

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION**

JOHN OSSIM and KRISTEN OSSIM,)	
)	
Plaintiffs,)	
)	
v.)	
)	Case No. 1:14-cv-00254-TWP-DKL
ANULEX TECHNOLOGIES, INC.,)	
ABC INC., and JOHN DOE, M.D.,)	
)	
Defendants.)	

ENTRY ON DEFENDANTS MOTION TO DISMISS

This matter is before the Court on Defendant Anulex Technologies, Inc.’s (“Anulex”) Motion to Dismiss ([Filing No. 6](#)) Plaintiffs’, John Ossim (“Mr. Ossim”) and Kristen Ossim (“Ms. Ossim”) (collectively, “the Ossims”), claims against it alleging tortious conduct and violation of federal regulations. For the following reasons, Anulex’s motion is **DENIED**.

I. BACKGROUND

Procedurally, this matter was removed to federal court by Anulex on February 20, 2014. Anonymous Defendants ABC Inc. and John Doe, M.D., cannot be identified pursuant to Indiana Code § 34-18-8-4, which states that an action cannot be filed in court against qualified medical care providers in their own names until a Medical Review Panel issues an opinion in accordance with the Medical Malpractice Act. The Medical Review Panel underlying the process dealing with ABC Inc. and John Doe, M.D. is ongoing in this case. The Court has previously found that remand is not proper and the matter may proceed.

Because this matter is before the Court on a motion to dismiss, the following facts are taken from the Complaint and are considered true. Anulex designed, manufactured, sold, and distributed a surgical prosthetic device known as the Xclose Tissue Repair System (“Xclose device”). Anulex

marketed its Xclose device to spinal surgeons as a device to be used in lumbar disc surgeries. The Federal Drug Administration (“FDA”) requires surgical devices to complete regulatory requirements before obtaining approval for marketing. Anulex did not complete the approval process for the Xclose device to be used as a prosthetic device during the course of spinal surgery.

On January 20, 2012, Mr. Ossim’s surgeon implanted the Xclose device in his back in an experimental surgery performed at ABC Inc. Mr. Ossim was unaware that the Xclose device had been implanted until after January 20, 2012, when a second spinal surgery was required and pieces of the Xclose device were removed. Mr. Ossim suffered severe and permanent injuries to his lower back and spinal cord following the implantation of the Xclose device.

Based in part on Anulex’s failure to secure FDA approval and to warn Mr. Ossim of the dangers associated with the Xclose device, the Ossims filed this action alleging claims of strict product liability, negligence, breach of implied warranties, breach of express warranty, and negligent misrepresentation.

II. LEGAL STANDARD

When reviewing a 12(b)(6) motion, the Court takes all well-pleaded allegations in the complaint as true and draws all inferences in favor of the plaintiff. *Bielanski v. Cnty. of Kane*, 550 F.3d 632, 633 (7th Cir. 2008) (citations omitted). However, the allegations must “give the defendant fair notice of what the . . . claim is and the grounds upon which it rests” and the “[f]actual allegations must be enough to raise a right to relief above the speculative level.” *Pisciotta v. Old Nat’l Bancorp*, 499 F.3d 629, 633 (7th Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Stated differently, the complaint must include “enough facts to state a claim to relief that is plausible on its face.” *Hecker v. Deere & Co.*, 556 F.3d 575, 580 (7th Cir. 2009) (citations omitted). To be facially *plausible*, the complaint must allow “the court to draw the

reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted).

Here, Anulex has attached matters outside the pleadings as exhibits to its motion. “If, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56.” Fed. R. Civ. P. 12(d). However, the Seventh Circuit has taken “a relatively expansive view of the documents that a district court properly may consider in disposing of a motion to dismiss.” *Williamson v. Curran*, 714 F.3d 432, 443 (7th Cir. 2013). “A motion under Rule 12(b)(6) can be based only on the complaint itself, documents attached to the complaint, documents that are critical to the complaint and referred to in it, and information that is subject to proper judicial notice.” *Geinosky v. City of Chicago*, 675 F.3d 743, 745 n.1 (7th Cir. 2012). Anulex contends that the 510(k) documents and clinical study attached to its motion are critical to the Complaint, as they were mentioned in the February 11, 2011 warning letter attached by the Ossims to their Complaint. It further argues that the Court can take judicial notice of its exhibits, as they are available through the FDA’s website. The Court agrees that it can take judicial notice of the FDA 510(k) letters exhibits because the information is publically and readily available from the FDA. The Court, however, is not convinced that the clinicaltrials.gov materials are appropriate for judicial notice, as the information on the website is “provided and updated by the sponsor or principal investigator of the clinical study,” i.e., Anulex. “ClinicalTrials.gov Background,” <<http://clinicaltrials.gov/ct2/about-site/background>> (accessed September 30, 2014). So, rather than convert the motion to dismiss to one for summary judgment, the Court will not consider Anulex’s Exhibit C ([Filing No. 8-3](#)).

III. DISCUSSION

Anulex contends that the Ossims' claims are impliedly preempted by federal law under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), or alternatively, that they fail to state a claim upon which relief can be granted.

A. Implied Preemption

In *Buckman Co.*, the Supreme Court addressed plaintiffs' claims that Buckman Co. made fraudulent representations to the FDA to obtain approval to market orthopedic bone screws. Plaintiffs argued that such fraud was the "but for" cause of their injuries because without the representations, such devices would not have been approved by the FDA. *Id.* at 343. The Court found that such:

fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law. The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives.

Id. at 348.

In *Bausch v. Stryker Corporation*, 630 F.3d 546 (7th Cir. 2010), the Seventh Circuit considered the impact of *Buckman* on a plaintiff's tort law claims based on a manufacturing defect. Rather than find preemption, the Seventh Circuit noted that the Supreme Court "specifically distinguished such 'fraud-on-the-agency' claims, *i.e.*, claims not related to a field of law that states had traditionally occupied, from claims based on state law tort principles such as in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984)." *Id.* at 557. It went on to hold that the plaintiff's claim was grounded in the Illinois-recognized duty of a manufacturer to use due care in manufacturing a medical device. *Id.* at 558. The court stated that the plaintiff could pursue such claim "as long as she can show that she was harmed by a violation of applicable federal law." *Id.*

Anulex argues that this matter should be governed by *Buckman Co.* and that *Bausch* should be narrowly construed to apply only to claims rooted in an established and specific state law duty. The Court disagrees. The claims in this case are similar to those made in *Bausch*, and do not consist of the “fraud-on-the-agency” type claims at issue in *Buckman Co.* The Seventh Circuit has recognized, and a plain reading of *Buckman Co.* reveals, that the Supreme Court was concerned with balancing the regulatory structure dealing specifically with issues of fraud and misrepresentations to the FDA, not with “traditional state tort law principles of the duty of care owed.” 531 U.S. at 352. In the Court’s view, Anulex attempts to read *Buckman Co.* far too broadly and *Bausch* far too narrowly. Instead, *Bausch* stands for the proposition that state law tort theories based on a medical device manufacturer’s violation of federal law can be brought without preemption. 630 F.3d at 558. Thus, the Ossims’ claims are not preempted by federal law. The motion is **DENIED** under this theory.

B. State Law Claims

The Ossims bring state law claims of strict liability as well as negligence, breach of implied warranties, breach of express warranty, and negligent misrepresentation. The negligence claim references only Defendants ABC Inc. and John Doe, M.D., and is thus not before the Court. Anulex generally argues that the Ossims have failed to state adequate claims under Federal Rule of Civil Procedure 8 because they have not identified the specific defect that caused Mr. Ossim’s injuries. The Court disagrees that this is a basis for dismissal. In *Bausch*, the Seventh Circuit recognized that it is difficult to plead the type of claims brought by the Ossims. *See* 630 F.3d at 558. It instructed that, “district courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a

detailed statement of the specific bases for her claim.” *Id.* With this in mind, the Court considers the pleadings found in the Complaint.

The Indiana Product Liability Act (“IPLA”) “governs all actions brought by a user or consumer of a product, regardless of the substantive legal theory upon which the action is brought.” *Hitachi Constr. Machinery Co. v. AMAX Coal Co.*, 737 N.E.2d 460, 463 (Ind. Ct. App. 2000). “The [IPLA] generally imposes strict liability for physical harm caused by a product in an unreasonably dangerous defective condition. Ind. Code § 34-20-2-1.” *TRW Vehicle Safety Sys., Inc. v. Moore*, 936 N.E.2d 201, 209 (Ind. 2010). The Ossims’ strict liability claim alleges that Anulex marketed its Xclose device in violation of FDA law and regulations by failing to get approval for use in lumbar spine surgeries. For support, the Ossims attached an FDA warning letter regarding the Xclose device sent on February 11, 2011, and Mr. Ossim’s surgery took place on January 20, 2012. In essence, the facts alleged suggest that the Xclose device was used in an unapproved, and thus, unreasonably dangerous manner, and as a result Mr. Ossim suffered permanent and severe injury. As pleaded, the Ossims have sufficiently set forth a plausible claim for relief that can move forward. Therefore, the Court will **DENY** Anulex’s motion on this claim.

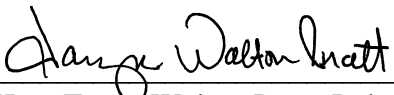
As for the Ossims’ breach of expressed or implied warranty claims and negligent misrepresentation claims, Anulex argues that the Ossims have failed to state a claim, but Anulex has not provided any legal analysis or authority for its position. It is not the Court’s duty to develop Anulex’s position when faced with a Complaint that is not deficient upon its face. Therefore, the Court will **DENY** Anulex’s motion on these claims.

IV. CONCLUSION

For the reasons set forth above, Anulex’s Motion to Dismiss ([Filing No. 6](#)) is **DENIED**.

SO ORDERED.

Date: 9/30/2014


Hon. Tanya Walton Pratt, Judge
United States District Court
Southern District of Indiana

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