UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF MISSISSIPPI
JACKSON DIVISION

JOHN DEESE PLAINTIFF

V. CIVIL ACTION NO: 3:11-CV-373-DPJ-FKB

IMMUNEX CORPORATION;
AMGEN, INC.; PFIZER, INC.;
AND JOHN DOES 1–3 DEFENDANTS

ORDER

This products-liability case is before the Court on the Motion [5] of Defendants Immunex Corporation, Amgen Inc., and Pfizer Inc. ("Defendants") to dismiss the Complaint [1] filed in this action. Plaintiff John Deese opposes the motion [7]. For the reasons stated below, the Court finds that Plaintiff's Complaint fails to state a claim but that he should be allowed leave to amend as to the failure-to-warn claims.

I. Facts and Procedural History

In 2001, Deese was prescribed and began taking the drug Enbrel for treatment of rheumatoid arthritis.[1] Deese continued taking Enbrel until roughly early 2007. Two years after ceasing his Enbrel therapy, Deese began to suffer from weakness, shortness of breath, and other symptoms. In August 2009, Deese was diagnosed with high-grade lymphoma in his heart, necessitating surgery and other treatment, including chemotherapy. The malignancy went into remission, though Deese continues to suffer from decreased cardiac function.

In June 2011, Deese brought the instant lawsuit against Immunex Corporation, which, according to Deese, manufactures Enbrel. He also sued Amgen, Inc. and Pfizer, Inc. as Enbrel's

[1]The facts included herein are taken from the Complaint [1].

marketers during all or part of the time he took the drug.[2] Deese alleges negligence, breach of warranty, and products-liability claims—including design defect, manufacturing defect, and failure to warn. Defendants seek dismissal of the Complaint pursuant to Rule 12(b)(6), which Deese opposes. Deese alternatively requests that the Court hold Defendants' motion in abeyance to allow the parties to seek discovery, or grant him leave to amend the Complaint. Pl.'s Resp. [7] at 4. The Court has personal and subject matter jurisdiction and is prepared to rule.

II. Standard of Review

In considering a motion under Rule 12(b)(6), the "court accepts 'all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff.'" *Martin K. Eby Constr. Co. v. Dallas Area Rapid Transit*, 369 F.3d 464, 467 (5th Cir. 2004) (quoting *Jones v. Greninger*, 188 F.3d 322, 324 (5th Cir. 1999)). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). To overcome a Rule 12(b)(6) motion, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. That "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 129 S.Ct. at 1949. "Factual 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 (citations and footnote omitted). "A claim has

[2]Pfizer contends it is not a proper party to this lawsuit because Deese's alleged use of Enbrel pre-dates Pfizer's acquisition of Wyeth in October 2009. Def.'s Mem. [6] at 3 n.3.

facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 129 S.Ct. at 1949. It follows that "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id*. at 1950 (quoting Fed. R. Civ. P. 8(a)(2)).

The Supreme Court's recent examination of the issue in *Iqbal* provides a framework for examining the sufficiency of a complaint. First, the district court may "begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." *Id*. Second, "[w]hen there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id*.

Finally, "a plaintiff's failure to meet the specific pleading requirements should not automatically or inflexibility result in dismissal of the complaint with prejudice to re-filing." *Hart v. Bayer Corp*., 199 F.3d 239, 248 n.6 (5th Cir. 2000) (citation omitted). Thus, "[a]lthough a court may dismiss the claim, it should not do so without granting leave to amend, unless the defect is simply incurable or the plaintiff has failed to plead with particularity after being afforded repeated opportunities to do so." *Id*. On the other hand, the Fifth Circuit has often observed that a "bare request [to amend] in an opposition to a motion to dismiss—without any indication of the particular grounds on which the amendment is sought—does not constitute a motion within the contemplation of Rule 15(a)." *Parham v. Clinton*, 374 F. App'x 503, 505–06 (5th Cir. 2010) (citations omitted, punctuation edited) (affirming dismissal without leave to amend).

III. Analysis

A. Mississippi Products Liability Act Claims

1. Design or Manufacturing Defect

Defendants seek dismissal of Deese's design and manufacturing defect claims, arguing Deese fails to allege any facts supporting these claims. The Mississippi Products Liability Act ("MPLA") provides a remedy if, when a product left the manufacturer or seller:

> (I) 1. The product was defective because it deviated in a material way from the manufacturer's specifications or from otherwise identical units manufactured to the same manufacturing specifications, or
>
> . . .
>
> 3. The product was designed in a defective manner . . . .

Miss. Code Ann. § 11-1-63(a)(i)(1), (3). A plaintiff must also prove: "(ii) The defective condition rendered the product unreasonably dangerous to the user or consumer; and (iii) The defective and unreasonably dangerous condition of the product proximately caused the damages for which recovery is sought." *Id.* § 11-1-63(a)(ii)–(iii). For a defective design claim under (a)(i)(3), the plaintiff must further prove that, at the time the product left the control of the manufacturer or seller:

> (i) The manufacturer or seller knew, or in light of reasonably available knowledge or in the exercise of reasonable care should have known, about the danger that caused the damage for which recovery is sought; and
>
> (ii) The product failed to function as expected and there existed a feasible design alternative that would have to a reasonable probability prevented the harm. A feasible design alternative is a design that would have to a reasonable probability prevented the harm without impairing the utility, usefulness, practicality or desirability of the product to users or consumers.

Id. § 11-1-63(f).

Deese claims that Defendants "designed and manufactured" and "marketed and distributed, an unreasonably dangerous pharmaceutical product," that was "unsafe and harmful to Plaintiff." Compl. [1] ¶ 17. "As a direct and proximate result of Defendants' wrongful design, manufacture and distribution of this unreasonably dangerous pharmaceutical product," Deese allegedly suffered serious injuries. *Id.* ¶ 18. Deese fails to offer any factual support for these conclusory allegations, however. *Iqbal*, 129 S.Ct. at 1949 ("A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do." (citing *Twombly*, 550 U.S. at 555)). Additionally, Deese fails to allege how Enbrel "deviated in a material way" from manufacturer's specifications or from other units, as required to show a manufacturing defect claim under the MPLA. Miss. Code Ann. § 11-1-63(a)(i)(1); *see also Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011). Neither does Deese allege what was defective about Enbrel's design, that Defendants knew or should have known about the danger, or that there was a feasible design alternative—all required to show a design defect claim. Miss. Code Ann. § 11-1-63(f).

In his Response, Deese makes a passing reference to manufacturing or design defects, but he otherwise fails to address the manufacturing and design defect claims. Instead, he essentially accepts Defendants' assessment that this is a "failure-to-warn" case, and because Deese offers no indication of the particular grounds supporting a manufacturing or design defect claim in an amended complaint, those claims are dismissed with prejudice.

2. Failure to Warn

Defendants seek dismissal of Deese's failure-to-warn claims, as well. Under the MPLA, a manufacturer or seller is liable if "[t]he product was defective because it failed to contain

adequate warnings or instructions." Miss. Code Ann. § 11-1-63(a)(i)(2). The plaintiff must prove that, at the time the product left the control of the manufacturer or seller, "the manufacturer or seller knew or in light of reasonably available knowledge should have known about the danger that caused the damage for which recovery is sought and that the ordinary user or consumer would not realize its dangerous condition." *Id.* § 11-1-63(c)(i). A warning is "adequate" if it:

> is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product; or in the case of a prescription drug, medical device or other product that is intended to be used only under the supervision of a physician or other licensed professional person, taking into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug, device or other product.

Id. § 11-1-63(c)(ii). Plaintiff must also prove that the failure to warn "rendered the product unreasonably dangerous to the user or consumer" and that "[t]he defective and unreasonably dangerous condition of the product proximately caused the damages for which recovery is sought." *Id.* § 11-1-63(a)(ii)–(iii); *see also Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 811 (5th Cir. 1992) (finding under Mississippi law, "a product may be unreasonably dangerous if the manufacturer fails to warn of a non-obvious risk associated with the normal use of the product" (citing *Wyeth Labs., Inc. v. Fortenberry*, 530 So. 2d 688, 691–92 (Miss. 1988)).

When the product is a prescription drug, Mississippi follows the "learned intermediary doctrine" which holds that "the manufacturer's failure to warn the patient of the product's risks does not render the product defective or unreasonably dangerous so long as the manufacturer adequately warns the learned intermediary." *Janssen Pharm., Inc. v. Bailey*, 878 So. 2d 31, 58

(Miss. 2004) (citing *Thomas*, 949 F.2d at 811)). Under this doctrine, "[a] drug manufacturer has a duty to adequately warn the prescribing physician of any known adverse effects which might result from use of its prescription drugs," but the "duty to warn only extends to physicians and not to laymen." *See Wyeth*, 530 So. 2d at 691 (citation and quotation marks omitted)).

Deese alleges that Defendants "failed to timely and adequately warn not only Deese of the potential for Enbrel to cause such malignancies [such as Deese's high-grade B-cell lymphoma] during his therapy period, but likewise failed to apprise Plaintiff's treating physicians of the same so that they could, in combination, make an informed decision as to the relative safety and/or efficacy of such Enbrel therapy." Compl. [1] ¶ 17. "As a direct and proximate result of Defendants'. . . collective failure to properly warn of the [unreasonably dangerous pharmaceutical product]," Deese suffered serious injuries. *Id.* ¶ 18.[3]

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[3]Defendants attach to their Motion Enbrel package inserts containing the drug's "warnings." *See* Defs.' Mot. [5] Exs. A & B. Deese fails to dispute the package inserts' authenticity, and because the warnings are referenced in the Complaint and Deese's failure-to-warn claim is based upon the adequacy of those warnings, the Court may consider the package inserts without converting the motion to dismiss to a motion for summary judgment. *Causey v. Sewell Cadillac-Chevrolet, Inc.*, 394 F.3d 285, 288 (5th Cir. 2004) (citation omitted); *Hayne v. Innocence Project*, No. 3:09–CV–218–KS–LRA, 2011 WL 198128, at *1–2 (S.D. Miss. Jan. 20, 2011). The 2001 Package Insert states, in the "Adverse Reactions" section:

> Malignancies: Seventeen malignancies of various types were observed in 1197 RA patients treated in clinical trials with ENBREL for up to 36 months. The observed rates and incidences were similar to those expected for the population studied.

Defs.' Mot. [5] Ex. A at 16.

The 2003 Package Insert added the following to the "Warnings" section:

> Malignancies: In the controlled portions of clinical trials of all the TNF-blocking agents, more cases of lymphoma had been observed among patients receiving the TNF blocker compared to control patients. During the controlled portions of ENBREL trials, 1 lymphoma was observed among

As a preliminary matter, the Court finds that, under Mississippi's learned intermediary doctrine, the relevant question is whether Defendants adequately warned Deese's prescribing physician of the adverse effects of Enbrel, not whether Deese himself was adequately warned.[4] *See Wyeth*, 530 So. 2d at 691; *see also* Miss. Code Ann. § 11-1-63(c)(ii) (in the case of a prescription drug "[a]n adequate product warning . . . is one that a reasonably prudent person in

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> 2502 ENBREL-treated patients versus 0 among 921 control patients (mean duration of controlled treatment approximately 6 months). In the controlled and open-label portions of clinical trials of ENBREL in rheumatoid arthritis patients, 6 lymphomas were observed in 3389 patients over approximately 8000 patient-years of therapy. This is 2-fold higher than that expected in the general population. While patients with rheumatoid arthritis, particularly those with highly active disease, may be at a higher risk (up to several fold) for the development of lymphoma, the potential role of TNF-blocking therapy in the development of malignancies is not known (see ADVERSE REACTIONS: Malignancies).

Defs.' Mot. [5] Ex. B at 15.

Then, in the "Adverse Reactions" section, the 2003 insert notes:

> Malignancies: Among 3389 rheumatoid arthritis patients treated with ENBREL in clinical trials for a mean of 28 months (approximately 8000 patient-years of therapy), 6 lymphomas were observed for a rate of 0.07 cases per 100 patient-years. This is 2-fold higher than the rate of lymphomas expected in the general population based on the Surveillance, Epidemiology, and End Results Database. An increased rate of lymphoma up to several fold has been reported in the rheumatoid arthritis patient population, and may be further increased in patients with more severe disease activity (see WARNINGS: Malignancies). Fifty-five malignancies, other than lymphoma, were observed. Of these, the most common malignancies were colon, breast, lung and prostate, which were similar in type and number to what would be expected in the general population. Analysis of the cancer rates at 6 month intervals suggest constant rates over three years of observation.

Id. at 19–20.

[4]Deese challenges the applicability of the learned intermediary doctrine by arguing that the warnings were insufficient, but that is a matter for another day. Pl.'s Resp. [8] at 3, 8.

the same or similar circumstances would have provided . . . taking into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug, device or other product"). But because Deese includes allegations that Defendants failed to warn his physician as well as himself, the learned intermediary doctrine does not dictate complete dismissal of Deese's failure-to-warn claims at this stage.

As for the alleged inadequacies, Deese offered the following averments:

> [T]here was no Black Box Warning alerting either [Deese] or his prescribing physicians during the period of 2001 to 2007 of the serious and significant dangers potentially visited upon him by Enbrel in the form of lymphoma. Any references to cancer or other malignancies were either deemed statistically insignificant and/or largely non-existent in adult users of this medication.

Compl. [1] ¶ 11 (incorporated by reference into product liability claim at ¶ 15). These contentions address the nature and location of the "warnings" and how Deese believes they were inadequate. The Court finds that they are minimally sufficient to place Defendants on notice of the alleged inadequacies.

That said, the claim is not completely stated. For example, Deese alleges that the failure to warn prevented Deese and his physician from "mak[ing] an informed decision as to the relative safety and/or efficacy of such Enbrel therapy," but he falls short of alleging that an adequate warning would have kept his physician from prescribing Enbrel. *See Janssen Pharm., Inc.*, 878 So. 2d at 58 ("The Plaintiffs bear the burden of establishing that [the drug] was the cause of their injuries and that 'an adequate warning would have convinced the treating physician not to prescribe the product for the [P]laintiff[s].'") (citation omitted). Thus, causation has not been sufficiently pleaded.

Although the failure-to-warn claims fall short in some respects, the Court concludes that Deese should be given the opportunity to amend his Complaint with respect to these claims. *See, e.g.*, *Hart,* 199 F.3d at 248 n.6.[5]

B. Negligence

First, Deese alleges Defendants are liable in negligence for breaching their duty "to design, adequately test, manufacture, market and/or distribute Enbrel as a prescription medication [for] the treatment of rheumatoid arthritis in a reasonably safe, prudent and responsible manner." Compl. [1] ¶ 13. To the extent Deese's negligence claim alleges a defective design or manufacturing defect when Enbrel left the manufacturer, his negligence claim fails for the same reasons the MPLA claims failed. *McSwain v. Sunrise Med., Inc.*, 689 F. Supp. 2d, 835, 846 (S.D. Miss. 2010) ("[T]he finding for the claims brought under the MPLA can be dispositive as to the product-based negligence claims such as negligent failure to warn and negligent design."); *see supra*. As for breach of a duty to adequately test, Deese generically mentions negligent testing in his Response but fails to offer any facts or arguments supporting such a claim.[6] Because Deese's negligence claims concerning breach of a duty "to design, adequately test, manufacture, market and/or distribute Enbrel" are not supported in the Complaint, nor defended in Deese's Response, the Court finds they should be dismissed with prejudice.

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[5]The Court's holding is limited to whether Deese's failure-to-warn claims were sufficiently pleaded. The Court makes no finding at this early stage concerning the adequacy of the warnings.

[6]Even if he did, it is unclear whether Mississippi law recognizes such a negligence claim separate and apart from the MPLA claims for negligent design or failure to warn. *McSwain*, 689 F. Supp. 2d at 847.

Second, Deese claims Defendants are liable in negligence for breaching their "duty to determine any dangerous and potentially life-threatening adverse consequences and thereafter warn both Deese and his treating physicians of the same so that an informed decision could be made by both patient and physician as to the efficacy and relative safety of such treatment." Compl. [1] ¶ 13. This claim tracks Deese's failure-to-warn claim under the MPLA, and should be treated the same. The claim is dismissed with leave to amend. *See supra*.

C. Breach of Warranties

Defendants seek dismissal of Deese's breach of express warranty claim. Though Deese fails to specify a common law or statutory basis for this claim, the MPLA recognizes a claim where a product:

> (i) . . . 4. breached an express warranty or failed to conform to other express factual representations upon which the claimant justifiably relied in electing to use the product; and
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> (ii) The defective condition rendered the product unreasonably dangerous to the user or consumer; and
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> (iii) The defective and unreasonably dangerous condition of the product proximately caused the damages for which recovery is sought.

Miss. Code Ann. § 11-1-63(a)(i)(4), (ii)–(iii). Deese alleges that "Defendants . . . through their advertising, marketing and product labeling, expressly warranted that Enbrel was reasonably safe for use as a prescription treatment for persons suffering from rheumatoid arthritis such as Deese," and that Defendants "breached these warranties . . . by providing him with a prescription medical product that was in fact more dangerous and detrimental to his overall health and well-being than the rheumatoid arthritis for which he consumed the medication." Compl. [1] ¶ 20. Deese's Complaint fails to identify, however, any express warranty or express factual representation made

by Defendants that they allegedly breached. Nor does Deese address his express warranty claim in his Response or challenge Defendants' assessment of that claim under the MPLA. Thus, Deese's express warranty claim does not allege enough facts to state a claim to relief that is plausible on its face and should be dismissed with prejudice. *Iqbal*, 129 S. Ct. at 1949; *Twombly*, 550 U.S. at 570.

Finally, Defendants seek dismissal of Deese's breach-of-implied-warranty claims. To show breach of an implied warranty of merchantability, a plaintiff must show a product was not "merchantable" as defined by statute:

> Goods to be merchantable must be at least such as:
> (a) Pass without objection in the trade under the contract description; and
> (b) In the case of fungible goods, are of fair average quality within the description; and
> (c) Are fit for the ordinary purposes for which such goods are used; and
> (d) Run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and
> (e) Are adequately contained, packaged and labeled as the agreement may require; and
> (f) Conform to the promises or affirmations of fact made on the container or label if any.

Miss. Code Ann. § 75-2-314(2). To properly state a claim of breach of an implied warranty of fitness for a particular purpose, "the plaintiff must prove that (1) the seller at the time of the contracting had reason to know the particular purpose for which the goods were required; (2) the reliance by the plaintiff as buyer upon the skill or judgment of the seller to select suitable goods, and (3) the goods were unfit for the particular purpose." *McSwain*, 689 F. Supp. 2d at 849 (citing

Watson Quality Ford, Inc. v. Casanova, 999 So. 2d 830, 835 (Miss. 2008)); *see* Miss. Code Ann. § 75-2-315.[7]

Here, Deese alleges:

> certain implied warranties under Mississippi law attended the sale, marketing and consumption of Enbrel as it pertains to Deese's use of the same for approximately 6 years between 2001 and 2007, including but not limited to, merchantability and fitness for a particular purpose. Plaintiff submits that the Defendants breached [these implied warranties] by providing him with a prescription medical product that was in fact more dangerous and detrimental to his overall health and well-being than the rheumatoid arthritis for which he consumed the medication.

Compl. [1] at ¶ 20. Defendants argue there is no factual support for this claim, and, to the extent it rehashes Deese's failure-to-warn claim under the MPLA, it suffers from the same defects that claim does. Defs.' Mem. [6] at 10–12. Deese fails to respond to Defendants' arguments, and the Court finds them well taken. Deese's breach-of-implied-warranty claims are therefore dismissed with prejudice.

D. Relief Sought in Plaintiff's Response

In his Response, Deese seeks alternative relief should the Court find his Complaint lacking. Deese first asks the Court to "hold Defendants' dispositive motion in abeyance for a reasonable period of time so as to allow the parties and their counsel to complete basic formal discovery." Pl.'s Resp. [7] ¶ 7. The request is denied. "Rule 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era, but it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Iqbal*, 129 S.Ct. at 1950.

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[7]Defendants concede that implied warranty claims are not abrogated by the MPLA. *See McSwain*, 689 F. Supp. 2d at 849 (citing *Bennett v. Madakasira*, 821 So. 2d 794, 808 (Miss. 2002)). But in his Response to the Defendants' motion, Deese fails to challenge Defendants' analysis of this claim under the Uniform Commercial Code, Mississippi Code Annotated Sections 75-2-314(2) & 75-2-315.

Deese next asks the Court to "grant him leave to amend the allegations" in the Complaint, "incorporating by reference the factual assertions and/or documentation set forth in [his] Response and the supporting Memorandum Brief." Pl.'s Resp. [7] ¶ 7.[8] As noted above, Deese will be permitted to amend his Complaint as to the failure-to-warn claims. The Court likewise finds that Deese may amend his Complaint to aver that Pfizer is Wyeth's corporate successor. *See* Pl.'s Resp. [7] Ex. H.

IV. Conclusion

For the foregoing reasons, the Court finds Defendants' Motion to Dismiss [5] should be granted. Plaintiff Deese's failure-to-warn claims under the MPLA and under a negligence theory are dismissed without prejudice. All other claims are dismissed with prejudice. Deese is granted leave to amend his failure-to-warn claims within 30 days of the entry of this Order. Failure to file an amended complaint or otherwise respond to this Order within that time will result in the entry of judgment in favor of Defendants.

SO ORDERED AND ADJUDGED this the 13th day of February, 2012.

s/ *Daniel P. Jordan III*
UNITED STATES DISTRICT JUDGE

[8]Deese failed to separately docket his Motion to Amend Complaint as required by Local Rule 7(b)(3)(C).