TADC PRODUCTS LIABILITY NEWSLETTER

Selected Case Summaries
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I. Summary

1. The United States Supreme Court held that a state law design defect claim based on the failure to strengthen warnings on a drug was preempted by federal law that expressly prohibits generic drug manufacturers from unilaterally changing the drug's label. *Mutual Pharm. Co., Inc. v. Bartlett*, 133 S.Ct. 2466 (2013).

2. Under Texas products liability law, failure to warn, inadequate testing, and design defect claims against a generic drug manufacturer are preempted by federal law. Furthermore, a plaintiff alleging a warning defect must plead sufficient facts to satisfy the learned intermediary doctrine. *Rojas v. Teva Pharm. USA, Inc.*, 920 F. Supp. 2d 772 (S.D. Tex. 2013).

3. Failure to warn claims brought under Texas law based on a failure to update a prescription drug label are not preempted by federal law if the generic drug manufacturer strengthens a warning or precaution on the drug label to match an updated brand-name label or to comply with instructions from the FDA. In addition, before a drug manufacturer may assert the presumption of non-liability under the Civil Practice & Remedies Code Section 82.007, the drug manufacturer must demonstrate that it distributed its product with the proper FDA-approved warnings and information. *Garza v. Wyeth LLC*, No. 2:12-CV-198, 2013 WL 878586 (S.D. Tex. Mar. 7, 2013).

4. A manufacturer's duty to warn extends to an intermediary hospital and its physical therapists, but does not extend to individual patients that are the ultimate users of the product. A manufacturer may reasonably rely upon a physical therapist to communicate warnings to ultimate users as long as the therapist is a certified healthcare professional with training and experience specific to the product's use, has read both the warnings on the product insert and in the product manual, has instructed the patient on the proper use of the band, and has demonstrated and supervised its use. *Seifried v. Hygenic Corp.*, No. 01-12-01093-CV, 2013 WL 3991987 (Tex. App.—Houston [1st Dist.] Aug. 6, 2013, no pet.).

5. On rehearing, the Houston [1st District] Court of Appeals held that a chemical plant employee injured by an acid addition system could bring a common law negligent-design claim against the plant's former owner that designed the system. The plaintiff was not restricted to bringing to strict products liability or premises liability claims, and therefore was not required to show that the former plant owner manufactured and placed the product in the stream of commerce or that the former owner owned and operated the plant when the plaintiff was injured. While the former owner owed a duty to the employee to be non-negligent in its engineering and design of the system, it did not owe a duty to keep the plant in a safe condition or to warn third parties of dangerous conditions. *Jenkins v. Occidental Chem. Corp.*, No. 01-09-01140-CV, 2013 WL 3354002 (Tex. App.—Houston [1st Dist.] July 2, 2013, no pet.).

II. Discussion

1. *Mutual Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466 (2013)

In *PLIVA, Inc. v. Mensing*, -- U.S. --, 131 S.Ct. 2567 (2011), the Supreme Court held that federal law prohibits generic drug manufacturers from independently changing their drugs' labels, and therefore, failure to warn claims against generic manufacturers are preempted. The Court's decision in *Bartlett* expanded on *Mensing* by holding that state law design defect claims that turn on the adequacy of a drug's warnings are preempted by federal law.

In December 2004, Karen Bartlett was prescribed a generic form of Clinoril to treat shoulder pain. She soon developed toxic epidermal necrolysis, which left her severely disfigured and disabled. At the time of the prescription, the generic drug label did not specifically refer to toxic epidermal necrolysis, but it did warn that the drug could cause severe skin reactions and death. In 2005, the Food and Drug Administration (FDA) completed a comprehensive review of the drug and recommended changes to the labeling to more explicitly warn about toxic epidermal necrolysis.

Bartlett sued Mutual Pharmaceutical Co. ("Mutual"), the generic drug manufacturer, claiming warning and design defects. The warning defect claim was subsequently dismissed, but the jury found Mutual liable on the design defect claim and awarded Bartlett over $21 million. The First Circuit affirmed, finding that neither the Federal Food, Drug, and Cosmetic Act (FDCA) nor the FDA's regulations preempted Bartlett's design defect claim. After analyzing the interplay between state products liability law and the FDCA, the Supreme Court reversed.

According to the FDCA, prescription drug manufacturers are required to obtain approval from the FDA before marketing any brand-name or generic drug. Once the FDA approves a drug, a manufacturer is prohibited from making major changes to the qualitative or quantitative formulation of the drug or the specifications on which the FDA based its approval. Unlike brand-name drug manufacturers, generic drug manufacturers may gain FDA approval upon a showing that the generic drug is equivalent to the approved brand-name drug. One factor in this determination is that the generic drug's labeling is the same as the approved brand-name drug. Once approved, the generic drug manufacturer is prohibited from unilaterally changing the drug's label or chemical makeup.

Under applicable New Hampshire law, manufacturers are under an affirmative duty to design products that are reasonably safe for foreseeable uses. New Hampshire employs a risk-utility analysis in determining whether a drug is unreasonably dangerous, and courts apply the following three factors: (1) the usefulness and desirability of the product to the public as a whole; (2) whether the risk of danger could have been reduced without significantly affecting the product's effectiveness or manufacturing cost; and (3) the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses.

Bartlett's design defect claim alleged that Mutual's generic drug was not reasonably safe because the drug could have been chemically redesigned to minimize the risk of danger and the drug label warning could have been more specific as to the hidden dangers of using the drug. The Court concluded that federal law preempted Barrett's state law claims because federal law forbids an action that New Hampshire state law required. If Mutual redesigned the generic drug by changing its active ingredients to reduce the risk of danger, it would violate the FDCA, which requires the generic drug to be the same as the FDA-approved brand-name drug. Since federal law barred redesigning the drug, Mutual's only remaining option to make the drug reasonably safe was to strengthen the warning label. However, strengthening the warnings on the label also violates the FDCA, which prohibits generic drug manufacturers from unilaterally changing the generic drug's label.

Bartlett's holding extends *Mensing* to design defect claims. Now, state law claims that require a generic drug manufacturer to make its drug safer by changing either its warning or drug design are preempted unless the generic drug's label or design matches its brand-name counterpart or complies with FDA instructions.

2. *Rojas v. Teva Pharm. USA, Inc.*, 920 F. Supp. 2d 772 (S.D. Tex. 2013)

In *Rojas*, Petra Rojas sued generic and brand-name manufacturers of the drug metoclopramide after she developed a neurological disorder as a result of prolonged use of the drug. After the case was removed from Texas state court and the brand-name defendants were dismissed, the remaining generic defendants moved for judgment on the pleadings. In granting the motion, the federal district court first analyzed the Supreme Court's decision in *Mensing* as it applies to Texas products liability law. After reviewing the Supreme Court's preemption analysis in *Mensing*, the district court concluded that state laws requiring generic drugs to have different labels than the FDA-approved brand-name labels are preempted. Therefore, under *Mensing*, all of Rojas's claims arising from a failure to warn that long-term use of metoclopramide causes neurological disorders were preempted. According to the district court, *Mensing* also preempted Rojas's inadequate testing claim and her claim that the generic manufacturers failed to adopt the 2004 FDA-approved labeling.

Further, the district court analyzed whether Rojas's remaining claims survived judgment on the pleadings. Specifically, the court addressed the viability of Rojas's design defect claim under Texas law after *Mensing*. The court's analysis foreshadowed the Supreme Court's holding in *Bartlett*, which was handed down four months later. Under Texas law, a plaintiff must prove the existence of a safer alternative design to prevail on a design defect claim. However, under federal law, the generic drug must be equivalent to the approved brand-name drug, and generic drug manufacturers are prohibited from unilaterally pursuing a safer alternative design in order to comply with state law. Therefore, design defect claims brought against generic drug manufacturers under Texas law are preempted if the generic drug manufacturer is required to either produce a drug that is different from the approved brand-name drug or is required to independently pursue a safer alternative generic drug design.

Additionally, the court addressed the viability of Rojas's claims that the defendants failed to update their drug labeling in 2004 as required by the FDA and failed to communicate that change to prescribers. Rojas argued that these state law claims were not preempted by federal law. However, the court bypassed Rojas's argument against federal preemption and dismissed on the grounds that Rojas did not state a claim under state law for a failure to warn based on the alleged failure to update the label. The court relied upon the Texas Supreme Court's holding in *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 169 (Tex. 2012), which clarified that the learned intermediary doctrine generally applies within the physician-patient relationship and allows a prescription drug manufacturer to fulfill its duty to warn end users of its product's potential risks by providing an adequate warning to the prescribing physician.

Based on *Centocor*, the learned intermediary doctrine applied to all of Rojas's claims, so she was required to show that the allegedly inadequate warning to the prescribing physician was a producing cause of her injuries. However, Rojas's pleadings were insufficient because she alleged that her doctor knew or should have known the side effects, instead of alleging that her doctor was unaware of the drug's side effects because of the inadequate warning.

3. *Garza v. Wyeth LLC*, No. 2:12-CV-198, 2013 WL 878586 (S.D. Tex. Mar. 7, 2013)

In *Garza*, the plaintiff was prescribed metoclopramide in June 2007 to treat gastroesophageal reflux disease. Two years later, she began exhibiting abnormal muscle movements as a result of prolonged exposure to the generic drug. In 2003, before Garza's doctor prescribed the drug, the FDA approved the addition of new warnings to the brand-name drug label. In July 2004, the FDA approved the addition of a bolded warning to the label for the brand-name drug stating that the drug should not be taken for over 12 weeks. Finally, in February 2009, the FDA ordered a black box warning, its strongest, stating that the drug could cause serious movement disorders.

Garza sued several manufacturers of the generic drug, alleging that the defendants' failure to update their labels to conform with the 2003, 2004, or 2009 FDA-approved brand-name drug labels constituted a warning defect under Texas products liability law.

The generic drug manufacturers argued that Garza's claims were preempted by federal law under *Mensing* and otherwise barred by the

rebuttable presumption of non-liability arising under the Texas Civil Practice & Remedies Code Section 82.007. The district court distinguished *Mensing* by emphasizing that the defendants here failed to update their labels to conform with the brand-name drug label, whereas the *Mensing* generic drug manufacturers' labels matched the brand-name labels. In *Garza*, the defendants' duty under Texas law to adequately warn consumers about the potential dangers of their drug was coextensive with their duty under federal law to ensure that their labeling was identical to the brand-name drug label.

Next, the defendants argued that Garza's failure-to-update claims must be dismissed because they are barred by Section 82.007 of the Texas Civil Practice & Remedies Code, which establishes a rebuttable presumption that a drug manufacturer or distributor is not liable if the warnings and information that accompany the drug are approved by the FDA. A plaintiff can rebut this presumption in several ways, including by establishing that the defendants committed fraud on the FDA in the application process. However, under Texas law, the fraud-on-the-FDA exception requires the plaintiff to show that the FDA itself found fraud. In this case, the FDA had not found the defendants' applications fraudulent, so Garza could not use this exception to rebut the presumption of non-liability.

However, the court concluded that Garza was not required to prove the fraud-on-the-FDA exception because the defendants failed to trigger the non-liability presumption in their pleadings. The court held that because the drug manufacturers did not first demonstrate that they distributed the generic drug with the proper FDA-approved warnings and information, they were not entitled to the non-liability presumption in Section 82.007.

4. *Seifried v. Hygenic Corp.*, No. 01-12-01093-CV, 2013 WL 3991987 (Tex. App.—Houston [1st Dist.] Aug. 6, 2013, no pet.)

In *Seifried*, the Houston Court of Appeals [First District] held that (i) a manufacturer's duty to warn extended to the intermediary hospital and its physical therapist, not to the patient; and (ii) the manufacturer's warning regarding eye injury was adequate as a matter of law.

During a physical therapy session at Memorial Hermann Katy Rehabilitation Hospital ("the Hospital") to treat his multiple sclerosis, Gary Seifried was using a Thera-band elastic resistance band to improve his strength. The band was manufactured by The Hygenic Corporation ("Hygenic"), which then distributed it to the Hospital in a large, bulk roll. Seifried was assisted by physical therapist Brenda Cossey who had developed the therapy regimen for Seifried's particular needs. As part of this plan, Cossey tied the Thera-band to a bar directly in front of Seifried at waist level. She then demonstrated the exercise and directed Seifried to pull the band toward him in a curling motion. When Seifried stretched the band, pulling it toward his head and shoulders, the band snapped and caused a severe eye injury.

Seifried sued Hygenic for negligent failure to warn. Hygenic moved for a traditional summary judgment, arguing it owed no duty to warn Seifried because it distributed the resistance bands to an intermediary (the Hospital), to whom it had provided an adequate warning. The trial court granted Hygenic's motion. Seifried appealed, arguing (i) he had produced enough evidence that Hygenic failed to warn him about the potential hazards of using the band; (ii) placing the warning on the resistance band itself was a better method of warning ultimate users; and (iii) Hygenic failed to timely raise its learned intermediary or bulk-supplier defenses.

On appeal, the court of appeals first considered whether the learned intermediary and bulk-supplier doctrines applied. The court began with the general rule that in a negligent failure to warn case, a manufacturer has a duty to warn if a reasonably prudent person in the manufacturer's position would warn of the hazards associated with the use of its product. However, in certain situations, the manufacturer may depend upon an intermediary to communicate the warning to the product's ultimate user. If the manufacturer has reasonable assurance that the intermediary will communicate its warning to the ultimate user, the manufacturer satisfies its duty to warn by adequately warning the intermediary.

Similarly, a bulk supplier may be excused from warning an ultimate user if the product is sold to another manufacturer or distributor, who then packages and sells the product to the public. If the bulk supplier can reasonably rely upon the

intermediary to communicate the warning to the ultimate user, the bulk supplier's duty to warn only extends to the intermediary. Under Texas law, three factors determine whether a bulk supplier may reasonably rely upon an intermediary to pass on the warning: (1) whether the intermediary is adequately trained; (2) whether the intermediary is familiar with the properties of the product and its safe use; and (3) whether the intermediary is capable of communicating its knowledge of the product to end users.

The court concluded that aspects of both doctrines applied to the case. Like a doctor who prescribes medication manufactured by a pharmaceutical company, a therapist who designs and supervises an individualized physical therapy regimen can pass on applicable warnings to a patient regarding the treatment utilized in a session. Physical therapists are similarly experienced in treating and caring for patients, are trained in and familiar with the use of resistance bands for physical therapy, and supervise and monitor the patients' use of the bands. The court also analogized Hygenic to a bulk supplier that provides its product to a distributor, which then packages the product for sale to the public. Hygenic supplied bulk rolls of Thera-band resistance bands to the Hospital. At the Hospital, physical therapists would cut portions of the band at the length suitable for each patient's body size and exercise regimen. The Hospital, through its physical therapists, then provided the Thera-band to Seifried, the ultimate user, to use with a therapist's instruction and supervision.

To determine whether Hygenic could reasonably rely on the Hospital and its physical therapists to communicate warnings to its patients, the court utilized the three factors listed above. On appeal, Seifried argued that a warning on the resistance band itself was feasible and could have directly warned the ultimate user. The court rejected this argument, concluding that feasibility is not the rationale behind either doctrine. Instead, the doctrine is based on the idea that an intermediary may be in the best position to effectively convey a warning to an end user, depending on an analysis of the three factors listed above.

After concluding that Hygenic satisfied its duty to warn Seifried by warning the Hospital and its physical therapists, the court analyzed whether Hygenic's warning was adequate. The court recognized that although adequacy of a warning is generally a fact question, a warning is adequate as a matter of law if it specifically mentions the circumstances made the basis of plaintiff's complaint. Because Hygenic's product insert and manual warned against drawing the band toward the user's head and recommended eye protection, the court concluded that the warning was adequate as a matter of law.

Seifried also argued that the trial court erred in considering Hygenic's motion for summary judgment because Hygenic did not plead the learned intermediary doctrine as an affirmative defense until after moving for summary judgment. The court overruled this point of error and clarified that the learned intermediary doctrine is not an affirmative defense, but rather a legal doctrine used to evaluate to whom a defendant owes a duty. As such, Hygenic properly asserted the doctrine in its motion for summary judgment and was not required to plead it separately as an affirmative defense.

5. *Jenkins v. Occidental Chem. Corp.*, No. 01-09-01140-CV, 2013 WL 3354002 (Tex. App.—Houston [1st Dist.] July 2, 2013, no pet.)

On rehearing, the Houston Court of Appeals [First District] held that an employee injured by a system used to add acid to a chemical could bring a common law negligent-design claim against the plant's former owner that designed the system, rather than a strict products liability or premises liability claim. The court also held that a plaintiff asserting negligent design against a non-manufacturer is not required to prove that the defendant manufactured the product and placed it in the stream of commerce, or that the defendant owned or operated the premises when the plaintiff was injured. The former owner owed a duty to third parties to be non-negligent in its engineering and design of the acid addition system, but it did not owe a duty to keep the plant in a safe condition or warn third parties of dangerous conditions.

In 1992, Occidental Chemical Corporation ("Occidental") installed an acid addition system to regulate the acidity of a chemical compound it produced. An Occidental employee developed the conceptual design for the system and collaborated with a team of Occidental engineers during the design process. Six years later,

Occidental sold the chemical plant with the acid addition system in place. In 2006, 14 years after selling the plant, Jenkins, an operator at the plant, was partially blinded when the system sprayed him in the face.

Jenkins sued Occidental for negligence in designing the system. Occidental asserted two statutes of repose as affirmative defenses. The first statute of repose—Section 16.008 of the Civil Practice & Remedies Code (CPRC)—relates to improvements to real property and equipment attached to real property, and protects only registered or licensed design professionals. The second statute—Section 16.009 of the CPRC—relates only to improvements to real property, but protects those who construct or repair such an improvement. Both statutes bar suits brought more than ten years after the substantial completion of the improvement or the beginning of operation of the equipment.

After a two-week trial, a jury found in Jenkins's favor on his negligent-design claim and assessed 75% liability to Occidental. However, the jury also found that (i) the acid addition system was an improvement and (ii) the system was designed under the supervision of a licensed engineer. Based on these jury findings, the trial court rendered a take-nothing verdict on Occidental's statute of repose defenses. Jenkins appealed, arguing that Occidental failed to conclusively established a right to rely on either statute.

The appellate court sustained Jenkins's points of error, concluding that neither statute of repose barred his claim. Occidental raised three cross-points on appeal: (1) the only cause of action available to Jenkins is a premises liability action, which Jenkins failed to plead, prove, or obtain a jury finding; (2) Jenkins cannot recover under a negligent design theory because he did not prove the elements of a strict products liability claim; and (3) Jenkins's claim is barred by the statute of limitations.

Occidental first argued that, because Jenkins was injured while operating an improvement to real property, his claim was limited to a premises liability theory. And since Occidental did not own the plant at the time of Jenkins's injury, Occidental could not be held liable for its negligent design of the system. The court dismissed this argument, reasoning that Occidental played two distinct roles—the role of the designer of the faulty improvement, who was subject to liability, and the role of the former premises owner who was not subject to liability. Thus, Occidental was liable for its design work because the jury's finding against Occidental was based upon the first role.

Next, Occidental argued that in order to recover for negligent design, Jenkins was required to establish that the acid addition system was a product that Occidental manufactured and placed in the stream of commerce. Jenkins responded that he was not required to prove these strict products liability elements because he asserted a common law negligent-design claim. The court of appeals narrowed the issue and considered whether Texas recognizes a negligent-design claim against a non-manufacturer outside the bounds of a strict products liability claim. If so, the issue is whether a party bringing such a claim must prove the elements of a strict products liability claim. After referring to case law and various statutes of repose and procedural requirements for strict liability claims against sellers, manufacturers, and design professionals, the court concluded that Texas law recognizes a negligent-design cause of action against non-manufacturers. Furthermore, a plaintiff asserting this theory is not required to prove that the improvement is a product that the defendant manufactured and placed in the stream of commerce.

On rehearing, Occidental urged the appellate court to affirm the trial court's judgment on the grounds that a premises defect claim is the exclusive negligence claim available for an injury arising out of a condition of property, rather than concurrent negligent activity. The court rejected this argument because Occidental did not own, operate, or control the plant when Jenkins was injured and its liability did not arise out of any ownership, operation, or control of the plant. The court reasoned that forcing injured third parties like Jenkins to frame negligent-design claims as if they were premises liability claims could either expand the duty to warn or make safe to architects, engineers, and other design professionals, or could insulate them from liability to third parties injured by their negligent work. The court concluded that Occidental did not owe a duty to keep the plant in a safe condition or to warn plant employees of dangerous conditions at the plant. However, Occidental did owe a duty to be non-negligent in

its engineering and design of the acid addition system.