Case No. 15-35403

IN THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

TAKEDA PHARMACEUTICALS 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

APPELLANTS' BRIEF

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the undersigned Counsel of Record for the Appellants certifies that the following is a full and complete list of any parent corporation and any publicly-held corporation that owns 10% or more of Appellants' stock:

1. Takeda Pharmaceuticals America, Inc., a Delaware corporation with its principal place of business in Illinois, is wholly owned by Takeda Pharmaceuticals U.S.A., Inc.

2. Takeda Pharmaceuticals U.S.A., Inc. (f/k/a Takeda Pharmaceuticals North America, Inc.), a Delaware corporation with its principal place of business in Illinois, is wholly owned by Takeda Pharmaceutical Company Limited.

3. Takeda Pharmaceutical Company Limited, a Japanese corporation with its principal place of business in Japan, is publicly traded on the Tokyo Stock Exchange. Takeda Pharmaceutical Company Limited has no parent company and no publicly traded company owns 10 percent or more of its stock.

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JURISDICTIONAL STATEMENT

A. Jurisdiction of the District Court.

The district court had jurisdiction over this action because it involves a federal question arising under the laws of the United States, was brought pursuant to 28 U.S.C. § 1331, and presents an actual controversy under 28 U.S.C. § 2201. The issue is whether the Blackfeet Tribal Court has adjudicatory jurisdiction over Blackfeet tribal member Victor Connelly's tort action against non-members Takeda Pharmaceuticals America, Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceutical Company Limited (collectively, "Takeda"), which allegedly arose from Connelly's receipt of a prescription drug from the federal government's Indian Health Service.

Questions of tribal court authority over non-Indians are matters of federal law, cognizable under 28 U.S.C. §1331. *Nat'l. Farmers Union Ins. Co. v. Crow Tribe of Indians*, 471 U.S. 845, 852-53 (1985) ("[t]he question whether an Indian tribe retains the power to compel a non-Indian . . . to submit to the civil jurisdiction of a tribal court is one that must be answered by reference to federal law and is a "federal question" under [28 U.S.C.] ¶ 1331."); *Evans v. Shoshone-Bannock Land Use Policy Comm.*, 736 F.3d 1298, 1302 (9th Cir. 2013) ("Non-Indians may bring a federal common law cause of action under 28 U.S.C. § 1331 to challenge tribal

court jurisdiction.") (quoting *Elliott v. White Mountain Apache Tribal Court*, 566 F.3d 842, 846 (9th Cir. 2009)).

B. Jurisdiction of the Court of Appeals.

The district court's Order and Judgment, which disposed of all parties' claims and terminated the action in the district court, were entered on April 24, 2015. Takeda timely filed its Notice of Appeal on May 19, 2015 pursuant to Federal Rule of Appellate Procedure 4(a)(1)(A). This is an appeal from the district court's final Order and Judgment, over which this Court has jurisdiction pursuant to 28 U.S.C. § 1291.

INTRODUCTION

Appellee Victor Connelly is a member of the Blackfeet Indian Tribe, who lives on the Blackfeet Reservation in Browning, Montana. Takeda manufactures and sells the prescription drug ACTOS® (pioglitazone hydrochloride) ("Actos"). Takeda is a non-member of the Blackfeet Tribe.

Takeda marketed Actos throughout the United States, including to the federal government's Indian Health Service in Oklahoma, which provides medical care to Indians around the nation. Connelly received medical care from an Indian Health Service clinic operated by the federal government on the Blackfeet Indian Reservation, where his doctor prescribed him Actos for the treatment of Type 2 diabetes mellitus. Connelly subsequently developed bladder cancer and sued Takeda in the Blackfeet Tribal Court, claiming that the drug was the cause. Connelly asserted that the tribal court had jurisdiction because Takeda marketed Actos to the IHS.

Indian tribal courts have limited jurisdiction over non-members of their tribes. They have no jurisdiction over non-members for activity that occurs off the reservation. Based on these fundamental jurisdictional principles, Takeda sought a declaratory judgment from the district court that the tribal court "plainly" lacks jurisdiction over the underlying tort action, and thus, that Takeda need not exhaust tribal remedies before seeking relief. The district court held that jurisdiction in the

tribal court was "plausible," and therefore Takeda must exhaust tribal court remedies first. The district court found "plausible" tribal court jurisdiction because Connelly obtained Actos at an IHS clinic and used it on the reservation. This holding represents an unprecedented expansion of tribal court jurisdiction and is contrary to precedent from both the United States Supreme Court and this Court. Thus, this Court should reverse the district court's judgment and declare that the tribal court lacks jurisdiction over Takeda in the underlying tort action.

STATEMENT OF THE ISSUES

1. Whether the district court erred in holding that an Indian tribal court had "plausible" jurisdiction over a non-member for its activities conducted entirely off the reservation?

2. Whether the district court erred in holding that an Indian tribal court had "plausible" jurisdiction over a non-member prescription drug manufacturer whose drug was prescribed at an Indian Health Service clinic located on reservation land?

STATEMENT OF THE CASE

A. Facts

The Takeda entities in this case are non-members of the Blackfeet Tribe. (ER 166). Appellants Takeda Pharmaceuticals America, Inc. ("TPA") and Takeda Pharmaceuticals U.S.A., Inc., ("TPUSA") are Delaware corporations with their principal places of business in Deerfield, Illinois, and Takeda Pharmaceutical Company Limited ("TPC") is a Japanese corporation. (ER 005, 166, 320). Pursuant to approval by the United States Food and Drug Administration ("FDA"), TPC manufactures the prescription diabetes drug Actos, TPUSA markets Actos, and TPA sells, markets, and distributes Actos for prescription by licensed physicians in the United States (ER 005, 166, 413-16), including physicians who practice at IHS facilities run by the federal government.

The Indian Health Service ("IHS") is a federal agency that operates within the Department of Health and Human Services ("HHS"), and is responsible for providing federal health services to American Indians. (ER 005, 166-67). The IHS operates medical facilities to provide healthcare to Indians throughout the nation, and provides medical care to Blackfeet tribal members at an IHS-operated clinic located on the Blackfeet Reservation. (*Id.*) This IHS clinic is located on land that the Tribe leased to the federal government's Public Health Service for the purpose of operating the clinic. (ER 005, 167, 344-45). The IHS operates the clinic and its employees are employed by the United States government. (ER 167, 321).

In 2005, Takeda marketed Actos to the IHS, and sought to have Actos added to the IHS national formulary, which would make the drug available for IHS doctors to prescribe to their patients. (ER 138, 214-16). Takeda's contacts with the IHS occurred in Oklahoma City, Oklahoma, where employees from Takeda's Managed Markets division communicated with the IHS. (ER 168, 329-30). As Connelly conceded and stipulated, Takeda did not market Actos at the IHS clinic on the Blackfeet Reservation, and no Takeda employees entered the reservation to market Actos there. (ER 173, 329-30).

Connelly is an enrolled member of the Blackfeet Tribe. (ER 165). Beginning in 2005, Connelly sought treatment for his diabetes from the IHS clinic on the Blackfeet Reservation. (ER 004-05). He obtained medical care and a prescription for Actos from his IHS doctor, and he filled his prescription for Actos at the IHS clinic. (ER 005). In 2008, Connelly was diagnosed with bladder cancer. (*Id.*).

On August 1, 2013, Connelly filed a tort claim against Takeda in the Blackfeet Tribal Court, alleging that Actos caused his bladder cancer. He sought recovery under theories of strict products liability, negligence, breach of warranty, fraud, and violation of the Blackfeet Consumer Sales Practices Act. (ER 391-411). In his Amended Complaint, Connelly claimed that the tribal court had jurisdiction because Takeda marketed Actos to the IHS, and because he took the Actos on the

reservation. (ER 006, 515-18). On August 30, 2013, Takeda filed a motion to dismiss in the tribal court, alleging that the tribal court lacked jurisdiction over the suit. (ER 447-461). The tribal court has never ruled on the motion, but instead has twice set the case for trial; these prior settings have been vacated and there is no current trial setting in the tribal court.

B. Procedural History

On July 8, 2014, Takeda filed a Complaint for Injunctive and Declaratory Relief in the United States District Court for the District of Montana, seeking a declaratory judgment that the tribal court lacked jurisdiction over the underlying tort case. (ER 354-389). Takeda asserted that it was "plain" that the tribal court lacked jurisdiction over non-member Takeda, and therefore it need not exhaust tribal court remedies before seeking relief. (ER 368-376). Connelly filed a motion to dismiss, asserting that Takeda was required to exhaust tribal remedies, including a trial on the merits, before seeking relief in the federal district court. (ER 332-53).[1] Takeda filed a motion for summary judgment on its declaratory judgment action. (ER 134-62). The district court heard argument on both motions on February 26, 2015. (ER 19-95).

C. The District Court's Ruling

On April 24, 2015, the district court granted Connelly's motion to dismiss.

[1] Connelly maintains that Takeda must proceed to a trial on the merits and appeal in tribal court in order to exhaust remedies.

(ER 003-016). The court held that it was "plausible" or "colorable" that the tribal court had jurisdiction over Takeda because the IHS clinic where doctors prescribed Actos to Connelly was located on reservation land and Connelly took Actos on the reservation. (ER 011-15). Without explaining how that holding subjected *Takeda* to tribal court jurisdiction, the court went on to hold that Takeda must exhaust tribal court remedies before seeking federal relief. (ER 015). The court dismissed Takeda's complaint for declaratory relief and denied Takeda's motion for summary judgment, both without prejudice. (ER 001-2, 016). This timely appeal followed.

SUMMARY OF THE ARGUMENT

The district court erred in holding that the Blackfeet Tribal Court had "plausible" or "colorable" jurisdiction over Connelly's tort claim against Takeda, based on its marketing of Actos to the federal government's Indian Health Service. Takeda's activities took place in Oklahoma, more than a thousand miles from the Blackfeet Reservation. Tribal courts "plainly" lack jurisdiction over non-members for activities occurring off the reservation.

The district court also erred in holding that the Indian Health Services clinic, located on reservation land leased to the federal government, was subject to the control of the tribe. This holding underpinned the court's conclusion that the tribal court had jurisdiction over Connelly's claim, which arose from his taking Actos prescribed at the clinic. When the tribe leased the land to the federal government for operation of the clinic, however, it did not retain the right to exclude or regulate the activities at the clinic. Tribal courts cannot adjudicate what the tribe cannot regulate, and therefore the tribal court lacks jurisdiction over clinic activities.

Because the Blackfeet Tribal Court "plainly" lacks jurisdiction over Connelly's suit, Takeda need not exhaust tribal remedies before seeking a declaratory judgment and injunctive relief in federal court. The district court erred in holding otherwise.

ARGUMENT AND CITATION OF AUTHORITY

I. Standard of Review

Whether a litigant must exhaust tribal court remedies before seeking relief from a federal district court is a question of law that this Court reviews *de novo*. *Evans v. Shoshone-Bannock Land Use Policy Comm.*, 736 F.3d 1298, 1301-02 (9th Cir. 2013), (quoting *Boozer v. Wilder*, 381 F.3d 931, 934 (9th Cir. 2004)). A district court's denial of summary judgment likewise is reviewed *de novo*. *Hansen v. Dep't of Treasury*, 528 F.3d 597, 600 (9th Cir. 2007).

II. The District Court Erred In Holding It Was "Plausible" That The Tribal Court Had Jurisdiction Over Takeda.

A. Even if the Tribe controlled the IHS clinic land, that would not confer jurisdiction over Takeda.

The district court held that the Tribe retained control over activities at the IHS clinic because the clinic was located on leased land on the reservation, thus giving rise to "colorable" jurisdiction in the tribal court. (ER 008-15). Even if the tribe retained control or authority over the operations of the IHS clinic or the land, however, that could not confer tribal jurisdiction *over Takeda*. Indeed, the district court's Order does not explain the leap it makes from finding that the land on which the IHS clinic sits is subject to control of the Tribe to finding that it is "plausible" that the tribal court has jurisdiction over Takeda. While the district court stated that the "actions underlying Connelly's claims took place on the Blackfeet Reservation" (ER 014), the activities to which the court refers are the

IHS doctor's prescriptions of Actos to Connelly. These are activities with which Takeda was uninvolved. Tribal jurisdiction is determined not by the tribal member's unilateral activities, but by the actions of the non-member defendant—here, Takeda. *See Smith v. Salish Kootenai Coll.*, 434 F.3d 1127, 1138 (9th Cir. 2006) (the "unilateral activity" of those claiming a relationship with a non-member cannot satisfy the requisite contacts with the forum).

Similarly, the IHS's decision to make Actos available to IHS patients would not confer tribal jurisdiction over the drug's manufacturer or seller. This was a decision IHS made that was wholly independent from any Blackfeet Tribal activities or authority.

Finally, Connelly's doctor's decision to prescribe Actos for him at an IHS clinic cannot confer tribal jurisdiction over Takeda. Simply put, the fact that IHS decided to make Takeda's product available to IHS doctors does not give the tribal court jurisdiction over its seller. The tribal court "plainly" lacks jurisdiction over a non-member on such attenuated facts.

B. Tribal court jurisdiction does not extend to a non-member's activities that occur off the reservation.

The district court appears to have accepted Connelly's argument that because Takeda could have anticipated that Actos would be prescribed on Indian reservations, Takeda is subject to tribal jurisdiction here. (ER 334-35, 338, 344-46). In finding jurisdiction "plausible," the court recognized that Connelly's

liability claim was based on allegations about "Takeda's contacts with IHS to market Actos to the [IHS] formulary" and Takeda's alleged "marketing tactics to drive Actos business in all IHS facilities." (ER 006).

With regard to Takeda's alleged actions, however, Connelly conceded and stipulated that:

- "no Takeda employees promoted or sold Actos directly on the Blackfeet Indian Reservation;"
- "Takeda's Managed Markets group was responsible for contacts with the IHS regarding the IHS's inclusion of Actos on the IHS formulary;" and
- "Takeda's Managed markets employee contacts with the IHS regarding the inclusion of Actos on the IHS prescription drug formulary occurred through the IHS agency offices in Oklahoma City."

(ER 168, 173, 329-330).[2]

In his Amended Complaint in tribal court, Connelly re-focused his initial claim that Takeda entered the reservation to market Actos, and instead pointed to Takeda's contacts with the IHS in Oklahoma as giving rise to liability. (ER 006, 173, 515-18). The court's finding of plausible tribal jurisdiction, therefore, is based upon Takeda's actions that occurred entirely *off the reservation i.e.*, Takeda's marketing Actos to IHS in Oklahoma City. But tribal jurisdiction does

[2] Connelly's stipulations were based on discovery in tribal court. Takeda produced its corporate representative who testified to these facts on behalf of the company. (ER 475-76), as well as other evidence. Although Connelly later claimed that he needed more discovery regarding Takeda's contacts with the IHS, no further discovery was or is necessary following Connelly's stipulations to these key jurisdictional facts.

not extend this far. In fact, the law plainly is to the contrary, as tribal courts clearly do *not* have jurisdiction over non-members for acts committed off the reservation.[3]

Tribal courts are not courts of general jurisdiction, but rather they have limited jurisdiction over the conduct of nonmembers. *Strate v. A-1 Contractors*, 520 U.S. 438, 445 (1997) ("[A]bsent express authorization by federal statute or treaty, tribal jurisdiction over the conduct of nonmembers exists only in limited circumstances.") (citing *Oliphant v. Suquamish Indian Tribe*, 435 U.S. 191 (1978)); *Nevada v. Hicks*, 533 U.S. 353, 367 (2001) ("[The] contention that tribal courts are courts of "general jurisdiction" is . . . quite wrong. . . . [A] tribe's inherent adjudicative jurisdiction over nonmembers is at most only as broad as its legislative jurisdiction."); *Montana v. United States*, 450 U.S 544, 565 (1981) ("[T]he inherent sovereign powers of an Indian tribe do not extend to the activities of nonmembers of the tribe."). Indeed, the Court noted in *Hicks* that it had "never

[3] On June 15, 2015, the United States Supreme Court granted certiorari to review the question whether Indian tribal courts "have jurisdiction to adjudicate civil tort claims against nonmembers" who enter into consensual business relationships with a tribe on the reservation. *Dollar Gen. Corp. v. Miss. Band of Choctaw Indians*, No. 13-1496, 2015 U.S. LEXIS 4003 (June 15, 2015); Petitioners' Brief, *Dollar Gen. Corp. v. Miss. Band of Choctaw Indians*, No. 13-1496, 2014 U.S. S. Ct. Briefs LEXIS 2217, at *4 (June 12, 2014). Takeda did not do business on the Blackfeet reservation. Thus, if the Court holds that tribal courts lack jurisdiction over non-members who do business in the reservation, Takeda certainly cannot be subject to tribal jurisdiction here for acts *outside* the reservation.

held that a tribal court had jurisdiction over a non-member defendant." 533 U.S. at 358, n. 2.

This Court addressed the scope of a tribal court's "colorable" jurisdiction over a non-member for activities occurring off the reservation in *Philip Morris USA, Inc. v. King Mountain Tobacco Co.*, 569 F.3d 932 (9th Cir. 2009). There, Philip Morris, the manufacturer of a well recognized brand of cigarettes, sued a Yakama Indian tribal corporation, King Mountain, in federal court for trademark violations involving its sale of cigarettes on the internet and outside the reservation. King Mountain, in turn, sued Philip Morris in Yakama Tribal Court, after which Philip Morris, a non-member, sought an injunction of the tribal court proceedings in the federal district court. *Id.* at 934-35. The district court stayed the federal proceedings, finding it "colorable" that the tribal court had jurisdiction over the claims. *Id.* at 935. Philip Morris appealed. Reversing the district court's finding of tribal court jurisdiction, this Court restated the "general rule [that] tribes do not have jurisdiction, either legislative or adjudicative, over nonmembers and [that] tribal courts are not courts of general jurisdiction." *Id*. at 938-39. The Court thus concluded that there was no colorable claim to tribal jurisdiction in the suit against non-member Philip Morris because the claims "arose off the reservation." *Id*. at 940, 945. As the Court aptly recognized, "[t]he jurisdiction of tribal courts does not extend beyond tribal boundaries." *Id*. at 938.

The Eighth Circuit Court of Appeals addressed a similar issue in *Hornell Brewing Co. v. Rosebud Sioux Tribal Court*, 133 F.3d 1087 (8th Cir. 1998). There, a tribal member sued brewing companies in the Rosebud Sioux Tribal Court for their sales of liquor off the reservation, claiming that the companies defamed the tribe's former leader, Crazy Horse, by their sale of "Crazy Horse Malt Liquor." *Id.* at 1089. The Eighth Circuit court rejected the claim of tribal jurisdiction, 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.

Id. at 1093. The court recognized the "fundamental fact . . . that the Breweries do not manufacture, sell or distribute Crazy Horse Malt Liquor *on the Reservation*." *Id*. (emphasis in original). Accordingly, the court held that there was no need to exhaust tribal remedies, because the "Tribal Court lacks adjudicatory authority over the dispute from the Breweries' use of the Crazy Horse name in the manufacturing, sale, and distribution of [the liquor] outside the Rosebud Sioux Reservation." *Id*. at 1094.

Here, as in these cases, Takeda's marketing of Actos at IHS offices in Oklahoma City is beyond the reach of the Blackfeet Tribal Court. The fact that

Connelly obtained and used Actos on the reservation does not confer tribal jurisdiction over Takeda for its activities in Oklahoma City. Under the district court's reasoning, all product sellers would be subject to tribal court jurisdiction whenever their products made their way through the stream of commerce onto an Indian reservation. This is an unprecedented expansion of tribal court jurisdiction. The tribal court lacks any plausible jurisdiction over Takeda on that basis. This alone requires reversal of the district court's Order and judgment.

C. There is no plausible basis for finding that the tribal court had jurisdiction over the federal government's IHS activities, much less the activities of a vendor of the IHS for activities that occurred off the reservation.

In *Montana v. United States*, 450 U.S. 544 (1981), the Supreme Court held that as a general rule, absent an express federal law or treaty, a tribe has no civil regulatory authority over non-tribal members for activities that occur on reservation land that is not subject to the control of the tribe. 450 U.S. at 563-65. Here, however, the district court assumed that *Montana* did not apply because the land on which the IHS clinic was located was leased from the Blackfeet Tribe. (ER 009-12). 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. Although this land was leased to the federal government for operation of the IHS clinic, the court assumed that the land was still subject to the control and authority of the tribe, with its attendant right to

exclude. (ER 014-16). This is incorrect.

In reaching this conclusion, the court ignored the fact that the tribe retained no rights in the leases to regulate or exclude the IHS activity that occurred on the land that it leased to the government. Lacking any authority to exclude, the leased land and the IHS clinic thereon simply are not subject to tribal control and adjudication.

The Blackfeet Tribe leases the land on which the IHS clinic is located to the United States Public Health Service for the operation of the IHS clinic to provide medical care to Indians. (ER 005, 166-67, 299). The leases between the Public Health Service and the Tribe that Connelly offered do not reserve to the Tribe any right of access, control, or authority over the operations of the medical clinic located on the land, nor did the Tribe retain any right of exclusion from the IHS clinic in those leases. (ER 186-208).

A tribal court's adjudicative jurisdiction does not exceed its legislative jurisdiction. *Strate v. A-1 Contractors*, 520 U.S. 438, 453 (1997). As this Court wrote, "[t]he plausibility of tribal court jurisdiction depends on the scope of the Tribes' regulatory authority as a 'tribe's adjudicative jurisdiction does not exceed its legislative jurisdiction.'" *Evans*, 736 F.3d at 1302 (citing *Plains Commerce Bank v. Long Family Land & Cattle*, 554 U.S. 316, 330 (2008)). Thus, if a tribe cannot legislate an activity, its tribal court cannot exercise jurisdiction over that

activity. *Strate*, 520 U.S. at 453.

Similarly, there 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." *Hicks*, 533 U.S. at 359; *Strate*, 520 U.S. at 456 (where cause of action arose on federal right of way in reservation land, the tribal court lacked jurisdiction); *Boxx v. Long Warrior*, No. 00-35073, 2001 U.S. App. LEXIS 24917 (9th Cir. Sept. 6, 2001) (no tribal jurisdiction over cause of action that arose on non-Indian fee land within the reservation); *Burlington N. RR Co. v. Red Wolf*, 196 F.3d 1059, 1064-65 (9th Cir. 1999), (no tribal jurisdiction where cause of action arose on railroad right-of-way within the reservation); *State of Mont. Dep't of Transp. v. King*, 191 F.3d 1108 (9th Cir. 1999) (no need to exhaust tribal remedies where cause of action arose on state highway within reservation); *Wilson v. Marchington*, 127 F.3d 805 (9th Cir. 1997) (no tribal jurisdiction over cause of action that arose on U.S. highway within reservation).

Like Takeda, the IHS is a non-member of the Blackfeet Tribe. Indeed, the IHS is part of the federal government, and no authority exists for the tribe to either exclude the government or regulate governmental activities on the reservation. Tribal courts likewise cannot adjudicate the government's activities on the reservation. *See, e.g.*, *Montana v. Gilham*, 133 F.3d 1133, 1137 (9th Cir. 1998) (inherent power of tribes over reservation land does not abrogate state's immunity

from suit in tribal court for acts on reservation); *United States v. Yakima Tribal Court*, 806 F.2d 853, 858-60 (9th Cir. 1986) (federal government cannot be sued in tribal court for acts on reservation).

Despite these longstanding principles, the district court presumed tribal jurisdiction over non-member Takeda due to Connelly's obtaining Actos on leased tribal land. (ER 012). But there is a presumption *against* tribal court jurisdiction over activities of non-members that occurs on land not subject to Indian control. In fact, this Court has held that "[t]ribal jurisdiction over non-members is highly disfavored and there exists a presumption against tribal jurisdiction. There must exist 'express authorization' by federal statute of tribal jurisdiction over the conduct of non-members." *Bugenig v. Hoopa Valley Tribe*, 229 F.3d 1210, 1215, 1217 (9th Cir. 2000) (emphasis added) *rev'd on other grounds*, 266 F.3d 1201 (9th Cir. 2001); *Strate*, 520 U.S. at 445 ("[A]bsent express authorization by federal statute or treaty, tribal jurisdiction over the conduct of nonmembers exists only in limited circumstances."). And for there to be an express delegation of jurisdiction over non-members, there must be a "clear statement" of such express delegation. *Bugenig*, 229 F.3d at 1218-19. No such delegation of powers exits here, express or otherwise. The district court thus erred in applying a presumption of tribal court jurisdiction.

Here, as *in Strate*, the tribe's loss of the "right of absolute and exclusive use and occupation . . . implies the loss of regulatory jurisdiction over the use of the land by others." *Strate*, 520 U.S. at 456 (quoting *South Dakota v. Bourland*, 508 U.S. 679, 689 (1993)). Simply 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 activities occurring within the IHS clinic.

This Court, in fact, reaffirmed this principle recently, holding that the Navajo Nation tribal court lacked jurisdiction over a tort claim arising from an accident on a state highway located within the reservation. *EXC, Inc. v. Jensen*, 588 Fed. App'x 720 (9th Cir. Dec. 23, 2014) (unpublished) (petition for cert. filed, No. 15-64, 2015 U.S. Briefs 64 (Jul. 13, 2015). The Court held that because the tribe had not retained the right to exclude non-members from the highway "the highway [was] the equivalent of non-Indian fee land for jurisdictional purposes," thus establishing that the tribal court could not exercise jurisdiction over the tort claim under *Strate*. *Id.* at 721-22. Here, the IHS clinic likewise is "the equivalent of non-Indian fee land for jurisdictional purposes."

By the district court's reasoning, the Blackfeet Tribe would retain the ability to control the operations of all federal government facilities located on the

reservation, such as the United States Post Office and the Bureau of Indian Affairs, and its tribal court likewise could adjudicate disputes arising from the government's activities in those offices. But neither Congress nor the courts have ever recognized such an expansive reach of Indian tribal courts.

Citing 25 U.S.C. § 450f, the district court recognized that Indian tribes are accorded certain rights under the Indian Self-Determination Act; for example, upon tribal resolution, tribes may request the HHS Secretary to allow them to take over the operation of certain programs for the benefit of Indians. The district court also found that 25 CFR §§ 162.021 (b) and (d),[4] give a tribe the power to contract or compact to administer leases on its land. (ER 009-010). This, of course, is correct. The record here reflects that the land on which IHS medical clinic was located *was* leased to the federal government—and also that it was under the control of the federal government at the relevant times in this case. While this statute and these regulations may allow the tribes to assert some authority over land or facilities upon request, they do not allow the tribe to regulate and control the federal

[4] 25 U.S.C. § 415 allows Indian tribes to lease certain tribal lands for public purposes, acting through the Bureau of Indian Affairs. 25 CFR § 162.021 sets out the BIA's obligations to assist the Tribes. While the district court stated that this regulation requires the BIA "to ensure that the use of tribal land comports with the Indian landowner's wishes and tribal law," (ER 009), the regulation actually requires the BIA to ensure that the use of the *land to be leased* comports with tribal desires and law. 25 C.F.R. § 16.021. Thus, neither of these sources give the tribes the right to control or regulate the activity on the leased land.

government's activities in a healthcare clinic that is not under the tribe's current control. The fact that a tribe could in the future assert control over the provision of healthcare services to its members does not mean that it controls the services now. Thus, the authority on which the district court relied does not support the proposition that the Blackfeet Tribe controlled the activities of the IHS clinic at any time relevant to this case, or even afterwards.

The court also relied on *McDonald v. Means*, 309 F.3d 530 (9th Cir. 2002) in finding that the IHS leased land was subject to tribal control. (ER 010-11). That case is inapposite. There, McDonald, a non-tribal member,[5] was involved in an accident with a tribal member, Means, on a Bureau of Indian Affairs ("BIA") road located on the Northern Cheyenne Reservation. *McDonald*, 309 F.3d at 535-36. When Means sued McDonald in Northern Cheyenne Tribal Court, McDonald objected to jurisdiction and filed a federal action. *Id.* at 536. The district court held that the road was "alienated non-Indian land," not subject to tribal control. *Id*. This Court disagreed, finding that the tribe retained control over the road pursuant to specific statutes and precedents. *Id*. In other words, it was still a "tribal road." *Id*.

More specifically, the Court held that "[i]n granting the Route 5 right of way, the Northern Cheyenne Tribe relinquished some, but not all of the sticks that

[5] McDonald was an Indian, but he was not a tribal member of the Northern Cheyenne tribe; thus he was considered a "non-member."

form the landowner's traditional bundle of gatekeeping rights. . . . [T]raffic on the road remains subject to the tribe, both in rulemaking and enforcement." *Id.* at 539-40. The Court found that in allowing public use of Route 5 and collaborating with the BIA to maintain the road, the tribe maintained significant rights. The Court pointed out that federal regulations treat BIA roads differently from other public roads, leaving to the tribe the administration and maintenance of the roads. *Id.* at 539. For example, in road planning, the planners must secure tribal consent at every stage of road construction and design, and in assigning any right of way even for surveying and construction. *Id*. Tribal officials maintain the right to set speed and weight limits and to erect the signs on the road. *Id*. The Commissioner of Indian Affairs may, on behalf of the tribe, close the road to public use. *Id*. The *McDonald* Court thus had ample basis to hold that "the Tribe retained enough of its gatekeeping rights that Route 5 cannot be considered non-Indian land." *Id*. at 540.

Here, by contrast, Connelly identified no statutes or regulations that give the Blackfeet Tribe authority to regulate and control the IHS clinic or its vendors. Takeda was not "on" a tribal road or reservation land in marketing Actos. The conduct for which Connelly claims Takeda is liable does not involve the use of the reservation land or the character of the land at all. Rather, Takeda's marketing to IHS occurred over a thousand miles away in an entirely different state—

Oklahoma. Moreover, a tribe's authority over a road is unlike control over a federal medical clinic—which is run and staffed by employees of the federal government. Thus, *McDonald* does not support the court's broad holding that the Blackfeet Tribal Court has "plausible" jurisdiction over Takeda.

The court's reliance on *Water Wheel Camp Recreational Area v. Larance*, 642 F.3d 802 (9th Cir. 2011), and *Grand Canyon Skywalk Development LLC v. Sa Nyu Wa Incorporated*, 715 F.3d 1196 (9th Cir. 2013), similarly is misplaced.[6] (ER 011-015). These cases are distinguishable and do not support tribal jurisdiction here. Each of these cases involved a real estate dispute over the control of reservation land. *See Water Wheel*, 642 F.3d at 805; *Grand Canyon*, 715 F.3d at 1199. Here, by comparison, Takeda's marketing of Actos to IHS, and even Connelly's use of Actos on the reservation, involve no dispute over control of or access to Indian land, or even the tribe's lease at all. Unlike in the cases the district court used to guide its analysis, the issues in the instant case are wholly unrelated to the character of the reservation land, whether it is tribal land, trust land, non-Indian fee land, or alienated land.

[6] The district court stated that these cases "[seem] to apply to Takeda's alleged interference with the Blackfeet Tribe's right to exclude." (ER 014). The court's allusion to "interference with the [tribe's] right to exclude" is puzzling. Connelly never suggested or identified any claim of "interference," nor was there any mention of this in the proceedings or record below.

In *Water Wheel*, the Indian tribal entity brought suit in tribal court against a non-member operator of a recreational resort located on the reservation who had leased Indian trust land from the tribe for his business. 642 F.3d at 805. The tribe claimed that the non-member had breached his contract and trespassed, after the tribe demanded that he vacate the reservation land at the expiration of his lease. *Id.* This Court held that the tribal court had jurisdiction over the dispute because the land at issue belonged to the tribe, and it was subject to their control and regulation. *Id.* at 816-20. Significantly, this dispute involved the character, ownership, and control of land by a party identified as a "trespasser." *Id.* at 812. Here by comparison, the character, ownership, and control of the IHS clinic land is not the key issue in dispute here. Regardless of whether the tribe or the IHS controls the leased land, it does not affect the core claim of liability here, which is Takeda's marketing of Actos to the IHS in Oklahoma.[7]

Grand Canyon similarly involved a dispute with a non-member over control of tribal lands that were subject to the tribe's inherent authority. 715 F.3d at 1199. There, the tribal entity sued the non-member operator of a tourist attraction—a

[7] The *Water Wheel* court cited recent Supreme Court authority that a tribe loses its inherent power to regulate reservation land when the tribe loses its right to exclude. 642 F.2d at 816 (citing *Plains Commerce Bank v. Long Family Land & Cattle Co.*, 554, U.S. 316, 328 (2008); *see also South Dakota v. Bourland*, 508 U.S. 679, 689 (1993) (recognizing that the change in land status from Indian to non-Indian abrogates the tribe's power to exclude and "implies the loss of regulatory jurisdiction over the use of the land by others").

skywalk over the Grand Canyon—which was built and operated on tribal land pursuant to a contract with the tribe, claiming that the operator breached its contract with the tribe. This Court held that the tribal court had jurisdiction over the dispute "arising when non-Indians choose to do business in Indian Country," because the tribe both owned and controlled the land on which the skywalk was operated. *Id.* at 1198. Again, the issue was the character and control of Indian tribal land—not conduct that occurred more than a thousand miles from the reservation.

As this Court acknowledged in *Grand Canyon,* the extension of jurisdiction in both *Grand Canyon* and *Water Wheel* emanated from a tribe's "inherent sovereignty" to "limit access…and exclude" non-members from the reservation. *Id*. at 1204. The extension of tribal court jurisdiction over a non-member such as Takeda –whose acts did not occur on the reservation– is a vast expansion of the "exclusion" concept which finds no support in judicial precedent. Moreover expanding the reading of "plausible" jurisdiction in this manner turns the concept of "limited jurisdiction over non-tribal members" on its head. Under the district court's analysis, jurisdiction over any manner of non-members could be justified, allowing the exception to swallow the general "limited jurisdiction" rule.

Finally, as noted above, Takeda is unaware of any authority to support the proposition that the tribe's lease with the United States would serve as a basis for

the tribal court to assert jurisdiction over the United States and its activities on that lease. *See e.g.*, *United States v. Yakima Tribal Court*, 806 F.2d 853, 858-60 (9th Cir. 1986) (federal government cannot be sued in tribal court for acts on Indian reservation).

The tribe cannot control the IHS's delivery of healthcare services at the clinic. The Tribe cannot dictate how IHS doctors treat diabetes, what drugs IHS doctors prescribe, or what drugs IHS will carry in its pharmacy. In sum, the Tribe lacks the authority to regulate, control, or dictate the operations at the IHS clinic. Thus, the court's basis for finding colorable jurisdiction is unsupported by both the record and precedent.

III. Because Jurisdiction Is Not Plausible, Takeda Need Not Exhaust Tribal Court 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 exception holds 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," *Hicks*, 533 U.S. at 369 (quoting *Strate*, 520 U.S. at 459 n. 14). The Court went on to hold that "since the lack of [tribal court] authority is clear, there is no need to exhaust the jurisdictional dispute in tribal court." *Id.* at 374.

Just last year, this Court applied this precedent to reverse a district court's dismissal of a non-member's declaratory judgment action for lack of exhaustion, upon finding the tribal court's jurisdiction "plainly lacking." *Evans*, 736 F.3d at 1300, 1302 (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 N. RR*, 196 F.3d at 1065-66 (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").

For the reasons discussed *supra*, Section II, it similarly is "plain" that the tribal court lacks jurisdiction here. Thus, the district court erred in holding that Takeda is required to exhaust tribal court remedies before seeking federal relief and its Order granting Connelly's motion to dismiss and denying Takeda's motion for summary judgment must be reversed.

IV. Even Though the District Court Did Not Reach the Issue, There Is No Tribal Court Jurisdiction Under *Montana v. United States*, 450 U.S. 544 (1981).

The district court determined that it need not consider *Montana* and its exceptions because the IHS clinic land at issue was both on the reservation and subject to tribal control. (ER 015). As explained here, this analysis was flawed. The clinic land here was not subject to tribal control and, as such, there is no basis for tribal court jurisdiction, whether under the district court's analysis or under

Montana. Given *Montana*'s rule and the record here, the Court need not remand for the district court to consider whether there is an alternative basis for tribal court jurisdiction, because it is "plain" that there is no jurisdiction under *Montana* either.

A. *Montana*'s general rule applies without exception.

In *Montana*, the Supreme Court held that as a general rule, absent an express federal law or treaty, a tribe has no civil regulatory authority over non-tribal members for activities that occur on reservation land alienated to non-Indians, *i.e.*, land not subject to the control of the tribe. 450 U.S. at 563-65. The Court recognized limited exceptions to this general rule, but only where the activity in question occurred on reservation land, and even then, only to protect tribal self-government, control internal tribal relations, or protect Indian health and safety. *Id.* at 565-66.

The tribe may regulate the activities of non-members on the reservation 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 that activity "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.[8]

B. *Montana*'s exceptions do not apply where the acts occurred off the reservation.

Montana addressed the extent of tribal jurisdiction over non-members for activities occurring 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.") (emphasis added.)

The activities for which Connelly claims Takeda is liable occurred over a thousand miles from the reservation, in Oklahoma City, where Takeda marketed Actos to the IHS, (ER 517-18) (alleging that Takeda "targeted members of the Blackfeet Tribe through the Indian Health Services formulary"). Connelly, in fact, stipulated that no Takeda employees promoted or sold Actos on the reservation, and that Takeda's contacts with IHS regarding the formulary occurred through the IHS agency offices in Oklahoma. (ER 168, 173, 329-330). In his Amended Complaint, he identified Takeda's marketing to IHS as giving rise to jurisdiction on the tribal court. (ER 006, 329-330). Thus, it is undisputed that the acts that Connelly claims give rise to Takeda's liability did not occur on the reservation, making *Montana*'s exceptions inapplicable.

[8] (ER 107-113, 342-347).

C. Connelly had no consensual relationship with Takeda.

Even if there were some basis to assume that Takeda had on-reservation contacts marketing Actos, and there is not, Connelly admits that he never communicated with Takeda. (ER 167). Instead he asserted that the IHS had a consensual relationship with Takeda and that he was the "end beneficiary" of this relationship. (ER 109). Although this argument is perhaps novel, it is unsupported by any authority for such a radical extension of tribal jurisdiction. Indeed, Connelly's position is inconsistent with this Court's precedent. For example, in *Smith v. Salish Kootenai College*, 434 F. 3d 1127 (9th Cir. 2006), this Court recognized 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*. (citing references omitted). Thus, even if Takeda knew the IHS would supply Actos to its facilities, this does not establish the requisite consensual relationship between Takeda and Connelly such that this *Montana* exception would apply.

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

Connelly cannot establish that his use of Actos or that Takeda's marketing of FDA-approved Actos to the IHS "impinges on" or is "catastrophic to" the Blackfeet Tribe's self-government. *Plains Commerce Bank*, 554 U.S. at 341; *Evans*, 736 F. 3d at 1305-06. Thus, the tribal court's exercise of jurisdiction is not

"necessary" to protect the Blackfeet Tribe's self-government or to control its internal relations. Here, as in *Strate*, the claims that Connelly makes in tribal court are "distinctly non-tribal in nature." *Strate*, 520 U.S. at 457. As such, these claims afford no basis for a legitimate exercise of tribal jurisdiction over Takeda.

E. Connelly's use of Actos does not affect the tribe's health and welfare.

Nor can Connelly show that his use of FDA-approved Actos or Takeda's sale of Actos to the IHS jeopardizes the entire tribe's "health and welfare," as required for application of this exception. Tort injuries to individual tribal members do not have a "direct effect on the health or welfare of the tribe," even where the safety of other tribe members 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 public highway running through a reservation endanger all in the vicinity and surely jeopardize the safety of [other] tribal members." *Id.* at 457-458. The Court refused the plaintiff's broad construction of tribal "health and safety," concluding that the interests of an individual tort plaintiff did not qualify as "tribal interests" to be protected by *Montana*'s exception. *Id.*; *see also Burlington N. RR*, 196 F.3d 1059, 1064-65 (rejecting tribal plaintiffs' claim that the deaths of their fellow 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).

Because none of the *Montana* exceptions apply, the Court need not remand for the district court to consider whether *Montana*'s exceptions provide a basis for tribal court jurisdiction; instead, the Court should reverse the district court's grant of the motion to dismiss and its denial of Takeda's motion for summary judgment, and enter judgment for Takeda on its declaratory judgment action.

CONCLUSION

Based on the foregoing, Takeda respectfully requests that this Court reverse the district court's judgment and enter judgment in favor of Takeda on its declaratory judgment action.

STATEMENT OF RELATED CASES

Appellants are unaware of any other cases pending in this Court that are related to this appeal.

Respectfully Submitted, this 28th day of August, 2015.

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CERTIFICATE OF COMPLIANCE WITH 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 of Appellate Procedure 32 (a)(7)(B)(iii) is 7,592 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 requirements 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/ Leslie A. Benitez
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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing APPELLANT'S BRIEF with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the Appellate CM/ECF system on August 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.

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