UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF LOUISIANA

STATE OF LOUISIANA, by and through its ATTORNEY GENERAL JAMES CALDWELL v. ASTRAZENECA AB, ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP, and AKTIBOLAGET HÄSSLE	CIVIL ACTION NO. 15-274 JUDGE: _____ MAGISTRATE: _____

NOTICE OF REMOVAL

PLEASE TAKE NOTICE that, Defendants AstraZeneca AB, AstraZeneca LP, AstraZeneca Pharmaceuticals LP, and Aktibolaget Hässle (collectively "AstraZeneca" or "Defendants"), pursuant to 28 U.S.C. §§ 1331, 1338, 1441, and 1446 and with a full reservation of rights, jointly remove to this Court the petition filed by Plaintiff the State of Louisiana ("Louisiana" or "Plaintiff") in the 19th Judicial District Court for the Parish of East Baton Rouge, State of Louisiana (the "Petition"), styled, *State of Louisiana, by and through its Attorney General James Caldwell v. AstraZeneca AB, AstraZeneca LP, AstraZeneca Pharmaceuticals LP, and Aktibolaget Hässle*, Civil Action No. 637960, Section 22 (the "State Court Action").

INTRODUCTION

1. The State Court Action concerns a challenge to the enforcement of patents for Toprol-XL®, a prescription drug manufactured by AstraZeneca and approved by the United States Food and Drug Administration (the "FDA") for the treatment of angina, hypertension and congestive heart failure and the federal regulatory structure in which pharmaceutical manufacturers must operate. Federal questions lie at the heart of this action.

2. Plaintiff alleges that AstraZeneca "unlawfully obtained and manufactured a monopoly for Toprol-XL and metoprolol succinate through intentional omissions and misrepresentations to the U.S. Patent and Trademark Office ("PTO") ... obtained U.S. Patent 5,001,161 (the "'161 patent) and U.S. Patent 5,081,154 (the "'154 patent") through inequitable conduct before the PTO" and that in the "absence of such conduct, the '161 and '154 patents would not have been issued."[1] Petition at ¶5. Plaintiff also alleges that AstraZeneca improperly "caused [the Toprol XL® Patents] to be listed in the Orange Book (defined below), which enabled them to falsely create and extend their market monopoly for Toprol-XL." *Id.* As part of the new drug approval process conducted by FDA, a brand manufacturer must provide to FDA information regarding which patents or patents cover that new drug. FDA "publishes the patent information that it receives in a publication entitled "Approved Drug Products With Therapeutic Equivalence Evaluation," more commonly known as the "Orange Book." Petition at ¶29. Plaintiffs further allege that AstraZeneca "wrongfully protected their patent-controlled monopoly by filing sham patent infringement litigation, when [AstraZeneca] knew or should have known that the patens were unenforceable *ab initio*." *Id.*

3. Essentially, the State Court Action centers on alleged conduct by AstraZeneca directed at the PTO and FDA as well as alleged "sham patent infringement litigation" against generic drug manufacturers in United States District Courts (situated in other states) pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub L. No. 98-417, 98 Stat. 1585 (1984 (codified as amended at 21 U.S.C §355 and 35 U.S.C §271(e))) (the "Hatch-Waxman Amendments").

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[1] The '161 patent and the '154 patent will be referred to collectively as the "Toprol-XL® Patents" for purposes of this Notice of Removal.

4. As discussed below, although the Petition asserts state law causes of action, federal question jurisdiction exists here because federal questions of law are necessarily raised, are actually disputed, are substantial and are capable of resolution in federal court without disrupting federal-state comity. *See Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg*, 545 U.S. 308, 314 (2005) (holding that federal question jurisdiction applies to certain state-law claims that implicate significant federal issues and outlining the four factor test to determine whether federal question jurisdiction applies); *see also Gunn v. Minton*, 133 S. Ct. 1059, 1065 (2013) (reiterating and applying the *Grable* factors).

BACKGROUND

5. This Court is a proper venue for removal pursuant to 28 U.S.C. §1441(a) because Plaintiff filed the State Court Action on March 18, 2015 in the 19th Judicial District Court for the Parish of East Baton Rouge, State of Louisiana.

6. Pursuant to 28 U.S.C. § 1446(a), AstraZeneca attaches to this Notice of Removal a copy of all process, pleadings and orders served upon it in the State Court Action as Exhibit A.

7. AstraZeneca LP and AstraZeneca Pharmaceuticals LP were served *via* their registered agent for service of process within the State of Louisiana on March 30, 2015. Accordingly, this Notice of Removal is being filed within thirty (30) days after receipt by AstraZeneca LP and AstraZeneca Pharmaceuticals LP, through service or otherwise, of a copy of the Petition. 28 U.S.C. § 1446(b)(1). A defendant has 30 days from formal service of the first pleading setting forth a removable claim to file a notice of removal in federal district court. *Id.* § 1446(b)(2)(B); *Murphy Bros., Inc. v. Michetti Pipe Stringing, Inc.*, 526 U.S. 344, 354-56 (1999) (requiring formal service to occur (or be waived) before the thirty-day period begins to run). This Notice of Removal is based on the Petition, which was formally served on AstraZeneca LP and AstraZeneca Pharmaceuticals LP less than 30 days ago, and is therefore timely filed.

8. As more fully stated below, the State Court Action is being "removed solely under [28 U.S.C. §] 1441(a)." 28 U.S.C. § 1446(b)(2)(A). As such, AstraZeneca LP and AstraZeneca Pharmaceuticals LP, i.e. the only defendants "who have been properly joined and served," to date, jointly remove this matter. *Id.* Further, because AstraZeneca AB, AstraZeneca LP, AstraZeneca Pharmaceuticals LP, and Aktibolaget Hässle are related corporate entities, and without prejudice to any Defendant's defenses (including, without limitation, lack of personal jurisdiction), all Defendants consent to this removal pursuant to 28 U.S.C. § 1446(b)(2)(A).

9. Pursuant to 28 U.S.C. §1446(d), undersigned counsel certifies that promptly after the filing of this Notice of Removal, copies of the Notice will be served on opposing counsel and filed with the Clerk of Court of the 19th Judicial District Court for the Parish of East Baton Rouge, State of Louisiana, as provided by law, to effect the removal of the State Court Action.

10. The State Court Action is removable because this Court has original jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) because Plaintiff's Petition requires the resolution of substantial questions of federal law, including federal patent law, and removal is, therefore, proper under 28 U.S.C. § 1441.

GROUNDS FOR REMOVAL

Federal Question Jurisdiction Exists Under the *Grable* Doctrine.

11. This Court has original jurisdiction over this action pursuant to 28 U.S.C. §§ 1441 and 1454 because this action originally could have been filed in this Court under 28 U.S.C. §§ 1331 and 1338(a). Under Section 1331, federal jurisdiction is present when a Plaintiff's well-pleaded complaint demonstrates 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.'" *Singh v. Duane Morris LLP*, 538 F.3d 334, 337-38 (5th Cir. 2008) (quoting *Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust,* 463 U.S. 1, 27-28 (1983)). The Supreme Court

has recognized that "federal jurisdiction over a state law claim will lie if a 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*, 545 U.S. at 314); *accord Hughes v. Chevron Phillips Chem. Co.*, 478 Fed. Appx. 167, 170 (5th Cir. 2012) (unpublished); *Bd. of Comm'rs of the Se. La. Flood Prot. Auth. – East v. Tenn. Gas Pipeline Co.*, 29 F. Supp. 3d 808, 853 (E.D. La. 2014). Each of the four *Grable* requirements is satisfied here. Thus, federal question jurisdiction exists and removal is appropriate.

A. Issues Of Federal Law Are Necessarily Raised By Plaintiff's Claims.

12. Federal question jurisdiction exists whenever a "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." *Conroy v. Fresh Del Monte Produce, Inc.*, 325 F. Supp. 2d 1049, 1054 (N.D. Cal. 2004) (citing *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 809 (1988)). This Court has jurisdiction because Plaintiff's claims necessarily require a determination regarding the validity and/or enforceability of AstraZeneca's Toprol-XL® Patents and whether AstraZeneca improperly asserted those patents.

13. 28 U.S.C. § 1338(a) mandates that "[t]he district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyright and trademarks." Federal question jurisdiction exists under § 1338(a) whenever a plaintiff pleads a claim that: (1) arises out of federal patent law; or (2) necessitates the resolution of a "substantial question" of federal patent law for plaintiff to prevail. *See Christianson*, 486 U.S. at 809.

14. Challenges to the validity and enforceability of a United States patent implicate federal law as equally as patent infringement claims. *See Conroy*, 325 F. Supp. 2d at 1055

("Challenges to the validity or enforceability of a patent . . . raise a federal question in the same way that an infringement claim otherwise would."); *see also Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1330 (Fed. Cir. 1998), *overruled on other grounds by Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999) ("In keeping with our precedent, we treat validity and enforceability the same as infringement. ... Each of these issues is substantial in the federal scheme, for they are essential to the federally created property right").

15. A petition need not explicitly state a federal claim for removal to be appropriate. Rather, any state law claim that requires the adjudication of a substantial question of federal patent law implicates federal jurisdiction. *See, e.g., Additive Controls & Measurement Sys., Inc. v. Flowdata, Inc.*, 986 F.2d 476, 478 (Fed. Cir. 1993) (under state law, "a business disparagement claim requires plaintiff to prove, as part of its prima facie case, the falsity of defendant's allegedly disparaging statements. ... To prove this aspect of its case (falsity), [plaintiff] must show that its product does not infringe the [patent at issue]. Thus, [plaintiff's] right to relief necessarily depends upon resolution of a substantial question of patent law[.]" (internal citation omitted)).

16. In this case, Plaintiff's claims are predicated on its contention that "Defendants prevented generic versions of Toprol-XL® from entering the market, by inter alia, improperly manipulating patent filings and filing baseless patent infringement lawsuits, thus unlawfully monopolizing and/or attempting to monopolize the domestic market for Toprol-XL® and its generic bioequivalents." *See e.g.* Petition at ¶ 4. In support of its contentions, Plaintiff makes several allegations that plainly require a determination of the validity and/or enforceability of AstraZeneca's Toprol-XL® Patents and whether AstraZeneca improperly asserted those patents.

17. As but one example, the Petition alleges that AstraZeneca engaged in inequitable conduct before the PTO in the prosecution of the Toprol-XL® Patents by failing to disclose an alleged inventorship dispute (*see* Petition at ¶¶87-109); that this failure to disclose was both "material" and "done with an intent to deceive" the PTO (*id.* at ¶107); that had the alleged inventorship dispute been disclosed, it would have "undoubtedly affected a reasonable patent examiner's decision to issue the patent" (*id.* at ¶108); and that because of the alleged inequitable conduct, the Toprol-XL® Patents "were and are unenforceable *ab initio*, and Defendants at no time could have reasonably asserted a patent claim on the basis of these inequitably obtained patents." *Id.* at ¶109.

18. Although presented as violations of the Louisiana Monopolies Act (La.R.S. 51:121, *et. seq.*) and the Louisiana Unfair Trade Practices and Consumer Protection Law (La.R.S. 51:1401, *et seq.*), success on Plaintiff's claims would require a finding of, *inter alia*, inequitable conduct, *Walker Process* fraud and/or sham patent infringement litigation. Both inequitable conduct and *Walker Process* fraud require resolution of substantial questions of federal patent law; *e.g.*, whether AstraZeneca engaged in unlawful conduct in the procurement of the Toprol-XL® Patents. *See, e.g.*, *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 685 (2d Cir. 2009) (noting that the *Walker Process* theory required resolution of a substantial question of patent law because materiality, justifiable reliance and "but-for" causation implicated issues of patentability); *see also Doran v. Purdue Pharma Co.*, 324 F. Supp. 2d 1147, 1151 (D. Nev. 2004) (substantial question of federal patent law existed in determination of whether defendants fraudulently obtained their patents through intentional misrepresentations to the PTO); *Coker v. Purdue Pharma Co.*, 314 F. Supp. 2d 777, 783–84 (W.D. Tenn. 2004) (noting that *Walker Process* claim required resolution of a substantial question of patent law). Plaintiff,

however, has already conceded that there are genuine issues of material fact regarding "the question of inequitable conduct" by citing to the Federal Circuit's decision in *In re Metoprolol Succinate Patent Litig.*, 494 F.3d 1011, 1020-21 (Fed. Circ. 2007), which remanded the district court's grant of summary judgment on the issue of inequitable conduct for that exact reason. Petition at ¶ 128.

19. Further, in order to prevail on its sham litigation theory, Plaintiff must prove, *inter alia*, that no reasonable litigant could have expected AstraZeneca to succeed in enforcing its Toprol-XL® Patents, which requires resolution of substantial questions of federal patent law. *See, e.g.*, *Doran*, 324 F. Supp. 2d at 1151 ("The question whether a litigant had a reasonable prospect of prevailing in a federal patent lawsuit can only be evaluated by reference to the standards of federal law for the enforcement of a patent.").

B. Federal Law Issues Upon Which Plaintiff's Claims Depend Are Actually Disputed.

20. Federal law issues in this case – *e.g.* (1) whether AstraZeneca engaged in inequitable conduct before the USPTO; (2) whether AstraZeneca improperly listed the Toprol-XL® Patents in the Orange Book; and (3) whether AstraZeneca filed "sham" litigation against the generics – are "actually disputed." *Grable*, 545 U.S. at 314; *Gunn*, 133 S. Ct. at 1065. In fact, those issues are the gravamen of Plaintiff's claims.

C. Federal Issues Upon Which Plaintiff's Claims Depend Are Substantial.

21. Whether AstraZeneca engaged in inequitable conduct before the PTO, whether AstraZeneca improperly listed the Toprol-XL® Patents in the Orange Book, and whether AstraZeneca filed "sham" litigation against the generics all involve substantial issues of federal law. Substantiality "looks to the importance of the issue to the federal system as a whole." *See Gunn v. Minton,* 133 S. Ct. at 1066; *accord Bd. of Comm'rs*, 29 F. Supp. 3d at 859.

22. In *Grable*, the Supreme Court held that whether the defendant was given adequate notice under federal law by the IRS was a substantial issue of federal law that supported federal question jurisdiction over a state-law quiet title action. The Supreme Court stated that the federal government has "a strong interest in the prompt and certain collection of delinquent taxes" and a "direct interest in the availability of a federal forum to vindicate its own administrative action" and held that the "controversy respecting the construction and effect of the [federal] laws is involved and is sufficiently real and substantial" to support federal question jurisdiction. 545 U.S. at 316.

23. In a recent case, the Eastern District of Louisiana found that federal question jurisdiction existed under *Grable* and *Gunn*, and set forth numerous factors that bear on the substantiality analysis:

> (1) whether the case includes a federal agency, and particularly, whether that agency's compliance with the federal statute is in dispute; (2) whether the federal question is important (i.e., not trivial); (3) whether a decision on the federal question will resolve the case (i.e., the federal question is not merely incidental to the outcome); and (4) whether a decision as to the federal question will control numerous other cases (i.e., the issue is not anomalous or isolated).

Bd. of Comm'rs., 29 F. Supp. 3d at 861 (quoting *Mikulski v. Centerior Energy Corp.*, 501 F.3d 555, 570 (6th Cir. 2007)). Those factors were present in *Bd. of Comm'rs* and are also present here.[2]

24. As stated in *Bd. of Comm'rs* "a federal issue may be substantial where state adjudication would 'undermine the development of a uniform body of [federal] law.'"). *Id.* at 859 (quoting *Gunn*, 133 S. Ct. at 1067). The federal government has a strong interest in a

[2] With respect to the first factor, in *Bd of Comm'rs*, the Court noted that "[w]hile Plaintiff may not be expressly challenging a specific action of a federal agency, the breadth of Plaintiff's claims amounts to a collateral attack on an entire regulatory scheme." 29 F. Supp. 3d at 862. In this action, Plaintiffs' claims touch on the issuance of the Toprol-XL® Patents and their listing in the Orange Book, which implicate the PTO and FDA and their respective regulations.

uniform body of law on the issues of inequitable conduct, *Walker Process* fraud and sham patent infringement litigation. The federal government also has a "direct interest in the availability of a federal forum" to review and redress such conduct. *Grable*, 545 F.3d at 315.

25. Plaintiff's state law claims are wholly dependent on, and cannot be resolved without, for example, evaluating AstraZeneca's conduct and patent infringement litigation to determine whether AstraZeneca engaged in inequitable conduct or *Walker Process* fraud, and if so, whether the patent infringement litigation AstraZeneca filed against would-be generic manufacturers of Toprol-XL® was a "sham." Resolving such issues necessarily implicates federal law. *See Conroy*, 325 F. Supp. 2d at 1055 ("Challenges to the validity or enforceability of a patent . . . raise a federal question in the same way that an infringement claim otherwise would."); *Hunter Douglas*, 153 F.3d at 1330 ("we treat validity and enforceability the same as infringement. . . . Each of these issues is substantial in the federal scheme, for they are essential to the federally created property right"). Similarly, evaluating the merits of AstraZeneca's Orange Book listing will implicate FDA regulations governing the same.

D. Federal Issues Are Capable Of Resolution In Federal Court Without Disrupting The Federal-State Balance Approved By Congress.

26. It is not typical for state court lawsuits to turn on the resolution of, *inter alia*, whether a patentee engages in alleged "inequitable conduct" before the PTO while prosecuting its patent, whether that patentee improperly listed those patents in the Orange Book, and/or whether that patentee's subsequent patent infringement litigation based on those patents was a sham. Rather, the Supreme Court has held that federal law preempts state causes of action that depend on establishing fraud on a federal agency. *See Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341347-48 (2001) (holding that state law claims for fraud on the Federal Food and Drug Administration were preempted by federal law and explaining that "the

relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.")

27. Therefore, resolving the issues that are squarely within the province of federal law will not disturb the federal-state balance approved by Congress. As the Supreme Court recognized, "policing fraud against federal agencies is hardly a field which the States have traditionally occupied." *Buckman*, 531 U.S. at 347; *see also Grable*, 545 U.S. at 315 ("[B]ecause it will be the rare state title case that raises a contested matter of federal law, federal jurisdiction to resolve genuine disagreement over federal tax title provisions will portend only a microscopic effect on the federal-state division of labor."); *accord Bd. of Comm'rs*, 29 F. Supp. 3d at 863 ("Plaintiff's claims in this matter are not typical state law negligence and contract claims.... federal courts are particularly familiar with the federal regulatory scheme that forms the foundation of Plaintiff's claims..."). As was true in *Grable*, "jurisdiction over actions like [Plaintiff's] would not materially affect, or threaten to affect, the normal currents of litigation," and thus "there is no good reason to shrink from federal jurisdiction over the dispositive and contested federal issue at the heart" of this lawsuit. 545 U.S. at 319-20.

28. Because this Court has original jurisdiction over the State Court Action, it is removable to this Court. *See* 28 U.S.C. §§ 1331, 1338, 1441, and 1446.

WHEREFORE, Defendants AstraZeneca AB, AstraZeneca LP, AstraZeneca Pharmaceuticals LP, and Aktibolaget Hässle hereby respectfully give notice that the State Court Action is removed to this Court.

April 28, 2015.

Respectfully Submitted by:

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the above and foregoing Notice of Removal has been served by e-mail or United States Mail, postage prepaid and properly addressed to the following counsel of record:

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Baton Rouge, Louisiana, this 28th day of April, 2015.

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