UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION

CIVIL ACTION NO. 3:15-CV-00894-JHM

ANNA HOUSE **PLAINTIFF**

V.

BRISTOL-MYERS SQUIBB COMPANY, ASTRAZENECA PLC, ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP, and ASTRAZENECA AB **DEFENDANTS**

MEMORANDUM OPINION & ORDER

This matter is before the Court on a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) by Defendants Bristol-Myers Squibb Company and AstraZeneca Pharmaceuticals LP[1] [DN 15]. Fully briefed, this matter is ripe for decision. For the reasons set forth below, the motion to dismiss is **GRANTED**.

I. BACKGROUND

This case is a personal injury action concerning Invokana, Invokamet, and Farxiga, which are prescription medications approved by the Food and Drug Administration ("FDA") for the treatment of type 2 diabetes. Plaintiff Anna House, a Kentucky resident, alleges that she developed diabetic ketoacidosis and kidney failure as a result of using these medications. (See Compl. [DN 1] ¶¶ 4, 8.) House asserts twelve claims against Defendants Bristol-Myers Squibb Company, a Delaware corporation; AstraZeneca PLC, a United Kingdom corporation; AstraZeneca LP, a Delaware corporation; AstraZeneca Pharmaceuticals LP, a Delaware corporation; and AstraZeneca AB, a Swedish corporation (collectively, the "Farxiga Defendants")

[1] The motion is brought by Defendants Bristol-Myers Squibb Company and AstraZeneca Pharmaceuticals LP, which have been served with the Complaint, though these Defendants note that the arguments in the motion would apply equally to the unserved Defendants AstraZeneca PLC, AstraZeneca LP, and AstraZeneca AB. (See [DN 15-1] 3 & n.1.)

based on her alleged use of and injuries caused by Farxiga. (Id. ¶¶ 6, 12–16.) House alleges that the Farxiga Defendants designed, developed, manufactured, marketed, distributed, and sold Farxiga into the stream of commerce. (Id. ¶ 34.)

In January 2014, Farxiga was approved by the FDA as a sodium-glucose cotransporter 2 ("SGLT2") inhibitor for the treatment of type 2 diabetes. (Id. ¶ 34.) SGLT2 inhibitors, including Invokana, Invokamet, and Farxiga, are designed to help diabetics reduce excess blood sugar. (Id. ¶ 29.) They work by blocking reabsorption of glucose in the kidneys, and, instead, they increase glucose secretion through urination. (Id. ¶ 30.) The FDA has since received a significant number of reports of diabetic ketoacidosis and severe kidney damage from Invokana, Invokamet, and Farxiga users. (Id. ¶ 36.) On May 15, 2015, the FDA issued a safety announcement regarding a risk of ketoacidosis associated with the SGLT2 inhibitor class of diabetes medications. (Id. ¶ 61.) House alleges that, despite the reported adverse events, the Farxiga Defendants failed and refused to conduct proper safety studies, failed to properly assess and publicize alarming safety signals, suppressed information revealing serious and life-threatening risks, willfully and wantonly failed to provide adequate instructions, and made willful misrepresentations regarding the nature and safety of their respective medications. (Id. ¶ 62.)

House began taking Farxiga on or about June 2014 (id. ¶ 48) and subsequently suffered diabetic ketoacidosis (id. ¶ 53.) Plaintiff filed her Complaint on December 22, 2015 [DN 1]. She asserts claims for strict liability design defect (Count I); strict liability failure to warn (Count II); gross negligence (Count III); negligence (Count IV); breach of express warranty (Count V); breach of implied warranty (Count VI); fraudulent misrepresentation (Count VII); negligent misrepresentation (Count VIII); negligent design (Count IX); fraudulent concealment (Count X);

fraud (Count XI); and violation of the Kentucky Consumer Protection Act (Count XII). Plaintiff asserts each of these twelve claims against the Farxiga Defendants based on their alleged role in the design, manufacture, marketing, and sale of Farxiga. (See Compl. [DN 1] ¶ 1.) Plaintiff also filed identical claims against Janssen Pharmaceuticals, Inc. ("Janssen"), Johnson & Johnson, and Mitsubishi Tanabe Pharma Corporation ("Mitsubishi"), based on her alleged use of and injuries caused by Invokana and Invokamet. After all properly-served Defendants moved to dismiss the claims against them, the claims against Janssen, Johnson & Johnson, and Mitsubishi were transferred to the District of New Jersey pursuant to an order by the United States Judicial Panel on Multidistrict Litigation. (See In re: Invokana (Canagliflozin) Products Liability Litigation, MDL No. 2750 (Dec. 7, 2016) [DN 43].) Thus, the only remaining claims before this Court are those asserted against the Farxiga Defendants.

II. DISCUSSION

A. Standard of Review

Upon a motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), a court "must construe the complaint in the light most favorable to plaintiff[]," League of United Latin Am. Citizens v. Bredesen, 500 F.3d 523, 527 (6th Cir. 2007), "accept all well-pled factual allegations as true," id., and determine whether the "complaint states a plausible claim for relief," Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009). Under this standard, the plaintiff must provide the grounds for his or her entitlement to relief, which "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007).

A plaintiff satisfies this standard only when he or she "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct

alleged." Iqbal, 556 U.S. at 678. A complaint falls short if it pleads facts "'merely consistent with' a defendant's liability," id. at 678 (quoting Twombly, 550 U.S. at 557), or if the alleged facts do not "permit the court to infer more than the mere possibility of misconduct," id. at 679. Instead, the allegations must "'show[] that the pleader is entitled to relief.'" Id. at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

When a plaintiff pleads claims which sound in fraud, those claims are subject to the heightened pleading standard of Federal Rule of Civil Procedure 9(b), which provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "At a minimum, the Sixth Circuit requires the allegations to contain the 'time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud.'" Our Lady of Bellefonte Hosp., Inc. v. Tri-State Physicians Network, Inc., 2007 WL 2903231, at *6 (E.D. Ky. Sept. 27, 2007) (quoting Coffey v. Foamex L.P., 2 F.3d 157, 161–62 (6th Cir. 1993)). "Generalized and conclusory allegations that the Defendant['s] conduct was fraudulent do not satisfy Rule 9(b)." Bovee v. Coopers & Lybrand C.P.A., 272 F.3d 356, 361 (6th Cir. 2001).

B. Analysis

1. Strict Liability Claims (Counts I & II)

House has asserted two strict liability claims based on the theory that Farxiga was defective, both in their design (Count I) and because the Defendants failed to warn of the risk of injury caused by the medications (Count II).

a. Strict Liability Design Defect Claim

Under Kentucky law, to prevail in a strict products liability action, a plaintiff must establish: "(1) that there is a product, which is (2) in a defective condition unreasonably dangerous to the user or consumer or his property, and (3) which reaches the user or consumer without substantial change in the condition in which it is sold; (4) that the product is sold by one who is engaged in the business of selling such a product which (5) results in physical harm to the ultimate user or consumer or his property." Bosch v. Bayer Healthcare Pharms., Inc., 13 F. Supp. 3d 730, 742 (W.D. Ky. 2014) (citations omitted). A plaintiff also must establish that there was "an alternative, safer design that is practicable under the circumstances." Id.

Defendants first argue that, because of comment k to section 402A of the Restatement (Second) of Torts, they are not subject to design defect liability, and therefore the Court should dismiss Count I of House's Complaint. Kentucky follows the Restatement (Second) of Torts, including comment k to section 402A. Prather v. Abbott Labs., 960 F. Supp. 2d 700, 706 (W.D. Ky. 2013) (citing McMichael v. Am. Red Cross, 532 S.W.2d 7, 9–11 (Ky. 1975)). Comment k "provides an exception to the general rule of strict liability for 'apparently useful and desirable product[s], attended with a known but apparently reasonable risk.'" Id. (quoting Restatement (Second) of Torts § 402A cmt. k). Where comment k applies, a prescription drug manufacturer "is not subject to strict liability for design defects. Instead, the manufacturer's liability is limited to manufacturing defects, for those cases in which the [drug] given had been improperly prepared, and warning defects, where a manufacturer's failure to market a drug . . . without adequate warnings of its dangers renders the product defective." Snawder v. Cohen, 749 F. Supp. 1473, 1476 (W.D. Ky. 1990); see Foister v. Purdue Pharma, L.P., 295 F. Supp. 2d 693, 705 (E.D. Ky. 2003).

In Kentucky, the scope of comment k is determined on a case-by-case basis. Prather, 960 F. Supp. 2d at 707; see Weiss v. Fujisawa Pharm. Co., No. CIV.A. 5:05-527-JMH, 2006 WL 3533072, at *1, *3–4 (E.D. Ky. Dec. 7, 2006). However, as the analysis under comment k is highly fact dependent, see Weiss, 2006 WL 3533072, at *4, and the cases relied on by Defendants were addressing comment k in the context of motions for summary judgment, the Court declines at this stage to dismiss House's strict liability design defect claim based on comment k. See id.

Defendants also argue that House's strict liability defective design allegations are deficient. According to Defendants, House has not identified what aspect of the drugs' design was allegedly defective, instead simply parroting the elements of a defective design claim by utilizing words such as "unsafe, defective, and inherently dangerous," "not reasonably safe as intended to be used," and "unreasonably dangerous when used by ordinary consumers, including Plaintiff, as intended." (Compl. [DN 1] ¶¶ 73–75.) Further, Defendants contend that House fails to allege how any defect in the drugs' design caused her injuries. Defendants note that though House alleges that SGLT2 inhibitors "are designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose" and that as a result, "excess glucose is not metabolized, but instead is excreted through the kidneys in a population of consumers already at risk for kidney disease," (id. ¶ 30), House does not allege how this or any other aspect of the drugs' design supposedly increases the risk of diabetic ketoacidosis or kidney failure. Defendants also argue that House fails to identify a specific feasible design alternative, instead making bare, conclusory allegations that such an alternative exists. (See id. ¶¶ 34, 74.)

House responds that the allegations in the Complaint state a plausible claim for relief for a strict liability design defect claim. House highlights a variety of allegations—including her

allegations that the drugs "contained unreasonably dangerous design defects and were not reasonably safe as intended to be used," (Compl. [DN 1] ¶ 74(a)), that the drugs "were defective in design and formulation, making use of the drugs more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the treatment of diabetes" (id. ¶ 74(b)), that Defendants "could have designed their respective [drugs] to make them less dangerous," (id. ¶ 83), and that there "was a practical, technically feasible safer alternative design that would have prevented the harm Plaintiff suffered without substantially impairing" the function of the drugs, (id. ¶ 84)—and contends that they are not merely formulaic recitation of elements.

In Fleming v. Janssen Pharmaceuticals, Inc., --- F. Supp. 3d ----, 2016 WL 3180299 (W.D. Tenn. 2016), the court found that a complaint's conclusory allegations of defectiveness were insufficient to state a defective design claim. The plaintiff in Fleming alleged that Invokana's design causes excess glucose excretion by the kidneys and that his injury was caused by the drug's "unreasonably dangerous and defective characteristics." Id. at *6–7. The Fleming court rejected the allegations as insufficient to state a plausible design defect claim, stating that "[t]he Court cannot reasonably infer from the generic description of SGLT2 inhibitors' mechanism of action that Invokana was defective or unreasonably dangerous." Id. at *7.

Just as in Fleming, the only assertion in the instant case as to how the product design was defective is a description of how the class of products works. (Compare Compl. [DN 1] ¶ 30 ("SGLT2 inhibitors, including INVOKANA, INVOKAMET and FARXIGA, are designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. As a result, excess glucose is not metabolized, but instead is excreted through the kidneys of a population of consumers already at risk for kidney disease."), with Fleming, 2016 WL 3180299, at *7 (quoting

Compl. ¶ 24 (identical except for the reference to Invokamet and Farxiga)).) The Court here "cannot reasonably infer from the generic description of SGLT2 inhibitors' mechanism of action that [Farxiga] was defective or unreasonably dangerous." Fleming, 2016 WL 3180299, at *7; see also Brazil, 2016 WL 4844442, at *9 (dismissing strict liability defect design claims where the plaintiff, who had pleaded facts that Invokana may cause diabetic ketoacidosis, had not alleged any specific design or manufacturing defect or tied diabetic ketoacidosis to any design or manufacturing defect). The rest of House's allegations are largely legal conclusions that are insufficient to meet the Twombly-Iqbal standard. Accordingly, House has failed to allege facts sufficient to state a strict liability design defect claim. Therefore, the Court **dismisses** without prejudice House's Count I as to all remaining Defendants.

b. Strict Liability Failure to Warn Claim

House's claims for failure to warn also fail for similar reasons. To plead a failure to warn claim in a prescription drug case, a plaintiff must allege facts for the Court to infer that (1) the manufacturer failed to provide her prescribing physician with adequate warnings about risks of which it knew or should have known and (2) the inadequate warnings proximately caused her injuries. Prather, 960 F. Supp. 2d at 708–09 (citations omitted). House contends that the Complaint adequately alleges how the warnings provided were defective and how they caused her injury. In Fleming, the court dismissed the plaintiff's almost identical failure-to-warn claim as insufficiently pled, as the "[p]laintiff has made only conclusory statements as to the failure of Defendants to warn about the dangers of Invokana." 2016 WL 3180299, at *7. So too, here.[2] Accordingly, Count II of the Complaint is **dismissed** without prejudice against all remaining Defendants.

[2] Of the paragraphs in the Complaint cited by House as evidence of her sufficient pleading, only paragraph 30, which is the generic description of SGLT2 inhibitors' mechanism of action, is a specific factual allegation. But this allegation, without further factual allegations, does not support a failure-to-warn claim.

2. Negligence-based Claims (Counts III, IV, & IX)

Under Kentucky law, to succeed on a negligence claim, House must establish that: (1) Defendants owed a duty of care to House; (2) Defendants breached its duty; and (3) the breach proximately caused House's damages. Bosch, 13 F. Supp. 3d at 741 (citing Mullins v. Commonwealth Life Ins. Co., 839 S.W.2d 245, 247 (Ky. 1992)). Count III of the Complaint asserts a claim for gross negligence, Count IV asserts a claim for negligence, and Count IX asserts a clam for negligent design.[3] The parties appear to agree that these claims are based on the same foundation as House's strict liability design defect and failure-to-warn claims. As the Court has found that House has failed to allege sufficient facts in support of her design defect and failure-to-warn claims, see supra Section II.B.1, the Court concludes that House's negligence-based claims likewise fail to the extent House alleges negligence in the designing and failing to warn. Accordingly, Count IV is **dismissed** without prejudice to that extent.

House's claim for gross negligence (Count III) is premised on the same insufficient allegations that underpin her strict liability design defect and failure-to-warn claims. Count III therefore fails for the same reasons that mandate dismissal of the strict liability claims. Accordingly, Count III of the Complaint is **dismissed** without prejudice.

Defendants also challenge House's negligence-based claims to the extent they allege negligence in the manufacturing or testing of Farxiga. Defendants contend that House "has not included any factual allegations as to how Defendants breached any such duty or how any such breach caused her purported injuries" and therefore that such a claim is insufficiently pled. See Bosch, 13 F. Supp. 3d at 741–42 (dismissing negligent manufacture claim because plaintiffs failed to "allege how their specific [intrauterine contraceptive] devices were defective due to

[3] The Court will address House's negligent misrepresentation claim (Count VIII) in its own section. See infra Section II.B.6.

manufacturing" and otherwise failed to assert "any facts to support" their conclusory allegations); see also Guidry v. Janssen Pharmaceuticals, Inc., 2016 WL 633673, at *4 (E.D. La. Feb1 17, 2016) (dismissing manufacturing defect claim where plaintiff failed to allege any facts as how the Invokana she ingested deviated from the intended design). In her brief, House does not address how Defendants breached a duty in the manufacture of the drugs, nor does she dispute that her negligence claim cannot be premised on a failure to properly test the drugs. See Allstate Ins. Co. v. Glob. Med. Billing, Inc., 520 F. App'x 409, 412 (6th Cir. 2013) (a party's failure to respond to or oppose an issue raised in a Rule 12(b)(6) motion may result in waiver of the issue). Further, Kentucky courts have treated failure to properly test pharmaceutical drugs as subsumed by a failure to warn claim. See Baird v. Bayer Healthcare Pharmaceuticals, Inc., No. CIV.A. 6:13-077-DCR, 2013 WL 5890253, at *2 (E.D. Ky. Oct. 31, 2013); Bosch, 13 F. Supp. 3d at 747. Accordingly, House's Count IV is **dismissed** without prejudice to the extent it is a negligent manufacture or testing claim.

"In Kentucky, a plaintiff can bring a defective design claim under a theory of strict liability or negligence, the foundation of both theories being that the product is 'unreasonably dangerous.'" Prather, 960 F. Supp. 2d at 712. House's negligent design claim (Count IX) is premised on the same insufficient allegations that underpin her strict liability design defect claim—that the drugs are unreasonably dangerous and should have been designed differently. (Compare Compl. [DN 1] ¶¶ 217, 222–223, with id. ¶¶ 71, 73, 83–84, 79, 89.) Count IX therefore fails for the same reasons that mandate dismissal of the strict liability design defect claim, as House has not alleged how the drugs were defectively designed. See Bosch, 13 F. Supp. 3d at 741–43 (dismissing negligent design and strict liability design defect claims because plaintiff failed to allege how intrauterine contraceptive device was "defectively designed" or how

they were "defective"). Accordingly, House's negligent design defect claim (Count IX) is **dismissed** without prejudice.[4]

3. Breach of Warranty Claims (Counts V & VI)

Count V of the Complaint asserts a claim for breach of express warranty, and Count VI asserts a claim for breach of implied warranty.

a. Breach of Express Warranty

Express warranties in Kentucky are governed by KRS 355.2–313, which states that an express warranty is created where: (1) the seller makes an affirmation of fact or promise; (2) that relates to the goods; and (3) becomes part of the basis of the bargain between the parties. KRS 355.2–313(1)(a). House asserts that Defendants "expressly represented" that the drugs were "safe and fit for their intended purposes," were of "merchantable quality," "did not produce any dangerous side effects," were "found to be safe and effective for the treatment of diabetes," and "include incomplete prescribing information that purports, but fails, to include the true risks associated with use" of the drugs. (Compl. [DN 1] ¶¶ 152–156.) House further alleges that these representations by Defendants constituted "affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain." (Id. ¶ 157.) According to House, Defendants breached these express warranties because the drugs are not safe, have numerous and serious side effects, and cause severe and permanent injuries, House and her physicians relied on such express warranties, and she suffered damages as a result. (Id. ¶¶ 158–165.)

The Court concludes these allegations are insufficient because they offer nothing more than "a formulaic recitation" of the elements of a claim for breach of express warranty,

[4] Because the strict liability and negligent design defect claims are dismissed under Rule 12(b)(6), the Court need not address Defendants' assertion that House's defective design claims are preempted by federal law.

Twombly, 550 U.S. at 555. Although House refers to an "express warranty," she has not detailed any particular affirmation or promise that formed part of the basis of the bargain with Defendants.[5] See Corwin v. Conn. Valley Arms, Inc., 74 F. Supp. 3d 883, 892 (N.D. Ill. 2014) (allegations that bullets "were reasonably fit for their intended uses without endangering human safety . . . are insufficient because they offer nothing more than 'a formulaic recitation' of the elements" of an express warranty claim); cf. Naiser v. Unilever U.S., Inc., 975 F. Supp. 2d 727, 733–36, 741 (W.D. Ky. 2013) (finding complaint alleged express warranty where it identified specific factual misrepresentations, such as representations that "the product's effects would last no longer than 30 days," when it "could be expected to last for months," and that "the product contained no formaldehyde," when it actually "contained a chemical known to release formaldehyde upon its use"). Further, a determination that a drug is safe and effective—a determination which is made by the FDA as part of its new drug approval process—is not, on its own, sufficient to create an express warranty. See, e.g., In re Meridia Prods. Liab. Litig., 328 F. Supp. 2d 791, 818 (N.D. Ohio 2004) (finding that assurances that a prescription drug was "safe and effective" was not sufficiently clear to create an express warranty), aff'd sub nom. Meridia Prods. Liab. Litig. v. Abbott Labs., 447 F.3d 861 (6th Cir. 2006); In re Avandia Mktg. Sales Practices & Prods. Liab. Litig., 588 F. App'x 171, 175–78 (3d Cir. 2014) (same). And House cannot base her express warranty claim on allegations that the Prescribing Information fails to include the "true risks" of the drugs and does not contain "adequate information," (Compl. [DN 1] ¶¶ 153, 155.) An express warranty is created by an "affirmation of fact or promise," not an

[5] Defendants also contend that House's breach of express warranty claim fails because House cannot establish that she is in privity with Defendants. See, e.g., Bland v. Abbott Labs., Inc., No. 3:11-CV-430-H, 2012 WL 524473, at *1 & n.1 (W.D. Ky. Feb. 16, 2012) (dismissing breach of express warranty claim in prescription drug case for lack of privity and confirming that "Kentucky courts have consistently affirmed Kentucky's [Uniform Commercial Code] requires privity"). This Court in Bosch denied a motion to dismiss an express warranty claim based on lack of privity. In so doing, the Court relies on its previous decision in Naiser v. Unilever U.S., Inc., 975 F. Supp. 2d 727 (W.D. Ky. 2013), for the proposition that "a manufacturer could nonetheless create privity in favor of an ultimate consumer who was the intended beneficiary of the manufacturer's express warranties." 13 F. Supp. 3d at 748.

omission. See KRS 355.2–313. Because House has not made allegations sufficient to describe an express warranty, the Court **dismisses** without prejudice her express warranty claim (Count V). The Court does not address at this point the other arguments made by Defendants in support of dismissal of this claim.

b. Breach of Implied Warranty

Defendants argue that House's claim for breach of implied warranty (Count VI) must be dismissed because there is no privity of contract between the parties. Under Kentucky law, privity of contract is an essential element of a claim for breach of an implied warranty. Baird, 2013 WL 5890253, at *3; Brown Sprinkler Corp. v. Plumbers Supply Co., 265 S.W.3d 237, 240 (Ky. Ct. App. 2007). "As a rule, privity of contract does not extend beyond the buyer-seller setting, and an intervening purchaser destroys privity." Gaunce v. CL Med. Inc., No. 5: 14-346-DCR, 2015 WL 893569, at *2 (E.D. Ky. Mar. 2, 2015) (citing Compex Int'l Co. v. Taylor, 209 S.W.3d 462, 465 (Ky. 2006)).

House argues that her implied warranty claim survives because she alleges in the Complaint that privity exists between her and Defendants. (See Compl. [DN 1] ¶ 173 ("Upon information and belief, Plaintiff and/or her health care professionals were at all relevant times in privity with the Invokana and the Farxiga Defendants.").) Defendants counter that the allegation in paragraph 173 is a non-binding, conclusory allegation and that House has alleged no facts to support the conclusion that privity existed. The Court agrees. In Bosch, the defendant argued that the plaintiffs' claims failed because the plaintiffs were not in privity of contract with the defendant. 13 F. Supp. 3d at 750. The plaintiffs "respond[ed] with one sentence, noting that Paragraph 242 of their Amended Complaint alleges that they 'are in the required privity with

Defendant.'" Id. The court found, however, "that this allegation in Paragraph 242 contradicts the factual allegations in the Amended Complaint." Id. The court stated:

> Plaintiffs have alleged that their Mirena® devices were inserted by healthcare providers during office visits. They have not alleged facts indicating that they purchased the Mirena® devices from Bayer. Therefore, Plaintiffs' legal conclusion regarding privity is not entitled to a presumption of truth, see Espinosa[v. Louisville Metro Gov't, No. CIV.A. 10-354-JBC], 2011 WL 2295055, at *1 [(E.D. Ky. June 10, 2011)]; Iqbal, 556 U.S. at 681, and the Court holds that Plaintiffs are not in a direct buyer-seller relationship with Bayer.

Id. (citations omitted).

Similarly, here, the Court finds that House's legal conclusion regarding privity is not entitled to a presumption of truth. See Iqbal, 556 U.S. at 678 ("[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions."). House alleges that the drugs are prescription drugs that were prescribed to her by her doctors. (Compl. [DN 1] ¶¶ 42, 48, 54.) She does not allege facts indicating that she purchased Farxiga from Farxiga Defendants. Because the Complaint fails to show that House and Defendants were in a buyer-seller relationship, House is not in privity with Defendants. See Bosch, 13 F. Supp. 3d at 749–50. Accordingly, House's breach of implied warranty claim (Count VI) is **dismissed** without prejudice.

4. Violation of KCPA (Count XII)

Count XII of the Complaint alleges a claim for violation of the Kentucky Consumer Protection Act. The KCPA declares unlawful "[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce." KRS 367.170(1). Here, House asserts that Defendants "falsely represented" that the drugs "are approved for use to assist diabetes patients with weight loss," that the drugs "are approved for treating cardiovascular conditions, such as

high blood pressure," and that the drugs "were safe for treating type 2 diabetes without warning consumers of serious side effects, including diabetic ketoacidosis, kidney failure, kidney damage, and kidney infection." (Compl. [DN 1] ¶ 267(a)–(c).) Further, House alleges that Defendants "misled consumers" into believing that the drugs "had been adequately developed, researched, designed, tested, manufactured, distributed[,] and sold so as to not produce serious injuries, such as those suffered by Plaintiff, which are not warned of." (Id. ¶ 267(d).)

The KCPA provides a private right of action for "[a]ny person who purchases or leases goods or services primarily for personal, family or household purposes and thereby suffers any ascertainable loss of money or property, real or personal" as a result of a violation of KRS 367.170. KRS 367.220(1). Accordingly, the KCPA requires that privity of contract exist between the parties. See Skilcraft Sheetmetal, Inc. v. Ky. Mach., Inc., 836 S.W.2d 907, 909 (Ky. Ct. App. 1992). Defendants urge the Court to dismiss House's KCPA claims because there is no privity of contract between the parties. House responds by referencing her breach of implied warranty argument. The Court dismissed the implied warranty claim because the Complaint fails to show that House was in privity with Defendants. See supra Section II.B.3.b. As the Complaint fails to show that House was in privity with Defendants, the KCPA provides no recovery. Accordingly, the Court **dismisses** without prejudice House's claim under the KCPA (Count XII).

5. Fraud-based Claims (Counts VI, X, & XI)

Count VI of the Complaint alleges a claim for fraudulent misrepresentation, Count X alleges a claim for fraudulent concealment, and Count XI alleges a claim for fraud. Each of these Counts makes similar accusations that Defendants knowingly hid the dangers of Farxiga from the health care community and the public at large. A plaintiff asserting a fraudulent

misrepresentation claim under Kentucky law must establish six elements: "(1) the defendant made a material representation to the plaintiff; (2) the representation was false; (3) the defendant knew the representation to be false or made it with reckless disregard for its truth or falsity; (4) the defendant intended to induce the plaintiff to act upon the misrepresentation; (5) the plaintiff reasonably relied upon the misrepresentation; and (6) the misrepresentation caused injury to the plaintiff." Giddings & Lewis, Inc. v. Indus. Risk Insurers, 348 S.W.3d 729, 747 (Ky. 2011) (citing Flegles, Inc. v. TruServ Corp., 289 S.W.3d 544, 549 (Ky. 2009)). To satisfy Rule 9(b), the complaint must: "(1) point to a particular allegedly fraudulent statement; (2) identify who made the statement; (3) plead when and where the statement was made; and (4) explain what made the statement fraudulent." Republic Bank & Trust Co. v. Bear Stearns & Co., 683 F.3d 239, 253 (6th Cir. 2012).

Reviewing House's fraudulent misrepresentation claim, the Court finds that House fails to allege sufficient facts for the claim to survive. House contends that the allegations in her Complaint meet the requirements of Rule 9(b). She does not state what specific statements are allegedly fraudulent, though she does string cite multiple paragraphs in the Complaint as her "pleading the content of Defendants' misrepresentations." A thorough review of the Complaint, however, reveals only vague representations, such as that the drugs "had been tested and found to be safe and effective for the treatment of diabetes," (id. ¶ 188(a)), and "were safer than other alternative medications," (id. ¶ 188(b)). This is not enough under Rule 9(b). See Gaunce, 2015 WL 893569, at *2. House does not specify the time, nature, and place of the alleged misrepresentation, and no fraudulent communication or its source is identified. Nor does the Complaint identify who made the allegedly fraudulent statements, beyond the logical inference that the Farxiga Defendants made the allegedly fraudulent statements about Farxiga. The

Complaint does not allege when or where the alleged statements were made, beyond highly generalized allegations. See Republic Bank, 683 F.3d at 245 ("Nowhere does it indicate when, where, or to whom the alleged misstatement was made. This defect is fatal. The claim may not proceed because Republic's complaint does not pass muster under Rule 9(b)."). Further, as it fails to allege what statement is at issue, the Complaint does not explain, with supporting factual detail, how and why it was fraudulent. Accordingly, House's allegations are insufficient under Rule 9(b) and the Court **dismisses** House's fraudulent misrepresentation claim in Count VII without prejudice.

"Fraud by omission is not the same, at law, as fraud by misrepresentation, and has substantially different elements." Republic Bank, 683 F.3d at 254–55 (quoting Rivermont Inn, Inc. v. Bass Hotels & Resorts, Inc., 113 S.W.3d 636, 641 (Ky. Ct. App. 2003)). "Unlike fraud by misrepresentation, which hinges on an affirmative misstatement, 'a fraud by omission claim is grounded in a duty to disclose.'" Id. at 255 (quoting Giddings & Lewis, 348 S.W.3d at 747). A plaintiff asserting a fraudulent concealment (or fraud by omission) claim under Kentucky law must establish four elements: "(1) the defendant had a duty to disclose the material fact at issue; (2) the defendant failed to disclose the fact; (3) the defendant's failure to disclose the material fact induced the plaintiff to act; and (4) the plaintiff suffered actual damages as a consequence." Giddings & Lewis, 348 S.W.3d at 747. "[A] party asserting a fraudulent concealment (or fraud by omission) claim must specify 'the who, what, when, where, and how' of the alleged omission." Gaunce, 2015 WL 893569, at *2 (quoting Republic Bank, 683 F.3d at 255–56). Therefore, to satisfy Rule 9(b), the complaint "must plead: (1) precisely what was omitted; (2) who should have made a representation; (3) the content of the alleged omission and the manner

in which the omission was misleading; and (4) what [Defendants] obtained as a consequence of the alleged fraud." Republic Bank, 683 F.3d at 255–56.

Like her fraudulent misrepresentation claim, House also fails to allege sufficient facts regarding her fraudulent concealment claim to satisfy Rule 9(b). Though House alleges that Defendants concealed "information about the severity of the substantial risks of using such drugs" and "information which demonstrated that [the drugs] were not safer than alternatives available on the market," (Compl. [DN 1] ¶ 231; see id. ¶ 249 (fraud claim)), she does not allege which Defendants concealed this information or when this alleged omission occurred. She alleges that Defendants committed fraud in unspecified "labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions," without identifying or referencing a single particular document or statement. (Id. ¶ 231.) As in Republic Bank, the Complaint's "vague allegations simply do not suffice under Rule 9(b)" because they discuss the alleged practices "only at a high level of generality." 683 F.3d at 256 (affirming dismissal of fraud by omission claim). Accordingly, the Court **dismisses** without prejudice House's fraudulent concealment claim (Count X) and fraud claim (Count XI) under Rule 9(b).

6. Negligent Misrepresentation (Count VIII)

Under Kentucky law, a plaintiff must identify the false or misleading information provided by the specific defendant. See Gaunce, 2015 WL 893569, at *2–3; Giddings & Lewis, 348 S.W.3d at 746. Additionally, a plaintiff must demonstrate: (1) the subject plaintiff was a reasonably foreseeable recipient of the information; (2) she justifiably relief on the information; (3) she exercised reasonable care in relying on the information; and (4) the false statements

allegedly made by the defendant were a proximate cause of the plaintiff's damage. Presnell Constr. Managers, Inc. v. EH Constr., LLC, 134 S.W.3d 575, 580 (Ky. 2004).

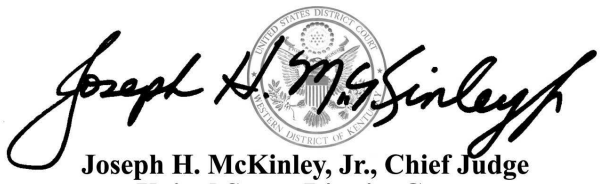
A plaintiff alleging a negligent misrepresentation claim under Kentucky law must meet the heightened pleading requirements of Rule 9(b). Republic Bank, 683 F.3d at 247–48. Like her fraudulent concealment and fraudulent misrepresentation claims, House's allegations fail to state a claim for negligent misrepresentation under Rule 9(b). The Complaint does not specify the statements in question, identify the speaker, or allege, beyond highly generalized allegations, when or where the alleged statements were made. It therefore fails to meet Rule 9(b)'s particularity requirements. See, e.g., Gaunce, 2015 WL 893569, at *2–3 (dismissing fraud, fraudulent concealment, and negligent misrepresentation claims where plaintiffs failed to "specify the time, nature, and place of the communications or omission" and the complaint discussed fraudulent actions at a "high level of generality, insufficient to sustain claims of fraud and fraudulent concealment under Rule 9(b)'s heightened pleading standard"). Accordingly, House's negligent misrepresentation claim (Count VIII) is **dismissed** without prejudice.

7. Leave to Amend Complaint

Finally, in her response to the motion to dismiss, Plaintiff requests in the alternative that, if the Court finds the complaint defective in any way, she be granted leave to amend the complaint. (Pl.'s Response [DN 26] at 16.) The Court does not consider this request an appropriate motion to amend. If Plaintiff wants the Court to consider such a request, she should submit a properly supported motion, with a copy of her amended complaint attached, no later than twenty-one (21) days from the entry of this Memorandum Opinion and Order. Thereafter, Defendants may file their responses, and the Court will address the merits of Plaintiff's motion.

III. CONCLUSION

For the reasons set forth above, **IT IS HEREBY ORDERED** that Defendants Bristol-Myers Squibb Co. and AstraZeneca Pharmaceuticals LP's Motion to Dismiss [DN 15] is **GRANTED**. If Plaintiff House wants the Court to entertain a motion to amend the complaint, **IT IS HEREBY ORDERED** that she shall submit her motion and amended complaint no later than twenty-one (21) days from the entry of this Memorandum Opinion and Order.



Joseph H. McKinley, Jr., Chief Judge
United States District Court

December 29, 2016

cc: Counsel of Record