UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARY CAROL GALLIEN, Plaintiff, -against- PROCTER & GAMBLE PHARMACEUTICALS, INC., SANOFI-AVENTIS US, INC., SANOFI-AVENTIS US, LLC, and ASTRAZENECA PHARMACEUTICALS SP, Defendants.	No. 09 Civ. 6903 (JFK) **OPINION AND ORDER**

APPEARANCES:

For Plaintiff:
Robert L. Salim, Esq.
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Natchitoches, LA 71457

For Defendants:
Erica A. Reed, Esq.
FULBRIGHT & JAWORSKI L.L.P.

JOHN F. KEENAN, United States District Judge:

Plaintiff Mary Carol Gallien ("Gallien" or "Plaintiff") filed the instant action against Procter & Gamble Pharmaceuticals, Sanofi-Aventis, and AstraZeneca Pharmaceuticals ("Defendants"), alleging that she sustained personal injuries as a result of using Defendants' bisphosphonate drug Actonel. Defendants move under Fed. R. Civ. P. 12(b)(6) to dismiss the complaint for failure to state a claim under the Louisiana Product Liability Act ("LPLA"). For the reasons that follow, Defendants' motion is granted in part and denied in part.

I. Background

Gallien is a resident of the state of Louisiana. In March 2005, she began taking Actonel for the treatment and prevention of osteoporosis. Gallien originally filed this lawsuit in the Western District of Louisiana, alleging that she sustained personal injuries, including osteonecrosis of the jaw ("ONJ"), as a result of using Actonel.[1] Without reference to any statutory provisions, Gallien generally asserts negligence, negligence per se, negligent misrepresentation, strict liability, breach of express warranty, breach of implied warranty, fraud and misrepresentation, fraudulent concealment, intentional infliction of emotional distress, and negligent infliction of emotional distress claims based on injury allegedly caused by her use of Actonel. She also alleges that Defendants violated "consumer protection statutes enacted in the State of Louisiana." (Compl. ¶ 146). Gallien requests relief in the form of redhibition, medical monitoring, disgorgement, compensatory damages, punitive damages, and attorneys' fees.

II. Legal Standards

On a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, the court must accept the factual allegations of the

[1] This action was transferred to the Southern District of New York pursuant to 28 U.S.C. § 1404(a) by stipulation of the parties.

complaint as true and draw all reasonable inferences in favor of the plaintiff. Vietnam Ass'n for Victims of Agent Orange v. Dow Chem. Co., 517 F.3d 104, 115 (2d Cir. 2008). The court, however, is not required to accept as true conclusory allegations or "a legal conclusion couched as a factual allegation." Papasan v. Allain, 478 U.S. 265, 286 (1986). The district court's function "is merely to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof." Geisler v. Petrocelli, 616 F.2d 636, 639 (2d Cir. 1980). Therefore, a complaint will be dismissed only where it fails to set forth sufficient facts to state a claim for relief that is "plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007).

Although the Complaint does not set forth the relevant statute under which Plaintiff seeks relief, the parties agree that Louisiana law applies. The LPLA provides the exclusive remedy for any plaintiff injured by a defective product. La. Rev. Stat. Ann. § 9:2800.52. In order to state a claim under the LPLA, plaintiff must establish that: (1) defendant manufactured the product in question; (2) the product proximately caused plaintiff's damages; (3) some defect rendered the product "unreasonably dangerous"; and (4) plaintiff's damages arose from a reasonably anticipated use of the product.

See id. § 9:2800.54(A); Gomez v. St. Jude Med. Daig Div., Inc., 442 F.3d 919, 932 (5th Cir. 2006). Under the LPLA, a manufacturer is liable for damages caused by a product that is "unreasonably dangerous" due to a: (1) manufacturing construction or composition defect;[2] (2) design defect; (3) failure to warn; and (4) breach of express warranty. La. Rev. Stat. Ann. § 9:2800.54(B). "These statutory mechanisms for establishing that a product is unreasonably dangerous 'are predicated on principles of strict liability, negligence, or warranty.' However, 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." Stahl v. Novartis Pharms. Corp., 283 F.3d 254, 261 (5th Cir. 2002) (quoting Jefferson v. Lead Indus. Assoc., Inc., 930 F. Supp. 241, 245 (E.D. La. 1996)).

III. Analysis

Defendants move to dismiss the Complaint, arguing that the causes of action asserted are not cognizable under the LPLA.

[2] Plaintiff apparently concedes that the Complaint does not state a claim for a composition or construction defect. In any event, the Complaint fails to provide any facts to establish that "the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer," as required under the LPLA. La. Rev. Stat. Ann. § 9:2800.55.

Additionally, Defendants argue that medical monitoring damages, punitive damages, and attorneys' fees are not recoverable under Louisiana law. Thus, the Court's task is to examine the factual allegations of the Complaint to determine the extent to which it adequately states claims under the LPLA.

A. Non-Cognizable Claims

Since the LPLA's exclusivity provision limits those theories under which Plaintiff can recover from a manufacturer for damage caused by a product, several claims initially must be dismissed under Louisiana law. Specifically, the negligence per se, negligent misrepresentation, breach of implied warranty, fraud and misrepresentation, fraudulent concealment, intentional infliction of emotional distress, negligent infliction of emotional distress, and violation of consumer protection statute claims fall outside the scope of the LPLA and therefore fail to state a claim. See King v. Bayer Pharms. Corp., No. 09 Civ. 0465, 2009 WL 2135223, at *4 (W.D. La. July 13, 2009) (dismissing negligence per se claim under the LPLA); Bladen v. C.B. Fleet Holding Co., 487 F. Supp. 2d 759, 770-71 (W.D. La. 2007) ("[T]his Court finds plaintiffs' [Louisiana Unfair Trade Practices and Consumer Protection Act] allegations . . . are not cognizable under the facts presented, and thus, must be dismissed for the following reasons in particular: (1) the LPLA language is clear and unambiguous and provides the exclusive

theory of liability against manufacturers; . . . (3) the LPLA contains no exception for [Unfair Trade Practices and Consumer Protection Act] claims. . . .”); Maurice v. Eli Lilly & Co., No. 04 Civ. 3105, 2005 WL 3542902, at *4 (E.D. La. Nov. 7, 2005) (dismissing negligent misrepresentation and intentional infliction of emotional distress claims under the LPLA); Grenier v. Med. Eng’g Corp., 99 F. Supp. 2d 759, 763 (W.D. La. 2000) (dismissing misrepresentation/fraud, fraud by concealment, and negligent infliction of emotional distress claims under the LPLA); Jefferson, 930 F. Supp. at 245 (dismissing fraud by misrepresentation and breach of implied warranty claims under the LPLA); Brown v. R.J. Reynolds Tobacco Co., 852 F. Supp. 8, 9 (E.D. La. 1994), aff’d, 52 F.3d 524 (5th Cir. 1995) (dismissing under the LPLA claims of fraudulent misrepresentation, concealment, conspiracy, and that the product was unreasonably dangerous per se).

B. Sufficiency of Allegations Under the LPLA

Plaintiff has adequately alleged that Defendants manufactured Actonel (Compl. ¶ 12), and that she used the product in a reasonably foreseeable manner to treat her osteoporosis. (Id. ¶ 31). Plaintiff further alleges that as a direct and proximate result of using Actonel, she developed ONJ. (Id. ¶ 32). Thus, the relevant inquiry is whether the Complaint states enough facts to establish that Actonel is

"unreasonably dangerous" in a manner recognized by Louisiana law. Although the Court would encourage more precise drafting, Plaintiff's failure to explicitly reference the LPLA is not fatal to the Complaint. A close reading of the underlying facts reveals allegations sufficient to state claims under the LPLA even though Plaintiff generically styles her causes of action as "negligence" and "strict liability." Cf. King, 2009 WL 2135223, at *5 ("Clearly, Plaintiffs' complaint contains the requisite factual allegations to state a claim under the LPLA. Moreover, the factual allegations support claims under the LPLA, even though Plaintiffs' complaint used titles for their claims that fell outside the LPLA.").

1. Design Defect

> A product has an unreasonably dangerous design if:
>
> (1) There existed an alternative design for the product that was capable of preventing the claimant's damage; and (2) The likelihood that the product's design would cause the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product.

La. Rev. Stat. Ann. § 9:2800.56.

The Complaint alleges that Actonel's "foreseeable risks exceeded the benefits associated with [its] design." (Compl. ¶ 72). Furthermore, the Complaint asserts that "[c]onsumers, including Plaintiff[], who have used Actonel for the treatment

or prevention of osteoporosis, have several alternative safer products available to them." (Id. ¶ 29). Although brief, this sufficiently establishes that Actonel could have been designed in such a way as to avoid the risks of ONJ inherent in the drug's current formulation. Thus, the Complaint states a claim that Actonel was defectively designed under the LPLA.

2. Failure to Warn

A product is unreasonably dangerous due to an inadequate warning "if, at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product." La. Rev. Stat. Ann. § 9:2800.57(A).

Plaintiff states that, in light of certain medical articles and studies, Defendants knew or should have known that Actonel can cause ONJ. However, Defendants negligently:

(a) Failed to use due care in designing and manufacturing the drug so as to avoid the aforementioned risks when the product was used for its intended purpose;
(b) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or defective nature of the drug and failed to accompany their product with proper and/or accurate warnings regarding the use of the product given its defective nature;
(c) Failed to warn Plaintiff[] of the severity and duration of such adverse side effects, as the

warnings given did not accurately reflect the defective nature of the product;

(d) Failed to conduct testing, including clinical testing and post-marketing surveillance to determine the safety of the drug;

(e) Failed to warn Plaintiff[], prior to actively encouraging the sale of the drug, either directly or indirectly, orally or in writing, about the defective nature of the drug.

(Compl. ¶ 52). Similarly, Plaintiff claims that Defendants should be held strictly liable because "[t]he drug as designed, manufactured, advertised, promoted, marketed, sold and distributed by Defendants is defective due to inadequate warnings and/or their failure to test or inadequate testing of the [product]." (Id. ¶ 80). These allegations are sufficient to make out a plausible claim that Actonel is unreasonably dangerous because Defendants did not provide a proper warning of the risk of ONJ associated with the product.

3. Breach of Express Warranty

"A product is unreasonably dangerous when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty 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." La. Rev. Stat. Ann. § 9:2800.58. The Complaint alleges that "Defendants expressly warranted in their written literature, advertisements and representations of their representatives and agents that their

drug was safe, effective, fit and proper for the use for which [it was] intended, and that the drug was adequately tested and fit for its intended use." (Compl. ¶ 89). Plaintiff further states that she relied on these representations in taking Actonel, and suffered damages because the product did not conform to the express warranties made. (Id. ¶¶ 90-95). Thus, the Complaint sets forth sufficient facts to establish a claim for breach of express warranty.

C. Redhibition

"Redhibition is the avoidance of a sale on account of some defect in the product that would render an item useless or so inconvenient to use that it would be presumed that a buyer would not have bought the thing had he known of the defect." Grenier, 243 F.3d at 206. The LPLA's exclusivity provision does not extend to bar redhibition claims, as the statute defines "damage" by explicitly excluding amounts recoverable under redhibition for damage to the product and other economic loss. See La. Rev. Stat. Ann. § 9:2800.53(5); Aucoin v. Southern Quality Homes, LLC, 984 So.2d 685, 691 n.8 (La. 2008). To be clear, redhibition claims are limited to recovery of economic loss only. Pipitone v. Biomatrix, Inc., 288 F.3d 239, 251 (5th Cir. 2002).

To the extent Plaintiff's Complaint seeks non-economic and personal injury damages in redhibition, those claims are

dismissed. However, the Complaint alleges that Actonel "contains a vice or defect which renders it either absolutely useless or renders its use so inconvenient and imperfect that buyers would not have purchased it had they known" about the risk of developing ONJ. (Compl. ¶ 163). Therefore, the Complaint adequately states a claim for recovery of economic loss in redhibition.

D. Medical Monitoring

Louisiana law provides that "[d]amages do not include costs for future medical treatment, services, surveillance, or procedures of any kind unless . . . directly related to a manifest physical or mental injury or disease." La. Civ. Code Ann. art. 2315. As Plaintiff has alleged that she sustained permanent injuries, including "the clinical manifestation of the symptoms [of ONJ] as they currently exist," as a result of using Actonel (Compl. ¶ 36), the Complaint adequately establishes that she has the requisite "manifest" physical injury to state a claim for medical monitoring damages. See In re FEMA Trailer Formaldehyde Prods. Liab. Litig., MDL No. 07-1873, 2008 WL 5217594, at *20 (E.D. La. Dec. 12, 2008); Hillard v. United States, No. 06 Civ. 2576, 2007 WL 647292, at *5 (E.D. La. Feb. 28, 2007) ("To the extent that plaintiffs' complaint alleges actual injuries suffered by plaintiffs, defendants' request for dismissal of the medical monitoring claim must be denied.

However, to the extent that the plaintiffs' complaint refers to possible future injuries or any future increased risk of injuries not yet manifested, defendants' request for dismissal is granted.").

E. Punitive Damages and Attorneys' Fees

Louisiana law does not allow for recovery of punitive damages or attorneys' fees unless expressly authorized by statute. See La. Code Civ. Proc. Ann. art. 1920 (attorneys' fees); Int'l Harvester Credit Corp. v. Seale, 518 So.2d 1039, 1041 (La. 1989) (punitive damages). The LPLA specifically proscribes recovery of attorneys' fees in product liability cases, see La. Rev. Stat. Ann. § 9-2800.53(5), and does not provide for recovery of punitive damages. See Bladen, 487 F. Supp. 2d at 770. Therefore, Plaintiff's claim for punitive damages is dismissed. Nor can Plaintiff recover attorneys' fees on her LPLA claims. However, attorneys' fees are recoverable insofar as they relate to recovery of economic loss on a redhibition claim. See La. Civ. Code Ann. art. 2545.

IV. Conclusion

The Complaint alleges adequate facts to establish design defect, failure to warn, and breach of express warranty claims under the LPLA. It also states a claim for pecuniary damages in redhibition, medical monitoring damages, and attorneys' fees related to the redhibition claim.

All other claims not arising under or authorized by the LPLA are dismissed with prejudice.

SO ORDERED.

Dated: New York, New York
March 4, 2010

John F. Keenan
United States District Judge