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Tenth Circuit

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PUBLISH

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

SUSAN SCHROCK; STEVE SCHROCK,

Plaintiffs–Appellants,

v.

WYETH, INC.; SCHWARZ PHARMA, INC.; PILVA USA, INC.; QUALITEST PHARMACEUTICALS, INC.,

Defendants–Appellees.

No. 12-6078

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA
(D.C. No. 5:08-CV-00453-M)

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Before **LUCERO**, **HARTZ**, and **HOLMES**, Circuit Judges.

LUCERO, Circuit Judge.

Susan and Steven Schrock filed suit against brand-name and generic manufacturers of the drug metoclopramide, alleging that Susan Schrock's use of generic metoclopramide caused her to develop tardive dyskinesia, a neurological disorder characterized by involuntary body movements. The district court dismissed all claims in favor of the manufacturers in a series of orders. On appeal, the Schrocks challenge the dismissal of their claims against PLIVA USA, Inc. ("PLIVA"), Qualitest Pharmaceuticals, Inc. ("Qualitest"), Schwarz Pharma, Inc. ("Schwarz"), and Wyeth, Inc. ("Wyeth").

Following oral argument, we abated this appeal pending the Supreme Court's decision in Mutual Pharmaceutical Co., Inc. v. Bartlett, 133 S. Ct. 2466 (2013). In light of the Court's opinion in Bartlett, we are compelled to conclude that the Schrocks' breach-of-warranty claims against PLIVA and Qualitest, the generic drug manufacturers, are preempted by federal law. We also agree with the district court that the Schrocks' non-warranty claims against the generic manufacturers are barred by Oklahoma's two-

year statute of limitations. Okla. Stat. tit. 12 § 95.

With respect to the Schrocks' claims against Schwarz and Wyeth, name-brand manufacturers of metoclopramide, we are in accord with the district court's determination that Oklahoma tort law would not provide a remedy. Given prior Oklahoma precedent and the clear consensus of courts in other jurisdictions, we predict that Oklahoma would not impose a duty on brand-name drug manufacturers to consumers of a generic manufacturer's products.

Finally, we reject the argument that the Schrocks' notice of appeal was untimely as to certain orders they seek to appeal. Exercising jurisdiction under 28 U.S.C. § 1291, we affirm.

I

A

Under the 1962 amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. 87-781, 76 Stat. 780 (1962) (codified at 21 U.S.C. §§ 301 et seq.), a manufacturer seeking federal approval to market a new drug "must prove that it is safe and effective and that the proposed label is accurate and adequate." PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2574 (2011) (citing 21 U.S.C. § 355(b)(1), (d)). Initially, the same rules applied to all drug manufacturers. See Mensing, 131 S. Ct. at 2574. However, Congress later passed the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 21 and 35 U.S.C.), known as the Hatch-Waxman Amendments, that created special rules

for generic drug manufacturers. See Mensing, 131 S. Ct. at 2574.

These Amendments were intended "to provide a swifter route for approval of generic drugs." Bartlett, 133 S. Ct. at 2471. "Under Hatch-Waxman, a generic drug may be approved without the same level of clinical testing required for approval for a new brand-name drug, provided that the generic drug is identical to the already-approved brand-name drug in several key respects." Id. To be approved for sale, a generic drug must be "identical [to its branded equivalent] in active ingredients, safety, and efficacy," as well as in "the safety and efficacy labeling." Mensing, 131 S. Ct. at 2574 & n.2 (quotation and alteration omitted).

After a generic or brand-name drug is approved, "the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" Bartlett, 133 S. Ct. at 2471 (quoting 21 C.F.R. § 314.70(b)(2)(i)). Generic manufacturers "are also prohibited from making any unilateral changes to a drug's label," thus "approval for a generic drug may be withdrawn if the generic drug's label is no longer consistent with that for the brand name drug." Id. (quotation and alteration omitted) (citing 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(10)).

B

Metoclopramide was first approved by the Food and Drug Administration ("FDA") under the brand name Reglan. Generic manufacturers began production of metoclopramide in 1985, the same year the FDA-mandated label for all versions of

metoclopramide was modified to warn that "tardive dyskinesia . . . may develop in patients treated with metoclopramide." Mensing, 131 S. Ct. at 2572. The labeling also added that "therapy longer than 12 weeks has not been evaluated and cannot be recommended." Id. (alteration omitted).

Over time, evidence began to suggest that long-term use of metoclopramide can cause tardive dyskinesia. Id. In 2004, brand-name manufacturers of the drug requested a label change, which the FDA approved, to add that "therapy should not exceed 12 weeks in duration." Id. (alteration omitted). In 2009, the FDA ordered a "black box warning"—the strongest warning issued by the agency—to be placed on the label of metoclopramide stating, "[t]reatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible . . . . Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases." Id.

Susan Schrock was prescribed brand-name metoclopramide (Reglan) on three occasions between March 2000 and March 2005. Each time, however, she purchased generic metoclopramide instead. On either May 2 or 3, 2005, Susan Schrock visited Dr. Michael Tribbey, a neurologist, complaining of "neck drawing and arm weakness" that began six to eight weeks prior. Dr. Tribbey diagnosed her with "a form of dystonia," a neurological movement disorder, that was "quite possib[ly] related to metoclopramide," and recommended that she stop taking it. Susan Schrock discontinued the drug, and researched side effects of metoclopramide online. Following a hiatus during which her symptoms abated, she reported a worsening of her uncontrollable neck twisting in

October 2006. In July of 2007, she was formally diagnosed with tardive dyskinesia.

C

On April 30, 2008, the Schrocks sued Schwarz and Wyeth, former manufacturers of Reglan, and PLIVA, a manufacturer of generic metoclopramide, along with others not at issue in this appeal. Claims of negligence, strict products liability, breach of warranties, misrepresentation, and fraud were advanced in the federal court proceedings. After the district court concluded that Schwarz and Wyeth did not owe a duty to the Schrocks because Susan Schrock used only generic versions of metoclopramide, it granted summary judgment in favor of those companies on March 11, 2007. Schwarz and Wyeth sought certification of the district court's order under Fed. R. Civ. P. 54(b). The district court entered a judgment in their favor on April 20, 2009, but did not explicitly certify the order as final under Rule 54(b).

On April 14, 2010, the district court granted the Schrocks' motion for leave to file an amended complaint adding claims against Qualitest, which pharmacy records showed had manufactured some of the generic metoclopramide that Susan Schrock used. Qualitest promptly moved to dismiss, arguing the suit was barred by the statute of limitations. PLIVA filed a motion for summary judgment on the same basis. On July 20, 2010, the district court granted summary judgment in favor of PLIVA, and dismissed all but the breach-of-warranty claims against Qualitest. On December 8, 2011, the district court dismissed the breach-of-warranty claims pursuant to a Rule 12(b)(6) motion by Qualitest, concluding the claims were preempted. On the same date, the court entered

final judgments in favor of PLIVA and Qualitest.

On January 5, 2012, the Schrocks filed a motion to alter or amend the December 8, 2011 judgment in favor of Qualitest. The district court denied the motion on February 24, 2012. On March 23, 2012, the Schrocks filed a notice of appeal designating the grants of summary judgment in favor of Wyeth, Schwarz, and PLIVA, and the grants of Qualitest's motions to dismiss as the orders being appealed.

II

We first determine whether the Schrocks' notice of appeal was timely. Schwarz and Wyeth argue that the district court's April 20, 2009 judgment in their favor was a final judgment, thus the Schrocks' March 23, 2012 notice of appeal is untimely under Fed. R. App. P. 4(a)(1)(A). After the district court granted Schwarz and Wyeth's motion for summary judgment, those companies filed a motion under Fed. R. Civ. P. 54(b). In granting this motion, the district court entered a judgment stating: "[i]n light of the Court's Order granting said defendants summary judgment and having reviewed the parties' submissions, the Court hereby enters judgment in favor of defendants WYETH, INC. and SCHWARZ PHARMA, INC. . . . ."

Under Rule 54(b), a "court may direct entry of a final judgment as to one or more, but fewer than all, claims or parties only if the court expressly determines that there is no just reason for delay." Fed. R. Civ. P. 54(b). Because "Rule 54(b) entries are not to be made routinely," we have held that:

[C]ertification under Rule 54(b) is only appropriate when a district court

> adheres strictly to the rule's requirement that a court make two express determinations. First, the district court must determine that the order it is certifying is a final order. Second, the district court must determine that there is no just reason to delay review of the final order until it has conclusively ruled on all claims presented by the parties to the case.

Oklahoma Tpk. Auth. v. Bruner, 259 F.3d 1236, 1242 (10th Cir. 2001).

Schwarz and Wyeth concede that the district court did not make the express determinations required by our decision in Oklahoma Turnpike; however, they urge us to follow an approach taken by other circuits and look beyond the text of the district court's order to determine whether it can be said to have made the requisite determinations. See, e.g., Denson v. United States, 574 F.3d 1318, 1335 n.52 (11th Cir. 2009); Askanase v. LivingWell, Inc., 981 F.2d 807, 810 (5th Cir. 1993). Under this approach, they argue that their motion seeking Rule 54(b) certification, considered along with the judgment, reflects the district court's intent to allow an immediate appeal.

Regardless of the desirability of this alternative rule, "one panel cannot overrule the judgment of another panel of this court . . . absent en banc reconsideration or a superseding contrary decision by the Supreme Court." Barber v. T.D. Williamson, Inc., 254 F.3d 1223, 1229 (10th Cir. 2001) (quotation omitted). In Oklahoma Turnpike, we noted that although Rule 54(b)'s "requirement that these determinations be stated explicitly in the district court's certification order is to some extent a formality, the requirement does provide district courts with one last opportunity to discover errors in their decision to certify an order for appeal." 259 F.3d at 1244. We have adhered to this formal requirement. See Stockman's Water Co., LLC v. Vaca Partners, L.P., 425 F.3d

1263, 1264-65 (10th Cir. 2005) (dismissing appeal for lack of jurisdiction without considering the merits of a Rule 54(b) certification or the motion seeking certification because district court did not make the necessary findings). Because the district court did not make the requisite determinations under Oklahoma Turnpike, we reject the argument that the district court's April 10, 2009 judgment was final for purposes of appeal.

PLIVA, Schwarz, and Wyeth also claim that the March 23, 2012 appeal is untimely on the theory that the Schrocks' Rule 59(e) motion—which challenged only the judgment in favor of Qualitest—did not toll the time to appeal with respect to the other defendants. We reject this argument. Federal Rule of Appellate Procedure 4(a)(4)(A) states: "[i]f a party timely files in the district court any of the following motions," including a motion to "alter or amend judgment under Rule 59," then "the time to file an appeal runs for all parties from the entry of the order disposing of the last such remaining motion." Fed. R. App. P. 4(a)(4)(A) (emphasis added).

Our opinion in TBG, Inc. v. Bendis, 36 F.3d 916 (10th Cir. 1994), is not to the contrary. TBG holds that "a motion to reconsider one final judgment does not extend the time to appeal another final judgment just because they are part of the same litigation." Id. at 921. Unlike the case at bar, however, in TBG the district court had "certified as final and appealable under Rule 54(b)" both of the separate judgments at issue, effectively severing the two judgments for appellate purposes. Id. We specifically recognized that the result would have been different, if, as in the case at bar, the judgments had not been properly certified as final and appealable. See id. (under Rule

4(a)(4), "a motion for a new trial by one [party] also extends the time to appeal a verdict in favor of a second [party], unless the district court certifies the judgments as separate and final under Rule 54(b)"). Because the district court did not properly certify the judgments at issue under Rule 54(b), we conclude that the Schrocks' Rule 59 motion tolled the time to appeal as to each of the orders. The notice of appeal is therefore timely as to each order appealed.

III

"We review a grant of summary judgment de novo, applying the same standard as the district court." Jaramillo v. Adams Cnty. Sch. Dist. 14, 680 F.3d 1267, 1268 (10th Cir. 2012). Summary judgment is appropriate only if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). We view all facts and evidence in the light most favorable to the party opposing summary judgment. Morris v. City of Colo. Springs, 666 F.3d 654, 660 (10th Cir. 2012).

We also review de novo a district court's grant of a motion to dismiss under Fed. R. Civ. P. 12(b)(6). Khalik v. United Air Lines, 671 F.3d 1188, 1190 (10th Cir. 2012). We accept as true "all well-pleaded factual allegations in a complaint and view these allegations in the light most favorable to the plaintiff." Kerber v. Qwest Group Life Ins. Plan, 647 F.3d 950, 959 (10th Cir. 2011). To survive a motion to dismiss under Rule 12(b)(6), a complaint must contain "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007).

All the parties agree that Oklahoma law controls our analysis. Accordingly, "our

task here is to interpret and apply the law of [Oklahoma] as we believe the [Oklahoma] Supreme Court would." High Plains Natural Gas Co. v. Warren Petroleum Co., 875 F.2d 284, 288 (10th Cir. 1989); see also United States v. DeGasso, 369 F.3d 1139, 1145 (10th Cir. 2004) ("It is axiomatic that state courts are the final arbiters of state law."). If a state supreme court has not resolved a legal issue, we "may seek guidance from decisions rendered by lower courts in the relevant state, appellate decisions in other states with similar legal principles, district court decisions interpreting the law of the state in question, and the general weight and trend of authority in the relevant area of law." Wade v. Emcasco Ins. Co., 483 F.3d 657, 666 (10th Cir. 2007) (citations and quotation omitted).

A

The district court concluded that the Schrocks' claims against PLIVA and Qualitest, other than their warranty claims, were barred by Oklahoma's two-year limitations period. See Okla. Stat. tit. 12, § 95; Kirkland v. Gen. Motors Corp., 521 P.2d 1353, 1361 (Okla. 1974). Oklahoma follows the "discovery rule," under which "the statute [of limitations in product liability cases] does not begin to run until the plaintiff knows, or as a reasonably prudent person should know, that he has the condition for which his action is brought and that the defendant caused it." Daugherty v. Farmers Coop. Ass'n, 689 P.2d 947, 950 (Okla. 1984) (quotation omitted). However, a plaintiff need not know the "extent of injury" or know that it is "permanent" for the limitations

period to commence. Kang v. Kang, 11 P.3d 218, 219 (Okla. Civ. App. 2000);[1] see also Daugherty, 689 P.2d at 950-51 (under the discovery rule, "acquisition of sufficient information which, if pursued, would lead to the true condition of things will be held as sufficient knowledge to start the running of the statute of limitations").

We agree with the district court that the Schrocks' non-warranty claims against PLIVA are untimely. It is undisputed that in May of 2005 Susan Schrock's doctor informed her that metoclopramide was "quite possib[ly]" responsible for her symptoms, including her uncontrollable neck movement. Yet the Schrocks did not file suit until April 30, 2008, nearly three years later.

We reject the Schrocks' assertion that the limitations period began to run only when Susan Schrock's symptoms returned, sometime in mid- to late-2006, because it was then that she developed tardive dyskinesia, rather than the previously diagnosed acute dystonia.[2] Susan Schrock admits that in May 2005 she understood that metoclopramide was causing her symptoms, recorded by her physician as including uncontrollable neck movements. At that time, the label for metoclopramide warned that involuntary

[1] "Although we are not required to follow the dictates of an intermediate state appellate court, we may view such a decision as persuasive as to how the state supreme court might rule." Sellers v. Allstate Ins. Co., 82 F.3d 350, 352 (10th Cir. 1996).

[2] Both dystonia and dyskinesia refer to involuntary movement disorders. The record indicates that acute dystonia refers to the abrupt onset of muscle spasms and often involves involuntary twisting and abnormal postures. Dyskinesia refers to any abnormal, involuntary movement resulting from certain drugs. "Tardive" means "tending to or characterized by lateness esp. in development or maturity." Webster's Third New Int'l Dictionary 2340 (1993). Thus, tardive dyskinesia features involuntary muscle movements that develop or persist after a drug is discontinued.

movement symptoms may "remit, partially or completely, within several weeks-to-months after metoclopramide is withdrawn" but that tardive dyskinesia is nevertheless "potentially irreversible." This was informed by the Schrocks' contemporaneous online research on the side effects of metoclopramide shortly after speaking with Dr. Tribbey. Based on these facts, we agree with the district court that the Schrocks acquired "sufficient information which, if pursued, would lead to . . . sufficient knowledge to start the running of the statute of limitations." Daugherty, 689 P.2d at 951.

Although Oklahoma law might recognize that some symptoms are "too isolated or inconsequential to trigger the running of the [s]tatute of [l]imitations," Wetherill v. Eli Lilly & Co. (In re N.Y. Cnty. DES Litig.), 678 N.E. 2d 474, 478 n.4 (N.Y. 1997), this is not such a case. Susan Schrock is suing based on involuntary muscle movements caused by metoclopramide: she was aware of both symptom and cause in May 2005. Oklahoma courts have squarely rejected an acute versus permanent distinction. See Kang, 11 P.3d at 219 (holding that the statute of limitations is not tolled until the discovery of permanent, as opposed to temporary, injuries). We therefore affirm the district court's dismissal of the Schrocks' non-warranty claims against PLIVA.

We reach the same conclusion as to the Schrocks' non-warranty claims against Qualitest.[3] The Schrocks did not amend their complaint to add these claims until April

[3] Qualitest argues that the Schrocks do not challenge the district court's dismissal of the non-warranty claims against them on appeal. In their opening brief, the Schrocks assert only a general statute of limitations argument without stating whether they are

Continued . . .

14, 2010, after pharmacy records indicated that Qualitest manufactured some of the generic metoclopramide taken by Susan Schrock. Under Oklahoma law, the Schrocks are charged with knowledge of facts they would have learned through "reasonable diligence" in acquiring evidence that would implicate a defendant. See Daugherty, 689 P.2d at 951. The Schrocks do not attempt to explain the reason they did not obtain Susan Schrock's own pharmacy records until two years after filing their complaint and approximately five years after first learning that metoclopramide was causing her symptoms. The district court correctly dismissed the Schrocks' non-warranty claims against Qualitest.

B

Summary judgment in favor of Wyeth and Schwarz was granted on the ground that the brand-name manufacturers do not owe a duty to the Schrocks because Susan Schrock did not take brand-name metoclopramide. Although the Oklahoma Supreme Court has not had an opportunity to speak on this issue, we predict—consistent with the trend among courts nationally and Oklahoma tort law in general—that it would not recognize a duty flowing from brand-name drug manufacturers to consumers of generic drugs.

Oklahoma courts usually require that a defendant have some relationship with the product alleged to have caused a plaintiff's injuries, either through manufacturing, selling, or distributing the product. This is clearly the case in strict products liability

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challenging the district court's orders in favor of Qualitest, PLIVA, or both. Due to this ambiguity, we decline to treat the issue as waived.

actions. See Kirkland, 521 P.2d at 1363 (to prevail on strict liability claim for a defective product, plaintiff must show the product was defective when it left the defendant's "possession and control"); see also Dutsch v. Sea Ray Boats, Inc., 845 P.2d 187, 190 (Okla. 1992) (plaintiff asserting manufacturer's product liability must establish that "the product was defective when it left the hands of the manufacturer"). Because Wyeth and Schwarz were never in control or possession of the metoclopramide Susan Schrock took, the Schrocks cannot establish this element of their strict liability claim.

Several federal district court cases that have applied Oklahoma law have rejected products liability claims on this basis. See Muniz v. Masco Corp., 744 F. Supp. 266, 267 (W.D. Okla. 1990) ("In Oklahoma, a product liability cause of action lies only against a manufacturer, seller, or supplier of a defective product."); Mayberry v. Akron Rubber Mach. Corp., 483 F. Supp. 407, 412 (N.D. Okla. 1979) (rejecting a products-liability claim based on the "critical" fact that the products at issue "were not manufactured by [defendant]"). And we have recently emphasized in an unpublished order and judgment that under Oklahoma tort law, "responsibility for the defect must still be traced to the proper Defendant." Edwards v. PepsiCo, Inc., 268 F. App'x 756, 762 (10th Cir. 2008) (unpublished).

In addition, the Schrocks contend that Oklahoma law permits claims against an entity that negligently designs, but does not manufacture, a product that causes harm if the plaintiff's resulting injury is foreseeable. They rely primarily on Keel v. Titan Construction Corp., 639 P.2d 1228 (Okla. 1981), in which the Oklahoma Supreme Court

held that plaintiffs could bring suit for negligent breach of contract against an architect who designed their home, absent privity between the plaintiffs and the architect. Id. at 1232. In Keel, however, the architects designed the particular structure that resulted in plaintiffs' injury. See id. at 1230. Keel is simply not analogous to the present case, in which a competitor of the brand-name manufacturers utilized a design originally conceived by them, and the competitors' product harmed the plaintiffs.

Oklahoma courts have also required a relationship between the defendant company and the product at issue for other theories of liability, including negligence. In Spence v. Brown-Minneapolis Tank, Co., 198 P.3d 395 (Okla. Civ. App. 2008), the court rejected a negligence claim premised on the same facts as a strict liability claim because the defendant "had nothing to do with the manufacture" of the product at issue and did not "occupy a relationship which gives rise to a legal obligation . . . for the benefit of the" plaintiff. Id. at 401. Similarly, in Copeland v. Admiral Pest Control, 933 P.2d 937 (Okla. Civ. App. 1996), the court noted that for a claim in negligence, "[w]hether or not a duty exists depends on the relationship between the parties." Id. at 939. The brand-name manufacturers do not have any relationship with the Schrocks.

We are directed to Independent-Eastern Torpedo Co. v. Price, 258 P.2d 189 (Okla. 1953), as supporting the Schrocks' negligence claim. In Price, the Oklahoma Supreme Court held that a company had a duty to warn an individual injured by a company employee. Id. at 201. The duty, however, was based on the employer-employee relationship between the defendant and the person who injured the plaintiff. Id. (citing

Southland Cotton Oil Co. v. Renshaw, 299 P. 425 (Okla. 1931)). Such a relationship is not present between the generic and brand-name manufacturers.

In support of their misrepresentation, fraud, and failure-to-warn claims, the Schrocks advance two arguments. First, they argue that the brand-name manufacturers concealed a latent defect in their product. However, in the Oklahoma cases they cite as permitting such claims, the plaintiff and defendant were engaged in a buyer-seller or other contractual relationship. See Rogers v. Meiser, 68 P.3d 967, 976 (Okla. 2003) ("[A] vendor is guilty of fraudulent concealment of a latent defect affecting the value of property for the purpose for which it was bought."); Dawson v. Tindell, 733 P.2d 407, 408-09 (Okla. 1987) (suit by home buyers against realtor); O'Quinn v. Nothaff, 205 P. 498, 500 (Okla. 1922) ("[T]he defendants induced the plaintiff to enter into the contract for the exchange of the cars by committing a fraud."); Von Brauchitsch v. Cravens, 604 P.2d 379, 380 (Okla. Civ. App. 1978) ("A latent soil defect, known to the seller of a house built on such soil, creates a duty of disclosure in the seller."). See also Okland Oil Co. v. Conoco Inc., 144 F.3d 1308, 1312 (10th Cir. 1998); Uptegraft v. Dome Petroleum Corp., 764 P.2d 1350, 1351-52 (Okla. 1988). No authority is cited to suggest that a manufacturer may be held liable under Oklahoma law for concealing a defect in a product that is never purchased or used by the plaintiff.

Second, the Schrocks argue that Oklahoma law imposes a duty upon brand-name manufacturers to speak rather than to remain silent in certain circumstances. The Schrocks recognize, however, "[i]n determining whether there is a duty to speak,

consideration must be given to the situation of the parties and the matters with which they are dealing." Silk v. Phillips Petroleum Co., 760 P.2d 174, 179 (Okla. 1988). Even accepting the Schrocks' assertion that the brand-name manufacturers conveyed "a false impression by the disclosure of some facts and the concealment of others," Deardorf v. Rosenbusch, 206 P.2d 996, 998 (Okla. 1949), it nonetheless remains true that the brand-name manufacturers had no relationship with the Schrocks; there were no "matters with which they [we]re dealing," Silk, 760 P.2d at 179.

To the same effect, the Schrocks argue that under Oklahoma law, liability may be imposed if a defendant has knowledge of a dangerous situation yet fails to warn of that danger. They cite two cases for this contention: one involves a relationship that clearly requires a duty, and in the other the court held that there was no duty. Wells v. Boston Ave. Realty, 125 F.3d 1335, 1339 (10th Cir. 1997) (holding that a "business owner is not liable for third person assaults"); Rogers v. Hennessee, 602 P.2d 1033, 1034 (Okla. 1979) (noting that the "parties stand in an undisputed invitor-invitee relationship"). These cases do not persuade us that Oklahoma courts would impose a duty on drug manufacturers to warn of dangers in their competitors' products.

The Schrocks do not develop any specific argument regarding their breach of warranty claims. Nonetheless, the Oklahoma Uniform Commercial Code contemplates such claims only as against the seller of the product at issue. See Okla. Stat. tit. 12A, § 2-313 (express warranties are "created" by the seller with representations that become "part of the basis of the bargain"); § 2-314 ("[A] warranty that the goods shall be

merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind."); § 2-315 ("Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose."). This cause of action does not apply.

We are told that the brand defendants may be held liable under "traditional theories of tort law." Several provisions of the Restatement (Second) of Torts, which recite general tort principles of duty and foreseeability, are relied on by the Schrocks. See, e.g., Restatement (Second) of Torts §§ 302A; 310; 315; 324A. Although several other provisions of the Restatement are cited by the Schrocks in response to Wyeth and Schwarz's motion for summary judgment, they did not bring these specific Restatement-based theories to the attention of the district court. Arguments that were not raised below are "waived for purposes of appeal." Quigley v. Rosenthal, 327 F.3d 1044, 1069 (10th Cir. 2003). This rule applies when a "litigant changes to a new theory on appeal that falls under the same general category as an argument presented at trial or presents a theory that was discussed in a vague and ambiguous way." Bancamerica Comm. Corp. v. Mosher Steel of Kan., Inc., 100 F.3d 792, 798-99 (10th Cir. 1996) (quotations omitted).

Moreover, as the foregoing discussion demonstrates, the Schrocks fail to cite Oklahoma case law suggesting that these general tort principles impose liability with respect to a defendant that did not sell, distribute, manufacture, or otherwise have contact

with the allegedly harmful product. Instead, they ask this court to expand the scope of tort liability under Oklahoma law by imposing a duty under entirely unprecedented circumstances. "As a federal court, we are generally reticent to expand state law without clear guidance from its highest court." Taylor v. Phelan, 9 F.3d 882, 887 (10th Cir. 1993). And the Schrocks' novel claims are not supported by "decisions rendered by lower courts in the relevant state" or "district court decisions interpreting the law of the state in question." Wade, 483 F.3d at 666 (citations and quotation omitted).

We may also look to "appellate decisions in other states with similar legal principles . . . and the general weight and trend of authority in the relevant area of law" in predicting whether the Oklahoma Supreme Court would recognize a cause of action against a brand-name drug manufacturer under the present circumstances. But the courts of other states have overwhelmingly rejected the very theory advanced by the Schrocks. See Mensing v. Wyeth, Inc., 588 F.3d 603, 613 (8th Cir. 2009) (the "overwhelming majority of courts" have declined to impose liability against brand-name manufactures on claims by consumers of a generic equivalent drug), rev'd in part on other grounds sub nom. PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011).

In Foster v. American Home Products, 29 F.3d 165 (4th Cir. 1994), the Fourth Circuit rejected "the contention that a name brand manufacturer's statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug." Id. at 170. The court explained:

Name brand advertising benefits generic competitors because generics are

> generally sold as substitutes for name brand drugs, so the more a name brand drug is prescribed, the more potential sales exist for its generic equivalents. There is no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control. This would be especially unfair when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer's statements by copying its labels and riding on the coattails of its advertising.

Id. Since Foster was decided, every federal circuit court to address this issue—applying the law of numerous states—has consistently followed. See Guarino v. Wyeth, LLC, No. 12-13263, 2013 WL 3185084, at *6, __ F.3d __ (11th Cir. June 25, 2013) ("[T]he overwhelming national consensus—including the decisions of every court of appeal and the vast majority of district courts around the country to consider the question—is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product."); Bell v. Pfizer, Inc., No. 12-1674, 2013 WL 2661189, at *3 716 F.3d 1087 (8th Cir. June 14, 2013) ("Because Bell never used Reglan the brand defendants manufactured, Bell cannot hold them liable under Arkansas law."); Demahy v. Schwarz Pharma, Inc., 702 F.3d 177, 183 (5th Cir. 2012) (per curiam) (under Louisiana law, plaintiff's "claims against Wyeth and Schwarz fail because they did not manufacture the medication she actually consumed"), rev'd in part on other grounds sub nom. Mensing, 131 S. Ct. 2567; Smith v. Wyeth, Inc., 657 F.3d 420, 423-24 (6th Cir. 2011) (argument "that the name-brand defendants' liability stems from the fact that the regulatory structure governing name-brand and generic drugs makes it foreseeable that patients and their physicians will rely on the name-brand labels to use and prescribe

generic drugs" was "rejected by all but one of the courts that have considered it"), cert. denied, 132 S. Ct. 2103 (2012); Mensing, 588 F.3d at 614 (concluding that "under Minnesota law Mensing has not shown that the name brand manufacturers owed her a duty of care necessary to trigger liability"), rev'd in part on other grounds sub nom. Mensing, 131 S. Ct. 2567.

Courts that have concluded brand-name manufacturers are not liable to consumers of generic drugs relied on three principal rationales. First, they based their view on traditional common law tort principles under which a manufacturer is liable for injuries caused by its own product. See, e.g., Mensing, 588 F.3d at 604, 613 (holding name brand manufacturers liable for harm caused by generic manufacturers "stretches the concept of foreseeability too far" (quotation and alteration omitted)). Second, they reason that brand-name manufacturers' warnings and representations do not create a basis for liability to consumers of competitors' products because brand-name manufacturers only "intend[] to communicate with their customers, not the customers of their competitors." Id. at 613 n.9; see also Stanley v. Wyeth, Inc., 991 So. 2d 31, 34 (La. Ct. App. 2008) ("A manufacturer cannot reasonably expect that consumers will rely on the information it provides when actually ingesting another company's drug."). Finally, they conclude that public policy considerations weigh against holding name-brand competitors liable for injuries caused by their generic competitor's drug. See, e.g., Foster, 29 F.3d at 170 (citing the expense in development, research, and promotion undertaken by name-brand manufacturers not undertaken by generic manufacturers).

In contrast to the dozens of cases holding to the contrary, only a handful of courts—and no federal courts of appeals—have held that brand-name manufacturers can be held liable for injuries caused by their generic counterparts. See Kellogg v. Wyeth, 762 F. Supp. 2d 694 (D. Vt. 2010); Easter v. Aventis Pasteur, Inc., No. 5:03-CV-141, 2004 WL 3104610 (E.D. Tex. Feb. 11, 2004) (unpublished); Wyeth, Inc. v. Weeks, No. 1101397, 2013 WL 135753, __ So. 2d __ (Ala. Jan. 11, 2013); Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008).

We predict that the Oklahoma Supreme Court would not recognize this novel theory of liability.[4] Accordingly, we affirm the district court's grant of summary judgment in favor of Wyeth and Schwarz.

C

Finally, the Schrocks argue that the district court erred in concluding that their breach of express and implied warranty claims against Qualitest were preempted by federal law under the doctrine of impossibility preemption.[5] The Supremacy Clause provides that the Constitution, laws, and treaties of the United States "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. State law is preempted if it is

[4] Notably, the Schrocks did not request certification of this issue to the Oklahoma Supreme Court.

[5] The Schrocks do not appeal the district court's dismissal of their breach of warranty claims against PLIVA.

"impossible for a private party to comply with both state and federal requirements." English v. Gen. Elec. Co., 496 U. S. 72, 79 (1990). As the Supreme Court explained in its recent FDCA preemption case, state tort law is preempted if it imposes a duty upon manufacturers to take some action that is prohibited under federal law, because such a regime "actually conflicts with federal law by making it impossible for a private party to comply with both state and federal requirements." Mut. Pharm. Co., Inc. v. Bartlett, 133 S. Ct. 2466, 2479 (2013) (quotation and alterations omitted).

Our analysis of whether the Schrocks' state law warranty claims are preempted thus "begin[s] by identifying [Qualitest's] duties under state law." Id. at 1473. Under Oklahoma law, an express warranty is defined as "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain," "[a]ny description of the goods which is made part of the basis of the bargain," or "[a]ny sample or model which is made part of the basis of the bargain." Okla. Stat. tit. 12A, § 2-313(1)(a)-(c). Unless excluded or modified, a warranty that goods are "merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Okla. Stat. tit. 12A, § 2-314(1). To comply with this warranty, goods must:

> (a) pass without objection in the trade under the contract description; and
> (b) in the case of fungible goods, [be] of fair average quality within the description; and
> (c) [be] 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) [be] 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.

§ 2-314(2) (a)-(f).

Consistent with these statutory provisions, the Schrocks alleged under the "Breach of Warranties" heading in their amended complaint that: (1) Qualitest "expressly and impliedly warranted that . . . metoclopramide [was] not unreasonably dangerous and instead [was] merchantable and fit for its intended use"; (2) Qualitest's metoclopramide "contained descriptions of the safety profile of the medication to which it did not conform"; (3) Qualitest's metoclopramide was "not adequately contained, packaged, and labeled, and did not conform to the promises [and] affirmations of fact made in the label which accompanied the drug"; and (4) Qualitest's "metoclopramide did not conform to express warranties present on its labeling, was not merchantable, was unfit for its intended use, and was unreasonably dangerous."

Both the complaint and the Oklahoma statute refer to the manner in which a product is labeled, packaged, and otherwise described to the consumer. See Okla. Stat. tit. 12A, § 2-313(1)(a)-(b) ("promise[s]" and "description[s]" of the goods); § 2-314(2) (a) ("pass without objection in the trade under the contract description"); § 2-314(2)(b) ("are of fair average quality within the description"); § 2-314(2)(e) ("are adequately contained, packaged, and labeled as the agreement may require"); § 2-314(2)(f) ("conform to the promises or affirmations of fact made on the container or label"). Repeatedly, the Schrocks' complaint refers to the "descriptions" and "labeling" of the

metoclopramide. These warranty claims are thus based on the theory that Qualitest provided improper descriptions or warnings in the labeling and packaging of metoclopramide or that the content of the metoclopramide Qualitest sold rendered it unreasonably dangerous or unmerchantable.

In Mensing, the Court recognized that federal law imposes "an ongoing federal duty of 'sameness'" that precludes generic drug manufacturers from altering their products labels. 131 S. Ct. at 2575 (citing Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (1992)). Further, generic manufacturers may not use "'Dear Doctor' letters to send additional warnings to prescribing physicians and other healthcare professionals." Id. at 2576. Deferring to the FDA's interpretation of its regulations, the Mensing Court held that "Dear Doctor letters qualify as 'labeling'" and thus such a letter "that contained substantial new warning information would not be consistent with the drug's approved labeling." Id. Based on these determinations, the Court held that state law failure-to-warn claims against generic drug manufacturers are preempted by federal regulations because it is impossible for a generic manufacturer of metoclopramide to unilaterally alter its drug's label to comply with state law without violating FDA regulations. Id. at 2577-78.

Key to the Mensing decision was the Court's deference to the FDA's broad-definition of "labeling." Id. at 2576. Under FDA regulations, the term "labeling" in the prescription drug context is expansive, including:

[b]rochures, booklets, mailing pieces, detailing pieces, file cards, bulletins,

> calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the "Physicians' Desk Reference") for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor . . . .

21 C.F.R. § 202.1(*l*)(2); see also Del Valle v. PLIVA, Inc., No. B:11-113, 2011 WL 7168620, at *4 (S.D. Tex. Dec. 21, 2011) (unpublished) ("In essence, virtually all communication with medical professionals concerning a drug constitutes labeling.") adopted sub nom. Del Valle v. Qualitest Pharm. Inc., 2012 WL 2899406 (S.D. Tex. June 22, 2012) (unpublished)).

Plaintiffs attempt to distinguish Mensing by asserting that it only addressed failure-to-warn claims in the context of a drug's label, which they appear to construe narrowly. Yet the same federal regulatory scheme that prevented generic manufacturers from unilaterally issuing label changes and "Dear Doctor letters" at issue in Mensing applies to a broad array of communications. No effort is made to identify a mechanism through which Qualitest could have modified or supplemented the warranties allegedly breached without running afoul of the duty of sameness identified in Mensing. Accordingly, the Schrocks' claims are preempted to the extent they rest on inadequate labeling as broadly defined by the FDA.

It is also alleged in the complaint that Qualitest's product "was not merchantable, was unfit for its intended use, and was unreasonably dangerous." See

Okla. Stat. tit. 12A, § 2-314(2)(c) (implied warranty that product is "fit for the ordinary purposes for which such goods are used"). Under Oklahoma law, products are "merchantable" or "fit" if they "operate for their ordinary purpose." Perry v. Lawson Ford Tractor Co., 613 P.2d 458, 463 (Okla. 1980). We conclude that these claims, based on allegations of dangerousness or ineffectiveness, are also preempted because Qualitest could not have altered the composition of the metoclopramide it manufactured without violating federal law. In Bartlett the Supreme Court held that the reasoning of Mensing extends to "warning-based design-defect cause[s] of action" asserted against generic manufacturers. Bartlett, 133 S. Ct. at 2477. The Court noted that under the state law at issue, a manufacturer has a duty to "ensure that the products they design, manufacture, and sell are not unreasonably dangerous," which can be "satisfied either by changing a drug's design or by changing its labeling." Id. at 2474. As in Mensing, the Court explained that labeling changes are preempted because generic manufacturers have a "federal-law duty not to alter [a drug's] label." Bartlett, 133 S. Ct. at 2473.

Further, the Court extended its reasoning in Mensing to claims that a generic drug is ineffective or unreasonably dangerous. "In the drug context, either increasing the 'usefulness' of a product or reducing its 'risk of danger' would require redesigning the drug: A drug's usefulness and its risk of danger are both direct results of its chemical design and, most saliently, its active ingredients." Bartlett, 133 S. Ct. at 2475. But "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is

based." Id. (citing 21 U.S.C. §§ 355(j)(2)(A)(ii)-(v) and (8)(B); 21 C.F.R. § 320.1(c)). Under Bartlett, a claim that a generic drug manufacturer's product is unfit for its intended use or unreasonably dangerous is one that would impose a duty to alter the composition of that drug. See Bartlett, 133 S. Ct. at 2474-75; see also Bartoli v. APP Pharm., Inc., (In re Pamidronate Prod. Liab. Litig.), 842 F. Supp. 2d 479, 485 (E.D.N.Y. 2012) (a "breach of implied warranty claim necessarily alleges that defendants should have changed the design of [a drug] to make it safe and fit for its intended uses" and is therefore preempted (quotation omitted)); In re Fosamax Prods. Liab. Litig. (No. II), No. 08-008, 2011 WL 5903623, at *8 (D.N.J. Nov. 21, 2011) (unpublished) ("[B]reach of implied warranty claim necessarily alleges that manufacturers should have changed [a drug's] design. This would be in violation of the federal duty of sameness, and therefore, this claim is preempted.").

In advancing their warranty claims, the Schrocks allege that Qualitest had a duty under state law to alter either the composition or the labeling, as broadly defined by the FDA, of its generic metoclopramide. Because Qualitest could not have taken either action under federal law, we conclude these claims are preempted. The Eleventh Circuit has reached the same conclusion. See Guarino, 2013 WL 3185084, at *1-2 (holding claims against generic manufacturer, including breach of warranty claim, preempted because all claims were "premised upon an allegedly inadequate warning"). And the Ninth Circuit summarily affirmed a district court decision concluding that similar warranty claims were preempted on remand from the Supreme Court following Mensing.

See Gaeta ex rel. A.G. v. Perrigo Pharms. Co., 469 F. App'x 556 (9th Cir. 2012) (unpublished); see also Gaeta v. Perrigo Pharms. Co., 562 F. Supp. 2d 1091, 1097-98 (N.D. Cal. 2008) (express and implied warranty claims preempted because generic manufacturer could not alter labeling and be consistent with federal law).[6]

In Metz v. Wyeth, LLC, 872 F. Supp. 2d 1335 (M.D. Fla. 2012), the Middle

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[6] In Bell v. Pfizer, Inc., 716 F.3d 1087 (8th Cir. 2013), the Eighth Circuit reversed a grant of summary judgment based on preemption because it was unable to determine whether plaintiff's "breach of implied warranty claims, other than those based on an inadequate warning or labeling, are in essence, failure-to-warn claims." Id. at 1096. As noted supra, however, the Supreme Court has since extended the holding of Mensing to cover not just failure-to-warn claims, but also those claims that would require a redesign of a generic drug. Bartlett, 133 S. Ct. at 2476-77.

We reject the Schrocks' reliance on the Eighth Circuit's decision in Fullington v. Pfizer, Inc., No. 12-2945, 2013 WL 3491060, __ F.3d __ (8th Cir. July 15, 2013). In Fullington, the court reversed the dismissal of warranty claims against generic manufacturers of metoclopramide because it concluded that the district court improperly "categorized [the claims] as failure-to-warn claims," and thus concluded the claims were preempted under Supreme Court precedent. Id. at *4. For the reasons stated supra, we hold that the Schrocks' warranty claims are properly characterized as failure-to-warn claims or as design defect claims. And as the Eighth Circuit states, "Bartlett casts doubt on the viability of [design defect claims]." Fullington, 2013 WL 3491060, at *5.

We are similarly not persuaded by the Schrocks' reliance on pre-Bartlett case law. For example, they cite Wyeth v. Levine, 555 U.S. 555, 574-75 (2009), for the proposition that the FDCA does not preempt all state torts against drug manufacturers. We are not inclined to make such a sweeping holding; we simply construe Bartlett as indicating the Schrocks' warranty claims are preempted. Bartlett stressed the Court had not "ignored Congress' explicit efforts to preserve state common-law liability," citing Levine. Bartlett, 133 S. Ct. at 2480. The Schrocks also point to Bates v. Dow Agrosciences, LLC, 544 U.S. 431 (2005), as providing the rule of decision in this case. But the majority in Bartlett explicitly rejected the argument that Bates was dispositive, explaining that in Bates "the design-defect claim in question was not a requirement for labeling or packaging" and also that Bates addressed a different statutory scheme than the FDCA, which was the relevant statute both in Bartlett and the case at bar. Bartlett, 133 S. Ct. at 2479 (quotations and emphasis omitted).

District of Florida held that metoclopramide-related warranty claims were preempted because they stemmed from a failure to warn. Id. at 1341. We are pointed to the court's dicta stating that "an implied warranty claim may survive preemption" if it is based on a claim that the generic manufacturer provided a warranty "contrary [to] the FDA approved label." Id. at 1342; see also Fisher v. Pelstring, 817 F. Supp. 2d 791, 820 (D.S.C. 2011) (claim that generic manufacturer did not update label to match changes in brand-name label not preempted); Couick v. Wyeth, Inc., No. 09-210, 2012 WL 79670, at *3-4 (W.D. N.C. Jan. 11, 2012) (unpublished) (same). There is no allegation, however, that Qualitest's label deviated from the FDA-approved label.

We do not lend credence to the Schrocks' argument that Qualitest could have complied with its alleged duty under state tort law and with the federal requirements by simply declining to manufacture metoclopramide. The Supreme Court squarely rejected this contention in Bartlett, holding that the "'stop-selling' rationale [is] incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." 133 S. Ct. at 2477.

Finally, we reject the argument that the state law warranty claims are not preempted because they simply parallel requirements imposed by federal law. See Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008) (federal law does not "prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements"). The

Schrocks argue that the requirements of Oklahoma state law regarding warranties parallel federal law because the metoclopramide was "misbranded" under 21 U. S. C. §352(j), and are therefore not preempted. But the Bartlett court indicated in dicta that "a drug is misbranded under federal law only when liability is based on new and scientifically significant information that was not before the FDA" and that allegations of dangerousness based on "the medical literature or published FDA analyses" would not qualify. 133 S. Ct. at 2477 n.4. A misbranding claim along these lines has not been advanced.

IV

We recognize the catch-22 situation in which existing jurisprudence places the Schrocks and similarly situated consumers of generic drugs. They cannot obtain relief from brand-name drug manufacturers because, as we predict, Oklahoma would not impose a duty on the brand-name manufacturers that flows to consumers of generic drugs. Yet the Schrocks' claims against generic drug manufacturers are preempted under Mensing and Bartlett. As a federal court, however, we have limited authority to correct this potential injustice. It is for the state courts, rather than this panel, to engage in the delicate policy considerations predicate to the expansion of the scope of state tort law. See Taylor, 9 F.3d at 887. Moreover, as the Mensing court acknowledged, courts are not asked "to decide whether the statutory scheme established by Congress is unusual or even bizarre" despite the "the unfortunate hand that federal drug regulation has dealt" consumers of generic drugs. 131 S. Ct. at 2581-82. If consumers of generic drugs are to

obtain federal relief, it must come from Congress.

We **AFFIRM**. PLIVA's motion to dismiss for lack of jurisdiction is **DENIED**.