

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

JULIO CRUZ, as Personal
Representative de sun tort
of the ESTATE OF ZINA CRUZ

Plaintiff,

v.

Case No.: 8:09-CV-1106-T17-EAJ

MYLAN, INC., MYLAN
PHARMACEUTICALS, INC., and MYLAN
TECHNOLOGIES, INC.,

Defendants.

ORDER

This cause is before the Court on Defendants, Mylan, Inc., Mylan Pharmaceuticals, Inc., and Mylan Technologies, Inc.'s, (collectively, "Defendants") Partial Motion to Dismiss (Dkt. 10), and response thereto (Dkt. 13).

BACKGROUND AND PROCEDURAL HISTORY

Plaintiff Julio Cruz ("Plaintiff") as Personal Representative de sun tort of the Estate of Zina Cruz originally filed this action on June 12, 2009 in the United States District Court for the Middle District of Florida, Tampa Division.

This complaint arises from the death of Zina Cruz ("Decedent"). Decedent was prescribed 75 mcg fentanyl patches for pain, which she had filled at a local pharmacy with 75 mcg Mylan fentanyl transdermal patches. (Compl. ¶ 6–7, 10.) At the time of her death on June 17, 2007, she had a fatal blood fentanyl level. (*Id.* at ¶ 10).

Plaintiff brings causes of action against Defendants for Strict Liability, Negligence, Negligent Misrepresentation, Breach of Implied Warranty of Fitness, Breach of Implied Warranty of Merchantability, and Breach of Express Warranty. Plaintiff also alleges Defendants engaged in gross negligence or intentional misconduct and seeks, among other relief, punitive damages.

STANDARD OF REVIEW

A Defendant may move to dismiss a complaint under Rule 12(b)(6) for “failure to state a claim on which relief can be granted.” Fed. R. Civ. P. 12(b)(6). To survive a Rule 12(b)(6) motion to dismiss, a plaintiff’s complaint must include “enough facts to state a claim to relief that is plausible on its face.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A complaint should not be dismissed for failure to state a claim unless it appears beyond a doubt the plaintiff can prove no set of circumstances that would entitle him to relief. *Am. Ass’n of People with Disabilities v. Smith*, 227 F. Supp. 2d 1276, 1280 (M.D. Fla. 2002). A trial court is required to view the complaint in the light most favorable to the plaintiff. *Ill. ex rel. Madigan v. Telemarketing Assoc., Inc.*, 538 U.S. 600, 618 (2003).

A complaint must contain “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). While a complaint attacked by a Rule 12(b)(6) motion need not be buttressed by detailed factual allegations, the plaintiff’s pleading obligation “requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555. Factual allegations must be enough to raise a right to relief above the speculative level on that assumption that all of the complaint’s allegations are true. *Id.* at 555. “The pleading standard Rule 8 announces does not require

‘detailed factual allegations,’ but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation.” *Ashcroft v. Iqbal*, 129 S. Ct 1937, 1949 (2009).

A complaint may not be dismissed under Rule 12(b)(6) “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.” *Lopez v. First Union Natl. Bank of Fla.*, 129 F.3d 1186, 1189 (11th Cir. 1997). On a motion to dismiss, the court limits its considerations to the pleadings and exhibits attached thereto. *GSW, Inc. v. Long Co., Ga.*, 999 F.2d 1508, 1510 (11th Cir. 1993).

DISCUSSION

I. Breach of Warranty Claims

A. Implied Warranty Claims (Counts Four and Five)

With respect to claims for breach of the implied warranty of fitness and the implied warranty of merchantability, Florida law requires privity between the contracting parties for an action to proceed. *Kramer v. Piper Aircraft Corp.*, 520 So. 2d 37, 39 (Fla. 1988). “A plaintiff who purchases a product, but does not buy it directly from the defendant, is not in privity with that defendant.” *T.W.M. v. American Medical Systems, Inc.*, 886 F. Supp. 842, 844 (N.D. Fla. 1995). Decedent obtained the fentanyl patches from the local pharmacy. As the fentanyl patch is an FDA-approved pharmaceutical, it is only available by prescription. Decedent could *only* have obtained the patches from the pharmacy and not from Mylan directly. Therefore, Plaintiff’s implied warranty claims must be dismissed for want of privity between the parties. Defendants’ motion to dismiss Counts Four and Five is granted.

B. Express Warranty Claim (Count Six)

Florida law indicates that to recover in an action for breach of an express warranty, the parties must be in privity. *Id.* at 844; *MacMorris v. Wyeth, Inc.*, Case No. 2:04-cv-596-FtM-29DNF, 2005 U.S. Dist. LEXIS 46657, at *11 (M.D. Fla. June 27, 2005).

Other [Florida courts] have held, however, that certain factual circumstances satisfy the privity requirement in the absence of a purchase directly from the manufacturer. *New Nautical Coatings, Inc. v. Scoggin*, 731 So. 2d 145, 147 (Fla. 4th DCA 1999) (finding privity when the paint manufacturer's representative was heavily involved in the transaction where the third-party paint shop provided the services to the plaintiff); *see also ISK Biotech Corp. v. Douberly*, 640 So. 2d 85 (Fla. 1st DCA 1994) (finding privity where manufacturer's representative informed the third-party fungicide seller that the seller could assure the plaintiff that the subject fungicide would not destroy the plaintiff's crop); *Cedars of Lebanon Hosp. Corp. v. European X-Ray Distribs. of Am., Inc.*, 444 So. 2d 1068, 1072 n.4 (privity existed where manufacturer's representative made express warranty through the direct contacts with the ultimate purchaser/consumer who bought the product from the third party distributor).

MacMorris, 2005 U.S. Dist. LEXIS 46657, at *11–*12. Existence of express warranties is a factual issue that is not usually decided on motion. *Mitchell v. VLI Corp.*, 768 F. Supp. 966, 970 (M.D. Fla. 1992) (citing [*Knipp v. Weinbaum*, 351 So. 2d 1081 \(Fla. App. 3 Dist. 1977\)](#)).

Whether or not there an express warranty exists, however, is not the pertinent question on a motion to dismiss.

Plaintiff alleges that Defendants made specific promises about the safety of the patch. Plaintiff argues that because Defendants directed these statements at the ultimate consumer, Defendants and Decedent were in privity. This allegation is sufficient to articulate a claim for

breach of express warranty in this situation because Plaintiff demonstrated that there exists some factual situation in which a court could find privity existed between the parties. *See Lady Di Fishing Team, L.L.C., v. Brunswick Corp.*, Case No. 3:07-cv-402-J-33TEM, 2007 U.S. Dist. LEXIS 80097, at *21–24 (M.D. Fla. Oct. 29, 2007) (refusing to dismiss an express warranty claim against manufacturer because plaintiff alleged some contacts with manufacturer and alleged an agency relationship between the manufacturer and dealer of the product). Therefore, Plaintiff’s allegation of an express warranty communicated from the Defendants to the ultimate consumer is enough to survive a motion to dismiss. Consequently, the motion to dismiss Count Six of the Plaintiff’s Original Complaint is denied.

**III.
Negligent Misrepresentation/Fraudulent Concealment (Count Three)**

While Plaintiff alleges *negligent misrepresentation* against Defendants, by definition, “misrepresentation” includes concealment of facts by fraud. Rule 9(b) requires Plaintiff to plead the circumstances of the fraud claim with particularity. Fed. R. Civ. P. 9(b). In *Adams*, the Florida Second District Court of Appeals held that where plaintiffs’ complaint alleged the defendant had misrepresented and omitted material facts about the product in question to the physician and patient, which induced them to rely on such misrepresentations and omissions to their detriment, the complaint stated a cause of action for fraud. *Adams v. G.D. Searle & CO., Inc.*, 576 So. 2d 728, 730 (Fla. App. 2 Dist. 1991). Plaintiff has failed to allege enough facts to satisfy Rule 9(b).

Defendant argues the Decedent could not have relied on Mylan’s representations because of the learned intermediary doctrine, which holds, “[a] manufacturer of a dangerous commodity,

such as a drug, does have a duty to warn but when the commodity is a prescription drug . . . this duty . . . is fulfilled by an adequate warning given to those members of the medical community lawfully authorized to prescribe, dispense and administer prescription drugs” acting as a “‘learned intermediary’ between the manufacturer or seller and the patient.” *Buckner v. Allegan Pharmaceuticals, Inc.*, 400 So. 2d 820, 822–823 (Fla. App. 5 Dist 1981). Patients do not have access to prescription substances directly from the manufacturer or without the aid of a physician; thus, the manufacturer does not owe a duty to warn the ultimate purchaser. *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1368 (S.D. Fla. 2007). The patient relies on the judgment of the doctor who has the duty to inform himself of the characteristics of the products he prescribes. *Buckner*, 400 So. 2d at 823.

Effectively, the pharmaceutical company’s duty to warn stops at the physician or prescriber and does not directly make statements to the ultimate purchaser. *But see Beale*, 492 F. Supp. 2d at 1374–5 (noting that the learned intermediary doctrine does not shield a company that advertises directly to the ultimate consumer and finding no misleading facts contained with the manufacturer’s direct communications and representations regarding the product in question). Similarly, the ultimate consumer of an alleged defective product cannot prove reliance on a misrepresentation of fact about which she has no knowledge. *Foreline Sec. Corp. v. Scott*, 871 So. 2d 906, 910 (finding that the ultimate consumer must have had knowledge about and relied upon the misrepresentation of fact herself, not upon a statement made to the intermediary). Because the ultimate consumer, Decedent, through this Plaintiff, did not allege knowledge of the representations made to the physician and failed to allege evidence of any direct advertising from

Defendant to the ultimate consumer, the learned intermediary doctrine bars this claim.

Therefore, Count Three of Plaintiff's Original Complaint is dismissed without prejudice.

IV.

Punitive Damages

In questions of procedural law, federal courts sitting in diversity are required to apply federal law and in questions of substantive law, such courts are required to apply state law. *Cohen v. Office Depot, Inc.*, 184 F.3d 1292, 1296, (11th Cir. 1999) vacated in part on other grounds, 204 F.3d 1069 (11th Cir. 2000) (referring to *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938)). In *Hanna*, the United States Supreme Court announced a two-part test to determine whether state or federal law should be applied. *Id.* at 1296 (citing *Hanna v. Plumer*, 380 U.S. 460 (1965)). Under this test, a court must first determine whether the pertinent state law conflicts with the Federal Rule of Civil Procedure. *Id.* If there is a conflict, then the court must apply the Federal Rule, unless “the advisory committee, the Supreme Court, and Congress have collectively erred and adopted a federal procedural rule that is either unconstitutional or should not have been adopted under the Rules Enabling Act process because it is a matter of substantive law.” *Hanna*, 380 U.S. at 471. Because Federal Rule 8(a)(3) conflicts with Florida Statutes section 768.72, the second part of the test need not be reached. *Cohen*, 184 F.3d at 1299; *see* FLA. STAT. § 768.72 (providing in part, “no claim for punitive damages shall be permitted unless there is a reasonable showing by evidence in the record or proffered by the claimant which would provide a reasonable basis for recovery of such damages”).

Defendants argue that while *Cohen* held that section 768.72 conflicts with Federal Rule of Civil Procedure 8(a)(3), the statute does not conflict with Rule 8(a)(2), which requires “a short

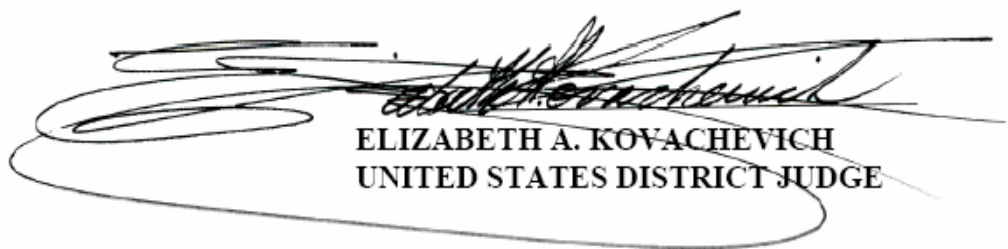
and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2); *see also Twombly*, 550 U.S. at 555 (requiring “more than labels and conclusions, and a formulaic recitation of the elements of a cause of action” to satisfy the well-pleaded complaint rule). Rule 8(a)(2) refers to a “claim,” which is not at issue in this case because a request that punitive damages be imposed is a request for relief and not itself a “claim” within the meaning of the Rule. *See Cohen*, 184 F.3d at 1297 (noting that “a request for punitive damages is not a ‘claim’ within the meaning of 8(a)(2); it is only part of the relief prayed for in a claim” and holding that “there is no conflict between [section] 768.72 and Rule 8(a)(2)”).

Defendants further argue the language in Paragraph 32 of Plaintiff’s Original Complaint is conclusory and similar to language dismissed by this Court in *Hogan*. The language at issue in *Hogan*, however, was not the request for punitive damages itself; rather, it was language purporting to set forth allegations relating to the causes of action. *Hogan v. Provident Life & Accident Ins. Co.*, Case No. 6:08-cv-1897-Orl-19KRS, 2009 W.L. 2169850 at *6–*7 (M.D. Fla. July 20, 2009). The allegations set forth in the rest of Plaintiff’s Complaint satisfy the *Twombly* standard because they contain facts in support of the causes of action sufficient to notify the Defendants of the grounds on which the claims rest. Additionally, the Eleventh Circuit has not adopted a heightened pleading standard for pleading punitive damages in Federal Court. *See Porter v. Ogden, Newell & Welch*, 241 F.3d 1334, 1341 (stating a plaintiff must set forth specific acts a defendant committed to entitle him to recover punitive damages). The standard articulated in *Porter* is consistent with the *Twombly* pleading standard, in that they both call for more than legal conclusions in the pleadings. In this complaint, the allegations are as specific as possible given the nature of the action, and they satisfy both *Twombly* and *Porter*.

In sum, the language in Paragraph 32 of Plaintiff's Original Complaint is not a "claim" that is subject to the requirements of Rule 8(a)(2) such that section 768.72 would apply. The allegations set forth in the complaint do set forth claims upon which relief could be granted. Thus, Defendant's motion is denied as to the pleading of punitive damages in Section V of the complaint. Accordingly, it is

ORDERED that Defendants' Partial Motion to Dismiss, is granted with prejudice as to Counts Four, Five, and without prejudice as to Count Three and denied as to Count Six and Section V of the complaint. Therefore, Plaintiff has ten days from this date to file an amended complaint.

DONE AND ORDERED in Chambers at Tampa, Florida, this 17th day of February, 2010.



ELIZABETH A. KOVACHEVICH
UNITED STATES DISTRICT JUDGE

Copies to: All parties and counsel of record.