Aucoin v. Amneal Pharmaceuticals, L.L.C. Doc. 33

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

RUSSELL JOSEPH AUCOIN	**CIVIL ACTION**
VERSUS	**NO. 11-1275**
AMNEAL PHARMACEUTICALS, LLC	**SECTION: "G"(5)**

ORDER AND REASONS

Before the Court is Defendant Amneal Pharmaceuticals, LLC's ("Defendant") Motion to Dismiss the pending action on the basis (1) that the suit is prescribed because it was brought outside of the one year statute of limitations that governs delictual actions under Louisiana law; (2) that Plaintiff Russell Joseph Aucoin's ("Plaintiff") claims brought under theories of recovery other than the Louisiana Products Liability Act ("LPLA") must be dismissed because the LPLA provides the exclusive theory of liability for the claims presented here; (3) that certain of Plaintiff's LPLA claims must be dismissed because, under Supreme Court precedent, they are preempted by federal law; and (4) that Plaintiff has failed to satisfy the appropriate pleading standard to state a claim regarding Plaintiff's other LPLA claims.[1]

Having considered the motion, the response, the reply, the supplemental memorandum in support of the motion, the record, and the applicable law, for the following reasons, the Court will grant the Motion to Dismiss on the grounds that Plaintiff cannot maintain claims on grounds other than the LPLA; Plaintiff's failure to warn claim and design defect claim are preempted by federal law; and Plaintiff has failed to state a claim regarding Plaintiff's design defect, construction or

[1] Rec. Doc. 4.

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composition defect, and express warranty claims. Accordingly, the Court will dismiss all of Plaintiff's claims with prejudice.

I. Background

A. Procedural and Factual Background

On May 27, 2011, Plaintiff filed his complaint in this matter,[2] bringing causes of action against Defendant under the LPLA, as well as alleging Defendant's negligence and strict liability and seeking attorney's fees. The case arises from injuries sustained by Plaintiff allegedly as the result of taking the pharmaceutical drug, Tramadol, which is manufactured by Defendant. Tramadol is a generic form of a brand-name drug, Ultram, which was originally designed and manufactured by a third party.[3]

Specifically, Plaintiff alleges that, while visiting the Cypress Bayou Casino in Charenton, Louisiana, he blacked out and fell backwards, striking his head on a cubicle in the casino.[4] Plaintiff further alleges that he was then transported by ambulance to Franklin Foundation Hospital, where he was treated for a blood clot in his brain.[5] According to Plaintiff, he had been taking Tramadol for relief from back pain caused by previous medical problems[6] and had suffered several other falls

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[2] Rec. Doc. 1.

[3] Rec. Doc. 4-2 at p. 1.

[4] Rec. Doc. 1 at ¶¶ 6-7.

[5] *Id.* at ¶ 7.

[6] *Id.* at ¶ 8.

prior and subsequent to the incident at the casino, including one incident that resulted in a neck fracture.[7]

The date of the incident at the casino is unclear; in his complaint, Plaintiff states in one paragraph that the incident occurred on May 27, 2010[8] and in another paragraph that it occurred on March 28, 2010.[9] In his complaint, Plaintiff alleges that his physicians informed him that his regular use of the prescription medication, Tramadol, caused his fall, although he does not state upon what date his physicians informed him of this.[10]

Plaintiff alleges that Defendant "failed to adequately or properly warn [him] of the dangers associated with the pharmaceutical drug, Tramadol, its design, and/or dangers inherent in the ordinary and normal use of the drug, Tramadol."[11] Although Plaintiff does not clearly allege that Defendant is liable under each one of the four theories of liability under the LPLA,[12] he quotes the applicable Louisiana statute for each theory.

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[7] *Id.* at ¶ 9.

[8] *Id.* at ¶ 6.

[9] *Id.* at ¶ 9. In Plaintiff's response in opposition to the motion, he also cites March 28, 2010 as the date of his fall at the casino. Rec. Doc. 7 at pp. 2, 3.

[10] Rec. Doc. 1 at ¶ 10.

[11] *Id.* at ¶ 11.

[12] These theories are: (1) that a product is unreasonably dangerous in construction or composition; (2) that a product is unreasonably dangerous in design; (3) that a product is unreasonably dangerous because an adequate warning about the product was not provided; and (4) that a product is unreasonably dangerous because it does not conform to an express warranty of the manufacturer. *See* La. R.S. § 9:2800.54.

B. The Pending Motion to Dismiss

On September 1, 2011, Defendant filed the pending Motion to Dismiss,[13] seeking to dismiss Plaintiff's action on several grounds. First, Defendant argues that Plaintiff's suit is prescribed because it was brought outside of the one year statute of limitations that governs delictual actions under Louisiana law. Second, Defendant argues that Plaintiff's claims not brought under the LPLA must be dismissed because the LPLA provides the exclusive theory of recovery for such claims. Third, Defendant argues that under Supreme Court precedent in *PLIVA, Inc. v. Mensing*,[14] Plaintiff's LPLA claims must fail as preempted by federal law. Specifically, Defendant argues that *Mensing* held that a failure to warn claim against a generic drug manufacturer was preempted by federal law and that the same principles that applied to preempt a failure to warn claim also preempt any design defect claim. Finally, Defendant argues that even if this Court is not persuaded by Defendant's other arguments, Plaintiff has failed to plead sufficient facts under the pleading standard of Federal Rule of Civil Procedure 8 to establish Plaintiff's entitlement to relief because he has cited statutory provisions and made conclusory allegations without providing facts to support his claims that the product was unreasonably dangerous due to a design defect, that the product was unreasonably dangerous in construction or composition, or that the product failed to conform to an express warranty by Defendant.

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[13] Rec. Doc. 4.

[14] 564 U.S. __, 131 S.Ct. 2567 (2011) (expressly barring recovery from generic manufacturers on failure to warn claims brought under state law as preempted by federal law that sets forth a generic manufacturer's duty as one of sameness).

Plaintiff filed his response in opposition on September 13, 2011.[15] Therein, Plaintiff argues that his claims are not prescribed and that the relevant date for prescription is not the date of the fall but instead the date when Plaintiff had constructive notice of the causal connection between the medication and the side effects experienced. However, Plaintiff cites the date of his constructive notice, when he first consulted a physician regarding the blackouts, as July 30, 2009.[16] Plaintiff then argues that "Aucoin filed his petition on May 27, 2011, within the one year prescriptive period [from this July 30, 2009 date]."[17] Regarding Defendant's second argument, that claims not brought under the LPLA must be dismissed because the LPLA provides the exclusive theory of recovery for such claims, Plaintiff's response is silent. Instead, Plaintiff proceeds to oppose Defendant's third argument, and Plaintiff contends that his LPLA claims are not preempted by *Mensing*. Plaintiff specifically argues that Defendant's inability to independently alter a warning label because of the generic manufacturer's duty of sameness did not preclude Defendant from taking other action as would support his state law duty, such as utilizing the Food and Drug Administration ("FDA") procedure to change a warning label or removing Tramadol from the market. Finally, Plaintiff responds that his complaint contained sufficient factual basis to state a claim because it set forth that Defendant manufactured the drug, that the drug was prescribed to Plaintiff who took the drug, and that Plaintiff suffered injuries as a result of taking the medication.

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[15] Rec. Doc. 7.

[16] *Id.* at p. 5.

[17] *Id.*

After seeking the Court's leave, on September 21, 2011, Defendant filed a reply memorandum in further support of the motion to dismiss.[18] Therein, Defendant notes that Plaintiff's response "offers facts in opposition that confirm that Plaintiff failed to file his complaint against Amneal within one year of obtaining actual or constructive knowledge of his alleged injury" and, thus, is "time barred."[19] Next, Defendant notes that Plaintiff's opposition failed to respond to Defendant's assertion that Plaintiff's non-LPLA claims must be dismissed because the LPLA establishes the exclusive theory of recovery for this matter. Defendant then argues that Plaintiff failed to adequately respond to the Supreme Court's decision in *Mensing*, that the arguments advanced by Plaintiff were explicitly rejected in *Mensing*, and that there exists no duty for Defendant to remove the drug from the market. Finally, Defendant contends that the formulaic quoting of relevant statutory provisions is insufficient to establish a claim under the pleading requirements of Federal Rule of Civil Procedure 8; specifically, Defendant responds that "Plaintiff fails to adequately allege any fact in support of his contention that the drug contained a construction or design defect that rendered it unreasonably dangerous" and that Plaintiff alleges no facts regarding the label, as would be necessary to establish a claim that the label failed to conform to an express warning.[20]

On March 28, 2012, Defendant filed a supplemental memorandum in support of the motion.[21] In Defendant's memorandum, Defendant reasserts its earlier arguments and also cites to recent

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[18] Rec. Doc. 12.

[19] *Id.* at p. 2.

[20] *Id.* at p. 7.

[21] Rec. Doc. 21. Defendant filed this memorandum pursuant to this Court's invitation to do so. This matter was originally before Judge Lance M. Africk, Section "I" of this Court. At the time this case was transferred to this Section, Section "G" of the Eastern District of Louisiana, the submission date for the instant motion had already passed. Accordingly, this Court reset the hearing date of the Motion to Dismiss and instructed the parties that they could file any additional briefings in accordance with the Local Rules, as necessary. *See* Rec. Doc. 15.

district court cases in Louisiana, rendered since Defendant's prior briefings, interpreting the *Mensing* decision as preempting not only claims brought by plaintiffs against generic drug manufacturers for failure to warn but also claims brought for alleged design defects.

II. Standard on Motion to Dismiss

The Federal Rules of Civil Procedure provide that an action may be dismissed "for failure to state a claim upon which relief can be granted."[22] "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'"[23] "Factual allegations must be enough to raise a right to relief above the speculative level,"[24] and a claim is facially plausible when the plaintiff has pled facts that allow the court to "draw a reasonable inference that the defendant is liable for the misconduct alleged."[25]

On a motion to dismiss, asserted claims are liberally construed in favor of the claimant, and all facts pleaded are taken as true.[26] However, although required to accept all "well-pleaded facts" as true, the court is not required to accept legal conclusions as true.[27] "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations."[28] Similarly,

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[22] Fed. R. Civ. P. 12(b)(6).

[23] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2008)).

[24] *Twombly*, 550 U.S. at 556.

[25] *Id.* at 570.

[26] *Leatherman v. Tarrant Cnty. Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 164 (1993); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322-23 (2007).

[27] *Iqbal*, 556 U.S. 662, 677-78.

[28] *Id.* at 679.

"[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements" will not suffice.[29] The complaint need not contain detailed factual allegations, but it must offer more than mere labels, legal conclusions, or formulaic recitations of the elements of a cause of action.[30] That is, the complaint must offer more than an "unadorned, the defendant-unlawfully-harmed-me accusation."[31]

From the face of the complaint, there must be enough factual matter to raise a reasonable expectation that discovery will reveal evidence as to each element of the asserted claims.[32] If factual allegations are insufficient to raise a right to relief above the speculative level, or if it is apparent from the face of the complaint that there is an "insuperable" bar to relief, the claim must be dismissed.[33]

III. Law and Analysis

A. Overview of the Louisiana Products Liability Act

Under Louisiana law, the LPLA establishes the exclusive remedy for injuries arising from product defects[34] and sets forth four theories of recovery under which a plaintiff may recover.[35] To

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[29] *Id.* at 678.

[30] *Id.*

[31] *Id.*

[32] *Lormand v. U.S. Unwired, Inc.*, 565 F.3d 228, 257 (5th Cir. 2009).

[33] *Moore v. Metro. Human Serv. Dep't*, No. 09-6470, 2010 WL 1462224, at * 2 (E.D. La. Apr. 8, 2010) (Vance, C.J.) (citing *Jones v. Bock*, 549 U.S. 199, 215 (2007); *Carbe v. Lappin*, 492 F.3d 325, 328 & n. 9 (5th Cir. 2007)).

[34] La. R.S. § 9:2800.52.

[35] La. R.S. § 9:2800.54.

establish liability under any of these theories, a plaintiff must prove: (1) that the defendant is a "manufacturer" of the product, as that term is defined under the statute; (2) that the plaintiff's damages were proximately caused by a characteristic of the product; (3) that the damage-causing characteristic made the product "unreasonably dangerous"; and (4) that the plaintiff's damages arose from a reasonably anticipated use of the product.[36] A plaintiff can establish that a product is unreasonably dangerous under any of four theories: (1) a defect in construction or composition; (2) a design defect; (3) a failure to provide an adequate warning; or (4) a failure to comply with an express warranty.[37]

B. Prescription

The Court will first consider Defendant's argument that Plaintiff's claims are prescribed by Louisiana law. Under the Louisiana Civil Code, delictual actions are subject to a one year prescriptive period.[38] This period commences on the date of injury, or when the plaintiff has constructive notice of the tortious act.[39] Therefore, "Louisiana's one-year prescriptive period does not begin to run until the plaintiff has actual or constructive knowledge of the tortious act, the damage, and the causal relationship between the tortious act and the damage."[40] Constructive knowledge exists when the alleged victim has information or knowledge that reasonably puts him

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[36] *Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 260-61 (5th Cir. 2002).

[37] La. R.S. § 9:2800.54; *see also Stahl*, 283 F.3d at 260-61.

[38] La. C.C. art. 3492.

[39] *Id.*; *Ducre v. Mine Safety Appliances, Inc.*, 963 F.2d 757, 760 (5th Cir. 1992) (citations omitted).

[40] *Knaps v. B & B Chem. Co.*, 828 F.2d 1138, 1139 (5th Cir. 1987) (citing *Duhon v. Saloom*, 323 So.2d 202, 204 (La. App. 3 Cir. 1975)).

on inquiry,[41] and the Louisiana Supreme Court has specifically held that "[p]rescription does not run against one who is ignorant of the facts upon which his cause of action is based, as long as such ignorance is not willful, negligent or unreasonable."[42] Thus, it is reasonable for a plaintiff to delay filing a lawsuit until there is some indication of a causal connection between the medical treatment and the resulting injury.[43]

"When a [complaint] reveals on its face that prescription has run, the plaintiff has the burden of showing why the claim has not prescribed."[44] Unless the plaintiff meets his burden to show the claim is not prescribed, then it is apparent from the face of the complaint that there exists an "insuperable"[45] bar to relief and that the case must be dismissed. Here, the date upon which Plaintiff sustained injury is unclear, although the injury sustained at the casino likely occurred on March 28, 2010.[46] However, the relevant date for this inquiry is the date upon which Plaintiff first obtained constructive notice that Plaintiff's use of Tramadol might be responsible for his injuries. Plaintiff provides no such date in his complaint, but in his response in opposition to the pending motion, he states this date as July 30, 2009.[47] Plaintiff filed his complaint in this matter on May 27, 2011.[48]

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[41] *Campo v. Correa*, 828 So.2d 502, 510-11 (La. 2001).

[42] *Griffin v. Kinberger*, 507 So.2d 821, 823 (La. 1987).

[43] *Id.*

[44] *Wimberly v. Gatch*, 635 So.2d 206, 211 (La. 1994).

[45] *See Moore*, 2010 WL 1462224, at * 2 (citations omitted).

[46] In Plaintiff's complaint, he alleged dates of May 27, 2010 and March 28, 2010 for when his injury occurred, but his opposition to the pending motion cites March 28, 2010 as the date of his fall at the casino. *See* Rec. Doc. 1 at ¶¶ 6, 9 and Rec. Doc. 7 at pp. 2, 3.

[47] Rec. Doc. 7 at p. 5.

[48] Rec. Doc. 1.

As such, Plaintiff cites a date of constructive notice that is more than one year prior to the initiation of this lawsuit, and Plaintiff does not allege that the prescriptive period has been interrupted or suspended. Accordingly, Plaintiff has not carried his burden to demonstrate that this suit is timely. Oddly, however, Plaintiff provided this July 30, 2009 date as evidence that his claim is, indeed, timely. Further, this alleged date of constructive notice precedes the fall that landed Plaintiff in the hospital. Thus, it appears that Plaintiff may have intended to state July 30, 2010 as the date upon which Plaintiff first consulted physicians about his blackouts and the date upon which he was informed that the blackouts were caused by his use of the prescribed drug. A constructive notice date of July 30, *2010* would make this suit timely.

Given this possible error and because the Court finds that dismissal of this action is merited on other grounds, the Court will assume that Plaintiff intended to cite a constructive notice date of July 30, 2010, which would be within the one-year prescriptive period, and the Court will dismiss the suit on other grounds rather than on the basis of prescription.

C. Claims Not Brought Pursuant to the Louisiana Products Liability Act

1. Plaintiff's Negligence and Strict Liability Claims

Defendant moves to dismiss Plaintiff's claims brought under theories of negligence or strict liability as precluded by the LPLA, which provides the only available avenue of recovery against a manufacturer. As noted above, by its plain language, the LPLA provides that it "establishes 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 this Chapter."[49] Therefore, under Louisiana law, independent theories of liability premised on strict liability, negligence, or warranty are not viable against a manufacturer, and courts in Louisiana routinely reject actions under these non-LPLA theories.[50] The United States Court of Appeals for the Fifth Circuit has explicitly acknowledged that "for causes of action arising after the effective date of the LPLA, negligence, strict liability, and breach of express warranty are not available as theories of recovery against a manufacturer, independent from the LPLA."[51]

Therefore, the law is clear that Plaintiff may not recover against Defendant under theories of negligence or strict liability here. In fact, Plaintiff has presented no opposition to Defendant's argument that these causes of action must be dismissed. Based upon the well-settled law, this Court will dismiss Plaintiff's negligence and strict liability claims.

2. Plaintiff's Claim for Attorney's Fees

Additionally, Defendant moves to dismiss Plaintiff's request for attorney's fees as unfounded under Louisiana law. The LPLA expressly provides that "[a]ttorneys' fees are not recoverable under this Chapter."[52] Given the LPLA's express prohibition of attorney's fees,[53] as well as the fact that this Court has already determined that Plaintiff's claims brought under other theories must be

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[49] La. R.S. § 9:2800.52. *See also Stahl*, 283 F.3d at 261; *Jefferson v. Lead Indus. Ass'n*, 106 F.3d 1245, 1250-51 (5th Cir. 1997).

[50] *See, e.g., Barette v. Dow Agrosciences, L.L.C.*, No. 02-1677, 2002 WL 31365598, at *4 (E.D. La. Oct. 8, 2002) (Zainey, J.); *Borskey v. Medtronicx, Inc.*, No. 94-2302, 1998 WL 122602, at *4 (E.D. La. Mar. 18, 1998) (Fallon, J.); *Humphries v. Cooper Truck Center*, 923 So.2d 940, 946 (La. App. 2 Cir. 2006).

[51] *Stahl*, 283 F.3d at 261(citation omitted).

[52] La. R.S. § 9:2800.53(5).

[53] The Court further notes that Plaintiff has presented no argument in opposition.

dismissed, this Court will also dismiss Plaintiff's request for attorney's fees.

D. Preemption

Next, the Court will consider Defendant's arguments that Plaintiff's failure to warn or design defect claims brought under the LPLA are preempted by federal law.

1. Applicable Law

Article VI of the United States Constitution provides, "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land."[54] Therefore, where federal and state law directly conflict, the state law must "give way."[55] When it is "impossible for a private party to comply with both state and federal requirements," such a conflict exists and the state law is preempted by the federal.[56] Therefore, "[w]hen the 'ordinary meaning' of federal law blocks a private party from independently accomplishing what state law requires, that party has established pre-emption."[57] However, the burden to establish the affirmative defense of impossibility preemption rests on the party seeking to establish it.[58]

In *Mensing*,[59] the United States Supreme Court was confronted with the question of whether

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[54] U.S. Const., Art. VI, cl. 2.

[55] *Mensing*, 131 S.Ct. at 2577 (citing *Wyeth v. Levine*, 555 U.S. 555, 583 (2009) (Thomas, J., concurring in judgment); *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000) ("state law is naturally preempted to the extent of any conflict with a federal statute")).

[56] *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995).

[57] *Mensing*, 131 S.Ct. at 2580.

[58] *See Wyeth v. Levine*, 555 U.S. 555, 573 (2009).

[59] 131 S.Ct. 2567.

a generic drug manufacturer's alleged failure to provide an adequate warning label in accordance with state law directly conflicted with federal drug regulations applicable to generic drug manufacturers, such that federal law would preempt claims brought against generic drug manufacturers for violations of applicable state laws.[60] A majority of the Court held that federal law did preempt such claims.[61] The case involved two separate actions that were consolidated before the Supreme Court, each of which brought claims under state tort law against a generic drug manufacturer for failure to provide adequate warning labels[62]; one of the plaintiffs, Julie Demahy, brought her claims under the LPLA.[63] In the consolidated action, the defendant manufacturers argued that federal statutes and FDA regulations preempted the state tort claims because the statutes and regulations required their labels to provide the same safety and efficacy labeling as the brand-name counterpart drugs.[64] Therefore, argued the defendant manufacturers, it was impossible for them simultaneously to comply with federal law and also to satisfy their state tort duties, which would require the generic manufacturers to use a different label than that currently used by their brand-name counterparts.[65]

The Court began by outlining the parameters of federal drug law, noting that a generic drug gains FDA approval by demonstrating that it is the same as an already-approved brand name

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[60] *Id.* at 2572.

[61] *Id.*

[62] *Id.* at 2573.

[63] *Id.*

[64] *Id.*

[65] *Id.*

version[66] and concluding that "brand-name and generic drug manufacturers have different federal drug labeling duties."[67] Specifically, the Court concluded that "generic drug manufacturers have an ongoing federal duty of 'sameness.'"[68] In response, the plaintiffs each presented several arguments that their state law claims were not preempted because, despite this duty of sameness, there existed actions that the generic drug manufacturers could have taken but did not.[69] Accordingly, argued the plaintiffs, there existed no impossibility such that their claims were preempted.

First, the plaintiffs each argued that there existed an FDA process – the "changes-being-effected" ("CBE") process – that allowed generic drug manufacturers to change their labels when necessary.[70] However, the Court noted that the FDA denied that generic drug manufacturers could unilaterally effect label change because a generic drug manufacturer would only be permitted to change a label to match an updated brand-name drug label or per FDA instructions[71]; accordingly, the Court deferred to the FDA and found that unilateral change, as would be required by the state laws in question, would violate the generic manufacturers' duty of sameness.[72] The plaintiffs further argued that there existed other avenues by which manufacturers could provide additional warnings to patients, such as "Dear Doctor" letters in which additional warnings were sent to physicians and

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[66] *Id.* at 2574-75 (stating that generic drugs "gain FDA approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA").

[67] *Id.* at 2574.

[68] *Id.* at 2574-75 (citing 57 Fed. Reg. 17961 (1992) ("[T]he [generic drug's] labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for [generic drug] approval.")).

[69] *Id.* at 2575-77.

[70] *Id.* at 2575.

[71] *Id.* at 2575.

[72] *Id.*

healthcare professionals.[73] Again, the Court deferred to the FDA and determined that such an avenue was unavailable to generic manufacturers because such letters would constitute labeling and, therefore, would be in violation of the duty of sameness.[74]

Having denied that generic manufacturers could use the CBE process or "Dear Doctor" letters to effect change, the FDA noted in its amicus brief that an additional avenue existed for generic manufacturers to strengthen a label: proposing a stronger warning label to the FDA.[75] However, the Court determined that even *if* there existed a duty for the generic manufacturers to work toward strengthening a drug's label, preemption nonetheless existed because the generic manufacturer still would not be in compliance with state law.[76] The Court stated:

> We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them. And even if they had fulfilled their [assumed] federal duty to ask for FDA assistance, they would not have satisfied the requirements of state law.[77]

The Court found that even such a duty "to ask the FDA for help in strengthening the corresponding brand-name label, assuming such a duty exists, does not change this analysis. Although requesting FDA assistance would have satisfied the Manufacturers' federal duty, *it would not have satisfied their state tort-law duty to provide adequate labeling.*"[78]

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[73] *Id.* at 2576.

[74] *Id.*

[75] *See id.*

[76] *Id.* at 2577 ("Because we ultimately find pre-emption even assuming such a duty existed, we do not resolve the matter [of whether a duty existed].")

[77] *Id.*

[78] *Id.* at 2578 (emphasis added).

However, the plaintiffs argued that because the defendant manufacturers had done nothing to attempt to change the labels, the plaintiffs' claims should not be preempted because the manufacturers might have been able to accomplish what state law required of them and, therefore, there existed no impossibility sufficient to support preemption.[79] Specifically, "Mensing and Demahy assert[ed] that when a private party's ability to comply with state law depends on approval and assistance from the FDA, proving pre-emption requires that party to demonstrate that the FDA would not have allowed compliance with state law."[80] Although this argument persuaded four members of the Court,[81] it did not persuade the majority.[82] The majority concluded that "[t]he question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it," and the majority determined that conflict preemption would be rendered largely meaningless if the Court were to accept plaintiffs' argument.[83] The Court concluded, "pre-emption analysis should not involve speculation about ways in which federal agency and third-party actions could potentially reconcile federal duties with conflicting state duties. When the 'ordinary meaning' of federal law blocks a private party from independently accomplishing what

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[79] *Id.* at 2578.

[80] *Id.* at 2578-79.

[81] *See id.* at 2582-83 (Sotomayor, J., dissenting).

[82] *Mensing*, 131 S.Ct. at 2579 ("Here, [plaintiffs] argue, the Manufacturers cannot bear their burden of proving impossibility because they did not even *try* to start the process that might ultimately have allowed them to use a safer label. This is a fair argument, but we reject it.") (internal citation omitted).

[83] *Id.* at 2579.

state law requires, that party has established pre-emption."[84] Therefore, the Court held that the plaintiffs' claims were preempted.[85]

In *Mensing*, the Court did not specifically reverse, or even address, one of the arguments that had been raised before the appellate court below.[86] There, Mensing had put forth an argument that the manufacturer could have removed the drug from the market and so could have accomplished its duties under state law.[87] However, on remand, the Eighth Circuit interpreted the Supreme Court's ruling in *Mensing* to encompass the failure-to-withdraw theory, and the Eighth Circuit vacated the portion of its opinion that had embraced that theory.[88] Moreover, other federal courts within Louisiana have considered this argument and have found it without merit:

> Charging a generic drug manufacturer with a duty to withdraw its product from the market fits uneasily into any of the four recognized claims under the LPLA. It is plainly not a manufacturing or design defect claim, nor is it a warranty claim. If anything, it is a failure to warn claim. The logic would go something like this: a manufacturer has a duty to warn consumers of dangers; the drug labeling indicates some of its dangers, but the labeling is not enough; federal law disallows stronger labeling, so the only way to responsibly account for the danger is to take the drug off the market altogether. *See Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009), *rev'd*, 131 S.Ct. 2567 (2011). But if it is this logic which permits a withdrawal from the market claim to stand, that claim did not survive the Supreme Court's reversal of the Eighth Circuit in *Mensing*. Such contentions cleverly dress up failure to warn claims in a tempting but ultimately illegitimate guise. If state law could *require* a generic drug manufacturer to wholly withdraw from the market based on

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[84] *Id.* at 2580; *see also id.* at 2581 ("[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.").

[85] *Id.* at 2581.

[86] *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009).

[87] *Id.* at 611.

[88] *See Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011).

> the unreasonable danger of the product (which is all a successful failure to withdraw from the market claim could be), it *necessarily* must repudiate the label approved by the FDA.[89]

Additionally, although the Supreme Court was only confronted in *Mensing* with the question of whether a plaintiff's failure to warn claim would be preempted by federal law, numerous lower courts have since confronted the question of whether a design defect claim is also preempted as a result of the generic manufacturer's duty of sameness. Overwhelmingly, these courts have found that such a claim is preempted,[90] largely on the basis that federal law requires a generic drug to be of the same design as its brand name counterpart.[91] A generic drug must be the same as the reference listed drug in active ingredients, safety, and efficiency.[92] Therefore, these courts have found, it would be impossible for a generic manufacturer to alter the design of its product without violating the generic manufacturer's federal duty of sameness, creating impossibility and thus preempting such claims.

2. Analysis

In this case, Plaintiff presents arguments of precisely the type rejected by the Supreme Court in *Mensing*, and this Court finds that both Plaintiff's failure to warn and design defect claims are preempted in accordance with that decision.

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[89] *Cooper v. Wyeth, Inc.*, No. 09-0929, 2012 WL 733846 (M.D. La. Mar. 6, 2012); *see also Johnson v. Teva Pharms. USA, Inc.*, No. 10-0404, 2012 WL 1866839, at *5 (W.D. La. May 21, 2012). Federal courts sitting in Louisiana are not alone in their conclusion that a failure to withdraw from the market argument does not overcome impossibility preemption. *See, e.g., Eckhardt v. Qualitest Pharms., Inc.*, No. 11-0235, 2012 WL 1511817 (S.D. Tex. Apr. 30, 2012).

[90] *See, e.g., Stevens v. PLIVA, Inc.*, No. 10-0886, 2011 WL 6224569, at *2 (W.D. La. Nov. 15, 2011); *Johnson*, 2012 WL 1866839, at *4; *Eckhardt*, 2012 WL 1511817, at *7 ("Therefore, Generics were required to produce a drug that was equivalent to the brand-name drug and were not free to unilaterally pursue a safer alternative design in order to comply with state law. The design defect claim is thus preempted and therefore dismissed.").

[91] *See* 21 U.S.C. § 355(j) (setting forth that a generic drug must be bioequivalent to its brand name reference drug to receive FDA approval via an abbreviated process).

[92] *Id.*

First, regarding Plaintiff's failure to warn claim, as in *Mensing*, the defendant here could not change, strengthen, or alter the label in any way without the prior approval of the FDA, and thus, Defendant "could [not] independently do under federal law what state law require[d] of it" without violating federal law, thus establishing preemption. Although Plaintiff argues that Defendant was not prevented "*from taking any action at all*" and argues that "[t]o the contrary," there was much that Defendant could have and was required to do,[93] the majority of the Supreme Court explicitly rejected these same arguments[94] – in fact, in support of these propositions, Plaintiff cites to the *dissent*.[95] Likewise, Plaintiff points out that the majority in *Mensing* assumed that there existed a duty for generic manufacturers to seek to change a drug's label if it had reason to believe that a change was necessary,[96] but Plaintiff ignores the fact that the Supreme Court explicitly held that even if such a duty did exist, the plaintiffs' claims were preempted nonetheless.[97] Therefore, the Supreme Court has previously explicitly rejected both of these arguments advanced here by Plaintiff.

Additionally, this Court finds that Plaintiff's arguments regarding Defendant's failure to withdraw from the market fail. Although not specifically addressed by the Supreme Court, this Court agrees with the reasoning advanced by other courts that have considered this issue since the *Mensing* decision was rendered.[98] To require a generic manufacturer to remove a drug from the market would repudiate the label approved by the FDA. Therefore, this Court concludes that in

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[93] Rec. Doc. 7 at p. 7.

[94] *Mensing*, 131 S.Ct. at 2579.

[95] Rec. Doc. 7 at p. 7.

[96] *Id.* at p. 8.

[97] 131 S.Ct. at 2577.

[98] *See, e.g., Cooper*, 2012 WL 733846; *Johnson*, 2012 WL 1866839; *Eckhardt*, 2012 WL 1511817.

accordance with the United States Supreme Court's decision in *Mensing*, Defendant has met its burden and Plaintiff's failure to warn claims are preempted because Defendant could not fulfill its state law duty to effect a stronger label without violating its federal duty of sameness.

Likewise, this Court finds that to the extent that Plaintiff even properly states a design defect claim,[99] *Mensing*'s reasoning warrants dismissal of this claim as well. In *Mensing*, the Supreme Court noted that a generic drug manufacturer has a duty of sameness, and federal law specifically requires a generic drug to be the bioequivalent of its name-brand counterpart.[100] Therefore, Defendant could not alter the design of the drug without violating federal law and this duty of sameness, making it impossible for Defendant independently to comply with both federal and state law. As such, this Court joins numerous other lower courts that have considered this issue and found the failure-to-warn reasoning of *Mensing* equally applicable to a design defect claim.[101] Therefore, to the extent that Plaintiff has properly stated a design defect claim, this Court finds that Defendant has met its burden to establish that such a claim is preempted.

E. Failure to Plead Sufficient Facts to State a Claim

In addition to the other arguments presented, Defendant contends that Plaintiff's complaint fails to plead sufficient facts to meet the pleading standard of Federal Rule of Civil Procedure 8 and fails to establish that Tramadol was unreasonably dangerous due to a design defect, that Tramadol was unreasonably dangerous in construction or composition, or that Tramadol failed to conform to

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[99] As discussed below, additionally or alternatively, this Court finds that Plaintiff has failed to satisfy the pleading standard necessary to properly state a claim regarding an alleged design defect.

[100] 21 U.S.C. § 355(j).

[101] *See, e.g., Stevens*, 2011 WL 6224569; *Johnson*, 2012 WL 1866839; *Eckhardt*, 2012 WL 1511817.

an express warranty by Defendant. Federal Rule of Civil Procedure 8(a)(2) requires "a short and plain statement of the claim showing that the pleader is entitled to relief." However, as explained previously, the mere recitation of elements of a cause of action is insufficient to meet this standard and to support a cause of action,[102] and a plaintiff must provide facts that, accepted as true, raise a right to relief above the speculative level.[103]

1. Applicable Law

Design Defect Claim

To establish a design defect claim, a plaintiff must establish that, at the time the product left the manufacturer's control, "[t]here existed an alternative design for the product that was capable of preventing the claimant's damage" and that the danger of the damage outweighed the burden on the manufacturer of adopting the alternative design.[104]

Construction or Composition Defect Claim

To establish a construction or composition defect claim, a plaintiff must establish that, at the time the product left the manufacturer's control, the product "deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical

[102] *Iqbal*, 556 U.S. at 678.

[103] *Twombly*, 550 U.S. at 556.

[104] La. R.S. § 9:2800.56.

products manufactured by the same manufacturer."[105] This LPLA provision provides a cause of action for a product that is defective because of a mistake in the manufacturing process.[106]

Claim for Failure to Conform to an Express Warranty

An express warranty exists where the manufacturer of a good voluntarily undertakes and extends a guarantee to customers.[107] Under the LPLA, an express warranty is defined as:

> a representation of alleged fact or promise about a product or its nature, material or workmanship that represents, affirms or promises that the product or its nature, material or workmanship possesses specified characteristics or qualities or will meet a specified level or performance. "Express warranty" does not mean a general opinion about or general praise of a product . . . .[108]

A warranty is not a warning, nor is it a mandatory packaging or labeling condition that constitutes a state-imposed requirement.[109] Under the LPLA, a manufacturer may be liable if a product contains an express warranty that has "induced the claimant or another person or entity to use the product and the claimant's damage was proximately caused because the express warranty was untrue."[110]

2. Analysis

For each of these three claims, Plaintiff has done no more than formulaically recite statutory provisions and make conclusory allegations, without alleging facts in support of his claims. Here,

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[105] La. R.S. § 9:2800.55. *See also Stahl*, 283 F.3d at 263.

[106] *Stahl*, 283 F.3d at 263 (citing La. R.S. § 9:2800.55).

[107] *Fields v. Walpole Tire Serv., L.L.C.*, 37 So.3d 549, 557 (La. App. 2 Cir. 2010).

[108] La. R.S. § 9:2800.53(6).

[109] *Fields*, 37 So.3d at 557 (citation omitted).

[110] La. R.S. § 9:2800.58.

even if Plaintiff's design defect claim was not preempted under *Mensing*, Plaintiff has not alleged that there existed an alternative design for the drug, an "essential element" of a LPLA design defect claim.[111] Further, Plaintiff has not alleged that the burden on the manufacturer to develop such a drug outweighed the dangers posed by the current design. Therefore, instead of alleging either of the elements for a design defect claim, Plaintiff has merely recited the elements of the cause of action. Likewise, regarding Plaintiff's construction or composition defect claim, Plaintiff has not alleged that the medicine he received deviated in any way from the manufacturer's production standards or from the manufacturer's otherwise identical products – he merely recites the elements of this cause of action.

The same is true of Plaintiff's claim that the product failed to conform to an express warranty by Defendant. Plaintiff has not alleged even the existence of an express warranty; Plaintiff has not alleged that Defendant made any representations other than those contained in the labeling.[112] Specifically, Plaintiff has not alleged that Defendant advertised its product, detailed its product to doctors, or made any other forms of communication regarding Tramadol. Moreover, Plaintiff has not alleged that he was induced to take Tramadol because of any alleged express warranty. Therefore, as with Plaintiff's design defect and construction or composition defect claims, Plaintiff's complaint provides only a direct quotation of the relevant legal standard, without alleging any facts that might support his claim.

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[111] *See, e.g., Ivory v. Pfizer*, No. 09-0072, 2009 WL 323061, at *3 (W.D. La. Sept. 30, 2009) (citing *Guidry v. Events Pharms., Inc.*, 418 F. Supp. 835, 842 (M.D. La. 2006); *Green v. BDI Pharms.*, 803 So.2d 68, 78 (La. App. 2 Cir. 2001)) .

[112] However, as explained previously, any claims based upon the drug's labeling are preempted under *Mensing*.

Nonetheless, Plaintiff argues that it would be "unreasonable" to hold him to "this depth of detail" and that it "would require that Plaintiff conduct a trial on the merits within the four corners of plaintiff's petition" for him to allege factual assertions regarding the nature of the defect, an available alternative design, how the defect deviated in a material way from the manufacturer's standards or specifications, and/or an express warranty.[113] These arguments fail; the statutory provisions are clear regarding what Plaintiff must allege, and as explained above, Plaintiff has failed to meet these requirements.[114] In fact, in similar situations, other courts have concluded that a failure to allege any facts regarding the elements of these claims must result in dismissal of the claims.[115]

"Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements . . . do not suffice" to state a viable cause of action."[116] Plaintiff has done no more than this here. Accordingly, it is only speculative that Plaintiff can recover under any of these three theories of liability, and Plaintiff has failed to plead sufficient facts to survive a motion to dismiss regarding Plaintiff's claims for Defendant's liability under the LPLA on Plaintiff's design defect claim, his construction or composition defect claim, and his claim for the product's alleged failure to conform to an express warranty by Defendant. Therefore, the Court will dismiss these claims.

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[113] Rec. Doc. 7 at pp. 9-10.

[114] Plaintiff concludes that the relevant pleading standard has been met because he alleges that he was prescribed and took Tramadol for pain, that he subsequently experienced blackouts and physical injuries, that his doctor informed him that Tramadol was the cause of his fall, and that Defendant did not warn Plaintiff of the dangers associated with Tramadol. *Id.* at p. 11. These allegations are insufficient to establish the requisite elements of design defect, construction or composition defect, or express warranty claims.

[115] *See, e.g., Cooper*, 2012 WL 733846; *Guilbeau v. Wyeth, Inc.*, No. 09-1652, 2011 WL 4948996 (W.D. La. Oct. 14, 2011).

[116] *Iqbal*, 556 U.S. at 678.

IV. Conclusion

For the reasons set forth above, the Court will opt not to dismiss this suit on the basis of prescription. However, the Court will dismiss all claims not brought under the Louisiana Products Liability Act as in contravention of the LPLA's exclusive remedy provision; will dismiss Plaintiff's request for attorney's fees as unfounded under Louisiana law; will dismiss Plaintiff's failure to warn claim as preempted under the United States Supreme Court's decision in *Mensing*; will dismiss Plaintiff's design defect claim as preempted under *Mensing*, or alternatively, for failure to satisfy the requisite pleading standard to state a claim; and will dismiss Plaintiff's construction or composition defects claim and express warranty claim based on Plaintiff's failure to satisfy the pleading requirements. Accordingly,

IT IS HEREBY ORDERED that Defendant's Motion to Dismiss[117] is **GRANTED** and that the above-captioned case is **DISMISSED WITH PREJUDICE**.

NEW ORLEANS, LOUISIANA, this 20th day of July, 2012.

Nannette Jolivette Brown

NANNETTE JOLIVETTE BROWN
UNITED STATES DISTRICT JUDGE

[117] Rec. Doc. 4.