TADC
PRODUCTS LIABILITY NEWSLETTER

Selected Case Summaries
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I. SUMMARY

1. The Texas Supreme Court reversed a jury verdict against an aerial lift manufacturer because the aerial lift at issue was not unreasonably dangerous because the risk of misuse did not outweigh its utility as a matter of law. *Genie Indus., Inc. v. Matak*, 462 S.W.3d 1 (Tex. 2015).

2. The San Antonio Court of Appeals held that, despite not being an engineer and never having designed or manufactured a similar product, a proffered tire expert's experience in the tire industry with tire manufacture and failure analysis qualified him to opine on the design defects of a steel-belted radial tire. The court held that the expert's opinion that a lack of nylon overlay contributed to the separation of the tire tread from the tire, causing an ambulance driver to lose control of the vehicle, had sufficient support to meet the *Robinson/Daubert* requirements. *Perez v. Goodyear Tire & Rubber Co.*, No. 04-14-00620-CV, 2015 WL 4933244 (Tex. App.—San Antonio Aug. 19, 2015, no. pet. h.).

3. In a case arising from off-label marketing of prescription medications, the United States District Court for the Southern District of Texas held the learned-intermediary doctrine could be a defense to claims under the False Claims Act. *U.S. ex rel. King v. Solvay S.A.*, 304 F.R.D. 507 (S.D. Tex. 2015).

4. In a case of first impression, the Texas Supreme Court held that a pharmacy and its employees were engaged in the dispensing of prescription medicines when they compounded an injectable lipoic acid. Thus a patient's claims against the pharmacy, even though couched as product liability claims, constituted health care liability claims subject to the requirements of the Texas Medical Liability Act. *Randol Mill Pharmacy v. Miller*, No. 13-1014, 2015 WL 1870058 (Tex. Apr. 24, 2015).

II. DISCUSSION

1. *Genie Indus., Inc. v. Matak*, 462 S.W.3d 1 (Tex. 2015).

In *Genie Industries, Inc. v. Matak*, the Texas Supreme Court held that, although the plaintiff had presented more than a scintilla of evidence of a safer alternative design for an aerial lift, the lift was not unreasonably dangerous because the risk from its design did not outweigh its utility as a matter of law.

A deceased worker's estate brought a product liability action against aerial lift manufacturer Genie Industries, Inc. after one of its lifts tipped over and the worker fell 40 feet. The lift tipped over because its users were attempting to move it while the worker was in the air. Signs on the lift and instructions in the user manual warned that the lift would tip over if moved while in use. In fact, one sign at eye level displayed an image of a man pushing the lift while elevated and in use, and stated:

> DANGER: Tip-over hazard. Attempting to move the machine while the platform is raised will tip the machine over and cause death or serious injury.

Genie proffered evidence that of the "millions of times" Genie's aerial lifts had been used, only three similar accidents had been reported. Nevertheless, the jury found that a design defect in the aerial lift had caused the accident. The court of appeals affirmed and the Texas Supreme Court granted Genie's petition for review.

In Texas, a product manufacturer is not liable for a design defect unless the plaintiff proves a feasible safer alternative design existed and the failure to use the reasonable alternative design renders the product defective and unreasonably dangerous, i.e., that the product's risks outweighed its utility. This is usually an issue of fact for the jury, but may become a legal issue when the evidence is such that reasonable minds cannot differ on the risk-utility balancing considerations. Here, Genie argued that plaintiffs produced no evidence of a safer alternative design or that the risk of an accident outweighed the lift's utility.

With respect to Genie's first argument, the Court reasoned that a safer alternative design is one that would have prevented or significantly reduced the risk of the injury, would not substantially impair the product's utility, and was economically and technologically feasible. At trial, plaintiffs offered expert testimony regarding three alternative designs. Though the evidence was weak, it was enough to support the jury's verdict.

With respect to Genie's second argument, the Court listed the following considerations to be used to determine whether a product's risks outweigh its utility:

> (1) The utility of the product to the user and to the public as a whole weighed against the gravity and likelihood of injury from its use;
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> (2) The availability of a substitute product which would meet the same need and not be unsafe or unreasonably expensive;
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> (3) The manufacturer's ability to eliminate the unsafe character of the product without seriously impairing its usefulness or significantly increasing its costs;
>
> (4) The user's anticipated awareness of the dangers inherent in the product and their avoidability because of the general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions; and
>
> (5) The expectations of the ordinary consumer.

The Court held that the evidence of the lift's utility was undisputed. The lift was designed to be small, lightweight, portable and relatively inexpensive. It could accommodate a variety of work environments, and could be used in narrow spaces and on uneven surfaces. Meanwhile, the risk that a user would ignore the obvious danger that the lift would tip if moved while fully elevated was "one in millions." Thus the risk of misuse could not outweigh the lift's utility as a matter of law, and the Supreme Court reversed and rendered judgment for Genie Industries.

2. *Perez v. Goodyear Tire & Rubber Co.*, No. 04-14-00620-CV, 2015 WL 4933244 (Tex. App.—San Antonio Aug. 19, 2015, no. pet. h.).

In *Perez v. Goodyear Tire & Rubber Co.*, the San Antonio Court of Appeals held:

> (1) A proffered tire expert was qualified to testify regarding design defects of a steel-belted radial tire;
>
> (2) The expert's opinion that a lack of nylon overlay contributed to separation of the tire tread from the tire, and that this separation caused the driver of an ambulance to lose control of the vehicle, were scientifically reliable; and
>
> (3) Expert testimony was required to establish the standard of care on claims of negligent marketing defect and failure to warn.

In 2006, Julio Perez, Sr. was being transported in a Ford E-350 van that had been converted into an ambulance. The tread of a Goodyear Wrangler tire separated during travel, causing the driver to lose control. The ambulance rolled over and Mr. Perez died from the injuries he sustained in the accident.

The Perez family ("Plaintiffs") filed suit against the ambulance company, the driver, Ford Motor Company, and Goodyear Tire & Rubber Company. Plaintiffs claimed that Goodyear was liable under strict liability for design defects and under negligence theories for negligently designing, manufacturing and marketing the tire at issue. In support of their claims, Plaintiffs offered the testimony of proffered tire expert William Woerhle. The trial court granted Goodyear's motion to exclude Woerhle's testimony and thus granted summary judgment in favor of Goodyear. Plaintiffs appealed.

The main issue before the San Antonio Court of Appeals was whether the trial court abused its discretion by excluding Woerhle's testimony. As a general rule, an expert witness may testify regarding scientific, technical, or other specialized matters if the expert is qualified, the expert's opinion is relevant to the issues in the case, and the opinion is based on a reliable foundation. An expert must be qualified by knowledge, skill, experience, training, or education to assist the trier of fact to understand the evidence or to determine a fact in issue. Tex. R. Evid. 702. To be reliable, the expert's opinion must be based on sound reasoning and methodology, and cannot contain analytical gaps. In *E.I. du Pont de Nemours & Co., Inc. v. Robinson*, 923 S.W.2d 549 (Tex. 1995), the Texas Supreme Court articulated the following factors that courts may consider when assessing the reliability of scientific evidence:

> (1) The extent to which the theory has been or can be tested;
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> (2) The extent to which the technique relies upon the subjective interpretation of the expert;
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> (3) Whether the theory has been subjected to peer review and/or publication;
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> (4) The technique's potential rate of error;
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> (5) Whether the underlying theory or technique has been generally accepted as valid by the relevant scientific community;
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> (6) The non-judicial uses that have been made of the theory or technique; and
>
> (7) Whether the expert has ruled out alternative causes of injury.

In its motion to exclude, Goodyear argued that Woerhle was not qualified to testify as to design defects because he was not a professional licensed engineer and had never designed or manufactured a steel-belted radial tire. However, Woerhle's affidavit described his extensive experience running tire tests and analyzing tire failure. Given his extensive direct experience in the tire industry and with manufacture and failure analysis, the court held that he was qualified to testify as an expert.

Goodyear also argued that Woerhle's design defect opinion failed to meet the requirements for reliability under *Robinson/Daubert*. In his affidavit, Woerhle explained how tire belt separation can occur and how it can be prevented by the addition of a nylon overlay. Woerhle's opinions that the lack of a nylon overlay caused the tire to fail, thus causing the ambulance driver

to lose control, were supported by his experience in the tire industry and documents from Goodyear showing that the addition of a nylon overlay would have alleviated the tread separation issue. In reaching his opinions, Woerhle ruled out alternative causes of the injury, including other potential causes of tire failure and driver error. Accordingly, the court held that Woerhle's opinions were sufficiently reliable and the trial court erred in excluding them.

Because Woerhle's expert testimony was improperly excluded, the court held that summary judgment on Plaintiffs' defective design and negligent design claims was improper. However, Plaintiffs had also asserted claims for marketing defect and negligent failure to warn. Strict liability marketing defect claims require expert testimony. Similarly, Plaintiffs' negligent marketing claim required expert testimony because the standard of care in marketing a particular tire is not within the experience of laymen. But Plaintiffs did not offer expert testimony to support these claims. Woerhle did not hold himself out as a warnings expert and did not have an opinion as to these issues. Thus, the court upheld summary judgment on Plaintiffs' marketing claims.

3. *U.S. ex rel. King v. Solvay S.A.*, 304 F.R.D. 507 (S.D. Tex. 2015).

In *U.S. ex rel. King v. Solvay S.A.*, the United States District Court for the Southern District of Texas did not preclude the use of the learned-intermediary doctrine as an affirmative defense to claims under the False Claims Act.

Relators brought a *qui tam* action on behalf of the United States and various states against Solvay Pharmaceuticals, Inc. ("SPI") and its affiliates pursuant to the False Claims Act. Relators alleged that SPI had marketed drugs for conditions other than the conditions for which the drugs were approved by the FDA, and offered kickbacks to physicians who prescribed these drugs. Relators moved for summary judgment on a number of SPI's affirmative defenses, as well as SPI's defense based on the learned-intermediary doctrine.

The Court reviewed the nature of and bases for the learned-intermediary doctrine:

> A patient-purchaser's doctor stands between the patient and the manufacturer, professionally evaluating the patient's needs, assessing the risks and benefits of available drugs, prescribing one, and supervising its use . . . . If the doctor is properly warned of the possibility of a side effect and is advised of the symptoms normally accompanying the side effect, it is anticipated that injury to the patient will be avoided. Accordingly, the doctrine excuses a drug manufacturer from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers.

The doctrine is commonly used to show that a defendant (usually a prescription drug manufacturer) owes the duty to adequately warn to prescribing physicians and not to the ultimate recipient of the medication. The doctrine bars a plaintiff's claims if he cannot show that the allegedly inadequate warning to the prescribing physician was a producing cause of his injury.

Relators insisted that the learned-intermediary doctrine does not apply to claims under the FCA. Specifically, Relators argued that SPI cannot rely on the learned-intermediary doctrine because there is no causal connection between the warnings given by the prescribing physicians and the alleged FCA violations. By contrast, SPI argued that, at trial, Relators should be forced to prove that inadequate warnings to the learned intermediary caused the injury.

The court denied Relators' motion for summary judgment, leaving the door open for the learned-intermediary doctrine to be used as a defense to Relators' FCA claims. However, the court noted that Relators could reassert their arguments at trial should it become evident that use of the doctrine is inappropriate as a matter of law.

4. *Randol Mill Pharmacy v. Miller*, No. 13-1014, 2015 WL 1870058 (Tex. Apr. 24, 2015).

In *Randol Mill Pharmacy v. Miller*—a case of first impression—the Texas Supreme Court held that a pharmacy and its employees were engaged in "the dispensing of prescription medicines" when they compounded an injectable

lipoic acid. Thus a patient's claims against the pharmacy and its employees constituted health care liability claims subject to the provisions of the Texas Medical Liability Act (the "Act").

In 2011, Stacey Miller's doctor treated her for hepatitis C by using weekly intravenous injections of lipoic acid, an antioxidant supplement. Ultimately Miller suffered a severe adverse reaction to the treatment, which required her to undergo multiple blood transfusions and caused permanent blindness. Randol Mill Pharmacy compounded the particular vial of lipoic acid to which Miller reacted.

Miller and her husband sued Miller's physician, Randol Mill, and several of its pharmacists. Miller alleged that "because of negligence in compounding, inadequate and inappropriate warnings and instructions for use, the compounded lipoic acid was defective, ineffective and unreasonably dangerous." Miller also alleged that the pharmacist defendants "breached their implied warranties in the design, manufacture, inspection, marketing, and/or distribution" of the lipoic acid.

Randol Mill and its pharmacists moved to dismiss Miller's claims with prejudice for failure to serve an expert report within 120 days of filing suit, as required under the Texas Medical Liability Act. The main issue in the case was whether Miller's claims against Randol Mill and its pharmacists should be treated as health care liability claims subject to the Act. The trial court held that the patient's causes of action were not health care liability claims, and the court of appeals affirmed. The Texas Supreme Court reversed.

The Act defines a pharmacist as "one licensed under Chapter 551, Occupations Code, who, for the purposes of this chapter, performs those activities limited to the *dispensing of prescription medicines* which result in health care liability claims and does not include any other cause of action that may exist at common law against them, including but not limited to causes of action for the sale of mishandled or defective products." Courts are generally in agreement that the Act applies to cases against pharmacies involving claims of misfiled prescriptions. But this case implicated a pharmacy's compounding services—the process by which a pharmacist mixes or alters drugs to create a medication that is tailored to the needs of an individual patient and that is not otherwise commercially available. The parties disputed whether Randol Mill's act of compounding the lipoic acid constituted "the dispensing of prescription medicines." The Supreme Court held that it did.

Because the Act does not define the word "dispense," the Court looked to the Texas Pharmacy Act, which defines "dispense" to mean "to prepare, package, compound, or label, in the course of professional practice, a prescription drug or device for delivery to an ultimate user or the user's agent under a practitioner's lawful order." The Court held that a pharmacist who compounds a drug for office use pursuant to a practitioner's lawful order is "dispensing" the drug, regardless of whether the order identifies the patients to whom the drug will be administered.

Also, the Court had to determine whether Randol Mill's actions resulted in health care liability claims. Miller argued that her claims were product liability claims expressly excluded by the Act. The Court held that, despite the language of Miller's "manufacturing" claim, Miller did not sue Randol Mill as retailers or manufacturers of a defective product. In effect, Miller alleged that Randol Mill and its pharmacists departed from accepted health care standards in dispensing the medication. The Court would not allow Miller to recast her health care liability claims as breach-of-warranty and product liability claims to avoid the Act. Thus, the Court reversed and remanded the case.