IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF OKLAHOMA

THE CHEROKEE NATION, Plaintiff, v. JOHNSON & JOHNSON, INC. AND JANSSEN PHARMACEUTICALS, INC., Defendants.	)	CASE NO. 6:15-cv-00280-JHP

PLAINTIFF'S REPLY AND BRIEF IN SUPPORT OF MOTION FOR REMAND AND REQUEST FOR ATTORNEY'S FEE AND COSTS

Plaintiff Cherokee Nation, pursuant to LCvR 7.1 (k), respectfully files this reply in support of Plaintiff's motion to remand this action to the District Court of Sequoyah County, State of Oklahoma because this Court lacks subject matter jurisdiction.

I. INTRODUCTION.

When there is no diversity of citizenship, and there is none in this case, removal is proper if a federal question is apparent on the face of Plaintiff's well-pleaded complaint. *Caterpillar, Inc. v. Williams*, 482 U.S. 386, 392 (1987). The well-pleaded complaint rule makes the plaintiff the master of the claim, able to avoid federal jurisdiction by relying exclusively on state law. *Id.* This rule is a "powerful doctrine [that] severely limits the number of cases in which state law 'creates the cause of action' that may be initiated or removed to federal district court...." *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 9–10 (1983).

Defendants argument hinges on the interpretation that *Grable & Sons Metal Prod., Inc. v. Darue Eng'g & Mfg*, 545 U.S. 308 (2005), overruled the well-pleaded complaint rule. However,

that is a mistaken position, as *Grable* by no means encompasses such a drastic shift in federal question jurisprudence. The Supreme Court has expressly limited the scope of *Grable* to an "exceedingly narrow" and "special and small category of cases." *Gilmore v. Weatherford*, 694 F.3d 1160, 1171 (10th Cir.2012) (citing *Empire HealthChoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 699 (2006)).

Reading *Grable* in isolation, Defendants argue that federal courts may exercise jurisdiction over any state-law claim that "implicates significant federal issues." *Grable*, however, did not implicitly overturn the well-pleaded complaint rule which has long been a basic principle marking the boundaries of the federal question jurisdiction of the federal district courts, in favor of a new test "implicat[ing] significant federal issues." *See* 545 U.S. at 312. Thus, contrary to Defendants' suggestions, *Grable* stands for the proposition that a state-law claim will present a justiciable federal question only if it satisfies *both* the well-pleaded complaint rule *and* passes the "implicat[ing] significant federal issues" test. This test requires that the federal issue within a state-law claim be "necessar[y]…actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Id*. at 314.

Federal subject matter jurisdiction jurisprudence is not an area of the law that lends itself to the application of broad principles. It is a precise analysis. The line is clearly drawn. As the Supreme Court cautioned:

> To define broadly and in the abstract "a case arising under the Constitution or laws of the United States" has hazards of a kindred order....[T]he courts have formulated the distinction between controversies that are basic and those that are collateral, between disputes that are necessary and those that are merely possible. We shall be lost in a maze if we put that compass by.

Gully v. First Nat. Bank, 299 U.S. 109 (1936). To follow Defendants' interpretation of *Grable* is indeed to put down that compass.

II. DEFENDANTS DO NOT SATISFY THE "EXCEEDINGLY NARROW," "SPECIAL," AND "SMALL" *GRABLE* EXCEPTION.

Regardless of Defendants' sweeping interpretation, *Grable* is inapposite as it is distinguishable from the case at bar. The Court in *Grable* itself distinguished the facts from those in *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804 (1986), upon which Plaintiff principally relies as controlling here. *Grable* noted that, unlike *Merrell Dow*, the plaintiff before it premised its claim on the IRS's failure to give adequate notice to plaintiff, as defined by federal law, and this was the "only legal of factual issue contested in the case." *Grable*, 545 U.S. at 315. The Court noted that in *Grable*, unlike *Merrell Dow*, whether plaintiff "received notice was an essential element of its claim, and that the federal statute's meaning was actually disputed." *Id.* at 309. *Grable* found that the federal issue was substantial because "[t]he Government ... has a direct interest in the availability of a federal forum to vindicate its own administrative action, and buyers (as well as tax delinquents) may find it valuable to come before judges used to federal tax matters." *Id*.

Grable presented a pure issue of law, one that could be settled once and for all and thereafter would govern numerous tax sales cases. In contrast, Plaintiff's case is fact bound and situation specific, as even Defendants contend, "Plaintiff will be required to establish wrongful conduct specifically as to the Cherokee Nation." [Dckt. # 19] Opposition to Remand at 6.

The Supreme Court has stressed that *Grable* is the rare exception to the general rule that federal-question jurisdiction exists only where there is a federal cause of action. *See Empire Healthchoice*, 547 U.S. at 699. The mere presence of a federal issue in a state suit does not, by itself, give rise to federal-question jurisdiction. *See Id.* at 701; *Merrell Dow*, 478 U.S. at 813.

In *Merrell Dow*, which is a more typical case than *Grable*, the plaintiffs alleged that the defendant had "misbranded" its drug Bendectin in violation of the FDCA and that this violation created a rebuttable presumption of negligence in a state tort action. *Id.* at 805–06. The Supreme Court held that reliance on an FDCA standard to prove an element of a state cause of action did not, by itself, confer federal jurisdiction. *Id.* at 817. The Court emphasized that Congress had not created a private right of action to enforce the FDCA in federal courts; thus, the Court reasoned, it would flout congressional intent to allow such claims for private relief into federal court through the backdoor of state causes of action. *Id.* at 811–12. This case falls within the broader *Merrell Dow* category of cases and not within the "narrow," "small," and "special" exception found in *Grable*, as more fully explained below.

A. The Federal Issue Is Not Necessary.

Defendants focus on a single alleged federal issue, Plaintiff's use of the term "misbranded" in its petition. This term, however, is only tangential to Plaintiff's claims. Contrary to Defendants' arguments, the petition does not turn on whether Plaintiff will have to prove a violation of a federal statute in order to be successful. Plaintiff can prove its claims without drawing into question the regulatory framework of the FDCA. Defendants' guilty plea of selling "misbranded" Risperdal in violation of the FDCA, simply establishes the underlying fact that Defendants sold a defective product. This is an admission against interest, not a federal issue.

Defendants would have this Court believe that Plaintiffs' state law consumer protection claims are an attempt to enforce federal regulations. Plaintiff's claims, however, are not based on a breach of the duty to, *e.g.*, provide adequate directions for use under the FDCA. Instead, Plaintiffs are suing Defendants for their breach of the duty to exercise reasonable care to represent the products they sell truthfully, accurately, and in accordance with their warranties.

These duties are traditional duties imposed by state, not federal law, and therefore a cause of action for breach of those duties is not an effort at private enforcement of the FDCA. The term "misbranded" could be replaced with "defective" and have the same effect in Plaintiff's claims. Whether Plaintiff purchased "misbranded" or "misrepresented" or "defective" Risperdal does not confer federal subject matter jurisdiction, where it is otherwise lacking.

B. This Case Involves No Disputed Federal Issue.

Even if the Court were to find that an issue of federal law is central to Plaintiff's claims, Defendants have *still* failed to demonstrate how there is any *dispute* as to the federal law at issue. To raise an "actually disputed" federal issue, a state cause of action must "really and substantially involv[e] a dispute or controversy respecting the validity, construction or effect of [federal] law." *Grable,* 545 U.S. at 313 (quoting *Shulthis v. McDougal,* 225 U.S. 561, 569 (1912)) (alterations in original) (quotation marks omitted). In *Grable,* for example, the state claim turned on the interpretation of the issue of "service" under the federal tax statute. In contrast, there is no dispute here over the meaning or construction of "misbranded." Plaintiff's reference to "misbranded" serves only as a short hand for what Defendants were implicitly representing and warranting their product to be. Whether Defendants complied with the "branding" requirements is primarily a *factual* inquiry—not a disputed legal question that could give rise to federal jurisdiction. *See, e.g., Hawaii v. Abbott Labs., Inc.,* 469 F. Supp. 2d 842, 853 (D. Haw. 2006) (rejecting federal jurisdiction where embedded federal standard was only a peripheral issue and there was no real disagreement over its proper construction); *Pennsylvania v. Tap Pharm. Prods., Inc.,* 415 F. Supp. 2d 516, 526 (E.D. Pa. 2005) (rejecting federal jurisdiction where there was no dispute over the proper construction of federal law). The interpretation or application of "misbranding" is not disputed in the present case, therefore, the referral to the "misbranding" issue in Plaintiff's Petition does not support federal jurisdiction.

In *Oregon ex rel. Kroger v. Johnson & Johnson*, 832 F. Supp. 2d 1250 (D. Or. 2011), the State of Oregon sued J&J, the same Defendant here, under Oregon's Unfair Trade Practices Act alleging that J&J's manufacturing, promotion, and sale of the drug "Motrin" did not comply with regulations in the FDCA concerning "current good manufacturing practices." The term "current good manufacturing practices" ("cGMPs") refers to certain regulations promulgated by the FDA pursuant to the FDCA. These regulations set out the baseline "methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." 21 C.F.R. § 210.1(a). Failure to comply with cGMPs renders a drug "adulterated." 21 C.F.R. § 210.1(b); 832 F. Supp. 2d at 1253.

After analyzing the *Grable* factors, the Court held:

> "In sum, the reference to cGMPs in some of Plaintiff's claims may constitute a "necessary" federal issue, but that issue is neither actually disputed nor substantial, and recognizing federal jurisdiction over it would disrupt the balance struck by Congress between state and federal judicial responsibilities. It therefore does not give rise to federal jurisdiction under 28 U.S.C. § 1331, making removal improper under 28 U.S.C. § 1441.

Id. at 1258. The same result is warranted here.

C. The Federal Issue Is Not Substantial.

It is undisputed that the FDCA does not provide a private cause of action. This fact counsels against a finding of substantiality. *See Gilmore v. Weatherford*, 694 F.3d 1160, 1171 (10th Cir. 2012) (explaining that the Supreme Court has "focused on whether the issue is an 'essential element' of a plaintiff's claim"). Plaintiff seeks recovery for Defendants' violation of state laws. Within the context of the FDCA regime in particular, the Supreme Court has concluded "that the presence of a claimed violation of the statute [FDCA] as an element of a

state cause of action is insufficiently 'substantial' to confer federal-question jurisdiction." *Merrell Dow,* 478 U.S. at 814. Plaintiff's well pleaded complaint asserts that Defendants violated their *state law duties*. As such, the Supreme Court's analysis of the issue in *Merrell Dow* is instructive.

In *Merrell Dow*, the Court found because Congress did not intend to create a private cause of action under the FDCA, *importing a standard from that statute* is not, by itself, sufficiently *substantial* to confer federal question jurisdiction. *Id*. at 812. "We conclude that a complaint alleging a violation of a federal statute as an element of a state cause of action, when Congress has determined that there should be no private, federal cause of action for the violation, does not state a claim arising under the Constitution, laws, or treaties of the United States." *Id*. at 817 (internal quotations omitted).

Grable defined a "substantial" federal issue as "a serious federal interest in claiming the advantages thought to be inherent in a federal forum," one that "justif[ies] resort to the experience, solicitude, and hope of uniformity that a federal forum offers." 545 U.S. at 312–13. Despite Defendants' arguments to the contrary, the application of the FDCA regulatory regime is not a federal interest that requires the experience, solicitude, or uniformity provided by federal courts. To the contrary, the Supreme Court has recognized that state courts have traditionally handled state claims with embedded FDCA standards. *See Wyeth v. Levine,* 555 U.S. 555, 574–75 (2009); *Merrell Dow*, 478 U.S. at 814–17. Indeed, the Supreme Court noted that even a *novel* FDCA issue raised as part of a state cause of action would not typically justify the exercise of federal jurisdiction. *See Merrell Dow*, 478 U.S. at 817.

Regarding the FDCA regulatory regime in particular, the Supreme Court has put great weight on Congress's decision not to create a federal remedy for violations of the FDCA. *See*

Wyeth, 555 U.S. at 574–75 (2009); *see also Grable*, 545 U.S. at 318 (summarizing *Merrell Dow's* reasoning regarding the FDCA regime). That is, Congress has affirmatively decided to keep such actions out of federal courts while tolerating overlapping regulation and litigation in state forums. This strongly indicates that drug-related consumer protection cases do not warrant a need for the "experience, solicitude, and hope of uniformity that a federal forum offers." *Grable*, 545 U.S. at 312.

D. Balance of Federal/State Responsibilities Favors Remand.

The substantiality and federalism prongs of *Grable* are closely intertwined. For the same reasons that an embedded FDCA standard does not generally constitute a "substantial" federal issue, the Supreme Court has concluded that Congress did not intend to preclude state courts from hearing FDCA-related actions. *See Wyeth*, 555 U.S. at 574. Indeed, it is not unprecedented for a state court to hear a state claim incorporating the FDCA standards. There are "widely available state rights of action" in food and drug cases. *Wyeth*, 555 U.S. at 574. Thus recognizing federal jurisdiction over such actions could attract "a horde of original filings and removal cases raising other state claims with embedded federal issues." *Grable*, 545 U.S. at 318. Finding federal jurisdiction here would open the federal courthouse door to a tremendous number of cases and would upset the congressionally approved division of labor between state and federal courts.

In sum, the reference to "misbranded" in some of Plaintiff's claims does not bring this case within the scope of the "exceedingly narrow, special, and small" exception recognized in *Grable* and exercising federal jurisdiction over it would disrupt the balance struck by Congress between state and federal judicial responsibilities. Just as in a state law "failure to warn" case, the mere existence of federal labeling law does not automatically invoke federal question

jurisdiction. Defendants' expansive interpretation of *Grable* would lead to a flood of filings in that every failure to warn personal injury case would be subject to federal question jurisdiction because the FDCA regulates warning labels. *Grable* did not intend, nor can it be interpreted to lead, to such an expansive federal jurisdiction result.

III. DIVERSITY DOES NOT EXIST WITH FEDERALLY RECOGNIZED INDIAN TRIBES AND DISCOVERY IS INAPPROPRIATE.

The Cherokee Nation is a federally recognized Indian tribe and its constitutional government operates it health care system, including the purchase of the Risperdal at issue in this litigation. Defendants request discovery that is completely meritless and unnecessary – especially given that the information they seek is in their own possession. Had Defendants made even a modest effort to search their own records or communicate with any of its employees familiar with drug sales to Indian tribes, it would have confirmed that the "real party in interest" was the Cherokee Nation and that their diversity jurisdiction argument was meritless.

Of course, this all ignores the very real problem with Defendants' hypothetical "real parties in interest": None of them can be found in the four corners of the well-pleaded Petition. As Defendants' own citations and arguments note, only in the face of inadequate jurisdictional pleadings can a defendant resort to discovery to meet its burden. Yet Defendants are not claiming that Plaintiff's Petition is *inadequate* on the issue of jurisdiction (as it is not). Instead, Defendants argue that the Petition is *incorrect*. And instead of records which *they have in their own possession* to demonstrate this misjoinder, they rely on supposition and conjecture. This is insufficient to not only meet their burden on maintaining jurisdiction here, but also to obtain jurisdictional discovery.

In conclusion, this case falls within the broader *Merrell Dow* category of cases, not least because it involves the same regulatory regime at issue in *Merrell Dow*. To the extent that

Grable can be argued to carve out an "exceedingly narrow," "special," and "small" exception to a certain category of cases, the present case does not fall within it. Even assuming *arguendo* that Plaintiff's reference to the term "misbranded" may be a stated federal issue that is "necessary" to Plaintiff's claims, that issue does not satisfy the remaining three prongs of the *Grable* analysis: it is not actually disputed, it is not substantial, and the invocation of federal jurisdiction over it would upset the balance of state and federal judicial responsibilities.

WHEREFORE, the Cherokee Nation respectfully requests that this action be remanded, the Court to award, pursuant to 28 U.S.C. § 1447(c), costs and expenses, including attorney's fees, incurred by Plaintiff as a result of the improper removal of this matter to this Court, and all other relief deemed just and equitable.

Respectfully submitted,

/s/ Curtis "Muskrat" Bruehl
Curtis "Muskrat" Bruehl, OBA # 19418
THE BRUEHL LAW FIRM
14005 N. Eastern Avenue
Edmond, OK 73013
(405) 509-6300
(405) 509- 6268 (Facsimile)
curtbrue@gmail.com

CERTIFICATE OF SERVICE (CM/ECF)

I hereby certify that a true and correct copy of the above document was served upon the attorneys of record through the Court's electronic filing system "ECF" on September 11, 2015.

/s/ *Curtis "Muskrat" Bruehl*