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SCAN

SHORT FORM ORDER

SUPREME COURT - STATE OF NEW YORK

Present:

HON. F. DANA WINSLOW,

Justice

TRIAL/IAS, PART 4
NASSAU COUNTY

MOTION DATE: 5/20/11

MOTION SEQ. NO.: 001
INDEX NO.: 023193/10

CHRISTOPHER VARVERIS,

Plaintiff,

-against-

ORTHOPAEDIC AND SPORTS ASSOCIATES OF LONG ISLAND, P.C., SALVATORE J. CORSO, M.D., I-FLOW, INC., STRYKER CORPORATION, STRYKER SALES CORPORATION, MCKINLEY MEDICAL LLC, PACIFIC MEDICAL, INC., MOOG INC., DJO LLC, DJO, INC. (FORMERLY KNOWN AS DJO ORTHOPEDICS, INC.) AND BREG INC.,

Defendants.

The following papers read on this motion (numbered 1-4):

Notice of Motion **1**
Affirmation in Opposition (Plaintiff) **2**
Affirmation in Opposition (Defendants Orthopaedic and Corso) **3**
Reply Affirmation **4**

PRELIMINARY STATEMENT

Defendant I-FLOW CORPORATION s/h/a I-FLOW, INC. ("I-FLOW") moves to dismiss the Second, Fourth and Fifth causes of action pursuant to **CPLR § 3211(a)(7)**, and the Seventh, Eighth, and Ninth causes of action pursuant to **CPLR §3211(a)(7)** and **CPLR §3016(b)**.

BACKGROUND

This is an action to recover for personal injuries allegedly sustained as a result of two arthroscopic Bankart reconstruction surgeries of plaintiff's left shoulder performed by defendants SALVATORE J. CORSO, M.D. and ORTHOPAEDIC AND SPORTS ASSOCIATES OF LONG ISLAND, P.C. Among other things, plaintiff alleges that the second open arthroscopic Bankart reconstruction surgery performed on July 16, 2007 included the insertion of an intra-articular pain pump (the "Pain Pump") manufactured by I-FLOW. The injuries relevant to this motion were allegedly sustained as a result of the insertion or use of the Pain Pump.

Plaintiff filed suit against the surgeons, and against several entities, including I-FLOW, as possible designers, manufacturers, or distributors of the Pain Pump. The Complaint, filed on December 20, 2010, states the following causes of action against these entities:

(Second): Strict products liability – design defect; failure to warn;
(Third): Negligent manufacture and distribution;
(Fourth): Punitive damages [against all defendants];
(Fifth): Breach of express warranties;
(Sixth): Breach of implied warranties;
(Seventh): Fraudulent misrepresentation;
(Eighth): Fraudulent concealment; and
(Ninth): Violation of State consumer fraud and deceptive trade practices.

I-FLOW initially moves to dismiss the Complaint in its entirety based upon plaintiff's failure to specifically and accurately identify the manufacturer of the Pain Pump. In opposition, plaintiff's attorney states that he obtained documents in discovery that identified I-FLOW as the manufacturer. The Syosset Hospital "Perioperative Flowsheet" for the surgery of July 16, 2007 (the "Flowsheet") indicates use of the "I-Flow On Q Pain Buster", Ref. No. PM013, Lot No. 722208, to deliver Marcaine 025%, at a dosage of 270 ml., 2 ml./hr. [Aff. In Opp. Exh. C]. Based upon such information, plaintiff's attorney states that he will discontinue the action against all other defendant pain pump manufacturers, namely: STRYKER CORPORATION, STRYKER SALES CORPORATION, MCKINLEY MEDICAL LLC, PACIFIC MEDICAL, INC., MOOG, INC., DJO LLC, DJO, INC. (formerly known as DJO ORTHOPEDICS, INC.) and BREG, INC. I-FLOW did not press the issue in reply, and therefore it is conceded. The Court shall address only the causes of action which I-FLOW seeks to dismiss on an individual basis.

DISCUSSION

Statute of Limitations

I-FLOW seeks to dismiss the second cause of action (strict products liability) and the fifth cause of action (breach of express warranties) on the ground that they are time barred pursuant to **CPLR § 214(5)**, which provides a three-year statute of limitations for personal injury actions. The final surgery was performed on July 16, 2007 and the Complaint was filed more than three years later on December 20, 2010.

The Court notes, at the outset, that the Uniform Commercial Code, as adopted by New York, provides a four-year statute of limitations for breach of warranty claims. [See **McKinney's Uniform Commercial Code §2-725**; **Weiss v. Herman**, 193 AD2d 383 (applying **UCC §2-725** to breach of warranty claim concerning breast implants); **Wiltshire v. A.J. Robins Co., Inc.**, 88 AD2d 1097 (applying **UCC §2-725** to breach of warranty claim concerning intrauterine device).]

Further, the record demonstrates that plaintiff was an infant at the time of both Bankart reconstruction surgeries. The Flowsheet indicated that plaintiff's date of birth was 04/24/1990 and that plaintiff was 17 years old at the time of the July 16, 2007 surgery. [Aff. In Opp. Exh. C]. According to the Complaint, plaintiff was 16 years old at the time of the first surgery on November 16, 2006 [Complaint ¶ 47]. Plaintiff's infancy at the time of the surgeries tolled the applicable statutes of limitations and afforded plaintiff an additional three years after he reached majority (for the personal injury claims) or four years (for the breach of warranty claims) to file an action. **CPLR §208.** The instant action was commenced on December 20, 2010, less than three years after plaintiff turned eighteen (04/24/2008). Accordingly, neither the second nor the fifth cause of action is time-barred.

CPLR 3211(a)(7) -- Standard of Proof

On a motion to dismiss for failure to state a cause of action pursuant to **CPLR § 3211(a)(7)**, "the court must afford the pleading a liberal construction, accept the facts as alleged in the complaint as true, accord the plaintiff the benefit of every favorable inference, and determine only whether the facts as alleged fit within any cognizable legal theory." **Feldman v. Finkelstein & Partners, LLP**, 76 AD3d 703, 704 (*internal citations omitted*). *See* **Leon v. Martinez**, 84 NY2d 83; **Introna v. Huntington Learning Centers, Inc.**, 78 AD3d 896. Whether the plaintiff can ultimately establish the allegations "is not part of the calculus." **Aberbach v. Biomedical Tissue Services, Ltd.**, 48 A.D.3d 716, 717-718, *quoting* **EBC I, Inc. v. Goldman, Sachs & Co.**, 5 N.Y.3d 11, 19. This standard applies with respect to all of the causes of action discussed below.

Second Cause of Action

The second cause of action is premised on the allegation that I-FLOW inserted into commerce a device that was inherently dangerous and defective when used for the infusion of anesthetics, such as Marcaine, in volumes of 250 cc's or more following Bankart shoulder reconstruction. Plaintiff alleges that I-FLOW failed to warn the U.S. medical community that the safety of its pain pumps and medications used in them had not been established for use in the shoulder joint space. Plaintiff further alleges that the labeling on such pain pumps failed to disclose potential risks, provide adequate instructions, or disclose FDA rejections. Plaintiff alleges that by reason of the foregoing design defects and failure to warn, plaintiff suffered injury to his left shoulder.

I-FLOW argues that its Pain Pump, as a prescribed medical device, belongs to the class of "unavoidably unsafe products," which are not deemed defective or unreasonably dangerous so long as they are accompanied by proper directions for use and adequate warnings as to potential side effects. *See* **Martin v. Hacker,** 83 NY2d 1, 8, quoting Restatement (Second) of Torts §402 A, comment *k*. *See also* **Lindsay v. Ortho Pharmaceutical Corp.,** 637 F.2d 1980. I-FLOW argues that inasmuch as the Pain Pump "'cannot legally be sold except to physicians, or under the prescription of a physician,' I-FLOW cannot be charged with Strict Liability." [I-FLOW Memo. Of Law, p.13, quoting Restatement, Torts 2d, §402 A, comment *k*.]

The Court finds that, under **Martin v. Hacker,** a manufacturer of an "unavoidably unsafe" product cannot escape liability without demonstrating that its product was accompanied by proper directions and adequate warnings. The fact that a product is sold only to physicians or by prescription is significant only insofar as it may qualify a product as "unavoidably unsafe" under the rule in **Martin v. Hacker**. The manufacturer still must show that the warning provided specific and detailed information on the potential hazards of the product (although the warning may be held to a different standard than when the product is intended for sale to consumers). **Martin v. Hacker,** 83 NY2d at 8. *See also* **Wolfgruber v. Upjohn Co.,** 72 AD2d 59, 61.

Assuming, without deciding, that the I-FLOW Pain Pump is the kind of "unavoidably unsafe" product contemplated by **Martin v. Hacker** and the Restatement (Second) of Torts §402 A, comment *k*, I-FLOW's defense to liability turns on the adequacy of its warning to the medical community. I-FLOW has provided no basis for avoiding liability on that ground. At this stage of the proceedings, the Court must accept as true the Complaint's allegations regarding the inadequacy of the warnings, and finds that such allegations fall within a cognizable legal theory sounding in strict products liability. Accordingly, the second cause of action is upheld.

Fourth Cause of Action

The fourth cause of action, as it pertains to I-FLOW, is for punitive damages, predicated upon the allegation that I-FLOW acted maliciously and wantonly in connection with the sale and distribution of its product. I-FLOW seeks to dismiss this cause of action on the grounds that New York does not recognize an independent cause of action for punitive damages. Plaintiff does not oppose this point.

It is well settled that "no separate cause of action for punitive damages lies for pleading purposes." **Paisley v. Coin Device Corp.**, 5 AD3d 748, 750. *See* **Crown Fire Supply Co. v. Cronin**, 306 AD2d 430. Thus, the fourth cause of action is dismissed.

Fifth Cause of Action

The fifth cause of action is premised on the allegation that I-FLOW expressly warranted to plaintiff, and/or his physicians and surgeons, and/or other health care providers, that its pain pumps were safe and well-accepted by users. Plaintiff further alleges that I-FLOW did not conform to those express representations because the pain pumps were not safe and caused side effects in patients who used them. I-FLOW seeks to dismiss this cause of action on the grounds that plaintiff did not plead the specific affirmation, fact and/or promise allegedly made by I-FLOW and relied upon by plaintiff or his physicians and surgeons.

On a cause of action sounding in breach of express warranty, the plaintiff must show that there was an "'affirmation of fact or promise by the seller, the natural tendency of which [was] to induce the buyer to purchase,' and that the warranty was relied upon." **Schimmenti v Ply Gem Indus.**, 156 AD2d 658, 659 *quoting* **Friedman v Medtronic, Inc.**, 42 AD2d 185, 188; *see also* **Schneidman v Whitaker Co.**, 304 AD2d 642, 643. Privity between the injured party and the manufacturer is not required to sustain the cause of action. *See* **Murrin v. Ford Motor Co.**, 303 AD2d 475; **Thomas v. Leary**, 15 AD2d 438 . Further, the warranty need not be an affirmation, promise or product description given directly to the product purchaser or injured party. Express warranties may arise from media advertisements or, in the case of medical products, from literature disseminated by the manufacturer to the medical profession. **Weiss v. Herman**, 193 AD2d 383; **Wiltshire v. A.J. Robins Co., Inc.**, 88 AD2d 1097.

Although the cause of action must be plead with sufficient particularity to give fair notice of the alleged terms of the express warranty [**CPLR §3013; Hickville Dry Cleaners, Inc. v. Stanley Fastening Systems, L.P.**, 37 Ad3d 218], the applicable pleading standard is less stringent than that imposed by **CPLR §3016.** *See* **Delaney v. Pfizer Inc.**, 2007 WL 2176912, *citing* **Edison Stone Corp. v. 42nd St. Dev. Corp.**, 145

AD2d 249, 257; **Lanzi v. Brooks,** 54 AD2d 1057, 1058, *affd* 43 NY2d 778. The **CPLR §3013** "fair notice" standard does not require that the plaintiff identify the specific advertisement or other representation upon which it relied. **DaSilva v. American Tobacco Co.,** 175 Misc.2d 424, *citing* **Marcus v. Jewish Nat'l Fund,** 158 AD2d 101. Rather, the facts must be set forth in sufficient detail so as to inform the defendant of the substance of the claim. **Id.**

Under the lesser pleading standard of **CPLR §3013**, the Court finds that plaintiff's express warranty cause of action is adequately pleaded. Plaintiff alleges, among other things, that I-FLOW represented to him, his physicians, and other healthcare providers that "the intra-articular pain pumps were safe and fit for the purposes intended, that they were of merchantable quality, that they did not produce any dangerous side effects in excess of those risks associated with other, non-defective analgesics and that the potential side effects and potential problems were accurately reflected in the warnings disseminated by the Defendant(s) and that the aforementioned intra-articular pain pumps were adequately tested and fit for their intended use." [Complaint, ¶ 101] The Court finds this sufficient. *See* **Ambers v. C.T. Industries, Inc.,** 161 AD2d 256 (allegation that manufacturer warranted its uniform as safe was sufficient); **Thomas v. Leary,** 15 AD2d 438 (allegation that defendant warranted to the public that chair was safe for normal use was sufficient).

The Court notes that the Complaint does not explicitly state that plaintiff or his physicians relied upon I-FLOW's representations. At this stage of the proceedings, however, this defect may be ignored. *See* **Wiltshire**, 88 AD2d at 1097. "Modern pleading rules are designed to focus attention on whether the pleader has a cause of action rather than on whether he has properly stated one." **Weiss,** 193 AD2d at 384 (internal quotation omitted). "[P]leadings are to be liberally construed and defects are to be ignored if a substantial right of a party is not prejudiced. . . . A pleading will not be dismissed merely because it is inartistically drawn." **Wiltshire**, 88 AD2d at 1097.

The Court considers that the information necessary to sustain the breach of warranty claim may be, in part, in the possession or control of defendants or non-parties, including SALVATORE J. CORSO, M.D. and ORTHOPAEDIC AND SPORTS ASSOCIATES OF LONG ISLAND, P.C. or plaintiff's other physicians. Plaintiff should have the opportunity to evince such information through discovery. Accordingly, the Court believes that dismissal at this stage of the proceedings would be premature. *See* **Wiltshire**, 88 AD2d at 1097. *See also* **Peterson v. Spartan Industries, Inc.,** 33 NY2d 463, 465.

Seventh, Eighth and Ninth Causes of Action

The seventh, eighth and ninth causes of action are premised on allegations of fraud on the part of I-FLOW in connection with the safety and testing of its Pain Pump. The seventh cause of action alleges, essentially, that I-FLOW falsely represented that its Pain Pump was tested and found to be to be safe and effective for the control of pain after shoulder surgery, despite knowledge that the FDA had rejected the testing of the subject intra-articular pain pumps and did not approve their use in open Bankart reconstruction surgery. The eighth cause of action alleges, among other things, that I-FLOW concealed: the risks associated with its Pain Pump, that the Pain Pump was improperly designed and tested, and that the test results were fabricated and false. The ninth cause of action alleges that I-FLOW's misrepresentations and misleading marketing of the Pain Pump violated the New York State Consumer Protection Statute(s).

I-FLOW argues that these pleadings fail to meet the stringent pleading requirements of **CPLR §3016(b)**, and that the claims are preempted by federal law. With respect to the pleading requirements, I-FLOW argues that plaintiff has failed to state the time, place and content of the misrepresentations allegedly made by I-FLOW, and has failed to allege any facts giving rise to a duty to disclose on the part of I-FLOW. In addition, I-FLOW, argues, plaintiff has failed to identify the specific statute or section of the Consumer Protection Statutes which I-FLOW has allegedly violated.

On a cause of action sounding in fraud, the plaintiff must prove "a misrepresentation or a material omission of fact which was false and known to be false by defendant, made for the purpose of inducing the other party to rely upon it, justifiable reliance of the other party on the misrepresentation or material omission, and injury." **Lama Holding Co. v. Smith Barney Inc.**, 88 NY2d 413, 421. Each of the essential elements of the fraud claim must be supported by factual allegations sufficient to satisfy **CPLR 3016(b)**, which provides that "the circumstances constituting the wrong shall be stated in detail." **Monaco v. NY Univ. Med. Ctr.**, 213 AD2d 167, 169, *lv dismissed in part and denied in part* 86 NY2d 882; **Megaris Furs v Gimbel Bros.**, 172 AD2d 209. **CPLR 3016(b)** "imposes a more stringent standard of pleading than the generally applicable 'notice of the transaction' rule of CPLR 3013." **Lanzi v Brooks**, 54 AD2d 1057, 1058, *affd* 43 NY2d 778. Allegations of fraud should be dismissed as insufficient where the claim is unsupported by specific and detailed allegations of fact. **Callas v Eisenberg**, 192 A.D.2d 349.

In the case at bar, the Court finds that the seventh, eighth and ninth causes of action lack sufficiently detailed allegations regarding plaintiff's or his physicians' reliance on specific misrepresentations or omissions on the part of I-FLOW. Plaintiff also fails to allege a specific statutory violation. Accordingly, the three causes of action

predicated upon fraud should be dismissed as insufficient. Nevertheless, the Court does not find that these causes of action are patently lacking in merit or wholly conclusory. Further, it appears that information necessary to sustain these claims may be in the control of co-defendants or plaintiff's other physicians.

In **Delaney v. Pfizer, Inc.**, [2007 WL 2176912], the Supreme Court, New York County, Friedman, J., considered fraud claims in connection with the marketing of a prescription drug for off-label uses. Plaintiffs alleged, essentially, that defendants affirmatively misrepresented that the drug was safe and effective for the particular off-label use. The Court found that plaintiffs had not met their burden under **CPLR §3016(b)**, but held that insofar as the allegations were not wholly conclusory, and that facts essential to the opposition might exist but could not then be stated, dismissal should not be granted without affording leave to replead at the conclusion of discovery. **Id.,** citing **CPLR §3211(d)**.

The Court agrees with this approach. **CPLR §3016(b)** should not be applied to preclude an otherwise valid cause of action, particularly where it may be impossible, at the time of a motion to dismiss, to state in detail the circumstances of the fraud. **Lanzi v Brooks** 43 N.Y.2d 778, 780. The Court holds that the seventh, eighth and ninth causes of action are dismissed, with leave to replead at the conclusion of discovery. In view of the foregoing, it is not necessary to reach the question of federal preemption.

CONCLUSION

The Court has considered the remaining contentions of the parties and finds them to be without merit or rendered academic by the foregoing. Accordingly, it is

ORDERED, that I-FLOW's motion to dismiss pursuant to **CPLR §§ 3016** and **3211** is **granted in part,** as follows:

1. The Fourth [punitive damages] cause of action is **dismissed** in its entirety;
2. The Seventh [fraudulent misrepresentation], Eighth [fraudulent concealment] and Ninth [violation of State consumer fraud and deceptive trade practices] causes of action are **dismissed with leave to replead**; and it is further

ORDERED, that I-FLOW's motion to dismiss pursuant to **CPLR §3211** is **denied in part,** to the extent that the Second [strict products liability] and Fifth [breach of express warranties] causes of action are upheld.

This constitutes the Order of the Court. Plaintiff shall serve a copy of this Order on all parties forthwith upon receipt from any source.

Dated: Sept 30, 2011

J.S.C.

ENTERED
OCT 21 2011
NASSAU COUNTY
COUNTY CLERK'S OFFICE