

**IN THE UNITED STATES DISTRICT COURT FOR
THE SOUTHERN DISTRICT OF WEST VIRGINIA**

HUNTINGTON DIVISION

STATE OF WEST VIRGINIA *ex rel.*
PATRICK MORRISEY, ATTORNEY GENERAL,

Plaintiff,

v.

CIVIL ACTION NO. 3:13-2546

PFIZER, INC., PFIZER IRELAND PHARMACEUTICALS,
WARNER-LAMBERT COMPANY,
WARNER-LAMBERT COMPANY LLC,
RANBAXY INC., RANBAXY PHARMACEUTICALS, INC.,
and RANBAXY LABORATORIES LIMITED,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending before the Court are Plaintiff's motion to remand this action to the Circuit Court of Mason County, ECF No. 10, and Defendants' motion to stay pending transfer to federal multidistrict litigation, ECF No. 21. For the following reasons, the Court **DENIES** Defendants' motion to stay and **GRANTS** Plaintiff's motion to remand.

I. BACKGROUND

In January 2013, the State of West Virginia, through its attorney general,¹ brought suit in the Circuit Court of Mason County, West Virginia. Defendants are corporate entities that manufacture, market, and sell pharmaceuticals. Defendants Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, and Warner-Lambert Company, LLC (collectively,

¹ When this action was originally filed, Darrell V. McGraw, Jr. was West Virginia's attorney general. West Virginia's current attorney general, Patrick Morrissey, was substituted by order dated February 20, 2013. ECF No. 8.

“Pfizer Defendants” or “Pfizer”) develop, manufacture, and sell “branded” or “pioneer” drugs. Defendants Ranbaxy Inc., Ranbaxy Pharmaceuticals, Inc., and Ranbaxy Laboratories Limited (collectively, “Ranbaxy Defendants” or “Ranbaxy”) manufacture and sell generic drug equivalents. The complaint alleges violations of the West Virginia Antitrust Act (“WVAA”), W. Va. Code § 47-18-1 *et seq.*, and the West Virginia Consumer Credit and Protection Act (“WVCCPA”), W. Va. Code § 46A-1-101 *et seq.* Specifically, Plaintiff claims that Pfizer Defendants submitted false patent information and prosecuted baseless patent infringement actions against prospective competitors regarding the drug Lipitor and its generic equivalent. Second, Plaintiff alleges that Defendants entered into an anticompetitive agreement to restrain trade in the market for the drug Lipitor and its generic equivalent. Finally, Plaintiff claims that these alleged antitrust violations constitute unfair or deceptive acts or practices in violation of the WVCCPA.

The Federal Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301 *et seq.*, regulates the development, manufacture, and sale of drugs in the United States. To gain approval to sell a new drug, the FDCA requires an applicant to submit a New Drug Application (“NDA”) to the Food and Drug Administration (“FDA”), demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b). Once FDA approves an NDA, the applicant owns the exclusive right to manufacture, sell, and license the drug throughout the term of its patent. The NDA applicant then lists its patent and approval information in FDA’s List of Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”). FDA relies on the accuracy of the patent information submitted to it; it does not independently verify such information before listing it in the Orange Book. One of the purposes of the Orange Book is to identify the approved generic therapeutic equivalent of branded drugs. Those interested in

applying with FDA to sell a generic drug equivalent may use the patent information documented in the Orange Book when deciding whether and when to submit an application.

After all patents on the pioneer drug expire, competitors are free to enter the market with approved bioequivalent (“generic”) drugs. Typically, generic drugs cost much less than the branded drug and therefore sales of the branded drug decline dramatically in the presence of generic competition. To obtain FDA approval to sell a generic drug, an applicant must file an Abbreviated New Drug Application (“ANDA”) with FDA, which provides an expedient mechanism by which to gain approval. An ANDA must affirm that the generic is bioequivalent to the pioneer drug and contains the same active ingredient(s). *Id.* § 355(j)(2)(A). Additionally, an ANDA must certify that the patent of the pioneer drug is either invalid or will not be infringed by the generic bioequivalent. *Id.* § 355(j)(2)(A)(vii). The pioneer NDA holder can challenge an ANDA’s certification regarding its patent by bringing suit. A suit triggers a stay of FDA approval of the generic for a period of 30 months or until the date of a final non-appealable determination as to the validity of the patent, whichever is earlier. *Id.* § 355(j)(5)(B)(iii). Once a generic drug is approved, the ANDA applicant is granted 180 days of exclusivity from the date of the first commercial marketing of the drug. *Id.* § 355(j)(5)(B)(iv). During this time, no subsequent ANDA for that particular drug will become effective, thereby allowing the first ANDA filer to sell its product for 180 days free of competition from other generics.²

The FDCA and its implementing regulations also allow persons to petition FDA to take a certain action regarding an ANDA; a petition may, for example, raise questions regarding the generic drug’s safety or efficacy, or ask FDA to subject the application to particularly high

² A successful ANDA applicant can forfeit the 180-day exclusivity period if, for example, it fails to market the drug within 75 days after approval, or if it enters into an agreement with another applicant or patent holder and there is a final decision of a court that the agreement violates the antitrust laws. 21 U.S.C. § 355(j)(5)(D).

scrutiny. 21 U.S.C. § 355(q); 21 C.F.R. § 10.30. This submission is commonly known as a “citizen petition.”

According to the complaint, the Pfizer Defendants developed, patented, and obtained FDA approval for the drug Lipitor. Lipitor (also known by its chemical name atorvastatin calcium) belongs to a class of drugs called statins and is used to lower cholesterol. Pfizer’s original patent for Lipitor (the “893 Patent”) protected various forms of the chemical compound, including the form sold as Lipitor. The 893 Patent expired March 24, 2010. The complaint alleges that Pfizer applied for another patent on the drug to protect its period of exclusivity. This subsequent patent application identified an isolated form of the chemical compound, including the calcium salt sold as Lipitor. The application stated that this isolated form of the compound was ten times more effective in inhibiting the production of cholesterol than its non-isolated form. The patent application was approved, and a new patent was issued (the “995 Patent”). According to Plaintiff, the 995 Patent was obtained by fraud and was duplicative of the 893 Patent. Specifically, Plaintiff claims that Pfizer knowingly misrepresented that the isolated compound was ten times more effective, when it was not. Plaintiff further alleges that Pfizer submitted misleading scientific data in support of the 995 Patent. Without these false and misleading representations, Plaintiff states, the 995 Patent would not have issued and the lower-cost generic form of Lipitor would have entered the market earlier than it ultimately did.

In August 2002, Ranbaxy filed the first ANDA for approval to sell a bioequivalent form of Lipitor. The complaint alleges that Pfizer sued Ranbaxy in federal district court for patent infringement—based on both the 893 and 995 Patents—to trigger the 30-month stay and delay FDA’s approval of Ranbaxy’s application. Pfizer also filed a citizen’s petition with FDA regarding Ranbaxy’s ANDA, arguing that the agency should consider additional information in

determining approval of Ranbaxy's application. Plaintiff argues that the petition was baseless and designed to keep Ranbaxy's product off the market as long as possible.

The patent litigation proceeded while Ranbaxy's ANDA was pending before FDA. The district court ruled in favor of Pfizer. The Court of Appeals for the Federal Circuit affirmed as to the initial 893 Patent, but reversed as to the subsequent 995 Patent.³ Pfizer then sought reissuance of the 995 Patent. While that application was pending, Pfizer and Ranbaxy entered into an agreement, allegedly to protect Pfizer's exclusive presence on the market. Under the terms of the agreement, Ranbaxy promised not to compete directly with Pfizer by launching its generic version of Lipitor. Ranbaxy also allegedly agreed not to relinquish its 180-day exclusivity period for marketing and selling the generic Lipitor pursuant to an approved ANDA. This provision would effectively grant Pfizer an additional 180 days as the sole seller of Lipitor. In exchange, Pfizer allegedly promised to forgive Ranbaxy's outstanding money judgments and permit generic Lipitor to be sold in at least eleven foreign markets.

These factual allegations comprise the basis for Plaintiff's state law antitrust claims against Defendants. According to Defendants, this case is one of thirty actions that have been filed against them in state and federal court since November 2011, alleging anticompetitive conduct based on nearly identical factual allegations. The other actions have been consolidated as multidistrict litigation before U.S. District Judge Peter G. Sheridan in the District of New Jersey. *In re Lipitor Antitrust Litig.*, MDL No. 2332 (J.P.M.L. Apr. 20, 2012). The Judicial Panel on Multidistrict Litigation issued a conditional transfer order transferring this action to the MDL

³ In a published decision, *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284 (Fed. Cir. 2006), the Court of Appeals for the Federal Circuit affirmed the district court's ruling that the 893 Patent was infringed. Regarding the 995 Patent, the circuit court found that one of its claims was invalid as drafted and therefore not infringed. The circuit court did not, however, address Ranbaxy's other claims challenging the validity of the 995 Patent, concluding that those issues were mooted by its decision. 457 F.3d at 1291-92.

court. Plaintiff objected and subsequently filed a motion to vacate the conditional transfer order, which is still pending before the JPML. Plaintiff now moves to remand this action to state court. Defendants in turn ask the Court to stay this case pending transfer to the federal MDL. With this background in mind, the Court now turns to the parties' arguments and applicable legal standards.

II. ANALYSIS

A. Motion to Stay

Defendants suggest that a stay of proceedings is appropriate here because, *inter alia*, a stay will promote judicial economy and conserve resources. The Court disagrees and sees no meaningful benefit to staying this action. As succinctly stated by another district court considering this very issue in a case asserting claims under Kansas state law:

While staying the proceedings might allow a single district court to rule on the jurisdictional issue in the various cases, a stay would not affect the law that applies to the present case and little would be gained by a stay of decision on the motion to remand. The parties would still be subject to Kansas law. No great judicial economy will be realized from a delay. The parties will not save time, for they have already briefed the remand issue. The Court is well versed in both Kansas and federal law, while the transferor court would need to apply the law of different states to different claims. For purposes of judicial economy, the jurisdictional issue should be resolved immediately. If federal jurisdiction does not exist, the case can be remanded before federal resources are further expended. In the Court's view, judicial economy dictates a present ruling on the remand issue.

Aetna U.S. Healthcare, Inc. v. Hoechst Aktiengesellschaft, 54 F. Supp. 2d 1042, 1047-48 (D. Kan. 1999) (citations and footnotes omitted); *see Schecher v. Purdue Pharma L.P.*, 317 F. Supp. 2d 1253, 1256-57 (D. Kan. 2004) (citing *Hoechst*). In this case, the MDL court would still apply West Virginia law to Plaintiff's claims. Similarly, the MDL court must consider separately each of the transferred actions' remand motions and alleged bases of jurisdiction. The parties here have already briefed the motion to remand. The Court concludes that a stay is not warranted here, and will therefore turn to the parties' arguments regarding the motion to remand.

B. Motion to Remand

Plaintiff argues that this Court lacks jurisdiction over these state law claims and should remand this action to state court. Defendants offer two bases for federal jurisdiction. First, federal jurisdiction exists because Plaintiff's right to relief arises under federal law—especially federal patent law. Second, there is federal diversity jurisdiction pursuant to the Class Action Fairness Act ("CAFA"). The Court will address each argument in turn.

1. Federal question jurisdiction

"Federal courts are courts of limited jurisdiction, possessing only that power authorized by Constitution and statute." *Gunn v. Minton*, 133 S. Ct. 1059, 1064 (Feb. 20, 2013) (quoting *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994)). Federal district courts have removal jurisdiction over civil actions brought in a state court if the district courts would have original jurisdiction. 28 U.S.C. § 1441(a). As relevant here, Congress has conferred upon the district courts original jurisdiction in "all civil actions arising under the Constitution, laws, or treaties of the United States," 28 U.S.C. § 1331, and specifically over "any civil action arising under any Act of Congress relating to patents," 28 U.S.C. § 1338(a). The Supreme Court has interpreted the phrase "arising under" in both sections identically and has applied the precedents for both sections interchangeably. *Gunn*, 133 S. Ct. at 1064 (citing *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 808-09 (1988)).

A case can "arise under" federal law in two ways. The first and most direct way is when a federal statute creates the cause of action. *Id.* at 1064 (citing *Am. Well Works Co. v. Layne & Bowler Co.*, 241 U.S. 257, 260 (1916)). Federal court jurisdiction, however, may still lie over certain cases that allege state law claims. This second avenue to federal jurisdiction has been described as a "special and small category." *Empire Healthchoice Assurance, Inc. v. McVeigh*,

547 U.S. 677, 699 (2006). A federal court will have “arising under” jurisdiction over state law claims if the federal issue is: “(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress.” *Gunn*, 133 S. Ct. at 1065 (citing *Grable & Sons Metal Prods., Inc. v. Darue Eng’g & Mfg.*, 545 U.S. 308, 314 (2005)). A federal issue is substantial if it “is significant to the federal system as a whole.” *Id.* at 1068. A federal question is insufficient to establish arising under jurisdiction if a state court’s resolution of the federal question would have an effect that is “fact-bound and situation-specific,” rather than being “controlling in numerous other cases.” *Empire Healthchoice*, 547 U.S. at 700-01.

The focus of this jurisdictional inquiry is on claims, not theories. *Christianson*, 486 U.S. at 811 (citing *Franchise Tax Bd. v. Construction Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 26, & n.29 (1983)). Regarding cases that involve patent law, this means that “as long as there is at least one alternative theory supporting the claim that does not rely on patent law, there is no ‘arising under’ jurisdiction under 28 U.S.C. § 1338.” *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 684-85 (2d Cir. 2009) (citations omitted). “[A] claim supported by alternative theories in the complaint may not form the basis for § 1338(a) jurisdiction unless patent law is essential to each of those theories.” *Christianson*, 486 U.S. at 810. Because in such a case “there are reasons completely unrelated to the provisions and purposes of federal patent law why petitioners may or may not be entitled to the relief they seek under their monopolization claim, . . . the claim does not ‘arise under’ federal patent law.” *Id.* at 812 (citations and quotations omitted).

In this case, Plaintiff asserts claims under two state statutes: the WVAA and the WVCCPA. The complaint establishes the following theories in support of these claims: (1) Pfizer fraudulently obtained a duplicative patent from the U.S. Patent and Trademark Office

(“PTO”) and then wrongfully listed that patent in FDA’s Orange Book; (2) Pfizer engaged in sham patent infringement litigation against Ranbaxy; (3) Pfizer filed a sham citizen petition with FDA regarding Ranbaxy’s generic ANDA; and (4) Defendants entered into an anticompetitive market allocation agreement. Compl. ¶ 4. According to Plaintiff, Defendants used these tactics to delay the entry of generic Lipitor on the market. As these are alternative theories for relief in support of Plaintiff’s claims, the Court must determine whether each of these theories arises under federal patent law. If any single theory does not sufficiently implicate patent or federal law, then this action must be remanded.

a. First and second theories

Defendant argues that Plaintiff’s first two theories necessarily depend on “resolution of a substantial question of federal patent law,” because both turn on how the 995 Patent was obtained. These theories require analysis of how patents are issued and the requirements for a successful patent application. Patentability is certainly at issue in Plaintiff’s first theory—“whether the patent would have been granted in the absence of the fraudulent representations or omissions.” *DDAVP*, 585 F.3d at 685. In fact, Plaintiff’s complaint explicitly alleges that “but for the Pfizer Defendants’ fraudulent misrepresentations to the PTO, the 995 Patent never would have issued.” Compl. ¶ 14. To prove this allegation, Plaintiff must prove that Pfizer made material misrepresentations to the PTO and that its patent is invalid.

For Plaintiff to prevail on the second theory, that Pfizer prosecuted sham patent infringement litigation, the Court must first conclude that the lawsuit is “objectively meritless,”

that is, “no reasonable litigant could realistically expect success on the merits.”⁴ *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993). Therefore, to address Plaintiff’s allegation that Pfizer’s infringement lawsuit against Ranbaxy was a sham designed to prolong its own market exclusivity, the Court would necessarily need to resolve questions of patent law in determining whether a reasonable litigant could realistically expect success on the merits in Pfizer’s patent infringement suit against Ranbaxy. Therefore, the patent question under both these theories is necessarily raised. The second element of *Grable*’s four-part inquiry is also plainly satisfied in both instances, because the validity of the patent and Pfizer’s conduct involved in obtaining the patent is actually disputed; Plaintiff argues that Pfizer had no grounds to obtain the 995 Patent, and Pfizer maintains that the patent was appropriately issued.

The parties disagree as to whether the patent issue is sufficiently “substantial” to meet *Grable*’s third requirement. In *Christianson*, the Supreme Court stated the inquiry as whether “the plaintiff’s right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims.” 486 U.S. at 808-09. The Court elaborated on this element in *Gunn*, emphasizing that what makes a federal question “substantial” is its importance to the federal system. Defendants argue that notwithstanding the ruling in *Gunn*, this Court should follow the Second Circuit’s opinion in *DDAVP* and find that federal question jurisdiction exists based on these patent fraud theories. In *DDAVP*, which was decided before *Gunn*, the Second Circuit summarily concluded without

⁴ Only if the challenged litigation is objectively meritless does the court then examine the litigant’s subjective motivation for filing the lawsuit. The Supreme Court thus created a “two-tiered process [that] requires the plaintiff to disprove the challenged lawsuit’s *legal* viability before the court will entertain evidence of the suit’s *economic* viability.” *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 61 (1993).

detailed analysis that the plaintiffs’ “fraud-on-the-PTO theory” fell within the court’s federal question jurisdiction. The Second Circuit, however, focused on the fact that this theory necessarily implicated “the issue of patentability . . . whether the patent would have been granted in the absence of the fraudulent representations or omissions.” *DDAVP*, 585 F.3d at 685. The court omitted any analysis of whether the patent issue was “substantial” in the relevant sense—it only analyzed the issue’s importance to the parties themselves. For these reasons, this Court does not find *DDAVP* persuasive on this issue. As the Supreme Court stated in *Gunn*, it is not enough that the federal issue be significant to the parties in this case; it must be important to the federal system as a whole. *Gunn*, 133 S. Ct. at 1066.

The Court concludes that the questions of patent law raised in Plaintiff’s first theory are not of such importance to the federal system that they must be decided by a federal court. First, the nature of Plaintiff’s claim here strongly resembles the hypothetical nature of the legal malpractice inquiry in *Gunn*. In *Gunn*, the question was, “*If* [the plaintiff’s] lawyers had raised a timely [patent] argument, would the result in the patent infringement proceeding have been different?” *Id.* at 1067. Here, the question is, if Pfizer had truthfully disclosed all the relevant facts known to it in the 995 Patent application (as alleged in the complaint), would PTO have issued the 995 Patent? This inquiry is highly factual and focuses on what Pfizer knew regarding the subject of its subsequent patent and whether it fully disclosed those facts in its patent application. Moreover, the decision of the state court would have no effect on the validity of the 995 Patent itself. *Jacobs Wind Elec. Co., Inc. v. Fla. Dep’t of Transp.*, 919 F.2d 726, 728 (Fed. Cir. 1990) (citing *Lear v. Adkins*, 395 U.S. 653 (1969)) (“[A]lthough a state court is without power to invalidate an issued patent, there is no limitation on the ability of a state court to decide the question of validity when

properly raised in a state court proceeding.”), *superseded by statute on other grounds* by Pub. L. 102-560.

Unlike *Grable*, the state court’s resolution of this patent question here would not be controlling in numerous other cases, including cases involving unrelated parties and claims. In *Grable*, the plaintiff challenged the actions of the IRS, alleging that it had failed to comply with certain federally imposed notice requirements, which rendered invalid a seizure and sale of property to satisfy a federal tax delinquency. *Grable*, 545 U.S. at 310-11. Plaintiff in this case has made no allegations that PTO violated any regulations or procedures in issuing the 995 Patent. The complaint instead alleges that *Defendants* acted wrongfully, and that PTO, following the same exact regulations and procedures, would not have issued the 995 Patent if Pfizer had been truthful in its application. Thus the federal question in this case does not pose the same type of importance to the federal system as that in *Grable*; the question here is highly factual and a state court’s resolution of any federal issues here would be of little consequence to later litigants in other actions.

The Court disagrees with Defendants’ contention that the state court’s resolution of the patent issues here “can have real-world effects on potential future patent infringement actions relating to the Atorvastatin Patents,” ECF No. 23 at 11, unlike the “merely hypothetical” nature of the patent issue in *Gunn*. Pfizer argues that it holds five additional patents related to atorvastatin, which are still in force and may be impacted by this litigation. It is unclear to the Court precisely how a state court determination regarding the validity of the 995 Patent would affect the other atorvastatin patents it holds. The Court does not see how the status of those other patents would be affected, especially because generic Lipitor has already been approved and is being sold on the market, notwithstanding the existence of those other patents. Equally meritless is Defendants’

argument that a decision on the patent issues in this case could have an “influential effect” on the other pending actions before the MDL court. ECF No. 23 at 11. A decision in any court may have an “influential effect” on proceedings in another forum regarding similar claims—in fact, our judicial system relies upon the doctrine of *stare decisis*. Simply because a decision may be “influential” in other cases does not mean that a federal court must decide the issue. *Cf. Empire Healthchoice Assurance, Inc.*, 547 U.S. at 700 (observing that the federal question in *Grable* was substantial because its resolution “would be *controlling* in numerous other cases”) (emphasis added).

Although the claims in this case under the first two theories require application of federal patent law, they do not present questions of federal law that are of such significance to the federal system that they must be resolved by a federal court. State courts have both the capability and responsibility to apply federal law when determining any federal issues that are presented to them as part of state claims. “[T]he possibility that a state court will incorrectly resolve a state claim is not, by itself, enough to trigger the federal courts’ exclusive patent jurisdiction, even if the potential error finds its root in a misunderstanding of patent law.” *Gunn*, 133 S. Ct. at 1068. Plaintiff’s claims under the first two theories do not require resolution of a *substantial* issue of federal patent law. Because Plaintiff’s claims therefore do not arise under federal law, this Court lacks federal question jurisdiction based on Plaintiff’s first two theories.

b. Third theory

Even if Plaintiff’s first two theories did require resolution of patent issues that were sufficiently substantial to the federal system to arise under patent law, the third theory does not. Under Plaintiff’s third theory, Pfizer violated the state antitrust laws when it filed a sham citizen petition with FDA asking it to carefully scrutinize Ranbaxy’s ANDA because of a higher risk of

reduced quality in the generic drug due to the variation in its chemical formulation, thereby delaying approval of the ANDA. *See* Compl. ¶ 209. Whether the citizen petition was a sham is an inquiry that does not implicate any question of patent law. *See DDAVP*, 585 F.3d at 686. The substance of Pfizer’s citizen petition does not implicate the issuance or validity of the atorvastatin patent. Even if Pfizer’s petition was a sham (a question that does not raise questions of patent law), however, “[p]roof of a sham merely deprives the defendant of immunity; it does not relieve the plaintiff of the obligation to establish all other elements of his claim.”⁵ *Prof’l Real Estate Investors*, 508 U.S. at 61. Therefore, the Court must determine whether the elements of Plaintiff’s antitrust claims turn on any question of patent law.

Count II of the complaint charges Pfizer with violating W. Va. Code § 47-18-4, which prohibits “[t]he establishment, maintenance or use of a monopoly or an attempt to establish a monopoly of trade or commerce.” The West Virginia Legislature has instructed its courts to follow federal judicial decisions interpreting the comparable federal antitrust laws. W. Va. Code § 47-18-16 (“This article shall be construed liberally and in harmony with ruling judicial interpretations of comparable federal antitrust statutes.”); *Princeton Ins. Agency, Inc. v. Erie Ins. Co.*, 225 W. Va. 178, 183-84 (2009).⁶ The monopoly offense under the parallel federal statute, 15

⁵ The parties did not argue whether Defendants’ petitioning activity is protected and immunizes them from liability here. The Court nonetheless notes that the First Amendment generally protects citizen petitions from antitrust liability; this principle is known as the *Noerr-Pennington* doctrine. *See E.R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 (1965). The *Noerr-Pennington* doctrine, however, does not extend immunity to “sham” petitioning activity—activity that is “nothing more than an attempt to interfere directly with the business relationships of a competitor.” *Noerr*, 365 U.S. at 144; *Prof’l Real Estate Investors*, 508 U.S. at 61.

⁶ This state statutory provision does not mean that all alleged violations of the West Virginia Antitrust Act necessarily “arise under” federal law. It merely instructs courts to interpret the state antitrust statute in line with federal decisions interpreting the federal antitrust statutes.

U.S.C. § 2, requires a plaintiff to prove two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident. *White v. Rockingham Radiologists, Ltd.*, 820 F.2d 98, 104 (4th Cir. 1987) (citing *United States v. Grinnell*, 384 U.S. 563, 570-71 (1966)). If any of these elements requires resolution of a substantial question of patent or other federal law, then this Court has federal question jurisdiction.

Defendants argue that Plaintiff cannot prove the requisite intent to monopolize without showing that the patent was invalid and unenforceable, which raises substantial questions of patent law. Defendants point out that this case is distinguishable from *DDAVP*, where the Second Circuit concluded that the sham citizen petition theory did not raise sufficiently substantial questions of patent law. In *DDAVP*, the relevant patent had been declared invalid during the pendency of the defendant's FDA citizen petition. The court concluded that the defendant's intent in maintaining the petition (rather than withdrawing it) after the patent was declared invalid did not raise substantial questions of patent law. *DDAVP*, 585 F.3d at 687. The court, however, did not find that the question of defendant's intent necessarily raised questions of patent law. *Id.* (“*Even if the defendants’ intent . . . raises questions of patent law . . .*”) (emphasis added). This Court concludes that the questions of Defendants’ wrongful intent in submitting the citizen petition do not necessarily raise questions of patent law. As alleged in the complaint, Pfizer petitioned FDA ostensibly in its role as a corporate citizen concerned with the quality and safety of generic versions of Lipitor, not as a patent holder. Pfizer’s petition was allegedly designed to thwart or at least to delay approval of the generic ANDA by raising baseless concerns, which would eliminate generic competition regardless of the status of Pfizer’s patents.

Defendants alternatively argue that even if the allegedly sham citizen petition does not raise substantial questions of federal patent law, it does raise substantial questions of federal food and drug law, which would support federal jurisdiction pursuant to 28 U.S.C. § 1331. Specifically, Defendants claim that to determine whether the citizen petition was meritless, the court must review and apply the ANDA approval and citizen petition process, and evaluate the chemical equivalence of the proposed ANDA product to Lipitor. Notice of Removal, ECF No. 1, ¶¶ 15-16. While the mechanics of filing and considering an FDA citizen petition are necessarily raised by this theory, that is not sufficient to support federal question jurisdiction, for many of the reasons the Court discussed in the previous section. In this case, Plaintiff alleges that in the citizen petition, Pfizer claimed that there was a “risk of reduced quality in the generic product,” and urged FDA to “‘carefully scrutinize’ such ‘potential differences in quality.’” Compl. ¶ 209. This theory therefore largely requires resolution of factual disputes, including whether sufficient scientific evidence existed to cause concern about the generic formulation as the petition stated, and whether Pfizer was motivated by a desire to inhibit competition when it filed the petition.

The Court concludes that although FDCA standards may be embedded in this claim, that does not constitute a substantial federal issue sufficient to confer jurisdiction, especially where the FDCA confers no private cause of action. *See Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804, 814 (1986) (“We simply conclude that the congressional determination that there should be no federal remedy for the violation of this federal statute is tantamount to a congressional conclusion that the presence of a claimed violation of the statute as an element of a state cause of action is insufficiently ‘substantial’ to confer federal-question jurisdiction.”); *see also Marcus v. Med. Initiatives, Inc.*, No. 8:12-cv-2864, 2013 WL 718630, at *6 (M.D. Fla. Feb. 27, 2013) (although the plaintiff’s state law claims alleging distribution of counterfeit drugs “may implicate

the FDCA, that is not sufficient to support federal question jurisdiction”). Additionally, Plaintiff is not challenging FDA’s conduct in following its ANDA procedures; it is instead challenging the specific actions and motives of Pfizer when it availed itself of the citizen petition mechanism. Therefore, this case is not one in which the Government has a “direct interest in the availability of a federal forum to vindicate its own administrative action.” *Grable*, 545 U.S. at 315.

Finally, Defendants argue that resolution of substantial issues of patent law is required for Plaintiff to show an antitrust injury. To have antitrust standing, a plaintiff must demonstrate an antitrust injury, which is “injury of the type the antitrust laws were intended to prevent and that flows from that which makes [the] defendants’ acts unlawful.” *Brunswick*, 429 U.S. at 489; *see also Kloth v. Microsoft*, 444 F.3d 312, 324 (4th Cir. 2006). According to Defendants, whether Plaintiff suffered damages implicates questions of the validity, scope, and enforceability of Pfizer’s patents, because the valid patents would legally protect Pfizer from generic competition. The Court acknowledges that such questions may be implicated here, but Supreme Court precedent indicates that this factor is insufficient to warrant federal question jurisdiction. The plaintiff in *Christianson*, for example, also asserted a monopolization claim, which would require showing of an antitrust injury. The Supreme Court nonetheless concluded that because the plaintiff asserted a theory for relief “completely unrelated to the provisions and purposes of federal patent law,” the claim did not arise under federal patent law. In so deciding, the Court did not address the need to resolve questions of patent law to determine injury. *Christianson*, 486 U.S. at 812-13; *see also Altman v. Bayer Corp.*, 125 F. Supp. 2d 666, 673 (S.D.N.Y. 2000) (“This Court can only assume that the United States Supreme Court was aware that an antitrust plaintiff had to prove injury-in-fact when it decided *Christianson*, and concluded (albeit *sub silentio*) that injury-in-fact, while a predicate to standing was not an “element” of a claim of

monopolization—even if this particular predicate to standing depended on a showing that the patent was invalid.”).

Accordingly, Plaintiff’s claim to relief under the third theory does not arise under federal law and gives this Court no basis for jurisdiction.

c. Fourth theory

Plaintiff’s final theory is an additional ground for relief that does not arise under federal patent law. Plaintiff’s fourth theory alleges that Defendants entered into a “pay-for-delay” agreement, an agreement ostensibly designed to resolve the patent infringement litigation and to protect Ranbaxy from infringement liability. Under this agreement, Ranbaxy promised not to launch its generic form of Lipitor until November 30, 2011. Ranbaxy also allegedly promised not to waive or relinquish the 180-day period of exclusivity it earned for being the first ANDA filer of the generic form of Lipitor. In exchange, Pfizer excused Ranbaxy from paying several substantial money judgments Pfizer had obtained against it, and permitted Ranbaxy to sell generic Lipitor in at least eleven foreign markets. Defendants argue that to prove Plaintiff’s claims under this fourth theory, Plaintiff must show that the 995 Patent would not have blocked Ranbaxy’s generic Lipitor absent the agreement. That is, Plaintiff must prove that Pfizer’s atorvastatin patents were invalid, not infringed, or unenforceable .

Defendants rely upon the proposition that “patent settlements consistent with the scope of the settled patent [are] lawful, barring fraud in the procurement of the patents or sham enforcement.” ECF No.1 ¶ 19 n.2. Therefore, Defendants reason, because the agreement at issue was evidently in settlement of the patent infringement lawsuit, it is presumed to be lawful and to overcome this presumption, Plaintiff must show that the patent was invalid. Assuming,

arguendo, that this is a proper presumption,⁷ it does not operate in Defendants' favor here because the alleged wrongful terms of the agreement extend beyond the expiration of the 995 Patent. The parties agree that the 995 Patent expired in June 2011. ECF No. 1 ¶ 18; Compl. ¶ 177. According to the complaint, however, Ranbaxy agreed that it would not compete with Pfizer until November 30, 2011. Therefore, the validity of the 995 Patent need not be questioned for Plaintiff to prevail, because the agreement allegedly protected Pfizer from generic competition for an additional five months *after* the 995 Patent expired. *See* Compl. ¶ 245. Therefore, Plaintiff's fourth theory supports a claim to relief that does not necessarily raise a substantial question of patent or other federal law. *See Hoechst*, 54 F. Supp. 2d at 1053-54 (concluding that a parties' alleged agreement, under which the generic drug manufacturer refrained from marketing its competitor drug, provided a theory for a claim to relief that was independent of patent law, because this theory did not implicate the validity of the patent).

Because none of the theories in support of Plaintiff's claims necessarily raises substantial questions of patent or other federal law, the claims do not arise under federal law. The Court therefore lacks federal question jurisdiction and must remand this action, unless diversity jurisdiction exists.

2. Federal diversity jurisdiction pursuant to CAFA

Defendants next argue that even if this Court lacks federal question jurisdiction, it has diversity jurisdiction pursuant to the Class Action Fairness Act ("CAFA"), 28 U.S.C. §

⁷ Defendants cite cases from the Eleventh, Second, and Federal Circuits for this legal presumption. ECF No. 1 ¶ 19 n.2. In response, Plaintiff cites a Third Circuit case, *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012), in which the court adopted a different presumption as to the validity of such patent infringement settlements. The Supreme Court will address this issue in *FTC v. Watson Pharmaceuticals, Inc.*, No. 12-416 (*cert. granted* Dec. 7, 2012).

1332(d)(2)(A). Specifically, Defendants claim that although this action is labeled a *parens patriae* action brought in the name of the state and attorney general, it is effectively a class action and subject to this Court’s CAFA-conferred jurisdiction.⁸ This argument, however, is foreclosed by the Fourth Circuit’s opinion in *West Virginia ex rel. McGraw v. CVS Pharmacy, Inc.*, 646 F.3d 169 (2011), *cert. denied*, 132 S. Ct. 761 (Nov. 28, 2011).

CAFA authorizes the removal of any civil action which is a class action in which (1) “the matter in controversy exceeds the sum or value of \$5,000,000, exclusive of interest and costs,” 28 U.S.C. § 1332(d)(2); (2) “any member of a class of plaintiffs is a citizen of a State different from any defendant,” *id.* § 1332(d)(2)(A); and (3) there are 100 or more plaintiff class members, *id.* § 1332(d)(5)(B). The statute defines “class action” to mean “any civil action filed under rule 23 of the Federal Rules of Civil Procedure or *similar State statute or rule of judicial procedure authorizing an action to be brought by 1 or more representative persons as a class action.*” *Id.* § 1332(d)(1)(B) (emphasis added).

In *CVS Pharmacy*, the West Virginia Attorney General brought suit in West Virginia state court alleging that various pharmacies were violating the WVCCPA, W. Va. Code §§ 46A-6-104, 46A-7-111, and West Virginia’s generic drug pricing statute, W. Va. Code § 30-5-12b(g). 646 F.3d at 171-72. The attorney general sought injunctive relief, restitution and disgorgement of overcharges, recovery on behalf of consumers of excess charges, civil penalties, interest, costs, and fees. *Id.* at 172. The defendant pharmacies removed, arguing that the action was a “disguised class action,” and therefore subject to federal jurisdiction under CAFA. The district court granted the plaintiff’s motion to remand, noting that the action was a “classic *parens patriae*

⁸ The Court notes that Defendants argue only that this case is removable as a CAFA “class action.” CAFA also permits removal of certain claims dubbed “mass actions.” 28 U.S.C. § 1332(d)(11)(B)(i). Because Defendants do not claim that this is a removable “mass action,” the Court need not address that issue.

action that is neither a class action nor a mass action contemplated by CAFA.” *West Virginia ex rel. McGraw v. CVS Pharmacy, Inc.*, 748 F. Supp. 2d 580, 596 (S.D. W. Va. 2010) (Copenhaver, J.). The district court noted that the WVCCPA authorized the Attorney General to act as an administrator of the law, independently of individual consumer complaints. *Id.* at 593.

On appeal, the Fourth Circuit relied principally on the fact that a “class action” must be filed under Federal Rule of Civil Procedure 23 or a “similar state statute or rule of judicial procedure” to determine that WVCCPA actions are not class actions subject to removal under CAFA. *CVS Pharmacy*, 646 F.3d at 174-75. The court decided that the West Virginia statutes authorizing the Attorney General to bring the suit, among them West Virginia Code §§ 46A-7-111(1)-(2) and 46A-6-101, “contain virtually none of the essential requirements” for a class action. *Id.* at 175. Critical to the Fourth Circuit’s opinion was its reasoning that in a *parens patriae* action, “[n]either the State nor the Attorney General is a member of the class purportedly represented, and neither suffered the same injury as the citizens in that class.” *Id.* at 177. The court focused on the role of the state and the attorney general in bringing the suit, and whether either “represented” the citizens of West Virginia in the relevant sense. It observed, “for a representative suit to be a class action, the representative party ‘must be part of the class and possess the same interest and suffer the same injury as the class members.’” *Id.* at 176 (quoting *Gen. Tel. Co. v. Falcon*, 457 U.S. 147, 156 (1982) (citations omitted)). Because the attorney general’s claim on behalf of the state did not “require the State to be a member of the class, to suffer the same injury as class members, or to have a claim typical of each class member’s claim,” the claims lacked the “type of representation essential to the representational aspect of a class action.” *Id.* at 176-77. For that reason, the court concluded that the attorney general’s *parens patriae* action, asserting claims under the WVCCPA, was not a class action and thus not

removable pursuant to CAFA.

Defendants' attempts to distinguish *CVS Pharmacy* from this case are unavailing. First, Defendants argue that *CVS Pharmacy*'s reasoning does not govern here, because unlike the complaint in *CVS Pharmacy*, this case involves claims asserted under the WVAA. The Court sees no meaningful difference between the WVAA and the WVCCPA that would justify allowing removal of cases involving the former but not the latter. Contrary to Defendants' assertions, the WVAA is no more similar to Rule 23 in the relevant sense than the WVCCPA. Defendants argue that the WVAA is more similar to Rule 23 than the WVCCPA because of the procedural protections it affords to those whose claims may be resolved by the attorney general's action. The WVAA requires the attorney general to publish notice of the action, to allow those "on whose behalf an action is brought" to elect to exclude their portion of the state claim from adjudication. W. Va. Code § 47-18-17(b), (c). The statute also requires court approval of any settlement. *Id.* § 47-18-17(e). It is true that these provisions resemble those required by Federal Rule of Civil Procedure 23. *See* Fed. R. Civ. P. 23(c)(2), (e). Although these "procedural protections" are similar to Rule 23, the WVAA contains no provisions similar to Rule 23's other requirements of "numerosity, commonality, typicality, and adequacy of representation." *CVS Pharmacy*, 646 F.3d at 174 (citing Fed. R. Civ. P. 23(a)). It is these requirements—not procedural protections—that cause a state statute to be "similar" to Rule 23 for purposes of CAFA. *Id.* at 175 ("Without this representative nature of the plaintiffs' action and the action's satisfaction of the four criteria stated in Rule 23(a), the action is not a class action."). These four requirements are arguably more important than procedural safeguards when it comes to determining whether an action is brought under a state statute or rule similar to Rule 23. *See id.* ("[W]hile a 'similar' state statute or rule need not contain *all of the other conditions and administrative aspects* of Rule 23, it

must, at a minimum, provide a procedure by which a member of a class whose claim is typical of all members of the class can bring an action not only on his own behalf but also on behalf of all others in the class”) (emphasis added). Therefore, the Court concludes that the Fourth Circuit’s ruling in *CVS Pharmacy* is equally applicable here, and this *parens patriae* action is not removable under CAFA.

Second, Defendants urge the Court to follow the reasoning of the pre-*CVS Pharmacy* case *West Virginia ex rel. McGraw v. Comcast Corp.*, 705 F. Supp. 2d 441 (E.D. Penn. 2010). In that case, which was transferred as part of an MDL action to the Eastern District of Pennsylvania, the plaintiff sought remand of a complaint alleging violations of the WVAA and the WVCCPA. 705 F. Supp. 2d at 444. The district judge concluded that CAFA’s requirements were satisfied, thus conferring federal diversity jurisdiction. In so ruling, the court applied a claim-by-claim analysis of the complaint, following *Louisiana ex rel. Caldwell v. Allstate Insurance Company*, 536 F.3d 418 (5th Cir. 2008), and found that certain West Virginia citizens—not the State of West Virginia—were the real parties in interest. *Id.* at 447, 449-50. The court also emphasized the “procedural protections” contained in the WVAA and their similarity to those in Rule 23, to conclude that the case was a class action. *Id.* at 452-53. This Court does not find *Comcast Corp.* persuasive. That case was decided before *CVS Pharmacy*, and thus that court lacked the benefit of the Fourth Circuit’s ruling. Furthermore, the Fourth Circuit directly considered and declined to follow *Comcast Corp. CVS Pharmacy*, 646 F.3d at 176-77. The Fourth Circuit rejected the defendants’ arguments, which cited *Caldwell* and *Comcast Corp.*, that the suit was a “disguised class action,” because the Attorney General acted on behalf of citizens, each of whom allegedly

suffered a common injury.⁹ *Id.* The court emphasized, “that type of representation is not the type that would make the State’s action a class action,” because a “class action is an action filed by an individual *as a member of a class* and whose claim is typical of the class members’ claims.” *Id.* at 176. Therefore, the Court concludes that the reasoning in *CVS Pharmacy* applies to *parens patriae* actions asserted under the WVAA.¹⁰

The power to sue as *parens patriae*—literally, parent of the country—is “inherent in the supreme power of every State.” *Mormon Church v. United States*, 136 U.S. 1, 57 (1890). In order to bring a *parens patriae* action, “the State must articulate an interest apart from the interests of particular private parties, i.e., the State must be more than a nominal party.” *Alfred L. Snapp & Son, Co. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 606 (1982). As *parens patriae*, the state may assert “quasi-sovereign interests,” which “are not sovereign interests, proprietary interests, or private interests pursued by the State as a nominal party. They consist of a set of interests that the State has in the well-being of its populace.” *Id.* at 602. A state may have a quasi-sovereign interest in “bringing an action to enforce its laws, disgorge the proceeds of ill-gotten gains, and refund them to its citizens.” *AU Optronics*, 2011 WL 4344079, at *6 (quoting *In re Edmond*, 934

⁹ Moreover, as this Court observed in *West Virginia ex rel. McGraw v. JPMorgan Chase & Co.*, 842 F. Supp. 2d 984 (S.D. W. Va. 2012), the claim-by-claim approach employed in *Caldwell* (and later, *Comcast Corp.*) is disfavored. 842 F. Supp. 2d at 997-98 (citing *LG Display Co. v. Madigan*, 665 F.3d 768, 773-74 (7th Cir. 2011)). See also, e.g., *South Carolina v. AU Optronics Corp.*, No. 3:11-cv-00731, 2011 WL 4344079, at *6 (D.S.C. Sept. 14, 2011); *Dep’t of Fair Empl. & Hous. v. Lucent Techs., Inc.*, 642 F.3d 728, 739-40 (9th Cir. 2011).

¹⁰ In *CVS Pharmacy*, the attorney general asserted claims under the WVCCPA, which the court properly recognized as a valid *parens patriae* action, because he was “authorized to file suit independently of any consumer complaints, as a *parens patriae*, that is, as the legal representative of the State to vindicate the State’s sovereign and quasi-sovereign interests, as well as the individual interests of the State’s citizens.” *CVS Pharmacy*, 646 F.3d at 175-76. The WVCCPA does not explicitly use the phrase “*parens patriae*” in authorizing suit, but the Fourth Circuit properly recognized it as such. The WVAA, on the other hand, explicitly authorizes the attorney general to bring an action as *parens patriae*. W. Va. Code § 47-18-17(a).

F.2d 1304, 1312 (4th Cir. 1991)). As recognized by *CVS Pharmacy*, and as applied to the facts here, this attorney general WVCCPA and WVAA action is brought by the state as *parens patriae*. The state's quasi-sovereign interests, not those of the individual purchasers, dominate the complaint, and it is not a class action.

Because this action was not brought under Federal Rule of Civil Procedure 23 or a similar state statute, CAFA does not permit its removal. This Court consequently lacks federal diversity jurisdiction. Having concluded that the Court lacks subject matter jurisdiction over this action, it must be remanded.

III. CONCLUSION

For the reasons discussed above, the Court concludes that there is no persuasive reason to stay this action pending its possible transfer to federal MDL proceedings. Accordingly, Defendants' motion to stay is **DENIED**. After evaluating the merits of the parties' arguments regarding remand, the Court determines that the claims asserted in the complaint do not arise under federal law, nor do they fall within this Court's diversity jurisdiction. Because this Court lacks subject matter jurisdiction, Plaintiff's motion to remand must therefore be **GRANTED**.

Therefore, the Court **DIRECTS** that this action be **REMANDED** to the Circuit Court of Mason County, West Virginia and **STRICKEN** from the docket of this Court. The Court **DIRECTS** the Clerk to send a copy of this written Opinion and Order to counsel of record and any unrepresented parties.

ENTER: May 13, 2013



ROBERT C. CHAMBERS, CHIEF JUDGE