IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

September 2017 Term

FILED
November 1, 2017
released at 3:00 p.m.
EDYTHE NASH GAISER, CLERK
SUPREME COURT OF APPEALS
OF WEST VIRGINIA

No. 16-0927

M.M.,
A MINOR, BY AND THROUGH HER MOTHER
AND NEXT FRIEND Jeanette M.,
Plaintiff Below, Petitioner

V.

PFIZER, INC.;
ROERIG, A DIVISION OF PFIZER, INC.; AND
GREENSTONE, LLC,
Defendants Below, Respondents

Appeal from the Mass Litigation Panel
Circuit Court of Kanawha County
Honorable James P. Mazzone, Judge
In re Zoloft Litigation
No. 14-C-7000
Civil Action No. 12-C-149

AFFIRMED

Submitted: October 17, 2017
Filed: November 1, 2017

Benjamin L. Bailey
Ryan McCune Donovan
J. Zak Ritchie
Bailey & Glasser LLP
Charleston, West Virginia
Bert Ketchum
Greene Ketchum
Huntington, West Virginia
Attorneys for the Petitioner

Michael J. Farrell
Erik W. Legg
Megan Farrell Woodyard
Farrell, White & Legg PLLC
Huntington, West Virginia
Mark S. Cheffo, *pro hac vice*
Quinn Emanuel Urquhart & Sullivan, LLP
New York, New York
Attorneys for the Respondents

JUSTICE DAVIS delivered the Opinion of the Court.

JUSTICE KETCHUM, deeming himself disqualified, did not participate in the decision of this case.

JUDGE REEDER, sitting by special assignment.

SYLLABUS BY THE COURT

1. "A motion for summary judgment should be granted only when it is clear that there is no genuine issue of fact to be tried and inquiry concerning the facts is not desirable to clarify the application of the law." Syllabus point 3, *Aetna Casualty & Surety Co. v. Federal Insurance Co. of New York*, 148 W. Va. 160, 133 S.E.2d 770 (1963).

2. "If there is no genuine issue as to any material fact summary judgment should be granted[.]" Syllabus point 4, in part, *Aetna Casualty & Surety Co. v. Federal Insurance Co. of New York*, 148 W. Va. 160, 133 S.E.2d 770 (1963).

3. "In general, this State adheres to the conflicts of law doctrine of *lex loci delicti*." Syllabus point 1, *Paul v. National Life*, 177 W. Va. 427, 352 S.E.2d 550 (1986).

4. "Product liability actions may be premised on three independent theories–strict liability, negligence, and warranty. Each theory contains different elements which plaintiffs must prove in order to recover. No rational reason exists to require plaintiffs in product liability actions to elect which theory to submit to the jury after the evidence has been presented when they may elect to bring suit on one or all of the theories." Syllabus point 6, *Ilosky v. Michelin Tire Corp.*, 172 W. Va. 435, 307 S.E.2d 603 (1983).

5. "In order to establish a *prima facie* case of negligence in West Virginia, it must be shown that the defendant has been guilty of some act or omission in violation of a duty owed to the plaintiff. No action for negligence will lie without a duty broken." Syllabus point 1, *Parsley v. General Motors Acceptance Corp.*, 167 W. Va. 866, 280 S.E.2d 703 (1981).

Davis, Justice:

The petitioner herein and plaintiff below, M.M.[1] ("M.M." or "the Petitioner"), a minor, by and through her mother and next friend Jeanette M., appeals from an order entered August 30, 2016, by the Mass Litigation Panel ("the Panel"). By its order, the Panel granted summary judgment to the respondents herein and defendants below, Pfizer, Inc.; Roerig, a division of Pfizer, Inc.; and Greenstone, LLC (collectively "Pfizer" or "the Respondents") upon its conclusion that there existed no genuine issue of material fact and that Pfizer was entitled to judgment as a matter of law. On appeal to this Court, M.M. assigns error to the Panel's order and contends that disputed issues of material fact preclude summary judgment, the Panel applied the wrong state's law under its choice of law analysis, and the asserted claims are not preempted by federal law. Upon our review of the parties' arguments, the pertinent authorities, and the record designated for consideration on appeal, we conclude that the Panel correctly determined that the Respondents are entitled to summary judgment. Accordingly, we affirm the August 30, 2016, order of the Mass Litigation Panel.

[1]Given that the instant proceeding involves an infant plaintiff, we will refer to her, and her mother, by their initials rather than by their full names. *See State ex rel. J.C. ex rel. Michelle C. v. Mazzone*, 235 W. Va. 151, 153 n.1, 772 S.E.2d 336, 338 n.1 (2015).

I.

FACTUAL AND PROCEDURAL HISTORY

M.M., an infant, by her mother, is one of nineteen minor plaintiffs who have alleged that they sustained birth defects as a result of their mothers' use of the prescription medication Zoloft. In the case *sub judice*, M.M. alleges that she sustained *in utero* injuries and resultant birth defects when her mother ingested sertraline hydrochloride while she was pregnant with M.M. Respondent Pfizer manufactures and markets sertraline hydrochloride as the antidepressant drug, Zoloft; Respondent Roerig is a former division of Pfizer, while Respondent Greenstone is a wholly owned subsidiary of Pfizer that sells an authorized generic version of this medication. More specifically, M.M., who, through her mother, filed her complaint in the Circuit Court of Wayne County in 2012, contends that the 2009 labeling information for Zoloft did not warn prescribing physicians that the use of Zoloft in pregnancy was linked to an increased risk of birth defects and that women should use contraceptives while taking Zoloft.

Since the action's filing, the Respondents repeatedly, but unsuccessfully, have attempted to remove the subject litigation to federal court; the case has been referred to the Mass Litigation Panel; and this Court has decided several procedural issues in the ongoing litigation. *See State ex rel. J.C. ex rel. Michelle C. v. Mazzone*, 235 W. Va. 151, 772 S.E.2d 336 (2015) (*forum non conveniens*); *State ex rel. J.C. v. Mazzone*, 233 W. Va. 457, 759

S.E.2d 200 (2014) (assigning matter consolidated case number instead of individual case numbers). In 2015, M.M. filed an amended complaint asserting specific claims for strict liability, failure to warn, and negligence. Thereafter, the Respondents filed a motion for summary judgment, which the Panel granted by order entered August 30, 2016. In short, the Panel concluded that Michigan law governs M.M.'s claims; federal law operates to preempt the exception to Michigan's failure to warn immunity where the subject drug has received FDA approval; no genuine issues of material fact remained in the case; and the Respondents are entitled to judgment as a matter of law. From this adverse ruling, M.M. now appeals to this Court.

II.

STANDARD OF REVIEW

The case *sub judice* comes to this Court on appeal from the Panel's order granting summary judgment to the Respondents. We previously have held that this Court will apply a plenary review to a summary judgment ruling. *See* Syl. pt. 1, *Painter v. Peavy*, 192 W. Va. 189, 451 S.E.2d 755 (1994) ("A circuit court's entry of summary judgment is reviewed *de novo*."). In determining whether a moving party is entitled to summary judgment, we have held that "[a] motion for summary judgment should be granted only when it is clear that there is no genuine issue of fact to be tried and inquiry concerning the facts is not desirable to clarify the application of the law." Syl. pt. 3, *Aetna Cas. & Sur. Co. v.*

Federal Ins. Co. of New York, 148 W. Va. 160, 133 S.E.2d 770 (1963). *Accord* W. Va. R. Civ. P. 56(c) (directing that summary judgment is proper when "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law"). Thus, "[i]f there is no genuine issue as to any material fact summary judgment should be granted[.]" Syl. pt. 4, in part, *Aetna*, 148 W. Va. 160, 133 S.E.2d 770. *See also* Syl. pt. 5, *id.* ("The question to be decided on a motion for summary judgment is whether there is a genuine issue of fact and not how that issue should be determined."). Mindful of these standards, we proceed to consider the parties' arguments.

III.

DISCUSSION

On appeal to this Court, M.M. assigns error to the circuit court's ruling and contends that genuine issues of material fact preclude summary judgment; West Virginia, not Michigan, law applies to M.M.'s claims; and, even if Michigan law applies, such law is not preempted by federal law. More specifically, M.M. argues that the Panel erred by granting summary judgment to Pfizer because there remain genuine issues of material fact so as to preclude summary judgment because, counsel contends, Pfizer knew of the dangers of Zoloft use during pregnancy, generated reports suggesting contraceptive use while taking the medication, and realized the import of the possibility of birth defects by specifically including contraceptive warnings on its European packaging for the drug. Based on these

facts, M.M. contends that a jury should be allowed to determine whether Pfizer was negligent or strictly liable for its failure to adequately warn of the possibility of birth defects linked to Zoloft usage by women of childbearing age.

Pfizer responds that the Panel correctly determined that, while worded as three separate and distinct claims for relief, *i.e.*, strict liability, failure to warn, and negligence, M.M.'s claims essentially all seek to impose liability for the same alleged shortcoming of Pfizer: failure to warn. Moreover, Pfizer argues that, under either Michigan or West Virginia law, M.M. cannot prevail because Michigan statutory law expressly forecloses a failure to warn claim where the medication in question has been approved by the FDA and the exception thereto is preempted by federal law. Furthermore, even if West Virginia law governs M.M.'s claims, the infant still is not entitled to relief insofar as there is no alleged duty with which Pfizer has failed to comply (negligence claim) and failure to warn is the only theory of strict liability advanced by M.M., which is foreclosed by Michigan statutory law. Accordingly, Pfizer contends that the Panel's order granting summary judgment in its favor should be affirmed.

In the infant's amended complaint, M.M. has asserted three causes of action against Pfizer: strict liability, failure to warn, and negligence. Pursuant to W. Va. Code § 55-

8-16(a) (2011) (Supp. 2011),[2]

> [i]t is public policy of this state that, in determining the law applicable to a product liability claim brought by a nonresident of this state against the manufacturer or distributor of a prescription drug for failure to warn, *the duty to warn shall be governed solely by the product liability law of the place of injury* ("lex loci delicti").

(Emphasis added). Here, there is no dispute that the injuries alleged by M.M. and the infant's mother all occurred in the State of Michigan. Thus, M.M.'s failure to warn claim is governed by Michigan law, which forecloses such a claim if the drug was approved by the FDA and the manufacturer complied with the FDA's labeling requirements:

> (5) In a product liability action against a manufacturer or seller, *a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.* However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the

---

[2]W. Va. Code § 55-8-16(a) (2011) (Supp. 2011) was amended in 2015, but we apply the version of the statute that was in effect at the time of the events giving rise to the case *sub judice*. *See* W. Va. Code § 55-8-16(b) (2011) ("This section shall be applicable prospectively to all civil actions commenced on or after July 1, 2011."). *Cf.* W. Va. Code § 55-8-16(a) (2015) (Repl. Vol. 2016) ("It is public policy of this state that, in determining the law applicable to a product liability claim brought by a nonresident of this state against the manufacturer or distributor of a prescription drug or other product, *all liability claims at issue* shall be governed solely by the product liability law of the place of injury (lex loci delicti)." (emphasis added)).

> defendant at any time before the event that allegedly caused the injury does any of the following:
>
> (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.
>
> (b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

Mich. Comp. Laws Ann. §§ 600.2946(5)(a-b) (West 1995) (emphasis added). While M.M. attempts to rely upon the fraud on the FDA exception set forth in subsection (b), such an exception is valid only if the FDA, itself, acknowledges the perpetration of such fraud, which M.M. has not alleged here. *See Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 381 (5th Cir. 2012) (holding that "a fraud-on-the-FDA provision . . . is preempted by the FDCA unless the FDA itself finds fraud"); *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004) (concluding that fraud on the FDA exception is not preempted where "the *FDA itself* determines that a fraud has been committed on the agency during the regulatory-approval process" (emphasis in original; citation omitted)). In all other respects, operation of this exception is preempted by federal law. *See generally Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348, 121 S. Ct. 1012, 1017, 148 L. Ed. 2d 854 (2001) ("hold[ing] that . . . state-law fraud-on-the-FDA claims conflict with, and are therefore

impliedly pre-empted by, federal law" (footnote omitted)). Thus, Michigan law forecloses M.M.'s failure to warn claim.

M.M.'s remaining claims also are thwarted, whether they are governed by Michigan law or West Virginia law. Ordinarily, M.M.'s strict liability and negligence claims would be governed by Michigan law insofar as the alleged injuries occurred in Michigan. That is so because, "[i]n general, this State adheres to the conflicts of law doctrine of *lex loci delicti*." Syl. pt. 1, *Paul v. National Life*, 177 W. Va. 427, 352 S.E.2d 550 (1986). *Accord McKinney v. Fairchild Int'l, Inc.*, 199 W. Va. 718, 727, 487 S.E.2d 913, 922 (1997) ("Traditionally, West Virginia courts apply the *lex loci delicti* choice-of-law rule; that is, the substantive rights between the parties are determined by the law of the place of injury." (citations omitted)). Under this standard, M.M.'s claims fail because both the strict liability and negligence claims allege that Pfizer improperly failed to include contraceptive and/or birth defect warnings on its labeling, which, again, constitute allegations that Pfizer failed to warn of the dangers of Zoloft. Such a claim is foreclosed by Mich. Comp. Laws Ann. §§ 600.2946(5)(a-b).

However, assuming *arguendo* that West Virginia law governs M.M.'s claims given that the Panel denied Pfizer's *forum non conveniens* motion because no other available

forum existed in which to try M.M.'s substantive claims,[3] M.M. still cannot prevail on the additional claims of strict liability and negligence set forth in the infant's amended complaint under West Virginia substantive law. *See Mills v. Quality Supplier Trucking, Inc.*, 203 W. Va. 621, 624, 510 S.E.2d 280, 283 (1998) ("We . . . adhere to the rule that the doctrine of lex loci delicti will not be invoked where 'the application of the substantive law of a foreign state . . . contravenes the public policy of this State.'" (quoting *Paul*, 177 W. Va. at 433, 352 S.E.2d at 556)).

This Court previously has held that, in West Virginia,

> [p]roduct liability actions may be premised on three independent theories–strict liability, negligence, and warranty. Each theory contains different elements which plaintiffs must prove in order to recover. No rational reason exists to require plaintiffs in product liability actions to elect which theory to submit to the jury after the evidence has been presented when they may elect to bring suit on one or all of the theories.

Syl. pt. 6, *Ilosky v. Michelin Tire Corp.*, 172 W. Va. 435, 307 S.E.2d 603 (1983). In the case

---

[3]*See generally* W. Va. Code § 56-1-1a(a)(1) (2008) (Repl. Vol. 2012) (including, within *forum non conveniens* analysis, consideration of "[w]hether an alternate forum exists in which the claim or action may be tried"); Syl. pt. 9, *Mace v. Mylan Pharms., Inc.*, 227 W. Va. 666, 714 S.E.2d 223 (2011) ("In considering 'whether an alternate forum exists in which the claim or action may be tried' pursuant to West Virginia Code § 56-1-1a(a)(1) (Supp. 2010), an alternate forum is presumed to 'exist' where the defendant is amenable to process. Such presumption may be defeated, however, if the remedy provided by the alternative forum is so clearly inadequate or unsatisfactory that it is no remedy at all. In such cases, the alternate forum ceases to 'exist' for purposes of forum non conveniens, and dismissal in favor of that forum would constitute error.").

sub judice, M.M. alleges all three of these theories of product liability: strict liability, negligence, and failure to warn. As noted above, M.M.'s failure to warn claim is governed by the law of the place of injury, *i.e.*, Michigan, and is foreclosed thereby. *See* W. Va. Code § 55-8-16(a); Mich. Comp. Laws Ann. §§ 600.2946(5)(a-b).

With respect to claims alleging strict liability, we have recognized that "a defective product may fall into three broad, and not necessarily mutually exclusive, categories: design defectiveness; structural defectiveness; and use defectiveness arising out of the lack of, or the inadequacy of, warnings, instructions and labels." *Morningstar v. Black & Decker Mfg. Co.*, 162 W. Va. 857, 888, 253 S.E.2d 666, 682 (1979). Counsel for M.M. concedes that, with regard to strict liability, he is not alleging that the Zoloft in question was, itself, defective but rather that Pfizer inadequately warned of the potential harm when used by pregnant women. However, this is merely a restatement of M.M.'s failure to warn claim which, as noted above, is governed, and foreclosed, by Michigan law. *See* W. Va. Code § 55-8-16(a); Mich. Comp. Laws Ann. §§ 600.2946(5)(a-b).

Finally, with respect to M.M.'s negligence claim, we have held that there first must exist a duty, and a breach of that duty, to hold a defendant liable for negligence. "In order to establish a *prima facie* case of negligence in West Virginia, it must be shown that the defendant has been guilty of some act or omission in violation of a duty owed to the

plaintiff. No action for negligence will lie without a duty broken." Syl. pt. 1, *Parsley v. General Motors Acceptance Corp.*, 167 W. Va. 866, 280 S.E.2d 703 (1981). *See also* Syl. pt. 2, *Sewell v. Gregory*, 179 W. Va. 585, 371 S.E.2d 82 (1988) ("In the matters of negligence, liability attaches to a wrongdoer, not because of a breach of a contractual relationship, but because of a breach of duty which results in an injury to others."). Again, though, the duty M.M. alleges that Pfizer breached is the duty to provide adequate warnings about the potentially harmful effects of Zoloft if used by pregnant women, which is merely a reiteration of M.M.'s failure to warn claim. *See* Syl. pt. 3, *Ilosky*, 172 W. Va. 435, 307 S.E.2d 603 ("For the duty to warn to exist, the use of the product must be foreseeable to the manufacturer or seller."). To recognize such a claim under West Virginia law where the same already is foreclosed *in the same case* by the law of another jurisdiction, however, would contradict the full faith and credit due our sister jurisdictions. *See, e.g.*, Syl. pt. 1, *Johnson v. Huntington Moving & Storage, Inc.*, 160 W. Va. 796, 239 S.E.2d 128 (1977) ("Under Section 1, Article IV of the Constitution of the United States, the judgment or decree of a court of record of another state will be given full faith and credit in the courts of this State, unless it be clearly shown by pleading and proof that the court of such other state was without jurisdiction to render the same, or that it was procured through fraud."); Syl. pt. 2, *International Harvester Co. of America v. Solazo*, 116 W. Va. 34, 178 S.E. 429 (1935) ("Under the full faith and credit clause of the federal constitution, the courts of this state may not refuse to enforce a judgment of another state because it involves some contravention of

the public policy of this state.").

Thus, while M.M. may have established a question of fact sufficient to overcome summary judgment as to the asserted claim of negligence,[4] because the failure to warn claim is subject to and precluded by Michigan law, Pfizer, and not M.M., is entitled to judgment as a matter of law as to the negligence claim. *See* W. Va. Code § 55-8-16(a); Mich. Comp. Laws Ann. §§ 600.2946(5)(a-b). In other words, because M.M.'s failure to warn claim is governed by Michigan law, and the governing Michigan statutes provide that a manufacturer cannot be held liable where it has complied with the FDA reporting, disclosure, and labeling requirements, there exists no duty that could have been breached so as to establish a claim for negligence.

Accordingly, the August 30, 2016, order of the Mass Litigation Panel granting Pfizer's motion for summary judgment as to M.M.'s claims of strict liability, failure to warn, and negligence is affirmed because no genuine issues of material fact require resolution and Pfizer, and the remaining Respondents, are entitled to judgment as a matter of law. *See* W. Va. R. Civ. P. 56(c); Syl. pt. 3, *Aetna*, 148 W. Va. 160, 133 S.E.2d 770.

---

[4]*See* Syl. pt. 4, *Ilosky v. Michelin Tire Corp.*, 172 W. Va. 435, 307 S.E.2d 603 (1983) ("The determination of whether a defendant's efforts to warn of a product's dangers are adequate is a jury question.").

IV.

CONCLUSION

For the foregoing reasons, the Mass Litigation Panel's August 30, 2016, order granting summary judgment to Pfizer and the remaining Respondents is hereby affirmed.

Affirmed.