IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION

NO. 7:19-CV-235-FL

ALBERT C. BURGESS, JR. Plaintiff, v. PFIZER, INC., Defendant.	)	ORDER

This matter is before the court on defendant's motion to dismiss (DE 4) and plaintiff's motion to amend (DE 14), which the court construes as including in part a motion to remand. These motions have been briefed fully, and the issues raised are ripe for ruling. Also before the court is plaintiff's motion for sanctions (DE 22). For the following reasons, defendant's motion is granted, plaintiff's motion to amend is granted in part as set forth herein, and plaintiff's remaining motions are denied.

STATEMENT OF THE CASE

Plaintiff commenced this action in New Hanover County Superior Court on August 14, 2019, asserting personal injuries from taking a prescription drug marketed and sold by defendant, known as Lyrica. Plaintiff seeks compensatory and punitive damages in excess of $11,000,000.00, for asserted inadequate or negligent warnings by defendant. Defendant removed plaintiff's action to this court on November 27, 2019, on the basis of diversity jurisdiction, relying upon its business corporation annual report prepared for the North Carolina Secretary of State.

Defendant filed the instant motion to dismiss on the same date, asserting that plaintiff's claims are preempted by federal law, and that plaintiff has alleged no facts to support his claims. Plaintiff filed the instant motion to amend on December 27, 2019, seeking to change the amount of damages sought from $11,000,000.00 to $74,999.00, with no other changes proposed. Further, in opposition to defendant's motion to dismiss, filed January 13, 2020, plaintiff argues that diversity jurisdiction is lacking and the matter should be remanded to state court, also relying upon a copy of the product label for Lyrica.

Defendant replied in support of its motion to dismiss, and responded to plaintiff's motion to amend, on January 17, 2020. Plaintiff filed a reply in support of his motion to remand on February 3, 2020. Plaintiff filed the instant motion for sanctions on February 27, 2020, and defendant is allowed until April 15, 2020, to file a response.

STATEMENT OF ALLEGED FACTS

Plaintiff alleges in the complaint that he is a resident of North Carolina, and that defendant is a Delaware corporation doing business in North Carolina, marketing numerous products including the drug Lyrica.

According to the complaint, from 2014 to 2016, plaintiff was prescribed Lyrica by a licensed physician, and plaintiff took the dose prescribed twice daily during this period. Plaintiff alleges that in 2016 the drug had "begun effecting the memory of the Plaintiff . . . unknown to him at the time." (Compl. ¶ 4). According to the complaint "the drug may have contributed to the Plaintiff developing Parkinson's disease as Lyrica does in fact effect the brain of humans." (Id.).

Plaintiff alleges that "Lyrica is an effective pain reliever," but at a "cost." (Id. ¶ 5). Plaintiff states that "Defendant in its advertisements of Lyrica does in fact state very plainly that Lyrica would negatively effect your 'CONCENTRATION.'" (Id. ¶ 6). According to plaintiff,

"concentration is directly controlled by the brain, which Lyrica admits effecting, although not to the degree that is alleged" in the complaint. (Id.).

Plaintiff alleges "[t]hat Lyrica when placed on the marked has submitted test to the FDA which were not inclusive of the degree that Lyrica would effect the brain because the data did not support the known facts about Lyrica which could only be ascertained by a long period of usage." (Id. ¶ 7). Plaintiff asserts defendant caused plaintiff "a substantial injury with his memory being damaged and with the contributor of Lyrica to Parkinson's disease, which the Plaintiff has contracted over the past five years and it continues to progress." (Id. ¶ 8). Plaintiff asserts defendant did not include "proper warning[] labels on its product" and "attempted to hide the negative effects with the wording on its warnings about Lyrica." (Id. ¶¶ 11-12).

COURT'S DISCUSSION

A. Motion to Amend

Plaintiff moves to amend his complaint solely to change the amount of damages demanded from $11,000,000.00 to $74,999.00. Rule 15(a)(1) allows amendment of a pleading once as a matter of course within 21 days after serving it or 21 days after responsive pleading or motion. Rule 15(a)(2) allows amendment with court leave, in all other cases, in which "[t]he court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2).

Here plaintiff signed his motion to amend on December 17, 2019, and it was filed on December 27, 2019. In this instance, the court grants plaintiff's motion to amend as a matter of course under Rule 15(a)(1). Due to the limited nature of the amendment, the court deems plaintiff's complaint amended and filed as of the date of the motion to amend, to reflect the change in amount of damages sought to $74,999.00. While ordinarily an amended pleading renders moot a motion to dismiss the original pleading, where here the amendment deemed filed changes only

the demand for damages, the court in its discretion deems defendant's motion to dismiss applicable also to the amended complaint.

B. Motion to Remand

In conjunction with plaintiff's motion to amend, and plaintiff's briefing in opposition to defendant's motion to dismiss, plaintiff suggests that the matter must be remanded due to lack of diversity jurisdiction.

First, plaintiff asserts that the amount in controversy for diversity jurisdiction now is lacking, because he has amended his complaint to reflect an amount in controversy under $75,000.00. However, where an "amendment occurred after removal, we look at the original complaints rather than the amended complaints in determining whether removal was proper." Pinney v. Nokia, Inc., 402 F.3d 430, 443 (4th Cir. 2005). It is well established that a post-removal "amendment of [plaintiff's] pleadings," that "reduces the claim below the requisite amount . . . does not deprive the district court of jurisdiction." St. Paul Mercury Indem. Co. v. Red Cab Co., 303 U.S. 283, 292 (1938). Accordingly, the amount demanded in plaintiff's original complaint, in excess of $11,000,000.00, is controlling and establishes the requisite amount in controversy for diversity jurisdiction.

Second, plaintiff argues that the parties are not diverse because defendant is a citizen of North Carolina, by virtue of its "minimum contacts" through business activities and licensing in North Carolina. (Pl's Reply (DE 21) at 1; see Pl's Reply (DE 18) at 1). Plaintiff cites Int'l Shoe Co. v. State of Wash., 326 U.S. 310, 316 (1945), for the proposition that "minimum contacts" suffice to establish jurisdiction. However, "minimum contacts" is a test for personal jurisdiction, not diversity of citizenship. See id. Diversity of citizenship is determined by the state(s) where a party is a "citizen." 28 U.S.C. § 1332(a)(1). For purposes of this determination, "a corporation

shall be deemed to be a citizen of every State and foreign state by which it has been incorporated and of the State or foreign state where it has its principal place of business" 28 U.S.C. § 1332(c)(1).

Where plaintiff alleges that defendant is a Delaware corporation, the issue remaining for purposes of diversity of citizenship is whether it has a principal place of business in North Carolina. A corporation's "principal place of business" refers to "the place where a corporation's officers direct, control, and coordinate the corporation's activities . . . [or] the corporation's nerve center," which in practice "should normally be the place where the corporation maintains its headquarters." Hertz Corp. v. Friend, 559 U.S. 77, 92-93 (2010). "In determining whether jurisdiction exists, the district court is to regard the pleadings' allegations as mere evidence on the issue, and may consider evidence outside the pleadings without converting the proceeding to one for summary judgment." Richmond, Fredericksburg & Potomac R. Co. v. United States, 945 F.2d 765, 768 (4th Cir. 1991).

Here, the allegations in the complaint are inconclusive as to the principal place of business of defendant. The complaint alleges that defendant is "doing business in North Carolina," (Compl. ¶ 3), but the product label attached to the complaint states "New York, NY" as defendant's location. (Compl. Ex. (DE 1-1)). The notice of removal, however, confirms that defendant's principal place of business is New York. (See Notice of Removal (DE 1) ¶ 7). Defendant's annual report, prepared for filing with the North Carolina Secretary of State, also demonstrates that New York is its "principal office." (Id. Ex. B. (DE 1-2) at 2).[1] Accordingly, there is no genuine dispute of fact that defendant's principal place of business is New York.

Where the requirements for diversity jurisdiction are met, plaintiff's motion to remand is denied.

[1] In addition, the court takes judicial notice of the same information available from the North Carolina Secretary of State website (https://www.sosnc.gov/online_services/search/by_title/_Business_Registration [https://perma.cc/TEC5-FVPL]).

C. Motion to Dismiss

1. Standard of Review

"To survive a motion to dismiss" under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "Factual allegations must be enough to raise a right to relief above the speculative level." Twombly, 550 U.S. at 555. In evaluating whether a claim is stated, "[the] court accepts all well-pled facts as true and construes these facts in the light most favorable to the plaintiff," but does not consider "legal conclusions, elements of a cause of action, . . . bare assertions devoid of further factual enhancement[,] . . . unwarranted inferences, unreasonable conclusions, or arguments." Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc., 591 F.3d 250, 255 (4th Cir. 2009) (citations omitted).

2. Analysis

Defendant seeks dismissal of plaintiff's action on the basis of preemption and insufficient factual allegations. The court addresses each ground in turn.

a. Preemption

Under the Food Drug and Cosmetic Act ("FDCA"), "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to [21 U.S.C. § 255(b) or (j)] is effective with respect to such drug." 21 U.S.C.A. § 355(a). In other words, "a manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate." PLIVA, Inc. v. Mensing, 564 U.S. 604, 612 (2011). Accordingly, the United States Supreme Court has held that "when a party cannot satisfy its state duties" under state tort law, "without the Federal

Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes" and a claim based upon such state law duties is preempted and must be dismissed. Id. at 623-24; Drager v. PLIVA USA, Inc., 741 F.3d 470, 479 (4th Cir.2014) (holding claims preempted where based on allegations "that, through its promotional and warning materials, [generic defendant] made negligent misrepresentations and fraudulently concealed information about the safety of its product from consumers and medical professionals").

Plaintiff's claims fall squarely under the Mensig preemption rule. Plaintiff claims that defendant was negligent by "not including proper warning labels on its product" and by attempting "to hide the negative effects with the wording on its warnings about Lyrica." (Compl. ¶¶ 11, 12). Because Lyrica is alleged to be a prescription drug (see id. ¶ 4), and plaintiff seeks to bring claims based upon the inadequacy of the drug label that must be approved under the FDCA, plaintiff's claims are preempted by federal law.[2]

Plaintiff argues that dismissal on the basis of preemption is not appropriate because FDA's approval of the Lyrica warning label is nowhere alleged in the complaint. But, plaintiff does allege that Lyrica is a prescription drug, and that when Lyrica was "placed on the market" defendant "submitted test[s] to the FDA." (Compl. ¶¶ 4, 7). In any event, it is not FDA approval of a product label that triggers preemption, but rather the federal law requirement that, in order to obtain FDA approval for a prescription drug, a manufacturer must "work with the FDA to develop an appropriate label." Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1673 (2019).

[2] Although not clearly asserted in the complaint, plaintiff suggests in the complaint that defendant fraudulently concealed negative effects or failed to warn of negative effects based upon newly acquired information. However, plaintiff does not allege facts of any newly acquired data that defendant had or should have had after the medicine's approval, in order to overcome preemption. Wyeth v. Levine, 555 U.S. 555, 569 (2009).

In sum, plaintiff's action for inadequate warning is preempted by the FDCA and must be dismissed on this ground.

b. Insufficient Allegations

In addition, and in the alternative, plaintiff fails to plead a claim of negligence based upon failure to warn. "In North Carolina, a failure to warn claim requires the plaintiff to prove that the defendant unreasonably failed to provide an adequate warning, such failure was the proximate cause of the plaintiff's damages, and the product 'posed a substantial risk of harm' without an adequate warning either at the time of or after leaving the manufacturer's control." Carlson v. Bos. Sci. Corp., 856 F.3d 320, 324 (4th Cir. 2017) (quoting N.C. Gen. Stat. § 99-B-5(a)). "Proof of proximate cause requires evidence that [plaintiff or his] treating physician relied on" the product label when prescribing the medication. Id.

With respect to a duty to warn, "a manufacturer or seller of a product, which to his actual or constructive knowledge involves danger to users has a duty to give warning of such dangers." Stegall, 260 N.C. at 464. Liability arises for a supplier of a product, "if the supplier (a) knows, or from facts known to him should realize, that the chattel is or is likely to be dangerous for the use for which it is supplied; (b) and has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition; and (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be so." Id. (quoting Restatement, Torts, § 388)).

Under North Carolina law, "state-of-the-art evidence helps shape the duty owed by the alleged tortfeasor." Horne v. Owens-Corning Fiberglas Corp., 4 F.3d 276, 280 (4th Cir. 1993). "State of the art represents all of the available knowledge on a subject at a given time, and this includes scientific, medical, engineering, and any other knowledge that may be available." Id.

"State of the art includes the element of time: What is known and when was this knowledge available." Id. at 281.

Here, plaintiff has not pleaded facts giving rise to a plausible inference of the elements of a failure to warn claim. Plaintiff has not alleged that defendant knew or should have known of dangers not included in its warning label. In addition, plaintiff has not alleged that the warning label played any role in the decision of plaintiff's physician to prescribe Lyrica or plaintiff's decision to take it, or that a different label plausibly would have changed that decision.[3]

Therefore, plaintiff's claims based upon failure to warn must be dismissed for failure to state a claim upon which relief can be granted. Where plaintiff's claims also are preempted and plaintiff has not suggested that amendment of the pleadings will cure the defects asserted by defendant, the court in its discretion dismisses plaintiff's claims with prejudice.

D. Motion for Sanctions

Plaintiff seeks sanctions against defendant on the ground that its motion and arguments asserted therein do not meet the minimal standard for reasonable representation under Federal Rule of Civil Procedure 11(b). However, where the court has determined herein that defendant's arguments have merit, plaintiff's motion for sanctions necessarily must be denied.

CONCLUSION

Based on the foregoing, plaintiff's motion to amend (DE 14) is construed as including a motion to remand. That part of the motion to amend seeking to change the amount of damages sought in this action is GRANTED on the terms set forth herein. That part seeking remand is DENIED. Defendant's motion to dismiss (DE 4) is GRANTED. Plaintiff's action is DISMISSED

[3] Similarly, to the extent asserted in the complaint, plaintiff has not alleged facts to support a claim of fraudulent concealment. See Bakery & Confectionary Union & Indus. Int'l Pension Fund v. Just Born II, Inc., 888 F.3d 696, 700 (4th Cir. 2018).

WITH PREJUDICE. Plaintiff's motion for sanctions (DE 22) is DENIED. The clerk is DIRECTED to close this case.

SO ORDERED, this the 9th day of April, 2020.

LOUISE W. FLANAGAN
United States District Judge