

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
WESTERN DIVISION  
No. 5:13-CV-868-BO

BENNIE EVANS, )  
Plaintiff, )  
 )  
v. )  
 )  
KENNETH RICH, M.D., )  
CAPITAL NEUROSURGERY, and )  
ANULEX TECHNOLOGIES, INC., )  
Defendants. )

**ORDER**

This cause comes before the Court on defendant Anulex’s motion to dismiss and plaintiff’s motions to strike and for entry of default, and for leave to file an amended complaint. For the reasons discussed below, plaintiff’s motion for leave to file an amended complaint is granted, defendant Anulex’s motion to dismiss is granted, and plaintiff’s motion to strike and for entry of default is denied.

**BACKGROUND**

Plaintiff filed this action in Wilson County Superior Court alleging claims of negligent misrepresentation, fraud, unfair and deceptive trade practices, and breach of the implied warranty of merchantability arising out of back surgery performed on plaintiff by defendant Rich. Plaintiff alleges that Dr. Rich used an “X-Close” suture device, manufactured by Anulex, while performing a microdissectomy with annular repair on plaintiff on November 15, 2010. Plaintiff further alleges that Annulex, which had obtained approval from the FDA for use of X-close sutures in soft tissue repair, had not obtained approval from the FDA to use the X-close device in annular repairs and that Dr. Rich did not obtain permission from plaintiff to participate in the investigation of the use of the X-close device in his annular repair.

Anulex removed plaintiff's action to this Court on December 20, 2013, pursuant to the Court's federal question jurisdiction. 28 U.S.C. §§ 1441; 1331. At the time of Anulex's removal, service had not been effected on the remaining defendants. 28 U.S.C. § 1446(b)(2). Anulex then filed the instant motion to dismiss for failure to state a claim upon which relief can be granted pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Plaintiff did not respond to the motion to dismiss. Plaintiff filed a motion to strike Anulex's motion to dismiss and for entry of default pursuant to Rule 55(a) of the Federal Rules of Civil Procedure against Anulex. Plaintiff then moved to amend his complaint, filing a proposed amended complaint in support of his motion almost one month later.

### **DISCUSSION**

#### I. MOTION FOR LEAVE TO FILE AMENDED COMPLAINT

The Court begins its analysis with plaintiff's motion for leave to file an amended complaint. Rule 15 of the Federal Rules of Civil Procedure provides that a party may amend his pleadings as a matter of right under certain circumstances or with the opposing party's consent or leave of court. Fed. R. Civ. P. 15(a)(1)-(2). Further, Rule 15 directs that leave to amend should be freely given when justice so requires. Fed. R. Civ. P. 15(a)(2). "This liberal rule gives effect to the federal policy in favor of resolving cases on their merits instead of disposing of them on technicalities." *Laber v. Harvey*, 438 F.3d 404, 426 (4th Cir. 2006). A court should only deny leave to amend a pleading when the amendment would be prejudicial to the opposing party, where there has been bad faith on the part of the moving party, or when the amendment would be futile. *Johnson v. Oroweat Foods Co.*, 785 F.2d 503, 509 (4th Cir. 1986) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

The Court finds no prejudice in allowing plaintiff to amend his complaint nor does it find any bad faith present. Because the Court will consider Anulex's motion to dismiss as addressed to plaintiff's amended complaint, it declines to consider here whether the proposed amendment is futile. Accordingly, plaintiff's motion for leave to file an amended complaint is GRANTED. The clerk is DIRECTED to correct the Court's docket to reflect that the amended complaint filed at docket entry twenty-one is "proposed" and is further directed to file the amended complaint as of the date of entry of this order.

## II. MOTION TO DISMISS

Although the Court has allowed plaintiff to file an amended complaint, it may consider Anulex's motion to dismiss as it relates to the remaining count raised against it in plaintiff's amended complaint. *See* 6 CHARLES A. WRIGHT, ARTHUR R. MILLER, AND MARY KAY KANE, FEDERAL PRACTICE AND PROCEDURE § 1476 (3d ed. 1998) ("defendants should not be required to file a new motion to dismiss simply because an amended pleading was introduced while their motion was pending."). Plaintiff's only claim in his amended complaint against Anulex is one for unfair and deceptive trade practices under N.C. Gen. Stat. § 75-1.1. As argued in Anulex's motion to dismiss, however, such claim is impliedly preempted under *Buckman Company v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001).

There is no private right of action under the Food, Drug, and Cosmetic Act (FDCA), as amended by the Medical Device Act (MDA). *Id.* at 352. Thus, where private litigants are effectively suing for a violation of the FDCA under the guise of state law, their claims are impliedly preempted. *Loreto v. Proctor & Gamble Co.*, 515 Fed. App'x 576, 579 (6th Cir. 2013) (citation omitted). The test for determining whether a state law claim is impliedly preempted is whether or not the claim would exist in the absence of the FDCA. *Id.* Though there is a narrow

class of state law claims which may survive *Buckman* preemption, *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009), *Buckman* has been applied in particular contexts to impliedly preempt such state law claims as breach of warranty, negligence per se, design defect, and failure to warn. *In re Medtronic, Inc. Sprint Fidelis Leads Products Liab. Litig.*, 592 F. Supp. 2d 1147, 1159-64 (D. Minn. 2009).

In his amended complaint, plaintiff alleges that Anulex conspired with physicians to use X-close sutures in annular repairs where patients had excellent prognoses for recovery in order to “stockpile” positive outcome cases so that it might gain FDA approval for use of X-close devices in annular repairs. At bottom, plaintiff seeks to hold Anulex liable for off-label promotion of its X-close suture device, but such claim is impliedly preempted as it exists solely by virtue of the requirements of the FDCA. *Buckman*, 531 U.S. at 353; *see also In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp.2d 1282, 190-91 (C.D. Cal. 2008) (off-label promotion violates the FDCA but the FDCA provides for no private right of action; nor can plaintiffs use “state unfair competition laws as a vehicle to bring a private cause of action that is based on violations of the FDCA.”).

Even if the Court were to assume *arguendo* that plaintiff’s UDTPA claim was not impliedly preempted by *Buckman*, plaintiff has failed to state a plausible claim for relief. “To prevail on a claim of unfair and deceptive trade practices, a plaintiff must show: (1) defendants committed an unfair or deceptive act or practice; (2) in or affecting commerce; and (3) that plaintiff was injured thereby.” *First Atl. Mgmt. Corp. v. Dunlea Realty Co.*, 131 N.C. App. 242, 252 (1998). A trade practice is unfair if it is immoral, unethical, oppressive, or substantially injurious. *Id.* (citation omitted). Plaintiff has alleged no facts that would support that any

actions taken by Anulex would rise to the level of an unfair trade practice as that term is defined by North Carolina law. Thus, plaintiff's sole claim against Anulex must be dismissed.

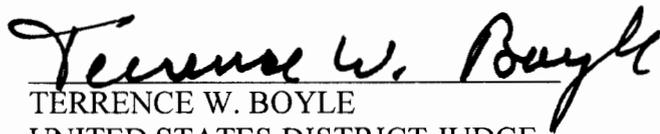
III. MOTION TO STRIKE AND FOR ENTRY OF DEFAULT

Plaintiff's motion to strike Anulex's motion to dismiss and for entry of default is denied. Anulex's motion to dismiss was filed within the time allowed by the clerk's order granting Anulex's motion to extend time to respond to plaintiff's complaint. Entry of default under Rule 55(a) of the Federal Rules of Civil Procedure is therefore inappropriate. Plaintiff's request that the motion to dismiss be stricken is improper and without merit. The motion is therefore denied.

**CONCLUSION**

For the foregoing reasons, plaintiff's motion to amend complaint [DE 18] is GRANTED and the clerk is DIRECTED to file plaintiff's amended complaint [DE 21] as of the date of entry of this order. The clerk is further DIRECTED to correct docket entry twenty-one to reflect that the amended complaint filed by plaintiff was "proposed." Plaintiff's motion for extension of time to file a memorandum of law [DE 19] is DENIED AS MOOT. Defendant Anulex's motion to dismiss [DE 9] is GRANTED and Anulex is DISMISSED from this action. Plaintiff's motion to strike and for entry of default [DE 15] is DENIED.

SO ORDERED, this 4 day of June, 2014.

  
TERRENCE W. BOYLE  
UNITED STATES DISTRICT JUDGE