**UNITED STATES DISTRICT COURT**

**WESTERN DISTRICT OF LOUISIANA**

**MONROE DIVISION**

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| **MELINDA LOFTON** | * | **CIVIL ACTION NO. 08-1224** |
| **VERSUS** | * | **JUDGE JAMES** |
| **PFIZER, INC.** | * | **MAGISTRATE JUDGE HAYES** |

## REPORT AND RECOMMENDATION

Before the court is a motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6) or alternatively, motion to stay [doc. # 6] filed by defendant, Pfizer, Inc. ("Pfizer"). The district court referred the motion to the undersigned magistrate judge for decision pursuant to 28 U.S.C. § 636(b)(1)(B). For reasons assigned below, it is recommended that Pfizer's motion to dismiss [doc. # 6] be GRANTED IN PART, insofar as it seeks dismissal of plaintiff's punitive damages claims and all other claims not arising under the Louisiana Products Liability Act or in redhibition. It is further recommended that Pfizer's motion to dismiss and alternative motion to stay [doc. # 6] otherwise be DENIED.

## BACKGROUND

On July 11, 2008, Melinda Lofton filed the above-captioned suit against Pfizer in the 5th Judicial District Court for the Parish of Richland, State of Louisiana. Plaintiff alleges that she suffered serious injuries following a July 2007 car accident while a passenger in a car operated by Daniel Williams. (Petition, ¶¶ 11, 19). Lofton states that in July 2007 Williams began using a prescription drug, varenicline, that was manufactured and sold by Pfizer under the trade name

Chantix. (Petition, ¶¶ 1, 11).[1] Lofton contends that as a result of Williams' Chantix use, he suffered a seizure which caused him to lose control of the car and crash. *Id*. at ¶ 19. Plaintiff alleges that due to Pfizer's "negligence, willful, wanton, and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts . . . [she] sustained injuries and damages including new onset seizures and aggravation of preexisting conditions and activation of latent conditions, and other such damages." *Id*. at ¶ 24. Plaintiff seeks compensatory damages for severe and permanent bodily injury, pain and suffering, disability, mental anguish, lost enjoyment of life, medical and nursing care expenses, lost wages, and loss of earning capacity. *Id*. at ¶ 23. Lofton further requests an award for punitive damages and attorney's fees. (Petition, Global Prayer for Relief).[2]

On August 19, 2008, Pfizer removed the case to federal court on the basis of diversity jurisdiction, 28 U.S.C. § 1332.[3] On September 18, 2008, Pfizer filed the instant motion to dismiss for failure to state a claim upon which relief may be granted, or alternatively to stay. The

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[1] Varenicline is prescribed to assist smoking cessation treatment. *Id*. at ¶ 29.

[2] On July 31, 2008, plaintiff filed a First Supplemental and Amending Petition for Damages which amended the ninth paragraph of her original petition to clarify that the amount in controversy exceeded $ 50,000, but was less than $ 75,000. (1st Suppl. & Amend. Petition, ¶ 2 [doc. # 9-2]).

[3] Plaintiff is a Louisiana citizen; defendant is a Delaware corporation, with its principal place of business in New York. (Notice of Removal, ¶ 10). Therefore, the parties are completely diverse. Although plaintiff alleged in her petition that her damages do not exceed $ 75,000, defendant has demonstrated that it is facially apparent that the type and severity of the specific damages *claimed* more likely than not exceeded the requisite jurisdictional minimum for the exercise of federal diversity jurisdiction at the time of removal. *See, De Aguilar v. Boeing*, 47 F.3d 1404, 1412 (5th Cir. 1995); *Gebbia v. Wal-Mart Stores, Inc.*, 233 F.3d 880 (5th Cir. 2000). Plaintiff has not otherwise argued or established to a legal certainty that her damages do not exceed $ 75,000. *De Aguilar, supra*.

motion contends that 1) plaintiff's exclusive remedy against a manufacturer such as Pfizer lies under the Louisiana Products Liability Act; 2) plaintiff is not entitled to punitive damages under Louisiana law; and 3) plaintiff's claims are preempted by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq*. Pfizer alternatively seeks to stay this matter pending resolution of a case addressing the preemptive effect of the FDCA that is currently before the U.S. Supreme Court, *Wyeth v. Levine*, No. 06-1429. On October 6, 2008, plaintiff filed a memorandum in opposition to the motion to dismiss. On October 15, 2008, defendant filed a reply brief. The matter is now before the court.

**12(b)(6) STANDARD**

Federal Rule of Civil Procedure 12(b) permits dismissal where the claimant fails "to state a claim upon which relief can be granted." Fed.R.Civ.P. 12(b)(6). "[W]hen the allegations in a complaint, however true, could not raise a claim of entitlement to relief, 'this basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court.'" *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1966 (2007) (quoting 5 CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 1216, 234)). In evaluating a motion to dismiss, "the District Court must take the factual allegations of the complaint as true and resolve any ambiguities or doubts regarding the sufficiency of the claim in favor of the plaintiff. *Fernandez-Montes v. Allied Pilots Association*, 987 F.2d 278 (5th Cir. 1993) (citation omitted). The factual allegations need not be detailed, but they must be more than labels, conclusions, or a recitation of the elements of the claim. *Twombly, supra*. Moreover,

> the '[f]actual allegations must be enough to raise a right to relief above the

> speculative level, . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)' and the non-moving party must plead 'enough facts to state a claim to relief that is plausible on its face.' **This standard 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary claims or elements**.

*In re Southern Scrap Material Co., LLC*, 541 F.3d 584 (5th Cir. 2008) (internal citation omitted) (emphasis added).

Nonetheless, a 12(b)(6) motion to dismiss "is viewed with disfavor and is rarely granted." *Kaiser Aluminum & Chem. Sales v. Avondale Shipyards*, 677 F.2d 1045, 1050 (5th Cir.1982).[4]

## ANALYSIS

Under the *Erie* doctrine, federal courts sitting in diversity apply state substantive law and federal procedural law." *Gasperini v. Ctr. for Humanities, Inc.*, 518 U.S. 415, 427, 116 S.Ct. 2211(1996); *see also Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78, 58 S.Ct. 817 (1938). In their memoranda, the instant parties both address plaintiff's claims in terms of Louisiana law, and thus implicitly agree that the substantive law of Louisiana applies to the instant dispute. *See, In re Katrina Canal Breaches Litigation*, 495 F.3d 191, 206 (5th Cir. 2007) (deferring to the parties' agreement that Louisiana substantive law controlled), *cert. denied sub nom. Xavier University of Louisiana v. Travelers Cas. Property Co. of America*, ___ U.S. ___, 128 S.Ct. 1230 (Feb 19, 2008); *Jefferson v. Lead Indus. Ass'n*, 106 F.3d 1245, 1250 (5th Cir. La. 1997) (applied

[4] In her opposition memorandum, plaintiff relied upon the oft-cited language from *Conley v. Gibson*, that a court will not dismiss a claim "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99 (1957). However, the Supreme Court recently clarified that *Conley* merely "described the breadth of opportunity to prove what an adequate complaint claims, not the minimum standard of adequate pleading to govern a complaint's survival." *Twombley, supra*.

Louisiana law where no party disputed that Louisiana law governed);[5] *In re Vioxx Prods. Liab. Litig.*, 478 F. Supp. 2d 897, 906 (E.D. La. 2007) (applied substantive law of plaintiff's home state in defective drug product case).

**a) LPLA Exclusivity**

Under Louisiana law, the Louisiana Products Liability Act ("LPLA"), Louisiana Revised Statute 9:2800.51, *et seq*., provides "the exclusive theories of liability for manufacturers for damage caused by their products. **A claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in [the LPLA].**" La. R. S. 9:2800.52 (emphasis added); *see also, Jefferson*, 106 F.3d at 1251.

Plaintiff does not contest that the LPLA applies to her cause of action; in fact, she argues that her petition states a claim thereunder. (Opp. Memo., pgs. 8-18). The result, however, is that Lofton's claims against Pfizer for strict liability, negligence, gross negligence, and breach of express warranty are not viable as independent theories of recovery outside of the LPLA framework. *Jefferson, supra*. The LPLA's exclusivity provision further precludes plaintiff's claims for intentional tort;[6] unjust enrichment;[7] breach of implied warranty;[8] and for fraudulent,

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[5] In *Jefferson*, the Fifth Circuit's decision incorporated the underlying district court opinion, 930 F. Supp. 241 (E.D. La. May 31, 1996) (J. Vance)

[6] *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254, 262 (5th Cir. 2002) (no intentional tort exception to exclusive remedy provision of LPLA).

[7] *See, Hilton v. Atlas Roofing Corp.*, 2006 U.S. Dist. LEXIS 30284 (E.D. La. May 17, 2006) (dismissing unjust enrichment claim as precluded by the LPLA). Plaintiff argues that her claim for unjust enrichment remains viable in the event that she is left with no other remedy at law. *See*, La. Civ. Code Art. 2298. However, unjust enrichment is a subsidiary remedy that is not available "if the law provides another remedy for the impoverishment or declares a contrary rule." *Id*. When there is a rule of law directed to an issue, an action for unjust enrichment may not be used to defeat the purpose of the rule. *Board of Sup'rs of Louisiana State University v.*

negligent, or reckless misrepresentation and concealment.[9] However, plaintiff's redhibition claim for economic loss is not precluded by the LPLA. *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 251 (5th Cir. 2002); *see also*, La. R.S. 9:2800.53(5).[10]

**b) Sufficiency of the LPLA Allegations**

Pfizer contends that plaintiff's petition fails to set forth a direct claim under the LPLA. To hold a manufacturer liable under the LPLA, a plaintiff must establish: "damage proximately caused by a characteristic of the product that rendered its product unreasonably dangerous when

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*Louisiana Agr. Finance Authority*, 984 So.2d 72, 81 (La. App. 1st Cir. 2008) (quoting *Carriere v. Bank of Louisiana*, 702 So.2d 648, 657 (La. 1996)). Unjust enrichment applies to fill a gap in the law where no express remedy is available. *Id*. (citations omitted). Here, of course, plaintiff has express remedies available under the LPLA. If plaintiff is unable to establish that Chantix contained an actionable defect sufficient to warrant relief under that legal theory, she cannot use unjust enrichment to circumvent the result dictated by the specifically applicable rule(s) of law.

[8] Assuming that Louisiana recognizes a breach of implied warranty claim separate and apart from a redhibition claim. *See, Dawson Farms, LLC v. BASF Corp.*, 2008 U.S. Dist. LEXIS 39826, *7 n2 (W.D. La. May 16, 2008).

[9] *See, Jefferson*, 106 F.3d at 1251 (dismissing claims for negligence, fraud by misrepresentation, market share liability, breach of implied warranty of fitness, and civil conspiracy); *Grenier v. Medical Eng'g Corp.*, 99 F. Supp. 2d 759, 763 (W.D. La. 2000) (dismissing claims for strict liability, negligence, breach of warranty of fitness for a particular purpose, breach of implied warranty; misrepresentation/fraud; fraud by concealment; false advertising; negligent infliction of emotional distress; and fear of future product failure), *affirmed*, 243 F.3d 200 (5th Cir. La. 2001); and *Ingram v. Bayer Corp.*, 2002 U.S. Dist. LEXIS 10402 (E.D. La. May 29, 2002) (dismissing claims for negligence, gross negligence, strict liability, fraud, misrepresentation, concealment, conspiracy, suppression and willful, wanton and reckless conduct)

[10] The court questions whether Lofton is authorized to bring a redhibition claim against the manufacturer if she did not purchase the drug. *See*, La. Civ. Code Arts. 2520, *et seq*. However, Pfizer did not seek dismissal of the redhibition claim on this basis. *See*, Reply Memo., pg. 4 ("The law of Louisiana is clear that Plaintiff's claims, except for Plaintiff's claim for Redhibition, must be dismissed). The parties may be able to resolve this issue by mutual agreement.

such damage arose from a reasonably anticipated use of the product by the claimant or another person or entity." La. R. S. 9:2800.54 A. The product is unreasonably dangerous if, and only if the product is: 1) unreasonably dangerous in construction, 2) unreasonably dangerous in design, 3) unreasonably dangerous due to an inadequate warning, or 4) unreasonably dangerous because it does not conform to an express warranty. La. R. S. 9:2800.54 B. In other words, to state a cause of action under the LPLA, plaintiff must prove:

1. that the defendant is a manufacturer of the product;

2. that the claimant's damage was proximately caused by a characteristic of the product;

3. that the characteristic made the product unreasonably dangerous in one of the four ways provided in the statute; and

4. that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else.

*Jefferson*, 106 F.3d at 1251.

While Lofton's petition is by no means a model of clarity or efficiency, and appears to have been drafted by national co-counsel principally for use in other states, it does contain the requisite factual allegations to state a claim under the LPLA. Moreover, even though plaintiff's factual allegations are often embedded within claims that do not exist outside of the LPLA, that does not bar their consideration for purposes of stating a claim under the LPLA. *See, Rathborne v. Rathborne*, 683 F.2d 914, 917 (5th Cir. 1982) ("complaint need not correctly categorize the legal theories giving rise to the claims; it must merely allege facts upon which relief can be granted.") (citation omitted). Indeed, here, plaintiff specifically alleges that Chantix was a defective product as defined by the LPLA. (Petition, ¶ 140). Plaintiff further alleges that Pfizer designed, manufactured, sold, and distributed Chantix. *Id*. at ¶ 1. Plaintiff states that the drug

was prescribed to Williams and that he used the drug in a reasonably foreseeable manner. *Id*. at ¶¶ 11-12. Plaintiff contends that there have been 86 reports of convulsions or seizures associated with varenicline use. *Id*. at ¶ 56(d). Plaintiff also recites a May 23, 2008, press release issued by the Federal Motor Carrier Safety Administration which states that the agency will withhold certification from bus drivers and interstate truckers who take Chantix "because the medication may adversely affect the driver's ability to safely operate a commercial motor vehicle." *Id*. at ¶ 62.

Albeit conclusory, the petition further alleges that "Chantix is unreasonably dangerous: a) in construction or composition; b) in design; c) because an adequate warning about the respective drugs was not provided; and d) because the respective drugs do not conform to an express warranty of the manufacturer about the product." (Petition, ¶ 149). The petition fleshes out these allegations by stating that the label contained no warning and/or an inadequate warning for risk of seizures, serious injury, and/or death. *Id*. at ¶ 84.[11] Plaintiff further alleges that Chantix was unreasonably dangerous as designed, because it failed to perform safely when used by ordinary customers when used as intended in a reasonably foreseeable manner. *Id*. at ¶ 140. Chantix was also unreasonably dangerous as designed because the risks of seizures, serious injury, and/or death posed by the drug exceeded any benefit that the drug was designed to bestow. *Id.* at ¶ 142.[12] Plaintiff alleges that defendant breached express warranties by representing that the product was safe and that it did not produce any unknown dangerous side

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[11] Plaintiff contends that defendant knew or should have known of this risk. *Id*. at ¶ 85.

[12] Plaintiff asserts that there were safer, alternative methods and designs for the product. (Petition, ¶ 144).

effects. (*See*, Petition, ¶¶ 169-170). The petition concludes that plaintiff suffered personal injuries and damage due to defendant's defective design of Chantix. *Id*. at ¶ 155. Moreover, had there been adequate warnings and instructions, Williams would not have taken Chantix, and would not have been at risk of seizure. *Id*. at ¶ 157.

The court recognizes that plaintiff's petition is understandably lean on specific factual allegations to support all four of the LPLA's methods to establish that a product is unreasonably dangerous. Nonetheless, plaintiff has alleged and factually supported a characteristic of Chantix which may prove to be unreasonably dangerous under the Act. Plaintiff's products liability allegations surpass mere speculation and "'raise a reasonable expectation that discovery will reveal evidence of' the necessary claims or elements." *In re Southern Scrap Material Co., LLC*, *supra*.

**c) <u>Punitive Damages</u>**

Throughout her various claims set forth in his petition, plaintiff asserts the right to recover punitive damages. However, exemplary or punitive damages are not recoverable under Louisiana law unless expressly provided for by statute. *Albert v. Farm Bureau Ins., Inc.*, 940 So.2d 620, 622 (La. 2006) (citation omitted).[13] It is manifest that plaintiff's complaint does not implicate the two specific circumstances where exemplary damages are authorized under Louisiana law. *See*, La. Civ. Code Arts. 2315.4 and 2315.7. Accordingly, dismissal is required.

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[13] Plaintiff does not argue that the law of any other state should apply to the issue of punitive damages. Under Louisiana's Conflict of Laws provisions, the issue of damages (including punitive damages) in a products liability case is governed by the law of Louisiana when, as here, 1) the injury was sustained in Louisiana by a person domiciled or residing in Louisiana; or 2) when the product was acquired in Louisiana and caused injury in Louisiana or injured someone domiciled in this state. La. Civ. Code Art. 3545.

**d) Preemption and Stay**

Defendant contends that plaintiff's remaining claims (including redhibition) are preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq*. As recently as last year, however, the court designated by the Judicial Panel on Multidistrict Litigation to coordinate discovery and pretrial matters in the Vioxx cases, rejected a similar argument advanced by the defendant drug manufacturer. *See, In Re Vioxx Products Liability Litigation*, 501 F. Supp. 2d 776 (E. D. La. 2007). Nevertheless, Pfizer argues that its position is championed by the Federal Drug Administration in a case currently pending before the Supreme Court, *Wyeth v. Levine*, O.T.2007, No. 06-1249. However, the question presented in that case is

> [w]hether the prescription drug labeling judgments imposed on manufacturers by the Food and Drug Administration ('FDA') pursuant to FDA's comprehensive safety and efficacy authority under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., **preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use.**

*Id.*, Petition for Certiorari (emphasis added).

Finally, even if the Supreme Court resolves the inadequate warning label issue favorably to drug manufacturers, it is not at all evident, to the extent the plaintiff's petition can be read to assert a claim that the defendant's reporting, testing, or labeling failed to comply with FDA requirements, that those claims would be preempted. It is however, quite evident that plaintiff's alternative theories of recovery under the LPLA or in redhibition would not be preempted.

For this same reason, a stay pending the Supreme Court's decision in *Wyeth v. Levine* is not warranted. In the interim, the instant parties may advance the case by conducting discovery regarding plaintiff's redhibition claim[14] and the three alternative bases for recovery under the

[14] *See* footnote 10.

LPLA. The parties can tailor their proposed discovery plan to defer discovery regarding the adequacy of the warning label, except as to any non-compliance with FDA requirements, until after the Supreme Court decides the *Wyeth* matter.

For the reasons set forth above,

**IT IS RECOMMENDED** that the motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6) [doc. # 6] filed by defendant, Pfizer, Inc. be **GRANTED IN PART**, and that judgment be entered in favor of Pfizer **DISMISSING WITH PREJUDICE** plaintiff's punitive damages claims and all other claims not arising under the Louisiana Products Liability Act or in redhibition.

**IT IS FURTHER RECOMMENDED** that Pfizer's motion to dismiss and alternative motion to stay [doc. # 6] otherwise be **DENIED**.

Under the provisions of 28 U.S.C. §636(b)(1)(C) and FRCP Rule 72(b), the parties have **ten (10) business days** from service of this Report and Recommendation to file specific, written objections with the Clerk of Court. A party may respond to another party's objections within **ten (10) business days** after being served with a copy thereof. A courtesy copy of any objection or response or request for extension of time shall be furnished to the District Judge at the time of filing. Timely objections will be considered by the District Judge before he makes a final ruling.

**A PARTY'S FAILURE TO FILE WRITTEN OBJECTIONS TO THE PROPOSED FINDINGS, CONCLUSIONS AND RECOMMENDATIONS CONTAINED IN THIS REPORT WITHIN TEN (10) BUSINESS DAYS FROM THE DATE OF ITS SERVICE SHALL BAR AN AGGRIEVED PARTY, EXCEPT ON GROUNDS OF PLAIN ERROR, FROM ATTACKING ON APPEAL THE UNOBJECTED-TO PROPOSED FACTUAL**

**FINDINGS AND LEGAL CONCLUSIONS ACCEPTED BY THE DISTRICT JUDGE.**

THUS DONE AND SIGNED at Monroe, Louisiana, this 31st day of October 2008.

KAREN L. HAYES
U. S. MAGISTRATE JUDGE