UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF LOUISIANA

STATE OF LOUISIANA CIVIL ACTION

VERSUS

SMITHKLINE BEECHAM CORPORATION NO.: 15-00055-BAJ-EWD

RULING AND ORDER

This case requires the Court to determine whether certain state law claims arise under 28 U.S.C. § 1331, which provides that "[t]he district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States."

I. BACKGROUND

On December 29, 2014, the State of Louisiana, through its Attorney General, (hereinafter, "Plaintiff") filed a *parens patriae* action against SmithKline Beecham Corporation d/b/a GlaxoSmithKline plc (hereinafter, "Defendant" and "GSK").[1] (Doc. 1-2). Plaintiff asserts that Defendant manipulated administrative procedures set forth by the Food, Drug, and Cosmetic Act (hereinafter "FDCA") and enforced by the Food and Drug Administration (hereinafter, "FDA") to delay the introduction of a generic version of the drug Flonase, a prescription drug manufactured by Defendant

[1] Plaintiff asserts that it "seeks to recover amounts paid by the State of Louisiana for illegally obtained funds . . . ." *Id.* at ¶ 6. Plaintiff further asserts that it brings its action "in its proprietary and/or sovereign capacity, which may include state departments, bureaus, agencies, political subdivisions, and other instrumentalities as purchasers (either directly, indirectly, or as assignees) or as purchasers under medical or pharmaceutical reimbursement programs, of Flonase." *Id.* at ¶ 7.

and approved by the FDA. (*Id.* at ¶¶ 1—2, 47—49, 86). Specifically, Plaintiff asserts that Defendant filed baseless citizen petitions to prevent or delay generic entry into the market.[2] (*Id.* at ¶54). Plaintiff further asserts that "[b]y preventing generic competitors from entering the market, GSK injured Plaintiff by causing it to pay more for fluticasone propionate products than they otherwise would have paid." (*Id.* ¶ at 86).

Plaintiff filed its action in the Nineteenth Judicial District Court for the Parish of East Baton Rouge, asserting claims for violations of the antitrust laws of Louisiana, LA. REV. STAT. ANN. § 51:121, *et seq.*, violations of the Louisiana Unfair Trade Practice and Consumer Protection Act, LA. REV. STAT. ANN. § 51:1401, *et seq.*, and unjust enrichment, LA. CIV. CODE art. 2298. (*Id.* at pp. 19—24). Plaintiff asserts that its

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[2] This process of filing baseless citizens petitions was succinctly described in litigation involving similar claims and allegations against Defendant:

> Under the Federal Food, Drug and Cosmetic Act ("FDCA"), drug manufacturers must receive FDA approval before selling a new drug. The manufacturer of a new drug who obtains FDA approval enjoys a period of market exclusivity during which their patent is protected. Once this period expires, other ("generic") manufacturers may market and sell the drug. Before the generic version is approved for sale, a prospective manufacturer of a generic drug must file an Abbreviated New Drug Application ("ANDA") with the FDA. The manufacturer must demonstrate to the FDA that the generic version is the "bioequivalent" of the brand name drug; in other words, the generic version must contain the same active ingredient(s), dosage form, route of administration, and strength. Once a generic drug enters the market, the price and sales volume of the name-brand drug typically drop. While the approval of a generic version is pending, "citizen petitions" may be filed with the FDA to express legitimate concerns regarding a product and to request that the FDA take, or refrain from taking, administrative action. Because citizen petitions can delay a generic drug's approval, they are open to abuse by pharmaceutical companies attempting to prolong their monopoly in the market.

In re Flonase Antitrust Litigation, 692 F. Supp. 2d 524, 530—31 (E.D. Pa. 2010) (internal footnotes omitted).

action is brought exclusively under Louisiana law, and that it makes no claims arising under the laws of the United States. (*Id.* at ¶ 6).

On February 4, 2015, Defendant filed a timely notice of removal asserting that the Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331. (Doc. 1 at ¶ 3). While Defendant recognizes that Plaintiff did not seek relief pursuant to a federal statute on the face of its petition, Defendant asserts that Plaintiff's state law claims necessarily turn on whether Defendant's conduct before the FDA was improper, which in turn implicates "a number of federal statutes and regulations and the FDA's implementation thereof." (*Id.* at ¶¶ 15). Accordingly, Defendant argues that Plaintiff's claims satisfy the test set forth in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005), wherein the Supreme Court clarified the limitations of "arising under" jurisdiction. (*Id.* at ¶¶ 4—21).

On March 6, 2015, Plaintiff moved to remand its action on the basis that the Court does not have subject matter jurisdiction over the claims contained therein, which are all expressly brought pursuant to state law.[3] (*See* Doc. 5). Plaintiff asserts that Defendant has failed to establish that its claims satisfy the strict "arising under" test set forth in *Grable*. On April 10, 2015, Defendant filed a response to Plaintiff's

[3] After Plaintiff filed its motion to remand, Defendant filed a Motion to Enforce Class Settlement on April 2, 2015 in the litigation cited in note 2, *supra*, which sought to enjoin some of Plaintiff's claims in this action. *See In re Flonase Antitrust Litigation*, 08-cv-3301, 2015 WL 9273274, at **3—7 (E.D. Pa. Dec. 21, 2015). On December 21, 2015, the United States District Court for the Eastern District of Pennsylvania ruled that Plaintiff was not bound by the settlement reached in that litigation. *Id.* The District Court for the Eastern District of Pennsylvania opined that some of Plaintiff's claims asserted in this action "encompassed the types of claims" covered by the settlement over which it retained jurisdiction, but ultimately concluded that Plaintiff did not waive its sovereign immunity. *Id.* at *4, *4 n.6. Accordingly, this Court now issues its Ruling and Order.

motion to remand, (Doc. 18), and both parties have thoroughly briefed this issue by way of replies and supplemental briefing,[4] (Docs. 25, 29, 30).

II. STANDARD AND APPLICABLE LAW

"A case aris[es] under federal law for § 1331 purposes if a well-pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law." *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 678 (2006) (internal quotations omitted). Because federal courts are courts of limited jurisdiction, it is presumed that a suit removed to federal court lies outside this limited jurisdiction, and the party seeking removal bears the burden of demonstrating that a federal question exists pursuant to 28 U.S.C. § 1331. *See Howery v. Allstate Ins. Co.*, 243 F.3d 912, 916 (5th Cir. 2001). Doubts about the propriety of removal are resolved in favor of remand. *See Gutierrez v. Flores*, 543 F.3d 248, 251 (5th Cir. 2008).

Absent a federal statutory cause of action, the Supreme Court has recognized the difficulty in determining when state law claims are so intertwined with issues of

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[4] In response to Plaintiff's motion to remand, Defendant briefly asserts—in the midst of an otherwise *Grable* centered analysis—that jurisdiction is also proper because Plaintiff's state law claims "conflict with the federal regulatory scheme" and are therefore preempted by federal law. (Doc. 18 at pp. 14—15). This argument was noticeably absent in the jurisdictional basis set forth in Defendant's notice of removal. (*See* Doc. 1 at ¶ 3—21). Regardless, the Court finds Defendant's argument on this point unpersuasive and the cases upon which it relies distinguishable. *See In re DDAVP Indirect Purchaser Antitrust Litigation*, 903 F. Supp. 2d 198, 219 (S.D.N.Y. 2012) (finding no federal preemption where state law antitrust and/or consumer protection claims were based in part on the defendant's filing of baseless citizen petitions). Furthermore, absent complete preemption, "[f]ederal-jurisdiction is not created by a federal defense, including the defense of preemption, even if the defense is the only contested issue in the case." *Magee v. Exxon Corp.*, 135 F.3d 599, 601 (8th Cir. 1998) (citing *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1, 14 (1983)).

federal law such that they "aris[e] under" federal law for purposes of 28 U.S.C. § 1331. *See Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804, 808 (1986) (some internal quotations omitted) (citing *Franchise Tax Board v. Constuction Laborers Vacation Trust*, 463 U.S. 1, 8 (1983)) ("There is no single, precise definition of that concept; rather, the phrase 'arising under' masks a welter of issues regarding the interrelation of federal and state authority and the proper management of the federal judicial system."). When a claim finds its origins in state rather than federal law, the Supreme Court has "identified a 'special and small category' of cases in which arising under jurisdiction still lies." *Gunn v. Minton*, ___ U.S. ___, ___, 133 S.Ct. 1059, 1065 (2013) (commenting also that "[i]n outlining the contours of this slim category, we do not paint on a blank canvas. Unfortunately, the canvas looks like one that Jackson Pollock got to first") (citations omitted).

As indicated by the parties, the most current and instructive test to determine if arising under jurisdiction is proper was set forth in *Grable*, 545 U.S. at 314. In *Grable*, the Supreme Court found that a dispute centering on whether action taken by a federal agency (the IRS) was compatible with a federal statute gave rise to federal question jurisdiction. *Id.* at 315 (commenting that "[w]hether Grable was given notice within the meaning of the federal statute is thus an essential element of its quiet title claim, and the meaning of the federal statute is actually in dispute; it appears to be the only legal or factual issue contested in the case."). In finding jurisdiction proper, the Supreme Court set forth a four-part test when it framed the inquiry as follows: "does a state-law claim necessarily raise a stated federal issue,

actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Id.* The decision in *Grable* further instructed that lack of a private cause of action under federal law is not dispositive of the question of whether arising under jurisdiction is proper and instead is simply a factor that weighs against exercising jurisdiction. *Id.* at 316—18 (discussing *Merrell Dow*, 478 U.S. 804).

Since *Grable*, district courts have been confounded by how to determine if a necessary and disputed federal issue is "substantial." *See Bd. of Comm'rs of the Se. Louisiana Flood Prot. Authority—East v. Tennessee Gas Pipeline Co., LLC*, 29 F. Supp. 3d 808, 859—63 (E.D. La. 2014) (addressing the elasticity of the substantiality inquiry). In *Gunn*, the Supreme Court did, however, expand on *Grable* and instruct that "for a case to be substantial in the relevant sense, it is not enough that the federal issue be significant to the particular parties in the immediate suit" and the substantiality inquiry "instead looks at the importance of the [federal] issue to the federal system as a whole." *Gunn*, 133 S.Ct. at 1066. In *Gunn*, the success of a state malpractice claim necessarily turned on the resolution of an issue of patent law. *Id.* at 1065—66. The Supreme Court held that arising under jurisdiction was not proper, because resolution of the patent issue would unlikely impact other cases and was not of "broader significance . . . for the Federal Government." *Id.* at 1066.

III. DISCUSSION

To the extent the federal regulations identified by Defendant necessarily raise disputed federal issues that are significant to the parties in this case, the Court finds

that such issues are not sufficiently substantial to meet the third element of *Grable's* four-part test. *See Gunn*, 133 S.Ct. at 1066—67. The federal regulations identified by Defendant are only tangentially relevant to Plaintiff's state law claims, as they do not challenge the FDA's conduct, its decision making, or its authority to regulate. *See In re Vioxx Products Liability Litigation*, 843 F. Supp. 2d 654, 668—71 (E.D. La. 2012) (declining to exercise arising under jurisdiction in *parens patriae* action where state law antitrust claims alleged facts regarding a drug manufacturer's conduct *vis a vis* the FDA, but where those facts were only some of the allegations among many); *cf. Hughes v. Chevron Phillips Chem. Co. LP*, 478 F.App'x 167, 170—71 (5th Cir. 2012) (where arising under jurisdiction was proper because the plaintiff's claims required a determination as to whether an administrative agency had authority to take certain action and whether it followed the proper procedures in doing so). Defendant's assertion that the "state attempts to insert itself directly into the federal relationship between [it] and the FDA" is simply overstated. (*See* Doc. 18 at p. 10).

At most, Plaintiff's assertion that Defendant filed objectively and subjectively baseless citizen petitions challenges the specific actions and motivations of Defendant when it availed itself of the citizen petition process. *See W. Virginia ex rel. Morrisey v. Pfizer, Inc.*, 969 F. Supp. 2d 476, 488 (S.D.W. Va. 2013) (finding that similar claims and facts do not arise under 28 U.S.C. §1331 pursuant to *Grable*). Because the purpose underlying Defendant's use of the citizen petition process will require factual determinations, resolution of Plaintiff's state law claims will have little, if any, bearing outside of the immediate suit. *See Gunn*, 133 S.Ct. at 1068 (quoting *Empire,*

547 U.S. at 701) (remarking that, "[s]uch 'fact bound and situation-specific' effects are not sufficient to establish federal arising under jurisdiction"); *see Singh v. Duane Morris LLP*, 538 F.3d 334, 339 (5th Cir. 2008) (rejecting arising under jurisdiction and observing that "[i]n contrast, this case involves no important issue of federal law. Instead, the federal issue is predominantly one of fact. . . ."). This finding is reinforced by the fact that Congress has already taken action to discourage the conduct alleged against Defendant in this action, thereby undercutting the need for a federal forum to weigh in. *See* 21 U.S.C. § 355(q) (allowing a citizen petition to be summarily denied if the FDA determines its primary purpose is to delay competition).

Defendant has not otherwise demonstrated that Plaintiff's claims require resolution of an issue of federal law under the FDCA, novel or not, that is currently unclear and important to the federal system as a whole. *Compare Empire*, 547 U.S. at 681 (commenting that "*Grable* presented a nearly pure issue of law, the resolution of which would establish a rule applicable to numerous tax sale cases. Empire's reimbursement claim, in contrast, is fact-bound and situation-specific"), *with Grable*, 545 U.S. 308 (where the meaning of an issue of federal law was in dispute, dispositive of the case, and controlling in other cases); *see also Adventure Outdoors, Inc. v. Bloomberg*, 552 F.3d 1290, 1300 (11th Cir. 2008) (finding that a federal issue was not substantial because, *inter alia*, the meaning of the federal law at issue was clear); *Vermont v. MPHJ Tech. Investments, LLC*, No. 13-cv-170, 2014 WL 1494009, at *9 (D. Vt. Apr. 15, 2014) appeal dismissed, 763 F.3d 1350 (Fed. Cir. 2014). Defendant assigns great weight to the "complexity" of determining, *inter alia*, bioequivalence

under the FDCA, (*see* Doc. 18 at pp. 2, 7—18), yet it has not persuaded the Court that the method to do so rests on unclear federal regulatory provisions that would give rise to a substantial federal issue pursuant to *Grable*. *See W. Virginia ex rel. Morrisey*, 969 F. Supp. 2d at 488.

In sum, while Defendant's alleged conduct "may be assessed against the backdrop of federal regulation," s*ee In re Vioxx*, 843 F. Supp. 2d at 669—70, the linchpin of Plaintiff's action is whether Defendant's conduct independently violated Louisiana law. *Id*. Looking beyond the importance of any federal regulatory issues to the parties, and instead focusing on the federal system as a whole, the Court finds that Plaintiff's state law claims do not rest on embedded federal issues that are substantial under *Grable*. *See Gunn*, 133 S.Ct. at 1066—67. It follows that Defendant has not demonstrated that this case needs to be heard in federal court to prevent disruption of the federal-state balance; any decision will have no precedential effect on federal law. *See W. Virginia ex rel. Morrisey*, 969 F. Supp. 2d at 488. And finally, while perhaps significant to Plaintiff's claims, a determination of whether Defendant abused the citizens petition process does not require "the experience, solicitude, and hope of uniformity that a federal forum offers." *Singh*, 538 F.3d at 339 (quoting *Grable*, 545 U.S. at 312).

IV. CONCLUSION

Arising under jurisdiction exists in a "special," "small," and "slim category" of cases. *Gunn*, 133 S.Ct. at 1065. After thoughtful review and a comprehensive assessment of the relevant federal authorities, the Court finds that Defendant has

not satisfied its burden of demonstrating that jurisdiction is proper within the cautionary parameters set forth by the Supreme Court in *Grable*. Plaintiff is the master of its complaint. While the Court may be frustrated by the jurisdictional limitations imposed upon it, the Court also remains cognizant of the fact that Congress could have provided private remedies under the FDCA and granted federal courts exclusive jurisdiction to hear such claims, but it declined to do so. *See Merrell Dow*, 478 U.S. 804.

For the foregoing reasons,

IT IS ORDERED that Plaintiff's **Motion to Remand (Doc. 5)** is **GRANTED**. This action is remanded to the Nineteenth Judicial District Court for the Parish of East Baton Rouge, Louisiana, for further proceedings.

Baton Rouge, Louisiana, this 4th day of February, 2016.

BRIAN A. JACKSON, CHIEF JUDGE
UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF LOUISIANA