Gari WEST and Larry West v. SEARLE & COMPANY, G.D. Searle & Company, and Seale Phamaceuticals, Inc.

90-49

806 S.W.2d 608

Supreme Court of Arkansas Opinion delivered March 18, 1991 [Rehearing denied April 29, 1991.*]

- JUDGMENT SUMMARY JUDGMENT WRONG PARTIES DID NOT ADDRESS ISSUE. — The trial court should not have ruled that there was no genuine issue of material fact on a particular issue where the parties offered no affidavits, counter-affidavits, or other proof on the issue.
- 2. APPEAL & ERROR RULING AFFIRMED IF CORRECT, EVEN IF WRONG REASON STATED. The appellate court will sustain a trial court's ruling if it reached the right result, even though it announced the wrong reason.
- PLEADING FACTUAL PLEADING REQUIRED, NOT NOTICE PLEADING. Arkansas requires factual pleadings, not notice pleadings.
- 4. JUDGMENT SUMMARY JUDGMENT GRANTED AFFIRMED BE-CAUSE OF FAILURE TO STATE A CLAIM EFFECT. When a summary judgment was granted in the trial court because of failure to have a claim, but was affirmed on the basis of failure to state a claim, the appellate court modified to make the dismissal without prejudice to afford the plaintiffs a chance to plead further.
- 5. Torts—strict liability—pleadings required.—In order to state a cause of action under the strict liability theory, the plaintiff must plead (1) that he has sustained damages; (2) that the defendant was engaged in the business of manufacturing, or assembling, or selling, or leasing, or distributing the product; (3) that the product was supplied by the defendant in a defective condition that rendered it unreasonably dangerous; and (4) that the defective condition was a proximate cause of plaintiff's damages.
- 6. TORTS PRODUCT DEFECTS THREE TYPES. Generally, there are three varieties of product defects: manufacturing defects, design defects, and inadequate warnings.
- 7. PLEADINGS ANSWER PROVIDED TACIT ADMISSION THAT COM-PLAINT STATED A CAUSE OF ACTION. — Although plaintiffs never factually pled that there was a defect in the design of the drug, nor gave an affidavit in opposition to the motion for summary judgment, where defendants answered by asserting the "unavoidably unsafe product" defense, the answer was a tacit admission by defendant that the complaint stated a cause of action in strict liability.

^{*}Brown, J., not participating.

- 8. PRODUCTS LIABILITY UNAVOIDABLY UNSAFE PRODUCTS DEFENSE ADOPTED AS AFFIRMATIVE DEFENSE. The "unavoidably unsafe product" defense contained in comment k to § 402A of the Restatement (Second) of Torts was adopted by the Arkansas Supreme Court as an affirmative defense requiring proof that the drug product was indeed unavoidably dangerous.
- 9. PRODUCTS LIABILITY UNAVOIDABLY UNSAFE PRODUCTS DEFENSE NECESSARY SHOWING. In order for the affirmative defense of unavoidably unsafe products to apply, the designer of the drug must show that the product is unavoidably unsafe, necessitating a showing that no feasible alternative design existed that would accomplish the product's purpose at a lesser risk, and that the benefit of the product "apparently" out-weighed the risk, considering the value of benefit, the seriousness of the risk, and the likelihood of both.
- 10. PRODUCTS LIABILITY EVALUATION OF ALTERNATIVE DESIGN AND PRODUCT'S ACTUAL DESIGN. The evaluation of a purported alternative design and the product's actual design should focus on (1) the magnitude of the product's risk that the alternative avoids, (2) the costs of the two designs; (3) the benefits of the two designs, and (4) the relative safety of the two designs.
- 11. PRODUCTS LIABILITY SCOPE OF UNAVOIDABLY UNSAFE PRODUCT DEFENSE. By its terms the unavoidably unsafe product defense exempts unavoidably unsafe products from strict liability only where the plaintiff alleges a design defect, but it does not offer protection from allegations of manufacturing flaws or inadequate warnings.
- 12. PRODUCTS LIABILITY UNAVOIDABLY UNSAFE PRODUCT ADE-QUATE WARNING PROTECTS SELLER FROM STRICT LIABILITY. — The seller of a product proven to be "unavoidably unsafe" is not held to strict liability for the unfortunate consequences of its use when the product is "accompanied by proper directions and warning" and "proper warning is given."
- 13. NEGLIGENCE DUTY TO WARN GENERAL RULE. Generally, under either the negligent or strict liability theories, a manufacturer has a duty to warn the ultimate user of the risk of its product.
- 14. Negligence Duty to Warn Learned intermediary exception. A drug manufacturer may rely on the prescribing physician to warn the ultimate consumer of the risk of a prescription drug, and its application is appropriate with respect to oral contraceptives.
- 15. Negligence Duty to warn Learned intermediary exception insufficient evidence of warnings. Where the prescribing physician referred to warnings contained in the

Physician's Desk Reference (PDR), but those warnings were not identified by the doctor and were not properly made a part of the deposition; where the copies of PDR warnings that were introduced should have been stricken because the PDR is periodically modified and counsel did not establish that the attached copies were from the same publication that the physician referred to; and where the appellate court could not render the error harmless by taking judicial notice of the PDR warnings because appellant had never been given the opportunity to be heard on the propriety of taking judicial notice and because the court did not know which version of the PDR the physician had referred to, the trial court erred in rulng that the drug companies' warning to the prescribing physician was proper.

Appeal from Arkansas Circuit Court; Russell Rogers, Judge; affirmed in part, as modified, reversed and remanded in part.

David Hodges and Josh McHughes, for appellant.

Friday, Eldredge & Clark, by: Elizabeth J. Robben, for appellee.

ROBERT H. DUDLEY, Justice. Appellants, Gari and Larry West, filed a products liability suit against appellees, Searle & Co., G.D. Searle & Co., and Searle Pharmaceuticals, Inc. In their complaint the Wests pleaded that Gari's use of Ovulen-28, a birth control medication, caused her to develop a hepatic adenoma, or a benign liver tumor, which eventually ruptured and caused a life threatening situation. The complaint next recites by conclusory, not factual, allegations, or issue pleadings, that the oral contraceptive was defectively designed and manufactured; that the appellee drug companies were negligent in warning of the danger of the drug; and that the product breached the warranty of fitness. Recovery was asked upon the theories of strict liability, negligence, and breach of warranty. The Wests' complaint additionally alleged that the product was designed, manufactured, and delivered by the appellees. After limited discovery, the appellee drug companies filed a motion for summary judgment. The trial court granted the motion. We affirm in part, as modified, and reverse in part the order granting summary judgment.

We do not address the eight points of appeal, and numerous sub-points, in the order they are argued. Instead, we divide the opinion into two main categories and address the points in that manner.

I. Negligence and Breach of Warranty

- [1-3] The trial court granted summary judgment on those counts of the complaint, among others, that alleged negligence and breach of warranty. However, neither side addressed those counts in the motion for summary judgment or the response. There were no affidavits, counter-affidavits, or other proof on those counts. They were wholly ignored by both sides. Obviously, the trial court should not have ruled that there was no genuine issue of material fact on those particular counts. Even so, we will sustain a trial court's ruling if it reached the right result, even though it announced the wrong reason. Armstrong v. Harrell, 279 Ark. 24, 648 S.W.2d 450 (1983). The trial court reached the right result on those counts because they do not state facts upon which relief can be granted. They give "issue notice" but not "factual notice." We require factual pleadings, not notice pleadings. ARCP Rule 8; Harvey v. Eastman Kodak Co., 271 Ark. 783, 610 S.W.2d 582 (1981).
- [4] Summary judgment may be granted on pleadings, Joev Brown Interest, Inc. v. Merchants Nat'l Bank, 284 Ark. 418, 683 S.W.2d 601 (1985), and that should have been done here. However, summary judgment based upon a failure to state a claim upon which relief can be granted is different from a summary judgment based upon a lack of disputed material facts, which results in a party's entitlement to the judgment as a matter of law. The first is the failure to state a claim, the second is the failure to have a claim. Id. When summary judgment is granted upon failure to have a claim, and the ruling is affirmed on that basis, the matter is ended with prejudice. Id. However, when summary judgment is granted in the trial court because of failure to have a claim, but is affirmed on the basis of failure to state a claim, we modify to make the dismissal without prejudice in order to afford the plaintiff-appellant a chance to plead further. Ratliff v. Moss, 284 Ark. 16, 678 S.W.2d 369 (1984); ARCP Rule 12(j). Accordingly, we affirm the trial court's granting of the motion for summary judgment on the counts alleging negligence and breach of warranty, but modify it to dismiss without prejudice in order to afford the plaintiff-appellant a chance to plead further.

II. Strict Liability

A. Defective Manufacture and Inadequate Warning

The trial court also granted summary judgment on the count of the complaint alleging strict liability. Again, the plaintiffappellant did not plead facts upon which relief can be granted.

- [5] In order to state a cause of action under the strict liability theory, the plaintiff must plead (1) that he has sustained damages; (2) that the defendant was engaged in the business of manufacturing, or assembling, or selling, or leasing, or distributing the product; (3) that the product was supplied by the defendant in a defective condition which rendered it unreasonably dangerous; and (4) that the defective condition was a proximate cause of plaintiff's damages. Ark. Code Ann. §§ 16-101 to -107 (1987); E.I. DuPont De Nemours & Co. v. Dillaha, 280 Ark. 477, 659 S.W.2d 756 (1983).
- [6] Generally speaking, there are three varieties of product defects: manufacturing defects, design defects, and inadequate warnings. Feldman v. Lederle Laboratories, 97 N.J. 429, 479 A.2d 374, 385 (1984). Here, the plaintiff-appellant did not plead facts sufficient to state a cause of action for defective manufacture of the product or inadequate warning. Accordingly, we treat these counts just as we did the counts on negligence and breach of warranty and affirm the granting of summary judgment, but modify it to a dismissal without prejudice in order to afford appellant a chance to plead further.

B. Defective Design

[7] Similarly, the plaintiff-appellant neither factually pleaded that there was a defect in the design of the drug, nor gave an affidavit in opposition to the motion for summary judgment. Of course, an argument can be made that this count should be treated the same as the previously discussed counts have been treated. However, there is a distinguishing factor. On this count, strict liability for defective design, the appellee drug companies pleaded that they were protected by the "unavoidably unsafe product" defense as set out in comment k to § 402A of the Restatement (Second) of Torts. This constituted a tacit admission by the appellees that the complaint stated a cause of action in strict liability for negligent design. The appellees' pleadings and

proof in support of their motion went to whether they were entitled to a summary judgment because of their defense. Accordingly, basic fairness and the appellee drug companies' waiver of appellants' failure to state the cause of action, necessitate that we address this issue, and, on it, we hold that the trial court erred in granting summary judgment.

1. Unavoidably Unsafe Product

The "unavoidably unsafe product" defense contained in comment k to § 402A of the Restatement (Second) of Torts provides in full:

Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Comment k represents a judgment that some products, such as certain prescription drugs, are so beneficial to society that their manufacturer should not be held strictly liable if the products are properly prepared and are accompanied by adequate warnings. See Note, Hill v. Searle Laboratories: The Decline of the Learned Intermediary Doctrine in Favor of Direct Patient Warnings of Drug Product Risks, 43 Ark. L. Rev. 821 (1990). Policy justifications for the comment k exception have been described as follows:

Dean Prosser stated an important justification for exempting prescription drugs from strict liability:

The argument that industries producing potentially dangerous products should make good the harm, distribute it by liability insurance, and add the cost to the price of the product, encounters reason for pause, when we consider that two of the greatest medical boons to the human race, penicillin and cortisone, both have their dangerous side effects, and that drug companies might well have been deterred from producing and selling them.

Comment k reflects the concern of American Law Institute members that large monetary judgments would deter drug manufacturers from undertaking research programs to develop socially beneficial pharmaceuticals. Therefore, the adoption of comment k was motivated by the fear that large judgments would increase the costs of beneficial and necessary drugs beyond the reach of the people who need them.

(Footnotes omitted.) Note, Hill v. Searle Laboratories: The Decline of the Learned Intermediary Doctrine in Favor of Direct Patient Warnings of Drug Product Risks, 43 Ark. L. Rev. 821 (1990).

[8] Although this court has never formally adopted comment k into our case law, we do so now, based upon the policy considerations set out above. We are aware of only one court that has declined to adopt comment k. See Collins v. Eli Lilly Co., 116 Wis. 2d 166, 342 N.W.2d 37 (1984). Our choice to adopt the

comment does not end the matter, however, but rather requires a second decision: Whether to apply it to all prescription pharmaceutical products, as California did in *Brown* v. *Superior Court*, 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988), or to apply it as an affirmative defense requiring proof that the drug product is indeed unvoidably dangerous.

The California court's policy decision, to apply the comment k defense to all pharmaceutical products is well summarized in the case note, Hill v. Searle Laboratories: The Decline of the Learned Intermediary Doctrine in Favor of Direct Patient Warnings of Drug Product Risks, 43 Ark. L. Rev. 821 (1990), and may be reviewed there as well as in the case itself.

On the other hand, a majority of jurisdictions interpret the comment to constitute an affirmative defense. See Hill v. Searle Laboratories, 884 F.2d 1064 (8th Cir. 1989) for a listing of those cases. We adopt this second view because of the wording of the comment itself and because it is the better public policy. In reading the comment it is obvious that the drafters did not intend to grant all manufacturers of prescriptive drugs a blanket exception to strict liability. As pointed out by the Supreme Court of Idaho, in Toner v. Lederle Laboratories, 112 Idaho 328, 732 P.2d 297 (1987):

[C]omment [k] refers to "some" products which are unavoidably unsafe; the comment states such products are "especially common in the field of drugs;" the comment cites certain examples from that field deserving of its protection and notes that "[t]he same is true of many other drugs. . . [and in particular] many new or experimental drugs. . . ." Obviously, the comment does not apply to all drugs.

This plain meaning is emphasized by the fact that a blanket exception was proposed, but rejected, at the American Law Institute meeting when section 402A and comment k were adopted. 38 A.L.I. Proc. 19, 90-98 (1961). Further, by its wording, the comment applies only to those products which supply a special social need. The last sentence of the comment discusses supplying "the public with an apparently useful and desirable product. . . ."

[9, 10] In order for this affirmative defense to apply, the designer of the drug must show that the product is "unavoidably unsafe." Necessarily then, there must be no feasible alternative design which accomplishes the product's purpose at lesser risk. The evaluation of a purported alternative design and the product's actual design should focus on: (1) the magnitude of the product's risk that the alternative avoids; (2) the costs of the two designs; (3) the benefits of the two designs; and (4) the relative safety of the two designs. See Toner v. Lederle Laboratories, 112 Idaho 328, 732 P.2d 297 at 306 (1987).

In addition, for the comment to protect the designer of the product, the benefit of the product must outweigh the risk. This weighing process must consider the value of the benefit, the seriousness of the risk and the likelihood of both. See Toner v. Lederle Laboratories, supra, at 306. However, in the weighing process it should be remembered that comment k only requires that the balance "apparently" tip toward the benefit of a product at the time of distribution. See last sentence of comment k.

[11] As mentioned previously, but its terms comment k exempts unavoidably unsafe products from strict liability only where the plaintiff alleges a design defect, but it does not offer protection from allegations of manufacturing flaws or inadequate warnings.

In the case at bar, the trial court either determined that comment k applied to all prescription pharmaceuticals, or it determined that there was no genuine issue of any material fact, that is, that the drug at issue met a special social need, that there was no feasible alternative, that the drug was unavoidably unsafe, and that the benefits of the drug outweighed the risks. We must reverse on either basis. As previously set out, (1) we reject the point of view that all prescription pharmaceuticals are covered by the comment, and (2) in this case, there is a genuine issue of fact as to whether the drug is "unavoidably unsafe." The appellee drug companies' proof did not meet all of the required criteria to show that Ovulen-28 was an unavoidably unsafe drug. Thus, the trial court erred in ruling that the drug companies' comment k defense entitled them to a summary judgment on the issue of negligent design. Accordingly, the matter must be reversed and remanded.

2. Warning of Danger

[12] There is a second, but equally important factor concerning applicability of the comment k defense: Whether there was an adequate warning of danger. Such a warning must be proved before a judgment is granted on the basis of the affirmative defense set out in comment k. The seller of a product proven to be "unavoidably unsafe" is not held to strict liability for the unfortunate consequences of its use when the product is "accompanied by proper directions and warning" and "proper warning is given." See comment k. The first issue then is, how is a proper warning given?

[13, 14] As a general rule, a manufacturer has a duty to warn the ultimate user of the risks of its product. This duty exists under either the negligence or strict liability theories. An almost universally applied exception to this general rule is known as the learned intermediary doctrine. Note, Hill v. Searle Laboratories: The Decline of the Learned Intermediary Doctrine In Favor of Direct Patient Warnings of Drug Product Risks, 43 Ark. L. Rev. 821 (1990); Comment, The Impact of Product Liability Law on the Development of a Vaccine Against the AIDS Virus, 55 U. Chi. L. Rev. 943, 958, n. 68 (1988). This doctrine provides that a drug manufacturer may rely on the prescribing physician to warn the ultimate consumer of the risks of a prescription drug. The physician acts as the "learned intermediary" between the manufacturer and the ultimate consumer. There are a number of arguments supporting the application of this exception to prescription drug products. They may be summarized as: First, a physician must prescribe the drug, the patient relies upon the physician judgment in selecting the drug, and the patient relies upon the physician's advice in using the drug. That is to say that there is an independent medical decision by the learned intermediary that the drug is appropriate. Second, it is virtually impossible in many cases for a manufacturer to directly warn each patient. Third, imposition of a duty to warn the user directly would interfere with the relationship between the doctor and the patient. Hill v. Searle Laboratories, 884 F.2d 1064 (1989); In re Certified Questions, 419 Mich. 686, 358 N.W.2d 873, 878 (1984). Note, Hill v. Searle Laboratories: The Decline of the Learned Intermediary Doctrine In Favor of Direct Patient Warnings of Drug Product Risks, supra.

A minority of courts have rejected the learned intermediary doctrine in cases involving oral contraceptives. All three of these cases were decided under Massachusetts and Michigan law. MacDonald v. Ortho Pharmaceuticals, 394 Mass. 131, 475 N.E.2d 65, cert. denied 474 U.S. 920 (1985); Odgers v. Ortho Pharmaceutical Corp., 609 F. Supp. 867 (E.D. Mich. 1985); and Stephens v. G.D. Searle & Co., 602 F. Supp. 379 (E.D. Mich. 1985). The basis of these decisions was that a patient chooses to take an oral contraceptive, and the prescribing physician plays only a passive role. The Massachusetts court wrote:

Whereas a patient's involvement in decision-making concerning use of a prescription drug necessary to treat a malady is typically minimal or nonexistent, the healthy, young consumer of oral contraceptives is usually actively involved in the decision to use "the pill," as opposed to other available birth control products, and the prescribing physician is relegated to a relatively passive role.

. (Footnotes omitted.)

In a case involving the CU-7, a prescription intra-uterine device (IUD), the Eighth Circuit predicted that this court would adopt a somewhat modified approach to the learned intermediary doctrine: "Our view of prescription drugs and the learned intermediary rule is that Arkansas would adopt the test set forth on the issue of adequate warning in Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir. 1974)." Hill v. Searle Laboratories, 884 F.2d 1064, 1070 (8th Cir. 1989). As the Eighth Circuit explained, the Reyes test is "that there must be either a warning [to the ultimate user] — meaningful and complete so as to be understood by the recipient — or an individualized medical judgment that this treatment or medication is necessary and desirable for the patient." Id. In other words, under Reves the mere fact that a prescription drug or device is involved does not automatically invoke the learned intermediary doctrine: there must be an intervening, individualized medical judgment. For example, in Reyes a mass immunization program with a polio vaccine was at issue. The Reyes court determined that because there was no individualized, medical judgment exercised in that situation, the learned intermediary doctrine would not apply, even though a prescription drug was involved.

Here, however, it is not necessary to decide whether we will follow the Eighth Circuit's prediction that we will adopt the Reves test because we are convinced that the stated public policy reasons for the learned intermediary doctrine are present with respect to oral contraceptives. For example, the patient would normally make the initial choice about birth control but, after that, the physician would exercise his medical judgment concerning the best method of contraception for his patient. In this case, for instance, the physician chose an oral contraceptive, Ovulen-28, because it contained the proper estrogen dosage for appellee Gari West. The doctor was fully aware of the risks associated with the drug and considered those risks in periodically renewing the prescription for her. Moreover, Gari West relied on his advice that the drug was the most suitable for her. Accordingly, application of the learned intermediary rule is appropriate in the case of oral contraceptives.

Here, the trial court applied the learned intermediary rule, but also held that there was no issue of any material fact, and that as a matter of law, the appellee drug companies' warning to the prescribing physician was proper.

[15] We must reverse that ruling because of a procedural matter which may be summarized as follows: In his deposition the prescribing physician referred to warnings contained in the Physician's Desk Reference. However, those warnings were not identified by the doctor and were not properly made a part of the deposition. The drug companies' attorney subsequently filed copies of warnings contained in the Physician's Desk Reference. The plaintiff, Gari West, moved that the copies of the warnings be stricken. The trial court should have stricken the warnings, see ARCP Rule 56(e), but did not do so, and considered the warnings as evidence in making his ruling. That was error. Even so, the drug companies argue that it was a harmless error because we can take judicial notice of the Physician's Desk Reference. They cite Edwards v. Sec. of Dept. of Health & Human Serv., 572 F. Supp. 1235 (1983) as an example. It is not subject to reasonable dispute that the *Physician's Desk Reference* is a reference book supplied to physicians throughout the United States to advise them as to the pharmacological actions of the drug they intend to prescribe. It is a manual found in physicians' offices, pharmacies, and attorneys' offices, and it is universally recognized as having

reasonably indisputable accuracy. Thus, under A.R.E. Rule 201, judicial notice of the book might be taken for some purposes. In addition, judicial notice may be taken at the appellate level as well as the trial level. See A.R.E. Rule 201(f).

However, we decline to take judicial notice of the warnings. We are not certain that the attachment warnings are of the same date as those to which the physician referred. Consequently, we must reverse the trial court's ruling that the drug companies' warning to the prescribing physician was proper.

Affirmed in part, as modified, and reversed and remanded in part, with the trial court to proceed in a manner consistent with this opinion.

HAYS, J., dissents.

Brown, J., not participating

STEELE HAYS, Justice, dissenting in part. I would apply the comment k defense to all prescription drugs so long as the drug is properly manufactured and accompanied by warnings of any dangerous propensities which are known or reasonably knowable at the time of distribution. First, it would facilitate the research, development and marketing of potentially beneficial new drugs. Second, the case by case approach of the majority will not give clear guidelines to drug manufacturers—one drug may receive the protection of comment k while another may not, and, equally undesirable, a manufacturer may be held strictly liable in one locale but not in another. Third, there is no feasible method to determine which drugs are extremely beneficial and which are not. Drug manufacturers should not be exposed to strict liability under conditions which would clearly have a chilling effect on the development of new medications.

In sum, I would adopt the view of the Supreme Court of California in its well reasoned opinion of *Brown* v. *Superior Court*, 44 Cal. 3d 1049, 751 P.2d 470 (1988).