UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

RAMON D. JOHNSON, II,	§	
Plaintiffs,	§	
	§	
v.	§	
	§	**Civil Action No. 5:19-cv-01087-OLG**
NOVARTIS PHARMACEUTICALS CORPORATION; TARO PHARMACEUTICALS USA, INC.; BAUSCH HEALTH US, LLC; SUN PHARMACEUTICAL INDUSTRIES LTD.; and TORRENT PHARMA, INC.,	§	
Defendants.	§	

ORDER

On this day, the Court considered the status of the above-captioned case. Currently pending before the Court are Defendants Sun Pharmaceutical Industries and Tara Pharmaceuticals USA's Motion to Dismiss (docket no. 8); Defendant Novartis Pharmaceuticals Corporation's Motion to Dismiss (docket no. 9); Defendant Torrent Pharma, Inc.'s Motion to Dismiss (docket no. 12); and Defendant Bausch Health US, LLC's Motion to Dismiss (docket no. 23). Also pending are Plaintiff's Motion for Leave to File a Combined Rebuttal to Defendants' Replies in Support of their Motions to Dismiss (docket no. 44) and Plaintiff's Motion for Leave to File a First Amended Complaint for a Civil Case and To Edit the Style of the Case (docket no. 47). Having considered each of these Motions and the record, the Court finds that Defendants' Motions to Dismiss should be GRANTED.

BACKGROUND

On September 10, 2019, Plaintiff Ramon D. Johnson II ("Plaintiff") initiated this lawsuit alleging that he suffered personal injuries resulting from his use of two drugs: Minocycline and Carbamazepine. *See* docket no. 1. Specifically, Plaintiff alleges that he was prescribed

Minocycline in April 2013 for an unrelated condition. *Id.* at p. 7. About one year later, Plaintiff noticed his first symptoms of Peyronie's Disease ("PD"). *Id.* In October of 2014, after seeing specialists for his PD, Plaintiff alleges that he stopped taking the Minocycline due to its waning effectiveness when he noticed that the pain and symptoms of PD went away. *Id.* That same month, Plaintiff restarted Minocycline and his PD symptoms "returned very quickly." *Id.* Plaintiff again stopped taking the Minocycline, and again his symptoms subsided. *Id.* On October 30, 2014, Plaintiff told his doctor that he suspected the drug was causing his PD, but the doctor told him "unequivocally" that the drugs do not cause the condition. *Id.* Another doctor told him the same thing in November 2014. *Id.*

On or about June 15, 2017, Plaintiff began taking Carbamazepine for the treatment of another unrelated condition. *Id.* On September 10, 2017, Plaintiff noticed new PD symptoms, and, the next day, he notified the prescribing doctor of his theory on the link between the drugs and PD. *Id.* at p. 8. As with Minocycline, each doctor he spoke to refuted that there was any known link between Carbamazepine and PD. *Id.* Plaintiff then ceased taking Carbamazepine and the PD pain "shortly went away." *Id.* On August 19, 2019, Plaintiff further researched his suspicion that both drugs are linked to PD, discovering articles that he alleges may indicate that his doctors were incorrect when they rejected the link. *Id.* Plaintiff notes that neither drug warned that PD could be a side effect. *Id.*

As a result, Plaintiff states five causes of action: strict liability, negligent manufacturing, negligent failure to warn/fraudulent misrepresentation, breach of express and/or implied warranty, and loss of consortium. *See id.* at pp. 6-7. Though Plaintiff's complaint asserts these causes of action generally against all Defendants, his response to the pending motions to dismiss clarifies the relationship between each Defendant and the allegedly harmful drugs. *Compare*

docket no. 1 *with* docket no. 39. Plaintiff states that the Minocycline capsule was manufactured by Ranbaxy, which was then acquired by Defendant Sun Pharmaceuticals and "spun off" to Defendant Torrent. Docket no. 39 at ¶ 1. Plaintiff further alleges that Minocycline's "label information" was copied from Defendant Bausch's label for its brand name drug Minocin. *Id.* With respect to the alleged injuries caused by Carbamazepine, Plaintiff states that the tablet was manufactured by Defendant Taro, with "label information from Novartis for their brand name drug Tegretol." *Id.*

Shortly after service of process, each Defendant moved to dismiss the claims based on various arguments. First, Novartis moved to dismiss Plaintiff's claims, asserting that it never manufactured the generic carbamazepine that Plaintiff ingested. *See* docket no. 9. Indeed, Novartis only manufactures the brand name version of carbamazepine—Tegretol. *Id.* Because Plaintiff did not ingest Tegretol, his claims against Novartis appear to be based on the company's design of its warning labels for Tegretol, which the generic carbamazepine copies. *Id.* However, Novartis argues that this theory of liability is known as "innovator liability" and has been widely rejected, including in Texas. *Id.* Moreover, Novartis moves to dismiss pursuant to 12(b)(2) for lack of personal jurisdiction, as it is a New Jersey citizen that made its marketing and labeling decisions in New Jersey. *Id.* Finally, Novartis argues that Plaintiff's fraud-based claims fail to meet Rule 9(b)'s heightened pleading standard. *Id.*

Similarly, Bausch moves to dismiss on the grounds that Plaintiff admits in his complaint that he did not ingest Bausch's product—the brand name drug Minocin. *See* docket no. 23. Instead, Plaintiff alleges that he took the generic Minocycline, meaning that his warning defect claims would again have to be based on "innovator liability." *Id.* Bausch also argues that Plaintiff's claims are time-barred, as Plaintiff's PD allegedly caused by Minocycline first

occurred in April 2014, and he admits in his complaint that he questioned his doctors on the link between the drug and PD in October 2014. Accordingly, the statute of limitations for his claims has passed. *Id.* Bausch also argues that Plaintiff's fraud-based claims fail under Rule 9(b), and that this Court does not have personal jurisdiction over it. Finally, Bausch argues that Plaintiff's state law claims are barred by the presumption of no liability for drug manufacturers after the FDA approves their labels. *Id.*

Sun and Taro filed a joint motion to dismiss presenting similar arguments. Though they manufactured the generic drugs that Plaintiff ingested, Sun and Taro argue that Plaintiff does not meet any of the exceptions to Texas's presumption that drug manufacturers are not liable for labels approved by the FDA. *See* docket no. 8. Finally, Sun and Taro argue that because their medications are generic, Plaintiff's state law claims are preempted by federal law's requirement that their labels conform with the brand name versions of their drugs. *Id.* Accordingly, they seek to dismiss Plaintiff's claims with prejudice.

Finally, Torrent moves to dismiss Plaintiff's claims against it, asserting much of the same arguments as the other defendants. First, Torrent points out that Plaintiff has not alleged that he took any drug that it manufactured. *See* docket no. 12. Second, Torrent cites the Texas presumption that it is not liable for claims related to warning labels approved by the FDA. *Id.* Third, because Torrent's Minocycline and Carbamazepine products are generic drug products, any state law claims are preempted by federal law. *Id.*

Plaintiff then filed an omnibus response to these motions. *See* docket no. 39. Each of the Defendants replied, and then Plaintiff filed a motion to permit a sur-reply. *See* docket no. 44.[1]

[1] The Court takes into consideration Plaintiff's sur-reply, noting the liberal standard courts must apply to pro se litigants' pleadings. *See Castro v. SN Servicing Corp.*, 2015 WL 11621152 (W.D. Tex. Sept. 2, 2015).

Finally, Plaintiff moves for leave to amend his complaint, attaching the proposed amended complaint. *See* docket no. 47. Each Defendant filed a response in opposition to the amended complaint. Though Plaintiff adds factual allegations to his claims, he asserts the same causes of action except for substituting Deceptive Trade Practices Act and Common Law Negligence claims for his loss of consortium claim. *Compare* docket no. 47-1 *with* docket no. 1. The crux of his allegations remains the same, however, as he still maintains that he ingested the generic drugs and that the Defendants are liable for their failure to warn him of the side effects. The Court turns to these Motions now.

ANALYSIS

Federal Rule of Civil Procedure 8(a) requires a complaint set forth "a short and plain statement of the claim showing that the pleader is entitled to relief[,]" and Federal Rule of Civil Procedure 12(b)(6) states that a complaint may be dismissed for failing to "state a claim upon which relief can be granted." In evaluating a motion to dismiss, the Court must determine if the complaint alleges "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). To be "plausible on its face," the complaint must contain allegations for each material element "necessary to sustain recovery under some viable legal theory." *Id.* at 562. The Court assumes the complaint's factual allegations, but not its legal conclusions, are true. *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 680-81 (2009). The complaint is dismissed if it fails to state enough facts to allow the Court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678.

With the pleading standard in mind, the Court finds merit in each of the arguments put forth by Defendants. As an initial matter, the Court acknowledges Plaintiff asserts multiple causes of action. However, each of these causes of action centers around a products liability

claim based on Defendants' alleged failure to warn. The Court will therefore treat Plaintiff's causes of action as a failure to warn claim. *See Lashley v. Pfizer, Inc.*, 750 F.3d 470, 474 (5th Cir. 2014) (construing negligence, fraud, and deceptive trade practices act claims as failure to warn, given that the allegations supporting each cause of action related specifically to the label's alleged failures); *see also* docket nos. 1 and 47-1.

1. *Innovator Liability – Brand Name Manufacturers*

The two "brand name" Defendants—Bausch and Novartis—each move to dismiss Plaintiff's claims as relying on innovator liability: or claims against a brand name manufacturer for injuries caused by a generic drug. *See, e.g.*, docket no. 23 at p. 7. Underlying this argument is the fact that both Plaintiff's original and proposed amended complaint fail to allege that he ever ingested Minocin or Tegretol, the two brand name drugs manufactured by Bausch and Novartis. Instead, his claims against Bausch and Novartis rely on the other Defendants' generic drugs copying the information from the brand name labels. *See* docket no. 1.

Texas law rejects this theory of liability. Indeed, products liability law generally requires allegations that the defendant supplied the allegedly defective product to the plaintiff. *See Hicks v. Charles Pfizer & Co. Inc.*, 466 F. Supp. 2d 799, 803 (E.D. Tex. 2005) (quoting *Gaulding v. Celotex Corp.*, 772 S.W.2d 66, 68 (Tex. 1989)). Moreover, a recent Fifth Circuit case addressed a very similar procedural posture. In *Eckhardt*, a plaintiff sued both generic and brand name manufacturers, even though he only ingested the generic drug. *See Eckhardt v. Qualitest Pharmaceuticals, Inc.*, 751 F.3d 674 (5th Cir. 2014). The Fifth Circuit upheld the district court's dismissal of the plaintiff's negligence, products liability, and fraud claims against the brand name manufacturers, noting that brand name manufacturers do not owe a duty to consumers of generic drugs. *See id.*; *see also Lashley*, 750 F.3d at 477 ("Del Valle admits that she did not

ingest the Schwartz brand defendants' product; thus, we find that Schwartz brand defendants are not liable under Texas products liability law."). Accordingly, because Plaintiff's original and amended complaint admits that he did not ingest Bausch or Novartis's products, his claims against them must be dismissed.

Defendant Bausch and Defendant Novartis's Motions to Dismiss are therefore GRANTED.

2. *Federal Preemption and FDA Approval – Generic Manufacturers*

All Defendants, including the generic drug manufacturers, assert two arguments based on the FDA's approval of their labels. First, Defendants point to Texas law's presumption of no liability for FDA-approved labels. *See, e.g.*, docket no. 8 at p. 14. Indeed, Texas Civil Practice & Remedies Code Section 82.007(a)(1) provides that FDA approval "presumptively insulates from liability, for failure to warn, defendants who made, prescribe, or sell drugs in accord with FDA standards." *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 279 (5th Cir. 2012). Texas law provides five ways this presumption of no liability can be rebutted: (1) "fraud on the FDA"; (2) the product was sold after the FDA ordered the product removed from the market; (3) if the manufacturer promoted the product for a use not approved by the FDA; (4) off-label prescriptions; and (5) bribery of a public official. *See* Tex. Civ. Prac. & Rem. Code § 82.007(b)(1)-(5).

Of these exceptions, Plaintiff principally pleads the "Fraud on the FDA" exception. *See* docket no. 39 at p. 10. Specifically, Plaintiff alleges that Defendants withheld from the FDA information related to the connection between the drugs and PD. *See id.* However, as each Defendant points out, the "Fraud on the FDA" exception is preempted by federal law unless the FDA has found fraud. *See Lofton*, 672 F.3d at 380 ("In cases like this, where the FDA has not

found fraud, the threat of imposing state liability on a drug manufacturer for defrauding the FDA intrudes on the competency of the FDA and its relationship with regulated industries."). Because Plaintiff does not allege that the FDA has found fraud on behalf of Defendants' related to these drugs, this exception is preempted and cannot provide the basis for liability.

Plaintiff also contends that Section 82.007(b)(3) applies, or that Defendants "recommended, promoted or advertised" these drugs "for an indication not approved by the [FDA]." However, pleading this exception requires alleging that (a) Defendants marketed and promoted the unauthorized use of the drugs to the prescribing doctors, that (b) Plaintiff relied on that specifically promoted use, and that (c) Plaintiff's injuries were caused by that off-label promotion. *See Lucas v. Abbott Laboratories*, 2013 WL 2905488, at *3 (N.D. Tex. June 13, 2013). Plaintiff fails to allege any facts related to Minocycline's "off-label" marketing. *See* docket nos. 1 & 39. Nor does he allege any facts related to Defendants Sun Pharmaceuticals or Taro's marketing of Carbamazepine for off-label uses, or, that his use of the drug was off-label. The Court therefore finds that Plaintiff has not alleged any facts rebutting Texas law's presumption of no liability resulting from FDA approval.

Alternatively, Plaintiff's state law claims against the generic manufacturers are preempted by federal law. This preemption argument relies on the Supreme Court's decision in *Mensing*, which held that federal law preempted state law causes of action related to a generic drug manufacturers failure to warn. *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) (finding it impossible for generic manufacturers to abide by state warning laws while also abiding by federal law mandating that they match brand name labels). Subsequently, the Supreme Court in *Bartlett* found design defect claims that were based on a generic manufacturer's failure to provide adequate warnings were also preempted under the same theory. *See Mutual*

Pharmaceutical Co., Inc. v. Bartlett, 570 U.S. 472, 480 (2013). The Fifth Circuit recently interpreted *Mensing* and *Bartlett* as preempting Texas law claims such as those Plaintiff asserts here. *See Lashley*, 750 F.3d at 473-76. In *Lashley*, the Fifth Circuit held that failure to warn and other design defect claims relating to a generic drug manufacturer's warning labels were preempted under federal law. *Id.* Thus, since Plaintiff's claims against the generic manufacturer Defendants are all based off their alleged failure to warn of the risk of PD, these claims are preempted.

In sum, Plaintiff's claims against the generic manufacturers fail because they do not rebut Texas law's presumption of no liability for drugs approved by the FDA. Moreover, and alternatively, Plaintiff's claims are preempted by federal law under Supreme Court and Fifth Circuit Precedent. Accordingly, Defendants Sun Pharmaceuticals, Taro, and Torrent's Motions to Dismiss are GRANTED.

3. Leave to Amend

Finally, Plaintiff moves for leave to amend his complaint. *See* docket no. 47. He attaches the proposed amended complaint to the motion. *See* docket no. 47-1. Federal Rule of Civil Procedure 15(a) governs amending pleadings, stating that Courts "should freely give leave when justice so requires." Generally, the rule "evinces a bias in favor of granting leave to amend," *Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 863 (5th Cir. 2003), and absent a significant reason, "such as undue delay, bad faith, dilatory motive, or undue prejudice to the opposing party, 'the discretion of the district court is not broad enough to permit denial.'" *Martin's Herend Imports, Inc. v. Diamond & Gem Trading United States of Am. Co.*, 195 F.3d 765, 770 (5th Cir. 1999) (quoting *Dussouy v. Gulf Coast Inv. Corp.*, 660 F.2d 594, 598 (5th Cir. 1981)).

As noted above, Plaintiff's claims fail against the brand name manufacturers Bausch and Novartis primarily because he does not allege that he ingested their drugs. Plaintiff's proposed amended complaint does not change this determination. Instead, he reiterates that he only ingested the generic drugs, and thus his amendment would be futile as to both Bausch and Novartis for the same reasons. *See Wells v. Wyeth Pharm., Inc.*, 233 F. Supp. 3d 534, 540 (W.D. Tex. 2017 (dismissing claims with prejudice and denying leave to amend complaint against brand name manufacturer in case where plaintiff did not ingest the brand name drugs). With respect to the generic manufacturers, as noted above, these claims are preempted by federal law. Even still, Plaintiff's amended complaint still fails to rebut Texas law's presumption of no liability for drugs approved by the FDA. Indeed, other district courts within the Fifth Circuit have dismissed these same claims with prejudice based on preemption. *See, e.g., Elmazouni v. Mylan, Inc.*, 220 F. Supp. 3d 736, 747 (N.D. Tex. 2016). Accordingly, the Court finds that permitting amendment would be futile and unduly prejudicial to Defendants. Plaintiffs motion for leave to amend is therefore denied. These claims are dismissed with prejudice.

CONCLUSION

IT IS THEREFORE ORDERED that Sun Defendants' Motion to Dismiss for Failure to State a Claim (docket no. 8); Defendant Novartis Pharmaceuticals Corporation's Motion to Dismiss (docket no. 9); Defendant Torrent Pharma, Inc.'s Motion to Dismiss (docket no. 12); and Defendant Bausch Health US, LLC's Motion to Dismiss Plaintiff's Complaint (docket no. 23) are **GRANTED**.

IT IS FURTHER ORDERED that Plaintiff's Motion for Leave to File a Combined Rebuttal to Defendants' Replies in Support of their Motions to Dismiss (docket no. 44) is

GRANTED. Sun Defendants' Original Motion to Dismiss (docket no. 7) is **DISMISSED AS MOOT**.

IT IS FURTHER ORDERED that Plaintiff's Motion for Leave to File Amended Complaint (docket no. 47) is **DENIED**. These claims are **DISMISSED WITH PREJUDICE**.

It is so **ORDERED**.

SIGNED this 7th day of May, 2020.

ORLANDO L. GARCIA
CHIEF UNITED STATES DISTRICT JUDGE