TADC
PRODUCTS LIABILITY NEWSLETTER

Selected Case Summaries
Prepared Fall 2008

Editor:

Joseph S. Pevsner
Thompson & Knight LLP

Contributing Editor:

Timothy L. Evans
Thompson & Knight LLP

I. Summary

1. Fifth Circuit holds the "read and heed" learned intermediary presumption does not apply under Texas law. Applying Texas law, in a prescription-drug case involving the learned-intermediary doctrine, the U.S. Fifth Circuit Court of Appeals refused to apply the "read and heed" presumption to shift the burden from the plaintiff. *Ackermann v. Wyeth Pharmaceuticals*, 526 F.3d 203 (5th Cir. 2008).

2. Consumer Products Safety Act standards preempted a design defect claim.

A design defect claim is preempted by federal law where the Consumer Products Safety Commission had engaged in a balancing of factors that would be disrupted by allowing the state-law claim. *BIC Pen Corp. v. Carter*, 251 S.W.3d 500 (Tex. 2008).

3. Evidence of simultaneously-forming blood clots was not sufficient to establish specific causation in design defect claims. Court of Appeals found that evidence of simultaneously-forming blood clots was not sufficient to prove that decedent's history of heart problems caused his death, reversing a $32 million verdict. *Merck & Co., Inc. v. Garza*, No. 04-07-00234-CV, 2008 WL 2037350 (Tex. App.—San Antonio, May 14, 2008, no pet.).

4. Texas' statutory contribution scheme applies to breach of implied warranty claims. A claim for breach of implied warranty and seeks personal injury or death damages requires application of Chapter 33 of the Civil Practice and Remedies Code. *JCW Electronics, Inc. v. Garza*, 257 S.W.3d 701 (Tex. 2008).

II. Discussion

1. JCW Electronics, Inc. v. Garza, 257 S.W.3d 701 (Tex. 2008).

In *JCW*, the Texas Supreme Court held that Chapter 33 of the Texas Civil Practice and Remedies Code applies to claims of breach of an implied warranty where damages are sought for personal injury or death.

Rolando Montez was arrested for public intoxication. After he made a phone call to his mother, Pearl Garza, to arrange for bail, Montez was found with him hanging in his cell from the phone cord he had taken after his call. Garza sued both the City of Port Isabel and JCW Electronics, the provider of the prison phone. At the jury trial, Garza succeeded on claims of negligence, misrepresentation, and breach of implied warranty of fitness. The jury allocated the fault 60% to Montez, 25% to the City, and 15% to JCW.

JCW moved for judgment, claiming that under Texas Civil Practice and Remedies Code chapter 33, the amount of fault apportioned to Montez precluded recovery by his estate. The trial court granted Garza a judgment notwithstanding the verdict against JCW on the theories of breach of contract and fraud.

The court of appeals reversed, holding that these theories had not been pled, but affirmed a judgment against JCW for breach of implied warranty. The court of appeals held that Chapter 33 did not apply to this claim because it would disrupt the UCC's purpose of furthering uniformity among the states.

The Texas Supreme Court reversed the court of appeals, holding that Chapter 33 does apply to breach of implied warranty claims seeking damages for death or personal injury. The Court noted that in 1995, Chapter 33 was amended to apply in any cause of action based on tort. The Court held that claims for breach of the implied warranty of fitness seeking damages for death or personal injury are tort claims and are therefore subject to Chapter 33.

The Court also held that although it had refused to apply Chapter 33 to claims under UCC Article 3 because of the reasons stated by the court of appeals, Article 2 lacked the same characteristics to exclude Chapter 33 application. The Court found that Article 2 lacked a comprehensive fault scheme such as the one found in Article 3. Instead, Article 2 allows for recovery from injury proximately caused by a breach without apportioning liability. Accordingly, the Court, applying the fault apportioned by the jury to the rules of Chapter 33, held that Montez's contributory negligence greater than 50% barred his recovery.

Justice Jefferson, joined by Justice O'Neill, concurred. Although they joined in the Court's decision, they wrote separately to address how the apportionment issue should be submitted to the jury.

2. BIC Pen Corp. v. Carter, 251 S.W.3d 500 (Tex. 2008).

In *BIC Pen*, the Court held that a standard set by the U.S. Consumer Product Safety Commission preempted a claim of design defect.

Six-year-old Brittany Carter was severely burned when her younger brother set her dress on fire with a BIC lighter. Carter sued BIC on manufacturing and design defect claims. After a jury trial, Carter was awarded $3 million in actual damages and $2 million in exemplary damages. BIC appealed, and the court of appeals affirmed the design defect claim, but did not address the manufacturing defect claim.

The Texas Supreme Court reversed the court of appeals and remanded to that court for further proceedings.

The Court first addressed the issue of whether Carter's design defect claim was preempted by the standards set by the U.S. Consumer Product Safety Commission.

The Court noted that federal preemption of state law may occur in three ways: (1) expressly; (2) impliedly, if the scope of the federal regulation sufficiently "occupies the field"; or (3) if there is a conflict between the federal and state laws such that it would be impossible to comply with both laws or compliance with the state law would obstruct the purposes of the federal law. Here the Court found that allowing a design defect claim, and thereby imposing a higher standard, would impermissibly conflict with the federal scheme.

The Court began its analysis by detailing the procedures that the Commission had undertaken to establish regulations governing the manufacture of lighters and protocols for testing lighters for child resistance. If a manufacturer does not comply with these standards and testing protocols, then they cannot receive a certificate of compliance from the Commission. The Court noted that the Commission made a deliberate decision in setting the standards, knowing that their decision struck a balance between safety and product usability. While the Commission could have required greater protection to reduce the risk of harm to children, doing so would have an adverse effect on competition and would disrupt manufacturing. The Court stated that this balancing was specifically considered by the Commission, which had been vested with the authority to do so, and that allowing a state-law claim to disrupt this balance would conflict with the federal scheme.

Further, the Court addressed the Commission's power to create state-specific exemptions to its regulations. Part of the act creating the Commission established a process by which states could apply for, and the Commission could consider, exemptions to regulatory standards. The Court reasoned that allowing Texas to raise the burden on manufacturers by application of the common law would negate the federal framework for dealing with this issue. Again, the Court held that this put the state-law claim in conflict with the federal law because the exemption process created by Congress would be superfluous if the state-law claim were allowed.

Finally, the Court considered a recent preemption case before the Supreme Court of the United States. In *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), the U.S. Supreme Court considered common-law claims related to products otherwise covered by the Medical Device Amendments (MDA). Although the Court noted that *Riegel* addressed an express preemption provision, it held that the same policy analysis applied. In both cases, the standards set by the federal entities were not just a floor for liability, but were a balancing of factors. Just as the U.S. Supreme Court held that common-law claims would impermissibly conflict with the MDA, the Texas Supreme Court held that design-defect claim would interfere with the standards of the Commission and held that the claim was preempted by federal law.

Also, BIC argued that the manufacturing defect claim was also preempted because it was no more than a "restatement" of the design defect claim. The Court disagreed, holding that the manufacturing

defect claim was a separate and distinct cause of action. Quoting a prior decision of the Court, it stated that the manufacturing claim arose when "a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous." Because the court of appeals did not address the manufacturing defect claim, the Court remanded the issue of sufficiency of the evidence to the court of appeals for its review.

Finally, the Court dealt with two remaining issues. First, it remanded BIC's appeal of the jury's award of malice because the court of appeals had affirmed it on the basis of the design defect claim, which the Court had reversed. Second, the Court considered the appropriate rate of post-judgment interest. BIC argued that legislation signed on June 20, 2003, immediately took effect and required a lower rate than imposed by the trial court. The Court held that Texas laws take effect immediately if passed by a recorded, two-thirds majority vote. Because the vote of the Senate was not recorded, the law was not immediately effective and the trial court applied the appropriate rate of interest.

3. **Ackermann v. Wyeth Pharmaceuticals**, 526 F.3d 203 (5th Cir. 2008).

Martin Ackermann suffered from clinical depression and was prescribed the antidepressant drug Celexa by his personal physician. Therefore, Ackermann began seeing a psychiatrist, Dr. Thomas Sonn. Sonn took Ackermann off of Celexas and gave him a sample pack of Effexor XR. After approximately one week on Effexor, Ackermann complained of side effects from the drug, stated he would no longer take the medication, and stopped his visits to Dr. Sonn. Sonn changed Ackermann's medication back to Celexa. Five days later, Ackermann committed suicide. At the time of his death, traces of Celexa (but not Effexor) were found in his system.

Ackermann's widow sued Wyeth, the manufacturer of Effexor XR, on a number of claims, including strict liability, negligence (including failure to warn), implied warranty theories under the common law and the DTPA, breach of express warranty, fraud, and misrepresentation. Wyeth moved for summary judgment. As to the warnings claims, Wyeth argued that the learned-intermediary doctrine barred Ackermann's recovery. Further, Wyeth contended that because Ackermann was only given a sample pack, and was not sold Effexor, there was no basis for implied and express warranty claims under common law or the DTPA. Finally, Wyeth argued that the fraud and misrepresentation claims warranted summary judgment because Ackermann did not identify any specific misrepresentations.

The magistrate judge recommended that the district court grant the motion for summary judgment, which it did, over Ackermann's objections. On appeal, Ackermann objected only to the district court's application of the learned-intermediary doctrine to her strict-liability and failure-to-warn claims.

The Fifth Circuit began its analysis by summarizing the learned-intermediary doctrine. Under this doctrine, a warning to an intermediary can fulfill a supplier's duty to warn consumers. This doctrine is most commonly seen in prescription-drug cases. In these cases, drug manufacturers are relieved from notifying every patient of the dangers associated with the drug when the manufacturers provide adequate warnings to the prescribing physicians. The doctrine is not an affirmative defense, but is used to determine to whom a manufacturer had a duty to warn: if the warning to the intermediary is insufficient, then the supplier would have a duty to warn the consumer directly.

The court continued its analysis by noting that when the doctrine is applied, the plaintiff bears the burden to show: (1) that the warning was inadequate; and (2) that the failure to properly warn was the producing cause of the injury. When a physician was aware of the risks associated with the drug and decided to prescribe it anyway, then the adequacy of the warning could not be the producing cause of the injury. But just showing an inadequate warning is not enough. The plaintiff must show that if the physician had been adequately warned, she would not have prescribed the product. To meet her burden, Ackermann first argued that Dr. Sonn offered conflicting testimony regarding whether he would have prescribed the drug had a stronger warning been given and, second, asserted that the "read-and-heed" presumption satisfied her burden to establish a causal connection between the warning and her late husband's suicide.

Ackermann's first argument against application of the learned-intermediary doctrine was that Dr. Sonn's testimony was inconsistent regarding whether he would have prescribed the drug had a stronger warning been given. The court rejected this argument. As part of her response to Wyeth's motion for summary judgment, Ackermann proposed a new warning that she argued should have been included

with Effexor. With Ackermann's permission, Wyeth showed this stronger warning to Dr. Sonn and asked if he would have changed his decision to prescribe the drug had this proposed warning been included. The court characterized Dr. Sonn's response as unequivocal: he would have prescribed the medicine regardless of which warning—the actual warning or the one proposed by Ackermann— had accompanied the drug. Finally, the court noted that the actual warning shipped with the drug included at least two references to the increased risk of suicide. For all these reasons, the court held that Ackermann's first argument did not warrant reversing the motion for summary judgment.

Ackermann's second argument was that the read-and-heed presumption satisfied her burden to establish a causal connection. Under the read-and-heed presumption, when a manufacturer fails to give adequate warnings, a presumption arises that the unwarned party would have read and heeded the warning. In effect, the burden is shifted from the plaintiff to defendant as to the issue of causation. The court concluded that the Texas Supreme Court would apply this presumption in a learned-intermediary situation. In making that determination, the court considered the policy justification for the presumption: it prevents self-serving testimony from raising fact issues regarding causation and aids plaintiffs where the injured party had died, making this evidence otherwise unavailable that policy would not be furthered here, the court reasoned, because it was Dr. Sonn, not Mr. Ackermann, whose testimony regarding the warning was relevant. Likewise, the court reasoned that the Texas Supreme Court had previously expressly rejected the "read-and-heed" presumption in the Restatement (Second) of Torts § 402(a) cmt. j.

Even if the presumption did apply, the court noted that Dr. Sonn's testimony would rebut the presumption. Dr. Sonn testified that he would have prescribed Effexor regardless of which warning he would have been given.

The court applied the learned intermediary doctrine and affirmed the trial court's motion for summary judgment.

4. **Merck & Co., Inc. v. Garza** No. 04-07-00234-CV, 2008 WL 2037350 (Tex. App.—San Antonio, May 14, 2008, no pet.).

In *Merck*, the court of appeals reversed a $32 million jury verdict (which had been reduced to $7.75 million after trial).

Leonel Garza died on April 21, 2001, at the age of 71. Garza, who had a history of heart problems, visited his cardiologist on March 27, 2001, complaining of numbness, pain in his left arm, and weakness. He was given a one-week prescription for Vioxx, his first time to take the drug. He also underwent several diagnostic exams, one of which showed a mild abnormality. Mr. Garza's wife testified that her husband was given an additional prescription for Vioxx. After his death, his wife and children sued Merck, the manufacturer of Vioxx, on design defect and marketing defect claims. Although the Garzas were awarded a jury verdict on both claims, the court of appeals reversed.

The court of appeals noted that both design defect and marketing defect claims require the plaintiff to prove both general and specific causation. While general causation asks whether the substance could cause the problem in the general population, specific causation asks whether the substance caused the particular person's injury. A plaintiff can use studies to show specific causation, but the plaintiff must also present evidence that excludes other plausible causes with reasonable certainty.

Here, Merck argued that the Garzas did not meet their burden on specific causation because they failed to rule out with reasonable certainty the most plausible explanation for Garza's death—the natural progression of his preexisting heart problems.

The Garzas argued that they did submit sufficient evidence to exclude Mr. Garza's history of heart problems with reasonable certainty when they established: (1) that his last two physicals, before he began taking Vioxx, indicated he had "stable cardiac status"; (2) that his death was caused by clots formed after he began taking Vioxx; (3) that the development of simultaneous clots was rare without a "causative agent" like Vioxx; and (4) that the formation of clots is associated with Vioxx. Additionally, the Garzas presented evidence from the autopsy that showed that the dual clots had formed in areas where tests had previously shown no evidence of blockage.

Given the extensive cardiac-related problems suffered by Mr. Garza that were presented at trial, the court of appeals held that the Garzas' evidence was not sufficient to meet the Plaintiffs' burden to exclude other plausible causes of Garza's injury with reasonable certainty. While the Garzas' expert testified that it was rare for someone to develop two clots, the court noted that there was no evidence presented that it was rare for someone with Mr.

Garza's medical history to develop the clots. Further, the court noted that there was no scientific evidence that linked less than twenty-five days of Vioxx to the development of the clots.

Because the court of appeals found that the Plaintiffs did not meet their burden of excluding other plausible causes of Mr. Garza's injury with reasonable certainty, it reversed and rendered in favor of Merck.