/Joe J. McKay_____
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CERTIFICATE OF COMPLIANCEWITH RULE 32(a)

Pursuant to Rule 32(a)(7)(b) of the Federal Rules of Appellate Procedure, I certify that this Brief contains no more than 14,000 words. Based on the word count of the word processing system used to prepare this Brief, the word count, excluding the parts of the Brief exempted by Federal Rule Appellate Procedure 32(a)(7)(B)(iii) is 8,308 words.

I also certify that this brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32 (a)(5) and the type style requirement of Federal Rule of Appellate Procedure 32 (a)(6) because this Brief has been prepared in a proportionally spaced font that includes serifs using Microsoft Word in 14 point Times New Roman font.

__s/_Joe J. McKay___
By: Joe J. McKay

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing APPELLEE'S BRIEF with the Cler of Court for the United States Court of Appeals for the Ninth Circuit using the Appellate CM/ECF filing system on October 28, 2015.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the Appellant CM/ECF system.

___/ Joe J. McKay___
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