IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

NANCI MATTOS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 12-1014-JWL
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	
	)	
	)	

MEMORANDUM AND ORDER

This diversity action is presently before the Court on defendant's motion to dismiss (Doc. # 15). For the reasons set forth below, the motion is **granted in part and denied in part**. The motion is granted with respect to plaintiff's claims of negligence, negligence per se, breach of implied warranty, breach of express warranty, misrepresentation by omission, and fraudulent misrepresentation, and those claims are hereby dismissed. Plaintiff's strict liability claim is deemed asserted under the Kansas Product Liability Act (KPLA). The motion is also granted with respect to plaintiff's claim under the Kansas Consumer Protection Act (KCPA), although plaintiff is granted leave to amend that claim on or before **June 4, 2012**. The motion is denied with respect to plaintiff's claim under the KPLA.

I. Plaintiff's Complaint

Plaintiff alleges the following facts in her complaint: Defendant manufactures the prescription medication Cymbalta, which is indicated for various mental health disorders. In November 2009, plaintiff's physician prescribed Cymbalta for her anxiety, and plaintiff began taking the drug. Subsequently, as a result of her taking Cymbalta, plaintiff suffered an adverse skin reaction. Specifically, plaintiff was diagnosed with Stevens-Johnson Syndrome (SJS), and she developed a severe cutaneous adverse reaction (SCAR).

Plaintiff alleges that defendant knew or should have known in 2009 that Cymbalta presented a substantial risk of a patient's development of SCAR disorders, including SJS, which may result in severe injury or death. Plaintiff further alleges that defendant failed to include an adequate warning of that risk in Cymbalta's product insert or its Patient Medication Guide (PMG). Plaintiff also alleges that Cymbalta was defectively designed in light of that risk. Based on those allegations, plaintiff asserts the following causes of action: strict product liability; negligence; negligence per se, based on an alleged violations of federal and Kansas state laws and regulations; breach of implied warranty; breach of express warranty; misrepresentation by omission; fraudulent misrepresentation; and a violation of the KCPA, K.S.A. §§ 50-626, -627.

II. Standards for a Motion to Dismiss

Defendant seeks dismissal of most of plaintiff's claims for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6). The Court will dismiss a cause of action for failure to state a claim only when the factual allegations fail to "state a claim to relief that is plausible on its face," *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007), or when an issue of law is dispositive, *see Neitzke v. Williams*, 490 U.S. 319, 326 (1989). The complaint need not contain detailed factual allegations, but a plaintiff's obligation to provide the grounds of entitlement to relief requires more than labels and conclusions; a formulaic recitation of the elements of a cause of action will not do. *See Bell Atlantic*, 550 U.S. at 555. The Court must accept the facts alleged in the complaint as true, even if doubtful in fact, *see id.*, and view all reasonable inferences from those facts in favor of the plaintiff, *see Tal v. Hogan*, 453 F.3d 1244, 1252 (10th Cir. 2006). Viewed as such, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Bell Atlantic*, 550 U.S. at 555. The issue in resolving a motion such as this is "not whether [the] plaintiff will ultimately prevail, but whether the claimant is entitled to offer evidence to support the claims." *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 511 (2002) (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)).

III. Merger of Causes of Action

Defendant seeks dismissal of all claims other than a single claim under the KPLA on the basis that those other claims are all merged into a single product liability claim under the KPLA, K.S.A. § 60-3301 *et seq.*[1] Section 60-3302(c) defines the claim authorized by the KPLA as follows:

> "Product liability claim" includes any claim or action brought for harm caused by the manufacture, production, making, construction, fabrication, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging, storage or labeling of the relevant product. It includes, but is not limited to, any action based on[] strict liability in tort, negligence, breach of express or implied warranty, breach of, or failure to, discharge a duty to warn or instruct, whether negligent or innocent, misrepresentation, concealment or nondisclosure, whether negligent or innocent, or under any other substantive legal theory.

Id. § 60-3302(c). By virtue of this definition, the KPLA "consolidates all product liability actions, regardless of theory, into one basis for liability." *See David v. Hett*, 293 Kan. 679, 685 (2011) (citing *Patton v. Hutchinson Wil-Rich Mfg. Co.*, 253 Kan. 741, 756 (1993)). Thus, because they seek redress for harm caused by Cymbalta's design or warnings, plaintiff's strict liability, negligence, warranty, and misrepresentation claims (but not her claim under the KCPA) are merged into and subsumed by a single claim under the KPLA. *See Cooper v. Zimmer Holdings, Inc.*, 320 F. Supp. 2d 1154, 1163 (D.

[1]Plaintiff alleges that she is a Kansas resident, and the parties agree that plaintiff's claims are governed by Kansas law. *See Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941) (forum state's choice-of-law rules determine which state's substantive law applies); *Ling v. Jan's Liquors*, 237 Kan. 629, 634-35 (1985) (in Kansas, tort claims are governed by the law of the state in which the tort occurred, that is, where the wrong was felt).

Kan. 2004) (Lungstrum, J.) (stating reasons why KCPA claims should not merge into KPLA claims).

Plaintiff argues that her fraud claims also should not be merged into her KPLA claim. The statute's definition clearly encompasses claims based on misrepresentation or concealment, however, or on any "substantive legal theory." *See* K.S.A. § 60-3302(c). Plaintiff's misrepresentation claims are based on her same allegations that defendant failed to warn of risks associated with Cymbalta; accordingly, those claims are also subsumed by the KPLA claim.

Plaintiff also notes that she seeks damages for medical expenses and for lost wages, and she argues that she may seek to recover such "economic" damages under her alternative causes of action. For purposes of the above definition of a product liability claim, "harm" is defined as follows:

> "Harm" includes: (1) Damage to property; (2) personal physical injuries, illness and death; (3) mental anguish or emotional harm attendant to such personal physical injuries, illness or death. The term "harm" does not include direct or consequential economic loss.

Id. § 60-3302(d). Plaintiff argues that because a product liability claim under the KPLA cannot redress "economic loss," her claims for medical expenses and lost wages may proceed under other theories. *See, e.g., Gonzalez v. Pepsico, Inc.*, 489 F. Supp. 2d 1233, 1242-43 (D. Kan. 2007) (claims for economic damage caused by defective products are not foreclosed by the KPLA but may be brought under a different legal theory, for instance under the UCC).

The Court rejects this argument. Kansas courts have defined "economic loss" for purposes of this exception to the KPLA as follows:

> [E]conomic loss [under the KPLA] includes damages for inadequate value, costs of repair, replacement costs, and loss of use of the defective product. Generally economic loss is a result of the failure of the product to perform to the level expected by the buyer, which is the core concern of traditional contract law.

Northwest Ark. Masonry, Inc. v. Summit Specialty Prods., Inc., 29 Kan. App. 2d 735, 742 (2001) (citations omitted); *see also City of Winfield, Kan. v. Key Equip. & Supply Co.*, 2012 WL 1207256, at * 2 (D. Kan. Apr. 11, 2012) (citing *Northwest*'s definition of economic loss); *Gonzalez*, 489 F. Supp. 2d at 1242 (same). Plaintiff's claims for medical expenses and lost wages do not constitute damages to the defective product itself or consequential business damages caused by the product's defect that are typically within the province of contract or warranty law; rather, these damages, although pecuniary, are traditional tort remedies that relate to plaintiff's physical injury claim. Thus, all of plaintiff's damages are recoverable under the KPLA and do not provide a basis for any alternative cause of action. *Cf. Kestrel Holdings I, L.L.C. v. Learjet Inc.*, 316 F. Supp. 2d 1071, 1076 (D. Kan. 2004) (plaintiff's alleged damages could be recovered under claims outside the KPLA because they related to the defective product itself and did not relate to personal physical injuries).

Finally, plaintiff argues that her non-KPLA claims need not be dismissed because of their merger into a single KPLA claim. Plaintiff cannot recover under those alternative theories of liability, however; thus, there is no reason to allow such causes of

action asserted by plaintiff to continue as claims in this case. Accordingly, plaintiff's claims for negligence, negligence per se, breach of implied warranty, breach of express warranty, misrepresentation by omission, and fraudulent misrepresentation are hereby dismissed for failure to state a claim, and plaintiff's strict liability claim is deemed asserted under the KPLA. Only plaintiff's claims under the KPLA and the KCPA remain.

IV. KPLA Claim – Failure to Warn

Plaintiff asserts two bases for liability under the KPLA—a failure to warn and a design defect. The Court first addresses plaintiff's failure-to-warn claim.

In her complaint, plaintiff alleges that defendant failed to include an adequate warning concerning the risk of certain skin disorders in either Cymbalta's product insert or the Patient Medication Guide (PMG) for the drug. Defendant first seeks dismissal of any claim based on a failure to include a warning in the PMG, which was intended for the patient, not the prescribing physician. Defendant relies on the learned intermediary doctrine, which has been adopted in Kansas. *See Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 974 (10th Cir. 2001). "Under that rule, the manufacturer's duty to warn its customers is satisfied when the prescribing physician is made aware of the risks and dangers of the product, since the patient cannot obtain the medical product except through the physician." *Id.* (citing *Humes v. Clinton*, 246 Kan. 590, 600 (1990)).

Defendant argues that because this doctrine allows it to warn only the prescribing

physicians, plaintiff cannot base her claim on an omission from a document intended for the patient, and that any analysis of this claim should consider only the product insert. The learned intermediary doctrine does not relieve defendant of its duty to warn plaintiff adequately of risks of the product, however; rather, it merely allows defendant to have satisfied that duty by warning plaintiff's physician. Defendant could also have satisfied that duty by warning plaintiff directly. Thus, plaintiff's allegation that defendant failed to warn of certain risks in either the product insert or the PMG is entirely appropriate. Plaintiff's failure-to-warn claim is not based on any particular document, but rather alleges that defendant failed to warn plaintiff adequately in a general sense. Thus, there is no basis to dismiss part of that claim as it pertains to particular documents.

The Court also rejects defendant's argument that plaintiff has failed to plead reliance and proximate causation sufficiently. Specifically, defendant argues that plaintiff has failed to allege specific facts concerning her physician's reaction to or reliance on particular warnings from defendant concerning Cymbalta. Plaintiff has alleged, however, that she and her physician relied on defendant's warnings; that she would not have consented to use Cymbalta, and her physician would not have prescribed it, if defendant had included adequate warnings; and that defendant's failure to warn caused her injuries. The Court concludes that these allegations are not so conclusory as to run afoul of *Twombly*. Moreover, as plaintiff points out, she is not necessarily required to prove causation, as an inadequate warning gives rise to a rebuttable presumption of causation in plaintiff's favor. *See Ralston*, 275 F.3d at 977 n.6 (citing

cases).

Finally, defendant argues that its product insert includes an adequate warning as a matter of law.[2] Defendant relies specifically on the following statement in the "adverse reactions" section of the product insert: "Serious skin reactions including Stevens-Johnson Syndrome that have required drug discontinuation and/or hospitalization have been reported with duloxetine [Cymbalta]." Defendant argues that this statement was adequate as a matter of law because it warned of the very conditions—SJS and severe skin disorders—that plaintiff allegedly suffered. Defendant cites to two cases in which warnings concerning SJS in the "adverse reactions" sections of inserts were deemed adequate. *See Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566, 573 (D. Md. 2006); *Serna v. Roche Labs.*, 684 P.2d 1187, 1188-90 (N.M. Ct. App. 1984).

The Court rejects this argument as well. "Under Kansas law, the standard for determining whether a warning is adequate is whether it is reasonable under the circumstances." *Ralston*, 275 F.3d at 975 (citations and internal quotations omitted). Even if a warning mentions the very harm suffered by the plaintiff, the warning must have been adequate. *See Johnson v. American Cyanamid Co.*, 239 Kan. 279, 288 (1986)

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[2]Defendant has attached the product insert to its motion and relies on that document in arguing for dismissal. In ruling on a motion to dismiss, "[i]n addition to the complaint, the district court may consider documents referred to in the complaint if the documents are central to the plaintiff's claim and the parties do not dispute the documents' authenticity." *Jacobsen v. Deseret Book Co.*, 287 F.3d 936, 941 (10th Cir. 2002). The product insert is central to plaintiff's failure-to-warn claim, and plaintiff has not disputed the authenticity of the document attached to defendant's motion; accordingly, the Court will consider the product insert.

(because warning warned of the plaintiff's injury, the question was one not of a failure to warn, but of the adequacy of the warning). The Court thus considers the product insert as a whole.

Cymbalta's product insert did not mention any skin reactions in its "warnings and precautions" section. In the "adverse reactions" section, with respect to reactions experienced in clinical trials of Cymbalta, the insert mentioned the following skin-related conditions: hyperhidrosis (excessive sweating), rash, pruritis (itchy skin), cold sweat, dermatitis contact (localized inflammation), erythema (redness), increased tendency to bruise, night sweats, photosensitivity reaction, and ecchymosis (small hemorrhage); that subsection did not mention SJS or SCAR disorders or any other severe skin condition. Then, in the "adverse reaction" section's subsection on "postmarketing spontaneous reports," the insert stated as follows:

> The following adverse reactions have been identified during postapproval use of Cymbalta. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
>
> Adverse reactions reported since market introduction that were temporally related to duloxetine therapy and not mentioned elsewhere in labeling include: anaphylactic reaction [allergic reaction], . . . erythema multiforme [a type of hypersensitivity skin reaction], . . . rash, ...
>
> Serious skin reactions including Stevens-Johnson Syndrome that have required drug discontinuation and/or hospitalization have been reported with duloxetine.

The Court cannot conclude that this language adequately warned of a risk of

SCAR disorders and SJS as a matter of law. In particular, the disclaimer language at the beginning of this subsection significantly weakens any warning imparted, as defendant was effectively stating that it did not know whether or not the listed conditions, including SJS, could be linked to use of the drug. The presence of that disclaimer easily distinguishes the present case from the cases cited by defendant. Moreover, the manufacturer's knowledge is relevant to the adequacy of a warning, *see Wheeler v. John Deere Co.*, 935 F.2d 1090, 1100 (10th Cir. 1991) (applying Kansas law); *Wooderson v. Ortho Pharmaceutical Corp.*, 235 Kan. 387, 400 (1984) (drug manufacturer's duty to warn is commensurate with its actual and constructive knowledge), and plaintiff has alleged that defendant knew or should have known that its product did cause an increased risk of SJS and SCAR disorders.

The Court's consideration of this issue is governed by the Tenth Circuit's decision in *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848 (10th Cir. 2003).[3] In *Thom*, the court reversed a district court's conclusion that a warning was reasonable and therefore adequate as matter of law. *See id.* at 853-55. The Tenth Circuit first noted that "[a]lthough the adequacy of warnings concerning drugs is generally a question of fact, it can become a question of law where the warning is accurate, clear and unambiguous."

[3]In *Thom*, the failure-to-warn claim was governed by Oklahoma law. Nevertheless, the case is instructive and provides persuasive authority because the court applied a standard of reasonableness under the circumstances, *see* 353 F.3d at 853, and the court relied almost entirely on cases from other jurisdictions, as if stating rules of law that would apply in any of the court's constituent jurisdictions, *see id.* at 853-55.

Id. at 853 (citations and internal quotation omitted). In concluding that the warning at issue there did not meet that standard, the court concluded that certain language noting a temporal relation but stating that a causal relationship had not been established was equivocal and thus was not adequate as a matter of law. *See id.* The court also noted that adequacy is commensurate with the manufacturer's knowledge of danger, which is therefore relevant to the analysis, and that a factual dispute existed concerning the defendant's knowledge in that case. *See id.* at 854-55.

Similarly in the present case, the Court cannot conclude that defendant's warning was adequate as a matter of law under the fact-dependent standard of reasonableness, particularly in light of the equivocal nature of the warning and the allegations of defendant's knowledge of the risk. Accordingly, defendant's motion to dismiss this claim on this basis is denied.[4]

V. KPLA Claim – Design Defect

Defendant seeks dismissal of plaintiff's claim of a design defect on the basis that plaintiff has not pleaded that claim with sufficient factual specificity. In a design-defect case under Kansas law, a plaintiff must show that the defendant's product was defective and unreasonably dangerous, and under the applicable "consumer expectation test," the

[4]The Court also rejects defendant's argument that plaintiff did not allege the inadequacy of defendant's warnings with sufficient specificity. Plaintiff's complaint includes numerous factual allegations in support of its failure-to-warn claim, and that claim therefore is not improperly conclusory.

product must have been dangerous to an extent beyond that contemplated by the ordinary consumer. *See Jenkins v. Amchem Prods., Inc.*, 256 Kan. 602, 630 (1994). Moreover, the plaintiff may not simply show that the product causes injury, but must put forth "a specific claim concerning what aspect of the design was defective." *See id.* at 636-37. Defendant argues that plaintiff has not alleged a specific defect in this case.

This Court ruled in a previous case that, although the plaintiff would be required at some point, under *Jenkins*, to identify specifically "what aspect of defendants' products was defectively designed," the failure to do so in the complaint did not provide a basis for dismissal. *See Burton v. R.J. Reynolds Tobacco Co.*, 884 F. Supp. 1515, 1522 (D. Kan. 1995) (Lungstrum, J.); *see also Vanderwerf v. SmithKlineBeecham Corp.*, 414 F. Supp. 2d 1023, 1026 (D. Kan. 2006) (citing *Burton* in concluding that the plaintiffs were not required to allege specifically how the products were defective at the pleading stage). Nevertheless, defendant argues that the Court should reach a different result under *Twombly*, which was decided after *Burton* and *Vanderwerf*.

The Court rejects this argument. The cases cited by defendant do not actually support defendant's statement that "the clear trend in federal district court decisions since *Twombly* and *Iqbal* is to hold that the plausibility standards require plaintiffs alleging design-defect claims against a pharmaceutical manufacturer to specify the *precise aspect* of the design or formulation that plaintiffs contend caused the product at issue to be defective." (Emphasis in original.) In fact, those cases are not really directed at the plausibility requirement; instead, they generally support a rule that under *Twombly*

a plaintiff may not merely allege a design defect, but must go beyond such a conclusory allegation or a formulaic recitation of elements and allege supporting facts. *See Tillman v. Taro Pharmaceutical Indus. Ltd.*, 2011 WL 3704762, at *4 (N.D. Ill. Aug. 17, 2011) (formulaic recitation of elements without specific facts to support design defect allegation was insufficient); *Rollins v. Wackenhut Servs.*, 802 F. Supp. 2d 111, 123-24 (D.D.C. 2011) (plaintiff did not plead sufficient non-conclusory allegations of design defect; plaintiff did not allege that risks outweighed benefits); *Bodley v. Foster Wheeler Energy Corp.*, 2011 WL 1576673, at *3 (D.V.I. Apr. 26, 2011) (a mere allegation of defective design is conclusory); *Ivory v. Pfizer Inc.*, 2009 WL 3230611, at *3 (W.D. La. Sept. 30, 2009) (pleading was insufficient where the plaintiff made no reference to an alternative design, which was a required element under the governing law); *Frey v. Novartis Pharmaceuticals Corp.*, 642 F. Supp. 2d 787, 795 (S.D. Ohio 2009) (formulaic recitation of elements without facts was insufficient).

In this case, plaintiff has not merely and conclusorily alleged a design defect without supporting facts. For instance, plaintiff has alleged a propensity of Cymbalta to cause SCAR disorders; that the benefits of the drug were outweighed by product risks for plaintiff and other consumers, particularly in comparison with alternative drugs or therapies; and that an alternative antidepressant drug with a more favorable benefit-risk profile was feasible. The Court concludes that these allegations are sufficient to state a

claim under the *Twombly* standard.[5]

Accordingly, the Court denies defendant's motion to dismiss plaintiff's KPLA claim based on an allegation of a design defect.[6]

VI. KCPA Claim

Plaintiff alleges that defendant committed deceptive and unconscionable acts in violation of the KCPA, based on plaintiff's allegation that defendant misrepresented the safety or concealed life-threatening characteristics of Cymbalta. Defendant argues that plaintiff's KCPA claim should be dismissed because plaintiff has failed to plead that claim with particularity as required by Fed. R. Civ. P. 9(b). *See Burton*, 884 F. Supp. at 1524 (concluding that Rule 9(b) applies to allegations of deceptive trade practices under the KCPA). Plaintiff does not dispute that Rule 9(b) applies to this claim. To comply with the rule, a complaint must "set forth the time, place and contents of the false representation, the identity of the party making the false statements and the consequences thereof." *See Tal v. Hogan*, 453 F.3d 1244, 1263 (10th Cir. 2006).

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[5]The Court expresses no opinion at this time concerning whether such allegations would eventually satisfy *Jenkins*'s requirement of a claim showing which aspect of the product's design is defective.

[6]The Court does not consider defendant's argument that the design was not defective as a matter of law, which defendant raised for the first time in its reply brief. *See, e.g., U.S. Fire Ins. Co. v. Bunge N. Am., Inc.*, 2008 WL 3077074, at *9 n.7 (D. Kan. Aug. 4, 2008) (court will not consider issues raised for first time in reply brief) (citing *Minshall v. McGraw Hill Broadcasting Co.*, 323 F.3d 1273, 1288 (10th Cir. 2003)).

Plaintiff notes that she has identified the time frame and the place in which she was prescribed Cymbalta, and the Court concludes that plaintiff has sufficiently identified the content that defendant allegedly omitted (i.e., the risks of which defendant allegedly should have warned). The Court agrees with defendant, however, that plaintiff's general references to marketing brochures and other materials, in which defendant allegedly made misrepresentations or misleading statements, are insufficient to satisfy Rule 9(b). Plaintiff must identify the particular acts that she alleges provide a basis for liability under the KCPA, and if she intends to rely on particular statements in particular documents as deceptive or unconscionable acts, she must identify those statements and documents with particularity. Accordingly, plaintiff's KCPA claim is subject to dismissal.[7]

Because there is no basis to believe that plaintiff could not cure this pleading defect, the Court grants plaintiff leave to amend her complaint to state this claim with the required particularity.[8] Plaintiff should file any such amended complaint on or before June 4, 2012.

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[7]The Court does not agree with defendant that plaintiff's allegations of reliance are insufficient under Rule 9(b). Plaintiff has alleged that she and her physicians relied on defendant's statements and omissions concerning Cymbalta, and the Tenth Circuit's standard for compliance with Rule 9(b) does not require more.

[8]In her complaint, plaintiff alleges that defendant failed to state material facts "and otherwise committed deceptive and unconscionable acts." To the extent that plaintiff intends to rely on allegedly deceptive or unconscionable acts other than misrepresentations or omissions by defendant, she must identify any such acts with particularity.

IT IS THEREFORE ORDERED BY THE COURT THAT defendant's motion to dismiss (Doc. # 15) is **granted in part and denied in part**. The motion is granted with respect to plaintiff's claims of negligence, negligence per se, breach of implied warranty, breach of express warranty, misrepresentation by omission, and fraudulent misrepresentation, and those claims are hereby dismissed. Plaintiff's strict liability claim is deemed asserted under the Kansas Product Liability Act (KPLA). The motion is also granted with respect to plaintiff's claim under the Kansas Consumer Protection Act (KCPA), although plaintiff is granted leave to amend that claim on or before **June 4, 2012**. The motion is denied with respect to plaintiff's claim under the KPLA.

IT IS SO ORDERED.

Dated this 23rd day of May, 2012, in Kansas City, Kansas.

s/ John W. Lungstrum
John W. Lungstrum
United States District Judge