

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

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SHEREEN KOCH,)
Plaintiff,)
v.) C.A. No. 09-441 S
I-FLOW CORP., HOSPIRA, INC.,)
APP PHARMACEUTICALS, LLC,)
APP PHARMACEUTICALS, INC.,)
ABRAXIS BIOSCIENCE, LLC,)
ABRAXIS BIOSCIENCE, INC.,)
ASTRAZENECA PHARMACEUTICALS LP)
and ASTRAZENECA LP,)
Defendants.)
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MEMORANDUM AND ORDER

WILLIAM E. SMITH, United States District Judge.

This matter is before the Court on Motions to Dismiss brought by Defendants, pursuant to Fed. R. Civ. P. 12(b)(6). Plaintiff has sued various pharmaceutical companies in a products liability action, in connection with a medical treatment she received following three arthroscopic shoulder surgeries in 2005 and 2006. The treatment consisted of the implantation of a pump designed to bathe Plaintiff's shoulder joint with a local anesthetic after surgery. According to Plaintiff, the treatment, which has not been approved by the federal Food and Drug Administration ("FDA"), resulted in serious permanent injury to her shoulder cartilage. Plaintiff asserts that, with the exception of total shoulder

replacement surgery (whereby her shoulder joint would be replaced with a prosthesis), there is no effective treatment for her condition.

Plaintiff has sued the manufacturer of the pain-pump, I-Flow Corporation ("I-Flow"). I-Flow has not joined in the present motions. In addition, Plaintiff sued the manufacturers of bupivacaine, the generic name for the anesthetic administered through the pain-pump. Defendant Hospira, Inc. ("Hospira") markets bupivacaine under the brand name "Marcaine." APP Pharmaceuticals, Inc., APP Pharmaceuticals, LLC, Abraxis Bioscience, Inc., Abraxis Bioscience, LLC, (collectively "APP") are related entities which market bupivacaine under the brand name "Sensorcaine."¹ For purposes of this memorandum, references to "Defendants" will indicate both bupivacaine-manufacturing Defendants, whose Motions to Dismiss set forth essentially the same arguments and, so, can be considered together.

Plaintiff's Complaint sounds in eight counts, each count is brought against all Defendants, including I-Flow. The claims are as follows: I) negligence and negligence per se; II) strict products liability; III) breach of express warranty; IV) breach of

¹ A third Defendant group originally named in the Complaint comprises Astrazeneca Pharmaceuticals, LP, and Astrazeneca LP ("Astrazeneca") which also uses the brand name "Sensorcaine." In April 2010, Plaintiff dismissed her claims against Astrazeneca.

implied warranties; V) fraudulent misrepresentation; VI) fraudulent concealment; VII) negligent misrepresentation; and VIII) fraud and deceit. Defendants move for the dismissal of the Complaint in its entirety, arguing that all claims fail to meet the minimum pleading requirements set forth in Fed. R. Civ. P. 8(a) and 9(b). After oral argument and review of the parties' submissions, the Court, for the reasons set forth below, denies Defendants' Motions in part and grants them in part. In addition, a Motion to Strike portions of the Complaint made by APP is denied.

I. Standard of Review

Defendants move to dismiss the claims against them pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure for failure to state a claim upon which relief may be granted. In considering a Rule 12(b)(6) motion, a court must accept as true all allegations in the complaint and draw all reasonable inferences in the plaintiff's favor. Aulson v. Blanchard, 83 F.3d 1, 3 (1st Cir. 1996). The United States Supreme Court, in abrogating Conley v. Gibson, 355 U.S. 41 (1957), restated the standard as follows: "once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 563 (2007). Since Twombly, the Supreme Court has further refined its requirements in Ashcroft v. Iqbal, ___ U.S. ___, 129 S. Ct. 1937 (2009):

To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully.

129 S. Ct. at 1949 (internal citations and quotations omitted).

II. Analysis

A. Counts I, II, III and IV

Plaintiff's Counts I through IV set forth state law claims for negligence and negligence per se, strict products liability, breach of express warranty and breach of implied warranties. In brief, Plaintiff alleges that Defendants disregarded numerous medical studies which established the connection between the continuous injection of bupivacaine and the destruction of shoulder cartilage, a condition known as chondrolysis. In addition, Defendants sought approval from the FDA for the post-surgical use of pain-pumps with bupivacaine, but were denied. Nevertheless, Defendants continued to market bupivacaine for this treatment, although they knew, or should have known, of its dangers. In their marketing, advertising and promotion of bupivacaine, Defendants, expressly and through implication, warranted to Plaintiff and/or her health care providers that bupivacaine was safe for use in pain-pumps.

While bupivacaine is marketed under the brand name "Marcaine" only by one manufacturer, Plaintiff asserts that "Marcaine" is frequently used generically by medical professionals for all brands of bupivacaine, in somewhat the same way the term "xerox" was, for many years, used to mean a photo-copy. This is significant because Plaintiff has not yet been able to conclusively identify the brand of bupivacaine that she received in her pain-pump. Plaintiff, through counsel, indicated during oral arguments on the present motions that she has promulgated interrogatories to Defendants that will enable her to identify which particular bupivacaine brand was used by her orthopedic surgeon. Because she cannot identify which Defendant manufactured the product that harmed her, Plaintiff has fashioned her Complaint so as to address each allegation to all three bupivacaine manufacturers collectively as DEFENDANT ANESTHETIC MANUFACTURERS, after having initially identified the individual Defendants APP and Hospira. This method of pleading is assailed by Defendants, who argue that Plaintiff's failure to identify the specific manufacturer that produced the bupivacaine with which she was treated is fatal to her claims.

1. Defendants' Arguments

Defendants argue that Plaintiff has failed to meet the minimum pleading requirements of Fed. R. Civ. P. 8(a)(2) because she has not identified the specific brand of medicine that harmed her.

Rule 8(a)(2) requires that a pleading must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Defendants characterize Plaintiff's allegations as a "fishing expedition," and assert that, by lumping the bupivacaine manufacturers together in each count, she has failed to establish the necessary specific causal link between their product and her injury. Plaintiff's method of pleading, Defendants argue, fails to meet the standard for facial plausibility established by the Supreme Court in Twombly, because the claims only establish the possibility that the manufacturer's drug harmed Plaintiff. Moreover, Defendants say, Plaintiff's pleadings fail to provide them with fair notice of the claims against them.

Defendants cite Rhode Island case law for the proposition that products liability claimants must identify the product that harmed them. See Clift v. Vose Hardware, Inc., 848 A.2d 1130 (R.I. 2004); Gorman v. Abbott Labs., 599 A.2d 1364 (R.I. 1991). Additionally, Defendants cite various unpublished decisions from federal courts across the country where their motions to dismiss have been granted in litigation involving the same or similar pain-pump therapy. See, e.g., Haskins v. Zimmer Holdings Inc., No. 09-236, slip op. (D. Vt. Jan. 29, 2010); Timmons v. Linvatec Corp., 263 F.R.D. 582 (C.D. Cal. 2010); Sherman v. Stryker Corp., No. SACV09-224-JVS, slip op. (C.D. Cal. March 9, 2009).

2. Twombly and Alternative Pleading

The Federal Rules of Civil Procedure provide for "notice" pleading, and represent a shift from the historical requirements of common law pleading and code practice, "when form reigned over substance, and a substantial claim could be lost for want of compliance with a technicality." Bottomly v. Passamaquoddy Tribe, 599 F.2d 1061, 1063 (1st Cir. 1979). Fed. R. Civ. P. 8(d)(2)-(3) provides for alternative or hypothetical statements of a claim, "either in a single count or defense or in separate ones," and permits a party to "state as many separate claims or defenses as it has, regardless of consistency." Fed. R. Civ. P. 20(a)(2)(A) permits the joinder of parties as defendants as long as "any right to relief is asserted against them jointly, severally, or in the alternative with respect to or arising out of the same transaction, occurrence, or series of transactions or occurrences." See George v. Long Transp. Co., 11 F.R.D. 305 (N.D. Ohio 1951). The need for permissive joinder is explained by Messrs. Wright and Miller in 7 Federal Practice and Procedure, § 1654 (3d ed. 2001): "The need for alternative joinder of defendants typically arises when the substance of plaintiff's claim indicates that plaintiff is entitled to relief from someone, but the plaintiff does not know which of two or more defendants is liable under the circumstances set forth in the complaint." The joinder of multiple, alternative defendants

is standard practice in products liability cases. See Cipollone v. Yale Indus. Prods., Inc., 202 F.3d 376 (1st Cir. 2000); Buonanno v. Colmar Belting Co., 733 A.2d 712 (R.I. 1999); Plouffe v. Goodyear Tire & Rubber Co., 373 A.2d 492 (R.I. 1977).

The Supreme Court, in tweaking its requirements for pleadings in Twombly and Iqbal, intended to preclude formulaic and conclusory allegations, as well as factually-sparse statements of legal conclusion. See Iqbal, 129 S. Ct. at 1948. Notwithstanding the increase in motion practice, Twombly and Iqbal do not mark a radical change in federal pleadings standards, but rather a fine tuning of sorts. See Remexcel Managerial Consultants, Inc. v. Arlequin, 583 F.3d 45, 54 (1st Cir. 2009); see also Aktieselskabet AF 21. November 2001 v. Fame Jeans Inc., 525 F.3d 8, 15 (D.D.C. 2008) ("We conclude that Twombly leaves the long-standing fundamentals of notice pleading intact."); Arista Records LLC v. Does 1-27, 584 F. Supp. 2d 240, 250 (D. Me. 2008) ("Twombly did not 'impose a probability requirement at the pleading stage.' 127 S. Ct. at 1965. All that is required are 'enough facts to raise a reasonable expectation that discovery will reveal evidence,' id., of either distribution or downloading.").

Defendants' assertion that Rhode Island products liability law requires product identification is mistimed. Yes, the product must be identified, but failure to do so is not fatal at the initial

pleading stage. In Gorman, the Rhode Island Supreme Court rejected the adoption of California's doctrine of market-share liability, stating, "[w]e are of the opinion that the establishment of liability requires the identification of the specific defendant responsible for the injury." 599 A.2d at 1364. In Clift, plaintiff's case was dismissed at summary judgment based on his inability to establish any facts to support his claim that the bungee cord that hit him in the eye had been manufactured or sold by any of the defendants. 848 A.2d at 1132.

In order to establish the liability of any one of Defendants herein, Plaintiff will ultimately be required to identify which of them manufactured the bupivacaine that was administered to her. However, at this stage of the litigation, the Court determines that Plaintiff has made out facially plausible claims against each Defendant, alternatively.² Consequently, the Court denies Defendants' Motions to Dismiss as to Counts I, II, III and IV.

B. The Fraud Counts - Counts V, VI and VIII

Plaintiff's fraud counts allege fraudulent misrepresentation (V), fraudulent concealment (VI), and fraud and deceit (VIII). The

² Plaintiffs who plead against alternative defendants sometimes state and restate each claim repeatedly, each time naming an alternate defendant. To insist that this redundant format be followed would be to elevate technical form over substance, and would be contrary to the intent of the Federal Rules' liberal pleading requirements.

essence of these claims is that Defendants knew the dangers of administering bupivacaine directly into the shoulder joint via a pain-pump, but they concealed and misrepresented this information and instead marketed, advertised, and represented to Plaintiff, the FDA, and the medical community that the product was safe for this purpose.

Defendants argue that Plaintiff's allegations fail to meet the heightened pleading requirements of Fed. R. Civ. P. 9(b), which state, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." The First Circuit looks for "the who, what, where, and when of the allegedly false or fraudulent representation." Rodi v. S. New England Sch. of Law, 389 F.3d 5,15 (1st Cir. 2004) (quoting Alternative Sys. Concepts, Inc. v. Synopsys, Inc., 374 F.3d 23, 29 (1st Cir. 2004)). "It is well-established in the First Circuit that, in fraud cases, Rule 9(b) requires a plaintiff to specify the time, place, and content of an alleged misrepresentation, 'but not the circumstances of evidence from which fraudulent intent could be inferred.'" Rhone v. Energy North, Inc., 790 F. Supp. 353, 361 (D. Mass. 1991) (quoting McGinty v. Beranger Volkswagen, Inc., 633 F.2d 226, 228 (1st Cir. 1980)).

Examination of Plaintiff's Complaint yields scant evidence of specific factual allegations. In Count V, Plaintiff asserts:

The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff SHEREEN KOCH and/or the FDA, and/or the public in general, that said products, the pain pumps and/or bupivacaine products, had been tested and were found to be safe and/or effective for the control of pain after shoulder surgery.

That representations made by Defendants were, in fact, false.

When said representations were made by Defendants, they knew those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.

(Complaint, ¶¶ 114-116.) Although the allegations continue, there is little more beyond the bare claim that Defendants committed the tort of fraudulent misrepresentation. In Count VI for fraudulent concealment, Plaintiff states, “[a]t all times during the course of dealing between Defendants and Plaintiff SHEREEN KOCH and/or Plaintiff’s healthcare providers, and/or the FDA, Defendants misrepresented the safety of the pain-pumps and/or bupivacaine products for their intended use.” Id. ¶ 127. Plaintiff then continues with a lengthy list of the dangers of the treatment, which she says Defendants “fraudulently concealed and intentionally omitted.” Id. ¶ 130.

In Count VIII for fraud and deceit, Plaintiff alleges that Defendants intentionally disseminated false information, and failed to disseminate other correct information, to “the public, the Plaintiff SHEREEN KOCH, her doctors, hospitals, healthcare

professionals, and/or the FDA." Id. ¶ 149. As for the "what, where and when" portion of the Rule 9(b) inquiry, Plaintiff states:

The information distributed to the public, the FDA, and the Plaintiff SHEREEN KOCH by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

Id. ¶ 152.

Because these allegations fail to set forth specific and particular facts concerning Defendants' alleged misrepresentations, they are insufficient to satisfy the requirements of Rule 9(b), as elucidated by the First Circuit. Accordingly, the Court grants Defendants' Motions to Dismiss Counts V, VI and VIII, dismissing these counts without prejudice.

C. Plaintiff's Count VII

Plaintiff's Count VII is for negligent misrepresentation. Defendants differ as to whether or not this count should be included with the fraud counts and dismissed for failing to include factual particulars, based on Rule 9(b).³ Misrepresentation is often considered a type of fraud. Rodi, 389 F.3d at 15. However, to determine if this count triggers Rule 9(b) and its heightened

³ The Court notes that Plaintiff characterizes Count VII as a "garden-variety state law fraud based cause[s] of action" in her Memorandum of Law in Opposition to APP's Motion to Strike, Doc. #44, p. 8.

pleading requirements, it is necessary to examine the allegations for averments that Defendants' actions were knowing. N. Am. Catholic Educ. Programming Found., Inc., v. Cardinale, 567 F.3d 8, 14 (1st Cir. 2009). Unfortunately, it isn't clear what Plaintiff is alleging in her Count VII, which states in paragraph 140, "[d]efendants had a duty to represent to the medical and healthcare community, and to the Plaintiff SHEREEN KOCH, the FDA and/or the public in general that said pain pumps and/or bupivacaine products, had been tested and found to be safe and effective for their intended use in shoulders." Because the Court is unable to ascertain precisely what Plaintiff is alleging, Count VII is dismissed without prejudice.

III. APP's Motion to Strike

APP has moved to strike portions of Plaintiff's Complaint based on three theories. First, APP invokes the "learned intermediary doctrine" to argue that it cannot be held liable for any failure to warn Plaintiff and the general public of the dangers of its product, because its duty is only to the medical community. Second, APP argues that Plaintiff's claims that it made fraudulent representations to the FDA are preempted by federal law. And, third, APP argues that Plaintiff's prayer for attorneys' fees must be stricken because it has no legal basis.

Fed. R. Civ. P. 12(f) provides that the Court may strike from a pleading "any redundant, immaterial, impertinent, or scandalous matter." However, motions to strike are viewed with disfavor. Amoco Oil Co. v. Local 99, Int'l Bhd. of Elec. Workers, AFL-CIO, 536 F. Supp. 1203, 1225 (D.R.I. 1982).

A. Learned Intermediaries

APP cites two Massachusetts cases in support of its argument that it has no duty to warn the general public about its product, and that references to this broad duty must be stricken from the Complaint. MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 68 (Mass. 1985), actually held that the manufacturer of birth control pills did have a duty to warn consumers of their risks, but that this might be an exception to the "learned intermediary doctrine." In Cottam v. CVS Pharmacy, 764 N.E.2d 814, 819-820 (Mass. 2002), the Supreme Judicial Court of Massachusetts held that a pharmacy did not have a duty to warn the consumer about prescription medication.

Plaintiff cites Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 783 (R.I. 1988) to illustrate that Rhode Island has held that pharmaceutical manufacturers may be liable for failing to warn the consumer of the risks of medication.

As stated above, courts "should treat motions to strike with disfavor and be slow to grant them." Narragansett Tribe of Indians

v. Southern R.I. Land Dev. Corp., 418 F. Supp. 798, 801 (D.R.I. 1976). Moreover, ruling on a motion to strike is not the proper occasion for the Court to make a determination concerning a disputed area of the law. Gilbert v. Eli Lilly & Co., 56 F.R.D. 116, 121 (D.P.R. 1972). The Court will therefore forego this opportunity to opine on the extent of APP's duty to warn Plaintiff and other non-members of the medical community of potential risks of its product, and deny APP's motion to strike these references from Plaintiff's Complaint.

B. Federal Preemption and the FDA

APP argues that the Supreme Court's decision in Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001), bars Plaintiff's allegations that it made fraudulent representations to the FDA. In Buckman, the plaintiffs claimed that they would not have been harmed but for the defendant's fraudulent misrepresentations to the FDA that resulted in its product's approval. Id. at 343. The Supreme Court concluded that, "State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." Id. at 350. Consequently, the claims were preempted by the Federal Food, Drug, and Cosmetic Act.⁴

⁴ 21 U.S.C. § 301, et. seq.

APP is correct that Plaintiff's claims that APP defrauded the FDA are preempted. Nonetheless, the Court refrains from striking these references in the Complaint for several reasons. First, unlike the claims in Buckman, these allegations are not the focus of Plaintiff's claims; they merely represent surplusage that accompanies Plaintiff's 'laundry-list' style of pleading. In addition, because the Court dismisses Plaintiff's fraud claims herein, any remaining references to the FDA are largely irrelevant to Plaintiff's remaining claims. The Court is confident that these issues will be satisfactorily narrowed as the litigation proceeds. See Cronovich v. Dunn, 573 F. Supp. 1330, 1338 (E.D. Mich. 1983) (holding that striking portions of the complaint is unwarranted because "requiring defendants to answer the Fourth Amended Complaint in its present form will impose no great burden of pleading").

C. Attorneys' Fees

APP argues that Plaintiff's request for attorneys' fees must be stricken from the Complaint because the request is not authorized by any statute, rule, or other law. APP is correct that in Rhode Island, in compliance with the American Rule, attorneys' fees may not be awarded to the prevailing party without express statutory or contractual authorization. Blue Cross & Blue Shield of R.I. v. Najarian, 911 A.2d 706, 710 (R.I. 2006). Plaintiff has

not provided the Court with the legal authority for her request for attorneys' fees in her Complaint, nor in her response to APP's Motion to Strike; and the Court is unable to fill in that blank for her. Nonetheless, the Court is reluctant to strike this portion of Plaintiff's prayer for relief, in part because of its general reluctance to grant a motion to strike and in part because the continued inclusion of this phrase in Plaintiff's prayer poses no burden or impact on APP or on this litigation going forward.

For all these reasons, APP's Motion to Strike is denied.

IV. Conclusion

For all of the reasons set forth above, the Court denies Defendants' Motions to Dismiss Counts I, II, III and IV of Plaintiff's Complaint, but grants the Motions as to Counts V, VI, VII and VIII, dismissing these counts without prejudice. APP's Motion to Strike is denied.

No judgments shall enter in this case until all claims are resolved.

It is so ordered.

/s/ William E. Smith

William E. Smith
United States District Judge
Date: June 7, 2010