IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

RICHARD ESPOSITO,

:

Plaintiff, : CIVIL ACTION

v. : NO. 10-cv-3883

: NO. 10-cv-3883

I-FLOW CORPORATION ET AL., Defendants.

:

MEMORANDUM

Tucker, J. October ____, 2011

Presently before this Court are the Motion of Defendants APP Pharmaceuticals, LLC and Abraxis Bioscience, Inc. (collectively, "APP" or the "APP Defendants") to Dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) (Doc. 21), the Motion of I-Flow Corporation ("I-Flow") to Dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) (Doc. 27), the Motion of Abbott Laboratories ("Abbott") and Hospira, Inc. to Dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) and Local Rule 7.1 (Doc. 30), Plaintiff's Responses, respectively, thereto (Docs. 31, 32, 33), and Defendant Abbott and APP's Replies (Docs. 41, 42). This Court has jurisdiction pursuant to 28 U.S.C. § 1332 as there is complete diversity of citizenship¹ and the amount in controversy exceeds \$75,000.00 exclusive of interest and costs. Venue is proper under 28 U.S.C.

¹ Plaintiff is domiciled in Pennsylvania. (Compl. ¶ 1.) APP Pharmaceuticals, LLC is domiciled in Delaware; Abraxis Bioscience, Inc. is domiciled in California; I-Flow is domiciled in California; Abbott is domiciled in Illinois; Hospira, Inc. is domiciled in Illinois; AstraZeneca Pharmaceuticals, LP is domiciled in Delaware; DJO, LLC is domiciled in California. (Compl. ¶¶ 3-9.)

§ 1391(a)(2). Upon consideration of the parties' motions with briefs, exhibits and declarations, this Court will grant Defendants' Motions to Dismiss all counts.

I. FACTS

This case arises from injuries suffered by Plaintiff following a shoulder surgery performed on August 8, 2008. (Am. Compl. ¶ 15.) The surgery was necessitated by an automobile accident and was performed in an unspecified location in Pennsylvania. (Am. Compl. ¶¶ 15, 18.) At the conclusion of his surgery, Plaintiff had pain pump catheters, which injected him with continuous doses of pain relief medication, inserted into his shoulder. (Am. Compl. ¶¶ 18, 19.) Subsequent to these events, Plaintiff developed complications including the "inability to raise his arm above shoulder level, arthritis/chondrolysis [and] narrowing of the joint space of his shoulder." (Am. Compl. ¶ 17, 19.) Arthritis/chondrolysis is the complete or nearly complete loss of cartilage in the shoulder joint, which Plaintiff alleges to have suffered due to the injections of the medications via the pain pump.² (Am. Compl. ¶¶ 19, 20.) Plaintiff also alleges to have suffered other side effects, including, but not limited to "other severe personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for ongoing medical treatment, monitoring and/or medications, loss of earnings and earning potential and the fear of developing other health consequences." (Am. Compl. ¶ 26.) Plaintiff did not discover that these injuries were a result of the 2008 surgery until July 26, 2010 when additional surgery was performed. (Am. Compl. ¶ 27.) Plaintiff now faces the prospect of shoulder replacement surgery. (Am. Compl. ¶¶ 17, 21.)

² It is unclear from the Complaint whether Plaintiff had only one pain pump catheter inserted into his shoulder or whether multiple pain pump catheters were inserted. <u>Compare</u> (Compl. ¶ 16) (referring to a single "[pain pump] catheter"), <u>with</u> (Compl. ¶ 19) (referring to multiple "pain pumps catheters").

Plaintiff alleges that the pain pump inserted into his shoulder was manufactured and distributed by Defendant I-Flow, and was filled with medication manufactured by Defendant Abbott, "or in the alternative by other defendants." (Am. Compl. ¶ 16.) Plaintiff further alleges that none of the Defendants warned Plaintiff or his surgeon about the risks associated with using the pain pump or pain pump medication, and that the surgeon used the pain pump and administered the pain pump medication in the manner intended and instructed by Defendants. (Am. Compl. ¶ 23.) Plaintiff submits that he justifiably relied on, and was induced by, the misrepresentations and active concealment of Defendants of the risks associated with their products. (Am. Compl. ¶ 25.)

Plaintiff, in his First Amended Complaint filed on October 28, 2010, alleges the following ten counts against all Defendants collectively: (1) fraudulent concealment; (2) strict liability; (3) breach of implied warranty of merchantability; (4) breach of implied warranty of fitness for a particular purpose; (5) negligent failure to warn; (6) negligence; (7) negligent misrepresentation; (8) breach of express warranty; (9) fraud; and (10) punitive damages. Plaintiff requests judgment against Defendants in an amount in excess of \$150,000.00, plus delay damages, interest, and costs.

II. STANDARD OF REVIEW

Motion to Dismiss Pursuant to Federal Rule 12(b)(6)

On a motion to dismiss for failure to state a claim pursuant to FED. R. CIV. P. 12(b)(6), the court is required to accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and to view them in the light most favorable to the non-moving party. See Oshiver v. Levin, Fishbein, Sedran & Berman, 38 F.3d 1380, 1384 (3d Cir.

1994). A complaint should be dismissed only if the alleged facts, taken as true, fail to state a claim. See In re Warfarin Sodium Antitrust Litig., 214 F.3d 395, 397-98 (3d Cir. 2000). The question is whether the claimant can prove any set of facts consistent with his or her allegations that will entitle him or her to relief, not whether that person will ultimately prevail. Scheuer v. Rhodes, 416 U.S. 232, 236 (1974); Semerenko v. Cendant Corp., 223 F.3d 165, 173 (3d Cir. 2000).

While a court will accept well-pled allegations as true for the purposes of the motion, it will not accept bald assertions, unsupported conclusions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegations. Morse v. Lower Merion Sch. Dist., 132 F.3d 902, 906 (3d Cir. 1997). The United States Supreme Court has recognized that "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007) (alteration in original). In Twombly, the Court made clear that it would not require a "heightened fact pleading of specifics," but only "enough facts to state a claim to relief that is plausible on its face." Id. at 570. A "pleader is required to 'set forth sufficient information to outline the elements of his claim or to permit inferences to be drawn that these elements exist." Kost v. Kozakiewicz, 1 F.3d 176, 183 (3d Cir. 1993) (citation omitted).

In 2009, the United States Supreme Court revisited the requirements for surviving a 12(b)(6) motion to dismiss in <u>Ashcroft v. Iqbal</u>, 129 S. Ct. 1937 (2009). In <u>Iqbal</u>, the Court made clear that "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements [will] not suffice" to defeat a Rule 12(b)(6) motion to dismiss. 129 S. Ct.

at 1949. "[O]nly a complaint that states a plausible claim for relief [will] survive[] a motion to dismiss." <u>Id.</u> at 1950.

In light of the decision in <u>Iqbal</u>, the Third Circuit set forth a two-part analysis to be applied by district courts when presented with a 12(b)(6) motion. First, the court must separate the legal elements and factual allegations of the claim, with the well-pleaded facts accepted as true but the legal conclusions disregarded. <u>Fowler v. UPMC Shadyside</u>, 578 F.3d 203, 210-11 (3d Cir. 2009). Second, the court must determine whether the facts alleged in the complaint demonstrate that the plaintiff has a "plausible claim for relief." <u>Id</u>. at 211 (citation omitted). If the court can only infer the mere possibility of misconduct, the complaint must be dismissed because it has alleged—but has failed to show—that the pleader is entitled to relief. <u>Id</u>.

Motion to Dismiss Pursuant to Federal Rule 9(b)

FED. R. CIV. P. 9(b) requires that in all averments of "fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." "The purpose of Rule 9(b) is to provide notice of the 'precise misconduct' with which defendants are charged" in order to give them an opportunity to respond meaningfully to a complaint, "and to prevent false or unsubstantiated charges." Rolo v. City Investing Co. Liquidating Trust, 155 F.3d 644, 658 (3d Cir. 1998) (quoting Seville Indus. Machinery v. Southmost Machinery, 742 F.2d 786, 791 (3d Cir. 1984). To satisfy Rule 9(b), a plaintiff must "plead with particularity the 'circumstances' of the alleged fraud." Id. Rule 9(b) "requires plaintiffs to plead 'the who, what, when, where, and how: the first paragraph of any newspaper story." In re Advanta Corp. Sec. Litig., 180 F.3d 525, 534 (3d Cir. 1999) (quoting DiLeo v. Ernst & Young, 901 F.2d 624, 627 (7th Cir. 1990)).

Plaintiffs need not, however, "plead the 'date, place or time of the fraud,' so long as they use an 'alternative means of injecting precision and some measure of substantiation into their allegations of fraud." Rolo, 155 F.3d at 658 (quoting Seville Indus. Machinery, 742 F.2d at 791). The Third Circuit has cautioned that courts should "apply the rule with some flexibility and should not require plaintiffs to plead issues that may have been concealed by the defendants." Id. at 658 (citing Christidis v. First Pennsylvania Mortg. Trust, 717 F.2d 96, 99 (3d Cir. 1983)).

III. DISCUSSION

Fraud-Related Claims—Counts One, Seven, and Nine: Fraudulent Concealment, Negligent Misrepresentation, and Fraud

Plaintiff's first count alleges that "Defendants fraudulently suppressed material information regarding the safety and efficacy of pain pumps, including information regarding the development of choncirolysis or osteoarthritis at the insertion site." (Am. Compl. ¶ 29.)

Plaintiff's seventh count alleges that "Defendants misrepresented that pain pumps were a safe and effective means of post-surgical pain management. Defendants also failed to disclose material facts regarding the safety and efficacy of pain pumps, including information regarding increased adverse effects, harmful side effects, and results of clinical studies showing that use of pain pumps could be life threatening." (Am. Compl. ¶ 70.) Plaintiff's ninth count alleges that "Defendants widely advertised and promoted pain pumps as a safe and effective method of post-surgical pain relief. Defendants had a duty to disclose all facts about the risks associated with use of pain pumps. . . . Defendants intentionally failed to disclose this information for the purpose of inducing consumers, such as Plaintiff, to purchase Defendants' dangerous product."

(Am. Compl. ¶¶ 87-89.) These counts must be dismissed because each fails to meet the pleading standard under FED. R. CIV. P. 9(b) for cases of fraud or mistake.³

Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting the fraud or mistake." FED. R. CIV. P. 9(b). The "particularity requirement of Rule 9(b) applies to claims of negligent misrepresentation." Hanover Ins. Co. v. Ryan, 619 F. Supp. 2d 127, 142 (E.D. Pa. 2007). "In cases involving multiple defendants, a plaintiff's complaint 'should inform *each defendant* of the nature of his alleged participation in the fraud' and '[a] complaint that lumps together numerous defendants does not provide sufficient notice of which defendants allegedly made the misrepresentations." Kester v. Zimmer Holdings, Inc., 2010 U.S. Dist. Lexis 59869 at *41 (W.D. Pa. June 16, 2010) (alteration in original) (emphasis added) (quoting Silverstein v. Percudani, 422 F. Supp. 468, 472-73 (M.D. Pa. 2006)).

In <u>Kester</u>, where fraudulent concealment, negligent misrepresentation, and fraud was also alleged against the manufacturers of pain pumps, the court granted defendants' motion to dismiss for failure to state a claim because the complaint "only collectively, generically, and wrongfully referred to . . . one unspecified and misleading entity: 'Defendants.'" 2010 U.S. Dist. Lexis 59869 at *41. The <u>Kester</u> complaint was deficient under Rule 9(b)'s particularity requirement as it further failed to provide "any alternative means of injecting precision [or] some measure of substantiation into [its] allegations of fraud." <u>Id.</u>

concealment on grounds that it is not recognized under Pennsylvania law).

³ Plaintiff's fraudulent concealment claim must additionally be dismissed because the "Pennsylvania Supreme Court has determined that negligence is the sole theory upon which a plaintiff may recover against a prescription drug manufacturer [or medical device manufacturer] in a suit based upon the manufacturer's failure to warn." <u>Kester v. Zimmer Holdings, Inc.</u>, 2010 U.S. Dist. Lexis 11043 at *12-13 (W.D. Pa. Oct. 18, 2010) (citation omitted) (dismissing plaintiff's claim for fraudulent

The Complaint in the instant case, like the complaint in Kester, generically lumps each individual defendant together as one entity by referring only to "defendants" collectively. Such a manner of pleading does not provide Defendants with the particular content of any alleged fraudulent statements or misrepresentations, when such alleged misrepresentations may have been made, or the specific Defendants who may have made them. Thus, the Complaint does not fulfill the purpose of the Rule 9(b) pleading requirement: to provide notice of the precise misconduct with which defendants are charged in order to give them an opportunity to respond meaningfully. This problem is especially acute because the Complaint refers to "pain pumps," but does not even once refer to the medications that may have been used in the pumps. The deficiency of the Complaint is not cured by any alternative means that inject precision or some measure or substantiation. Accordingly, Counts One, Seven, and Nine are dismissed.

Count Two: Strict Liability

Plaintiff's second count alleges strict liability against Defendants for designing, manufacturing, and placing into the stream of commerce defective and unreasonably dangerous pain pumps and for failing to warn or place adequate warnings and instructions on the pain pumps. (Am. Compl. ¶¶ 36-40.) This claim must be dismissed because it is not recognized under Pennsylvania law.

Pennsylvania follows comment k to the RESTATEMENT (SECOND) OF TORTS § 402A, which precludes a strict liability cause of action against "unavoidably unsafe products." Hahn v. Richter, 673 A.2d 888, 889-90 (Pa. 1996). Unavoidably unsafe products are "dangerous in that they are not without medical risks," but "are not deemed defective and unreasonably dangerous when marketed with proper warnings." Id. Prescription drugs and medical devices, including

pain pumps, are unavoidably dangerous products. <u>Id.</u> (noting that prescription drugs are unavoidably dangerous products); <u>Creazzo v. Medtronic, Inc.</u> 903 A.2d 24, 30 (Pa. Super. 2006) (noting that there was "no reason why the same rational [sic] applicable to prescription drugs may not be applied to medical devices").⁴ Therefore, there is no strict liability cause of action against the manufacturers of prescription drugs or pain pumps for failure to warn. Accordingly, Count Two is dismissed.

Counts Three and Four: Breach of Implied Warranties of Merchantability and Fitness for a Particular Purpose

Plaintiff's third and fourth counts allege breach of the implied warranties of merchantability and fitness for a particular purpose. (Am. Compl. ¶¶ 43-56.) These claims must be dismissed because they are not recognized under Pennsylvania law.

"Pennsylvania courts have held that the nature of prescription drugs and prescription medical devices precludes claims for breach of implied warranty." Kester, 2010 U.S. Dist. Lexis 59869 at *32-33 (dismissing claims for breach of implied warranties of merchantability and fitness for a particular purpose against pain pump manufacturers because they are not recognized under Pennsylvania law). Indeed, "the very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for 'ordinary purposes." Makripodis v. Merrell-Dow Pharm., 523 A.2d 374, 377 (Pa. Super. Ct. 1987) Accordingly, Counts Three and Four are hereby dismissed.

Counts Five and Six: Negligent Failure to Warn and Negligence

⁴ Despite the absence of a ruling by the Supreme Court of Pennsylvania as to whether medical devices are unavoidably dangerous products, the Eastern District of Pennsylvania has recently adopted the holding of <u>Creazzo</u> and reasoned that if given the chance "the Pennsylvania Supreme Court would apply comment k to medical devices." <u>Geesey v. Stryker Corp.</u>, 2010 U.S. Dist. Lexis 78677 at *13 (E.D. Pa. Aug. 3, 2010).

Count Five of the Complaint alleges that "[d]espite the fact that Defendants knew or had reason to know that pain pumps were dangerous, Defendants failed to exercise reasonable care in warning the medical community and consumers, including Plaintiff, of the dangerous conditions and facts that made pain pumps likely to be dangerous." (Am. Compl. ¶ 60.) Count Six alleges that "Defendants failed to exercise ordinary care in the manufacture, sale, warnings, quality assurance, quality control, and distribution of pain pumps in that Defendants knew or should have known that use of pain pumps created a high risk of unreasonable harm." (Am. Compl. ¶ 65.) Like Plaintiff's fraud-related claims, these counts must be dismissed because they generally refer to all defendants collectively as one misleading entity and are thus too speculative to satisfy the federal pleading standard.

Under Pennsylvania law, "a cause of action for negligence must fail unless defendant's conduct is shown to have been the . . . cause of plaintiffs [sic] injury." Kester, 2010 U.S. Dist. Lexis 59869 at *17 (alteration in original) (citation omitted). Without such causation, "there can be no allegations of duty [or] breach of duty . . . and hence there can be no liability." Id. (quoting Cummins v. Firestone Tire & Rubber Co., 495 A.2d 963, 967-68 (Pa. Super. Ct. 1985)).

The present Complaint, like the complaint in Kester, fails to establish causation because "the speculative and collective identification of the Defendants fails to adequately identify which Defendant caused Plaintiff's alleged injury and . . . therefore, is insufficient and speculative under Twombly and Iqbal." 2010 U.S. Dist. Lexis 59869 at *17. Also like the complaint in Kester, the present Complaint fails because it "merely posit[s] that it is possible that one or more of the named defendants manufactured the pain pumps . . . that *caused* [Plaintiff's] injuries. Such speculative pleading is not permissible under the plain text of [Fed. R. Civ. P.] 8." 2010

U.S. Dist. Lexis 59869 at * 24 (first, second, and fourth alterations in original) (emphasis in original).

This conclusion is further supported by several other districts' rulings, which dismissed plaintiffs' complaints under nearly analogous circumstances. See Sherman v. Stryker Corp., 2009 U.S. Dist. Lexis 34105 (C.D. Cal. Mar. 30, 2009); Dittman v. DJO, LLC, 2009 U.S. Dist. Lexis 96690 (D. Ariz. Oct. 15, 2009); Gilmore v. DJO, Inc., 2009 U.S. Dist. Lexis 96690 (D. Ariz. Oct. 15, 2009); Combs v. Stryker Corp., 2009 U.S. Dist. Lexis 115920 (E.D. Cal. Dec. 14, 2009); Haskins v. Zimmer Holdings, Inc., 2010 U.S. Dist. Lexis 7690 (D. Vt. Jan. 29, 2010); Timmons v. Linvatec Corp., 2010 U.S. Dist. Lexis 33066 (C.D. Cal. Mar. 30, 2010); Peterson v. Breg, 2010 U.S. Dist. Lexis 48985 (D. Ariz. April 29, 2010); Kester v. Zimmer Holdings, Inc., 2010 U.S. Dist. Lexis 110403 (W.D. Pa. Oct. 18, 2010); Daugherty v. I-Flow, Inc., 2010 U.S. Dist. Lexis 49038 (N.D. Tex. April 29, 2010). The aforementioned cases support the proposition that a complaint is not adequately plead if it names several defendants whose products might have been used, but does not actually identify which defendants' products allegedly caused the injury. The present Complaint is patently inadequate when examined under this standard, as it names several Defendants, but fails to pinpoint which products from which specific Defendants caused Plaintiff's injuries.⁵ Accordingly, Counts Five and Six are dismissed.⁶

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⁵ The deficiency of the Complaint is not saved by Plaintiff's ability to initially name I-Flow as the manufacturer of the pain pump used in his treatment because "the remaining factual bases for [Plaintiff's] claims are similarly conclusory and vague, and lack the requisite factual information to suggest that plaintiffs' claims are facially plausible." See Id. at 24 (quoting Peterson, 2010 U.S. Dist. LEXIS 48985 at *7-8 (citations omitted) (internal quotation marks omitted) (dismissing complaint that failed to identify which manufacturers' products were actually used despite initially naming defendant as manufacturer of pain pump used in surgery).

⁶ Due to extensive briefing on the issue, this Court feels obliged to address the parties' discussion of the Learned Intermediary Doctrine. Under Pennsylvania law, "where drugs . . . or a medical device[] are available only through a prescription" the manufacturer owes a duty to adequately warn the prescribing physician, but not the patient. Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 749 (W.D. Pa. 2004) (citing Baldino v. Castagna, 478 A.2d 807, 812 (Pa. 1984)). Thus, although Defendants' are correct in pointing out that they owed no duty to adequately warn Plaintiff (Doc. 27 at 23), they did, however, owe a duty to adequately warn Plaintiff's physician. At this stage of the litigation, it is unnecessary to consider whether Plaintiff's physician was adequately warned because the Complaint fails to identify which, if any, Defendant allegedly *caused* the injury. Because Plaintiff has not plausibly plead causation, he has not established that a duty existed and thus cannot plausibly plead breach.

Count Eight: Breach of Express Warranty

Plaintiff's eighth count alleges breach of an express warranty. (Am. Compl. ¶ 77-85.)

This claim must be dismissed because Plaintiff has not sufficiently plead that Defendant made any express statement or representation whatsoever.

Under Pennsylvania law, an express warranty "arises out of the representations or promises of the seller . . . and must be directed at consumers in order to induce purchases of the products." Kester, 2010 U.S. Dist. Lexis 59869 at *29 (citations omitted). Under Rule 12(b)(6), "a plaintiff cannot make a conclusory recitation of the elements of a cause of action and assume that it is sufficient to establish the existence of an express warranty." Id. at 30. Instead, a plaintiff must establish that the seller made an affirmation of fact or a promise to the buyer "which relates to the goods and becomes part of the basis of the bargain." Id. at 30 (citations omitted); see Simmons v. Stryker Corp., 2008 U.S. Dist. Lexis 93306 at *7 (D.N.J. Nov. 17, 2008) (dismissing breach of express warranty claim because "[p]laintiff identifie[d] no source whatsoever of any alleged warranty"). "A plaintiff meets the basis of the bargain requirement by proving that she read, heard, saw or knew of the advertisement containing the affirmation of facts or promise." Id. (citations omitted).

In the instant case, Plaintiff fails to identify the source of any alleged warranty made by any of the defendants, and fails to identify that any particular promises or affirmations of fact were directed at Defendants. In fact, Plaintiff fails to plead that any promises or affirmations of fact were made by any Defendant whatsoever. The Complaint is merely a conclusory recitation of the elements of a breach of express warranty claim. Thus, Count Eight is hereby dismissed.

Count Ten: Punitive Damages

Plaintiff's tenth count alleges punitive damages. (Am. Compl. ¶¶ 93-101.) The Supreme Court of Pennsylvania has held that "punitive damages may be awarded for conduct that is outrageous, because of defendant's evil motive or his reckless indifference to the rights of others ... [p]unitive damages must be based on conduct which is malicious, wanton, reckless, willful, or oppressive." Grant v. Kingswood Apts., 2001 U.S. Dist. Lexis 15815 at *13 (E.D. Pa. Oct. 2, 2001) (first alteration in original) (quoting Feld v. Merriam, 485 A.2d 742, 747-48 (Pa. 1984)). As all other above counts have been dismissed, and the Complaint avers no particulars from which the Court can infer conduct warranting punitive damages, the Court finds it appropriate to dismiss Count Ten.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss the Complaint will be GRANTED as to all counts.

An appropriate order follows.