[Cite as Perotti v. Johnson & Johnson Vision Products, Inc., 2004-Ohio-7149.]

COURT OF APPEALS OF OHIO, EIGHTH DISTRICT

COUNTY OF CUYAHOGA

NO. 84278

TIMOTHY M. PEROTTI

Plaintiff-appellant

JOURNAL ENTRY

vs.

AND

OPINION

JOHNSON & JOHNSON VISION PRODUCTS, INC., ET AL.

Defendant-appellee

DATE OF ANNOUNCEMENT OF DECISION: DECEMBER 30, 2004 CHARACTER OF PROCEEDING: Civil appeal from Common Pleas Court, Case No. CV-495641 Affirmed. JUDGMENT: DATE OF JOURNALIZATION: **APPEARANCES**: For plaintiff-appellant: THOMAS I. PEROTTI, ESQ The Bank One Building 100 Center Street, #170 Chardon, Ohio 44024 For defendant-appellee: JEFFREY M. WHITESELL, ESQ. Tucker Ellis & West LLP 1150 Huntington Bldg. 925 Euclid Avenue Cleveland, Ohio 44115-1475 KARPINSKI, J.: **{1}** Plaintiff appeals the trial court granting summary

judgment in favor of defendants, Johnson & Johnson Vision Care,

Inc. and Vistakon. For the reasons that follow, we agree with the judgment of the trial court.

 $\{\P 2\}$ For two consecutive nights in March, 2001, plaintiff borrowed and wore his wife's prescribed ACUVUE contact lenses to bed. When he awoke the second morning, plaintiff had pain in his right eye and went to a hospital emergency room.¹ He was later diagnosed with a corneal ulceration of his right eye.

{¶3} Plaintiff brought suit against defendants alleging their negligent design, manufacture and/or failure to warn about the ACUVUE lenses, which, he claims, are the proximate cause of his injury.

 $\{\P4\}$ Defendants filed a motion for summary judgment arguing that plaintiff, a non-prescribed user of their lenses, had no basis to sue them under any theory of negligence or Ohio's products liability statute, R.C. 2307.71 et seq. After the trial court

 $\{\P5\}$ granted defendants' motion,² plaintiff filed this appeal in which he presents one assignment of error:

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¹The subject lenses were disposed of in the emergency room and are not, therefore, part of the evidence in this case.

²When it granted defendants' motion, the trial court struck plaintiff's Exhibits B through L as unauthenticated and, therefore, non-evidentiary material. The exhibits include an emergency room document from University Hospitals (Exhibit B); a letter addressed to Thomas Perotti, Esq. from Abrams Eye Center, Inc. (Exhibit C); a letter to Thomas Perotti from Dr. Harvey Fishman (Exhibit D); website pages from "www.acuvue.co.uk/lens" (Exhibit E); website pages from "contact lens superstore" (Exhibit F); website pages from the U.S. Food and Drug Administration: Center for Devices and Radiological Health (Exhibit G); a document entitled "The National

THE TRIAL COURT ERRED WHEN IT GRANTED DEFENDANTS' MOTION FOR SUMMARY JUDGMENT WHEN DEFENDANTS ARE NOT ENTITLED TO JUDGMENT AS A MATTER OF LAW *AND* THERE EXISTS A QUESTION OF MATERIAL FACT.

 $\{\P6\}$ Plaintiff argues that the trial court erred in granting defendants' motion for summary judgment. We disagree.

 $\{\P7\}$ Under Civ.R. 56, summary judgment is proper when: "(1) No genuine issue as to any material fact remains to be litigated; (2) the moving party is entitled to judgment as a matter of law; and (3) it appears from the evidence that reasonable minds can come to but one conclusion, and viewing such evidence most strongly in favor of the party against whom the motion for summary judgment is made, that conclusion is adverse to that party." *Temple v. Wean United, Inc.* (1977), 50 Ohio St.2d 317, 327, 364 N.E.2d 267.

 $\{\P8\}$ In Dresher v. Burt (1996), 75 Ohio St.3d 280, 662 N.E.2d 264, the Ohio Supreme Court explained each party's burden of proof in a summary judgment action:

A party seeking summary judgment, on the ground that the nonmoving party cannot prove its case, bears the initial

Contact Lens Enforcement Petition" (Exhibit H); a copy of what appears to be a box for ACUVUE lenses (Exhibit I); a copy of what appears to be a container for one set of ACUVUE lenses (Exhibit J); a copy of what appears to be an insert for ACUVUE lenses (Exhibit K); a copy of what appears to be an insert for ACUVUE lenses (Exhibit L). These exhibits were attached to plaintiff's brief in opposition to defendants' motion for summary judgment. After reviewing these exhibits, we conclude that they wholly fail to meet the evidentiary requirements set forth in Civ.R. 56. Accordingly, we do not consider any of the exhibits in determining the merits of plaintiff's brief in opposition to defendant's motion for summary judgment.

burden of informing the trial court of the basis for its motion, and identifying those portions of the record that demonstrate the absence of a genuine issue of material fact on the essential element(s) of the nonmoving party's claims. The moving party cannot discharge its initial burden under Civ.R. 56 simply by making a conclusory assertion that the nonmoving party has no evidence to prove its case. Rather, the moving party must be able to specifically point to some evidence of the type listed in Civ.R. 56(C) which affirmatively demonstrates that the nonmoving party has no evidence to support the nonmoving party's claims. If the moving party fails to satisfy its initial burden, the motion for summary judgment must be denied. However, if the moving party has satisfied its initial burden, the nonmoving party then has a reciprocal burden outlined in Civ.R. 56(E) to set forth specific facts showing that there is a genuine issue for trial, and, if the nonmovant does not so respond, summary judgment, if appropriate, shall be entered against the nonmoving party.

Id. at 293.

 $\{\P9\}$ On appeal, our review of a trial court's decision to grant summary judgment is de novo. Jones v. A-Best Prods. Co., Cuyahoga App. No. 81792, 2003-Ohio-6612.

{¶10} In the case at bar, defendants moved for summary judgment on each of plaintiff's claims: strict products liability for failure to warn pursuant to R.C. 2307.76, negligent failure to warn, negligent design, and negligent manufacture.

{¶11} Whether labeled strict liability or negligence, all four claims require plaintiff to show that his injury was proximately caused by defendants' product. *Freas v. Prater Constr. Corp., Inc.* (1991), 60 Ohio St.3d 6, 573 N.E.2d 27; R.C. 2307.73(A)(1) and (A)(2).³

³R.C. 2307.73 specifies the following:

 $\{\P 12\}$ In a case claiming negligent design, negligent manufacture, negligent failure to warn, or products liability failure to warn⁴, the plaintiff must show that a duty was owed by defendant. Id.

*** If there is no duty, then no legal liability can arise on account of negligence. Where there is no obligation of care or caution, there can be no actionable negligence. *** Whether a duty exists depends largely on the foreseeability of the injury to one in the plaintiff's position. *** Only when the injured person comes within the circle of those to whom injury may reasonably be anticipated does the defendant owe him a duty of care. *** If the actor's conduct creates such a recognizable risk of harm only to a particular class of persons, the fact that it in fact causes harm to a person of a different class, to whom the actor could not reasonably have anticipated injury, does not make the actor liable to the persons so injured. (Citations omitted; emphasis added.)

Jeffers v. Olexo (1989), 43 Ohio St.3d 140, 142, 539 N.E.2d 614.

(A) A manufacturer is subject to liability for compensatory damages based on a product liability claim only if the claimant establishes, by a preponderance of the evidence, both of the following:

(1) Subject to division (B) of this section, the product in question *** was defective due to inadequate warning or instruction as described in section 2307.76 of the Revised Code, *** ;

(2) A defective aspect of the product in question as described in division (A)(1) of this section was a proximate cause of harm for which the claimant seeks to recover compensatory damages.

* * *

⁴ "The standard imposed upon the defendant in a strict liability claim grounded upon an inadequate warning is the same as that imposed in a negligence claim based upon inadequate warning." *Crislip v. TCH Liquidating Co.* (1990), 52 Ohio St.3d 251, 556 N.E.2d 1177, syllabus at paragraph 3. {¶13} The test for foreseeability is "whether a reasonably prudent person would have anticipated that an injury was likely to result from the performance or nonperformance of an act." Menifee v. Ohio Welding Products, Inc. (1984), 15 Ohio St.3d 75, 77, 472 N.E.2d 707. Whether a manufacturer has a duty is a question of law. Mussivand v. David (1989), 45 Ohio St.3d 314, 544 N.E.2d 265, 269. "If an injury is the natural and probable consequence of a negligent act and it is such as should have been foreseen in the light of all the attending circumstances, the injury is then the proximate result of the negligence." Id.

{¶14} In the instant case, the threshold question is whether plaintiff is a foreseeable user of defendants' product. In other words, does plaintiff come within the circle of those persons to whom injury should have been reasonably anticipated by defendants. Do defendants owe plaintiff a duty of care?

{¶15} Plaintiff argues that he was a foreseeable user of defendants' ACUVUE contact lenses because he and his wife's contact lens prescriptions were virtually identical. As a foreseeable user, therefore, plaintiff argues that defendants had a duty to warn him that sleeping with the ACUVUE lenses could cause corneal abrasions. We disagree.

{¶16} The uncontested evidence establishes that the ACUVUE lenses plaintiff wore while sleeping on two consecutive nights were prescribed not for him, but only for his wife. During deposition,

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plaintiff admitted that he has been wearing contact lenses since 1995. He acknowledged that his own contact lenses were specifically prescribed for him. Plaintiff admits that prescribed contact lenses are fitted for each person's eyes and that they are prescribed according to particular sizes and strengths.

{¶17} In support of their motion for summary judgment, defendants appended the affidavit of Stanley J. Rogaski, Vice President of Quality Assurance and Regulatory Affairs for defendant Vistakon. In his affidavit, Rogaski stated:

Contact lenses, including ACUVUE contact lenses, are prescription medical devices which require a valid and current prescription for their use. Both Federal and U.S.A. law prohibit dispensing contact lenses without a prescription.

*** Contact lenses, including ACUVUE contact lenses, are manufactured in different sizes and types to address individual patient needs. A patient is only to wear the lenses of the type, size and power that are prescribed for that patient.

Rogaski Affidavit, ¶3 and ¶4.

{¶18} In response to defendants' motion for summary judgment, plaintiff argued that because their contact lens prescriptions were "almost identical[,]" he "borrowed" his wife's lenses and "never worried about adverse affects." Plaintiff's affidavit, ¶3 and ¶4. Plaintiff argued that, despite the lenses being prescribed for his wife, defendants should have included a warning to any non-prescription user that corneal ulcers could arise if that user sleeps wearing the lenses. He argues that this

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warning should be on each individually packaged lens, not just on the box.

{**¶19**} On this record, we find no evidence to establish that plaintiff falls within the circle of persons defendants should have anticipated would use their prescription ACUVUE contact lenses. To the contrary, the undisputed evidence establishes that defendants did not owe plaintiff a duty because they could not have foreseen him as a potential user of his wife's prescription ACUVUE Even if we were to conclude that defendants did owe lenses. plaintiff a duty as an ultimate user of their ACUVUE lenses, his claims still fail. Plaintiff has not produced any medical evidence to show that wearing his wife's contact lenses was the proximate cause of his injury. Other than his own affidavit, plaintiff offered no other evidence under Civ.R. 56 to show that his injury was the natural and probable consequence of defendants' failure to warn, design, or manufacture of the ACUVUE lenses prescribed only for plaintiff's wife.

{**920**} At oral argument, plaintiff argued that the doctrine of res ipsa loquitur applies in this case. This doctrine is a "'rule of evidence which permits the jury, but not the court in a jury trial, to draw an inference of negligence where the instrumentality causing the injury is under the exclusive management and control of one of the parties and an accident occurs under circumstances where in the ordinary course of events it would

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not occur when ordinary care is observed. ***'" Wise v. Timmons, 64 Ohio St.3d 113, 1992-Ohio-117, 592 N.E.2d 840, citing Glowacki v. North Western Ohio Ry. & Power Co. (1927), 116 Ohio St. 451, 157 N.E. 21, paragraph one of the syllabus.

{1 In the case at bar, plaintiff offered no medical evidence that his wife's ACUVUE lenses caused his injury. Moreover, plaintiff admits that the lenses he wore to sleep were prescribed for his wife and that he borrowed them from her. These facts establish that even if the lenses caused plaintiff's injury, he was not wearing them in the ordinary course of events nor can we conclude that he was observing ordinary care in wearing lenses not prescribed for him. On this record, the doctrine of res ipsa loquitur is inapplicable.

 $\{\P 22\}$ Even though we find no merit to plaintiff's sole assignment of error for the reasons just described, we, nonetheless, observe that defendants were also entitled to summary judgment under "The Learned Intermediary Rule." Under this doctrine, physicians, as learned intermediaries between the product manufacturer and the patient, have a duty to convey manufacturer product warnings to the patient for whom the product is prescribed. *Vaccariello v. Smith & Nephew Richards, Inc.*, 94 Ohio St.3d 380,

2002-Ohio-892, 763 N.E.2d 160.

The learned intermediary doctrine does not relieve the manufacturer of liability to the ultimate user for an inadequate or misleading warning; it only provides that the

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warning reaches the ultimate user through the learned intermediary.

Id., at 384-385, citing *Tracy v. Merrell Dow Pharmaceuticals, Inc.* (1991), 58 Ohio St.3d 147, 149-150, 569 N.E.2d 875. As noted by the Supreme Court of New York:

[The] doctrine has evolved in the field of prescription drugs and requires such a manufacturer to warn of all potential dangers of which it knows or should know are associated with its product and, further, to take such steps as reasonably necessary to bring that knowledge to the attention of the medical community. The manufacturer discharges its duty in this regard by providing adequate warnings to the prescribing physician, who then acts as an informed intermediary between the manufacturer and the patient, "assessing the risks and benefits of the drug and advising the patient of its possible risks and side effects."

Bukowski v. CooperVision, Inc. (1993), 185 A.D.2d 31, 34, 592 N.Y.S.2d 807 citing Martin v. Hacker, 185 A.D.2d 553, 554.

 $\{\P 23\}$ In the case at bar, defendants established that their ACUVUE contact lenses came with a package insert⁵ intended for the physician's use and reference. The insert further establishes that the prescribing physician is responsible for providing the patient with the appropriate warnings about product use or misuse. It is undisputed that this insert repeatedly warns of the risk of corneal ulcers with improper contact lens use.

{¶24} Further, each contact lens patient is provided with
an "ACUVUE Patient Instruction Guide," which repeatedly warns the

 $^{^{5}\}mbox{Attached}$ to defendants' motion for summary judgment as Exhibit B-1.

patient about corneal ulcers and how to avoid getting them by proper use and cleaning.⁶

 $\{\P 25\}$ Moreover, both the ACUVUE physician insert and the Patient Instruction Guide warn that "[w]hen daily wear users wear their lenses overnight (outside the approved indication), the risk of ulcerative keratitis⁷ is 9 times greater than among whose who do not wear them overnight."⁸

{926} Under "The Learned Intermediary Rule," defendants' physician insert and patient information guide sufficiently warn prescribed users about the risks associated with their ACUVUE lenses. And since the "Learned Intermediary Rule" applies only to prescribed product users, plaintiff in this case cannot challenge the adequacy of defendants' warnings under the rule because he was not a prescribed user of his wife's ACUVUE lenses.

{¶27} On the record before this court, we conclude that defendants did not owe plaintiff a duty in the first instance and, even if they did, plaintiff has not shown that wearing his wife's prescription ACUVUE contact lenses was the proximate cause of his injury. Moreover, defendants discharged their duty to warn under the "Learned Intermediary Rule."

⁶The patient information guide was attached to defendants' motion for summary judgment as Exhibit B-2.

⁷Synonymous with corneal ulcers.

⁸Exhibit B-1, p. 5 and Exhibit B-2, p. 6.

{¶28} Accordingly, the trial court did not err in granting
defendants' motion for summary judgment. Plaintiff's sole
assignment of error is overruled.

Judgment affirmed.

[Cite as Perotti v. Johnson & Johnson Vision Products, Inc., 2004-Ohio-7149.]

It is ordered that appellees recover of appellant its costs herein taxed.

The court finds there were reasonable grounds for this appeal.

It is ordered that a special mandate issue out of this court directing the Common Pleas Court to carry this judgment into execution.

A certified copy of this entry shall constitute the mandate pursuant to Rule 27 of the Rules of Appellate Procedure.

PATRICIA A. BLACKMON, P.J., AND

ANTHONY O. CALABRESE, JR., J., CONCUR.

DIANE KARPINSKI JUDGE

N.B. This entry is an announcement of the court's decision. See App.R. 22(B), 22(D) and 26(A); Loc.App.R. 22. This decision will be journalized and will become the judgment and order of the court pursuant to App.R. 22(E) unless a motion for reconsideration with supporting brief, per App.R. 26(A), is filed within ten (10) days of the announcement of the court's decision. The time period for review by the Supreme Court of Ohio shall begin to run upon the journalization of this court's announcement of decision by the clerk per App.R. 22(E). See, also, S.Ct.Prac.R. II, Section 2(A)(1).