NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ETHEL STANGER, et al.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 09-05166 (JAP)
APP PHARMACEUTICALS, LLC, et al.	:	
	:	**OPINION**
Defendants.	:	

PISANO, District Judge.

This is a diversity action in which plaintiffs Ethel Stanger ("Mrs. Stanger") and Marvin Stanger (together with Mrs. Stanger, "Plaintiffs") bring claims for product liability against APP Pharmaceuticals, LLP ("APP"), Hospira, Inc. ("Hospira") and Baxter Healthcare Corporation ("Baxter" and, collectively with APP and Hospira, "Defendants"). Presently before the Court are motions by Baxter and Hospira to dismiss the second amended complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). Oral argument was held October 18, 2010. For the reasons below, Defendants' motions are granted in part and denied in part.

I. Background[1]

On or around January 12, 2007, Mrs. Stanger was admitted to Jersey Shore Medical Center for aortic valve replacement surgery. As part of the treatment for her surgery, Mrs.

[1]In addressing a motion to dismiss, the Court must accept as true the allegations contained in a complaint. *See Toys "R" US, Inc. v. Step Two, S.A.*, 318 F.3d 446, 457 (3d Cir. 2003); *Dayhoff, Inc. v. H.J. Heinz Co.*, 86 F.3d 1287, 1301 (3d Cir. 1996). Accordingly, the facts recited herein are taken from the second amended complaint unless otherwise indicated and do not represent this Court's factual findings.

Stanger was administered a drug product called heparin, which is an anticoagulant used to prevent the formation of clots and the extension of existing clots within the blood. Heparin is administered either by intravenous or subcutaneous injection and must be given frequently or as a continuous infusion. A side-effect associated with the administration of heparin is known as heparin-induced thrombocytopenia ("HIT"). HIT develops as a result of a patient's reaction to heparin and causes, rather than prevents, clotting within the blood. On or around January 16, 2007, Plaintiff was diagnosed with HIT, underwent several platelet transfusions and experienced various severe adverse health problems, including acute renal failure.

Plaintiffs filed the second amended complaint in the action on May 28, 2010 [docket entry no. 21], alleging eight causes of action, including strict liability for failure to warn and design defect (Counts I and II), negligence (Count III), breach of implied warranty (Count IV), breach of express warranty (Count V), negligent misrepresentation (Count VI), fraud by concealment (Count VII) and loss of consortium (Count VIII). The second amended complaint alleges that Defendants manufacture, market, distribute and sell several forms of heparin throughout the United States, including the State of New Jersey, and that Mrs. Stanger was exposed to Defendants' heparin products. As a result of the administration of Defendants' heparin products, Mrs. Stanger suffered injuries to her health, strength and activity, employed physicians to examine, treat and care for her and incurred hospital, medical and incidental expenses.

Plaintiffs allege that Defendants were aware, or should have been aware, of the risks of HIT because information was available to Defendants with respect to the defects and dangerous nature of heparin, but that Defendants failed to cure the defects or issue adequate warnings with respect to HIT. Specifically, Plaintiffs allege that Defendants omitted information with respect

to health hazards and risks associated with the administration of heparin from their literature, packaging and labeling and downplayed the known adverse and serious health effects of the drug. In addition, Plaintiffs claim that Defendants' heparin products were placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition, as the foreseeable risks exceed the benefits associated with the design and they are unreasonably dangerous and more dangerous than an ordinary consumer would expect.

II. Legal Discussion

A. Motion to Dismiss Standard

Under Federal Rule of Civil Procedure 12(b)(6), a court may grant a motion to dismiss if the complaint fails to state a claim upon which relief can be granted. When considering such a motion, the district court judge is "required to accept as true all of the allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the plaintiff." *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997).

The Supreme Court set forth the standard for addressing a motion to dismiss under Rule 12(b)(6) in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 562, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). The *Twombly* Court stated that, "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, ... 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[.]" *Id.* at 555 (internal citations omitted). Therefore, for a complaint to withstand a motion to dismiss under Rule 12(b)(6), the "[f]actual allegations must be enough to raise a right to relief above the speculative level, ... on

the assumption that all the allegations in the complaint are true (even if doubtful in fact) ..." *Twombly*, 550 U.S. at 555 (internal citations and footnote omitted).

More recently, the Supreme Court has emphasized that, when assessing the sufficiency of a civil complaint, a court must distinguish factual contentions and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009). A complaint will be dismissed unless it "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* at 1949 (quoting *Twombly*, 550 U.S. at 570). This "plausibility" determination will be "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009) (citing *Iqbal*, 129 S.Ct. at 1940).

B. Counts I and II: Strict Liability Claims

In a New Jersey products liability action, a plaintiff must prove "that the defendant manufacturer actually made the particular product accused of having caused the injury." *Pipon v. Burroughs-Wellcome Co.*, 532 F.Supp. 637, 637-638 (D.N.J. 1982) (citing *Scanlon v. General Motors Corporation*, 65 N.J. 582, 326 A.2d 673 (1974)). Defendants contend that Plaintiffs' strict liability claims fail because the second amended complaint does not adequately allege that Defendants' products injured Plaintiff. In particular, Defendants argue that Plaintiffs have not alleged that each individual Defendant was the manufacturer of the heparin product that caused Mrs. Stanger's injury.

The Court notes that the second amended complaint defines "Defendants" as "APP, Baxter and Hospira." As such, Plaintiffs have alleged that all of the Defendants manufacture heparin products, that all of those heparin products were administered to Mrs. Stanger and that

all of those administrations of heparin caused Mrs. Stanger's injury. The Court finds that these factual allegations are "more than labels and conclusions" and, instead, when accepted as true, are sufficient to state a claim that is plausible on its face. Thus, the Court finds Plaintiffs' strict liability claims adequately state a claim for relief and Defendants' motions with respect to Counts I and II are denied.

C. Counts III, IV, VI and VII: Negligence, Breach of Implied Warranty, Negligent Misrepresentation and Fraud by Concealment Claims

Defendants argue that Plaintiffs' negligence, breach of implied warranty, negligent misrepresentation and fraud by concealment claims are common law products liability claims that are abrogated by the New Jersey Products Liability Act ("PLA"). The New Jersey Legislature enacted the PLA based on an "urgent need for remedial legislation to establish clear rules with respect to certain matters relating to actions for damages for harm caused by products." N.J.S.A. 2A:58C-1(a). In so doing, "[t]he Legislature intended ... to limit the liability of manufacturers so as to balance [ ] the interests of the public and the individual with a view towards economic reality." *Zaza v. Marquess & Nell, Inc.*, 144 N.J. 34, 675 A.2d 620, 627 (N.J.1996) (internal quotations omitted). The New Jersey Supreme Court has observed that "[t]he language chosen by the Legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products." *In re Lead Paint Litigation,* 191 N.J. 405, 924 A.2d 484, 503 (N.J.2007). A product liability action is defined as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J.S.A. 2A:58C-1(b)(3).

At the heart of this matter is the potential for harm caused by a drug product, heparin, allegedly manufactured and supplied in a defective and unreasonably dangerous condition and

containing inadequate warnings of the product's dangerous characteristics. The Court finds it evident that this is an action brought by Plaintiffs for harm caused by a product and, therefore, Plaintiffs' cause of action is encompassed by the PLA. Thus, the Court finds Plaintiffs' negligence, breach of implied warranty, negligent misrepresentation and fraud by concealment claims are improperly raised and Counts III, IV, VI and VIII are dismissed.

D. Count V: Express Warranty Claim

Defendants argue that Plaintiffs have failed to allege facts to support a claim for breach of express warranty and, therefore, Count V of the second amended complaint should also be dismissed. As correctly noted by Defendants, an express warranty can be created under New Jersey law by the following:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

N.J.S.A. § 12A:2-313.

Plaintiffs' breach of express warranty claim does not allege any facts that support the existence of an express warranty. Plaintiffs have not alleged that they were in privity with Defendants or that Defendants made an express warranty to the Plaintiffs. In fact, Plaintiffs have failed to identify any specific promise, affirmation, description or sample which might form the basis of the express warranty. Instead, there is simply a conclusory recitation of the elements of the claim. *See Delaney v. Stryker Orthopaedics*, 2009 WL 564243, at *6 (D.N.J. March 5, 2009) (dismissing express warranty claims in product liability action where plaintiff provided labels

and conclusions, rather than the grounds upon which his claim was based); *Simmons v. Stryker Corp.*, 2008 WL 4936982, at *2 (D.N.J. Nov. 17, 2008) (dismissing express warranty claims in product liability action where plaintiff's claim "is devoid of any 'factual matter' to support the existence of an express warranty"). Thus, Count V of the second amended complaint is dismissed.

E. Punitive Damages Claim

Defendants argue that Plaintiffs' punitive damages claims should also be dismissed. The general rule under New Jersey Law is that punitive damages cannot be awarded in a products liability action based on an FDA-approved drug product. N.J.S.A. 2A:58C-5(c). While the PLA does provides an exception to this rule "where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question…", N.J.S.A. 2A:58C-5(c), the New Jersey Appellate Division has subsequently held that the exception is preempted by federal law. *McDarby v. Merck & Co., Inc.*, 401 N.J. Super. 10, 87-94 (App. Div. 2008). It is undisputed that heparin is an FDA-approved drug product; thus, the Court finds that all claims for punitive damages stated in the second amended complaint are dismissed.

III. Conclusion

For the reasons above, Defendants' motions to dismiss are granted as to Counts III, IV, V, VI and VII and with respect to the claims for punitive damages. Defendants' motions are denied in all other respects. Plaintiffs shall be granted leave to amend the second amended complaint within 20 days of the date hereof to correct, if possible, any deficiencies identified herein and to add additional causes of action if appropriate. An appropriate Order accompanies this Opinion.

/s/ JOEL A. PISANO
United States District Judge

Dated: November 30, 2010