It is time again for the "Year in Review" edition of our newsletter. Once again, we asked our ALFA members to report on the most noteworthy product cases issued in their jurisdictions in 2011 to encompass a broad array of decisions at varying levels. The result is a compendium of case notes discussing traditional and non-traditional product liability related concepts and concerns. We hope you find the review a useful guide in navigating the legal potholes and roadblocks in the various jurisdictions where you do business or practice law. As always, we welcome your suggestions for topics or articles for our next edition and look forward to keeping you posted on breaking developments in 2012.

Editors Colleen Murnane, Stan Shuler & Jack Ables
Arizona Court of Appeals Rules that the Economic Loss Doctrine Does Not Bar Plaintiffs’ Product Liability Tort Claim When the Defective Product Damages Other Property


In Miidas, the Arizona Court of Appeals analyzed Arizona Supreme Court case law and determined that the Economic Loss Doctrine did not bar product liability tort recovery by a greenhouse for economic losses arising from allegedly defective peat moss in the greenhouse’s action against the moss supplier and producer.

Miidas claimed that it suffered damages when it lost all its seeds and crops as a result of its use of allegedly defective peat moss that was supplied by the defendants. A few days after Miidas planted its seeds in the peat moss, the seeds had not sprouted as they should have. Some plants sprouted, but they were deformed and “started drying out.” Miidas alleged that subsequent tests of the peat moss determined that it was too acidic for vegetable seed germination and cultivation of seedlings and was “hydrophobic,” meaning that it lacked the native moisture content to enable it to absorb water. Miidas brought contract claims and product liability and negligent misrepresentation claims against the defendants. The defendants asserted that the Economic Loss Doctrine barred Miidas’ tort claims. The trial court agreed and dismissed those claims. Miidas appealed to the Arizona Court of Appeals.

In Arizona, the economic loss doctrine precludes tort recovery for economic losses absent personal injury or damage to other property and limits a contracting party to contractual remedies for the recovery of economic losses unaccompanied by physical injury to persons or other property. As noted in Miidas, “different policies are served by tort and contract law and that those policies should serve as the bases for determining when a party should be entitled to seek tort remedies and when the party should be limited to contract remedies.” Strict liability promotes product safety and spreads the costs of accidents. Contract law, in contrast, seeks to preserve freedom of contract and to promote the free flow of commerce. These goals are best served by allowing the parties to specify the consequences of a breach of their agreement.

The Miidas Court stated that, in determining whether tort law or contract law should be applied in a product liability case, it must keep these competing policies in mind and consider three factors: 1) the nature of the product defect, 2) the manner in which the loss occurred, and 3) the type(s) of loss or damage that resulted. With respect to the nature of the alleged product defect, the Miidas Court stated that, “although the peat moss clearly did not pose a ‘danger’ to persons or property as an explosion or large fire would, it was dangerous to the seeds that were placed in it because it destroyed them.” Regarding the manner in which the loss occurred, the Court indicated that the “focus…is on the fact that the damage caused by the peat moss was calamitous to the seeds… [and] the peat moss here did not simply fail to meet Miidas’s expectation that it would improve the seeds’ germination rate. Rather, it destroyed the seeds so that they failed to germinate altogether.” Finally, as for the type of damage that occurred, the Court noted that the subject peat moss damaged the seeds, which were purchased from another supplier and were property clearly separate from the allegedly defective product. Accordingly, the Miidas Court determined that all three factors support a finding that the economic loss rule should not be applied to bar the tort
claims. The Court noted that its decision was supported by decisions in several other states.

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ARKANSAS

Arkansas’s Statutory Punitive Damages Cap Found to Violate the Arkansas Constitution


In Schafer, the Arkansas Supreme Court held that a statutory punitive damages cap violated the Arkansas Constitution’s prohibition of limitations on the amounts recoverable for personal injury, wrongful death, and property damage.

Schafer arose from the defendants’ alleged sale of genetically modified rice. Before trial, the lower court had ruled, without explanation, that Arkansas’s statutory cap on punitive damages violated the Arkansas Constitution. The jury ultimately returned a verdict for the plaintiffs and awarded $21,000,000 in punitive damages against two defendants. This award greatly exceeded the statutory cap on punitive damages.

As originally enacted as part of the Arkansas Civil Justice Reform Act of 2003, punitive damages were generally capped at the greater of either $250,000 or three times the award of compensatory damages, with an upper cap of $1,000,000. Ark. Code Ann. § 16-55-208(a). The cap did not apply if the plaintiff could prove, by clear and convincing evidence, that the defendant intentionally pursued a course of conduct for the purpose of causing injury and did in fact injure the plaintiff. Ark. Code Ann. § 16-55-208(b). Further, the fixed cap amounts were tied to the Consumer Price Index and were to be adjusted every three years. Ark. Code Ann. § 16-55-208(c).

Article 5, section 32 of the Arkansas Constitution provides that, with the exception of workers’ compensation statutes, “no law shall be enacted limiting the amount to be recovered for injuries resulting in death or for injuries to persons or property.” In prior cases involving this provision, the Arkansas Supreme Court had held that it prohibited limitations on “tort liability” for “physical injuries” to persons or property. See Stapleton v. M.D. Limbaugh Constr. Co., 333 Ark. 381, 969 S.W.2d 648 (1998); Sw. Bell Tel. Co. v. Wilks, 269 Ark. 399, 601 S.W.2d 855 (1980).

The defendants argued that this provision only prohibited limitations on the amount of compensatory damages. They further relied on the fact that under Arkansas law, punitive damages are not intended to compensate for injuries and may properly constitute a windfall to the plaintiff.

The Arkansas Supreme Court rejected these arguments, noting that, under Arkansas law, punitive damages may not be awarded in the absence of compensatory damages and that in previous cases, the Court had found the issues of compensatory and punitive damages to be so interwoven that an error in one required reversal of the whole case. Thus, the Court concluded, “Although compensatory and punitive damages serve differing purposes, an award of punitive damages is nonetheless an integrant part of ‘the amount recovered for injuries resulting in death or for injuries to persons or property.’” Accordingly, the statutory cap on punitive damages violated the Arkansas Constitution’s prohibition on limitations of tort liability for personal injuries, wrongful death, and property damages.

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COLORADO

Colorado Federal District Court Precludes Defendant From Showing Video of Accident as “Substantially Similar” Because Inconsistencies with the Subject Accident Would Create Confusion of the Issues, Mislead the Jury and Be Unfairly Prejudicial


Plaintiff alleges her husband’s death in a tractor-trailer rollover accident was caused by design defects in the truck, which was manufactured by Defendant.

Factual Background:

Decedent was involved in a tractor-trailer rollover accident on Highway 50 near Monarch Pass in Gunnison County, Colorado. Decedent was riding in the sleeper compartment while another man drove the truck. The truck rolled over and came to rest at the bottom of an embankment.

Defendant sought to show at trial a video of an accident along California’s Donner Pass that Defendant contends was similar to the subject accident. Defendant argued that the Donner Pass video could demonstrate the general mechanics and physics of a tractor-trailer rollover and also argued that it was “substantially similar” to the subject accident.

Court Holding:

As for the issue of substantial similarity, the Court found that video evidence was relevant, but its relevance was substantially outweighed by the risk of prejudice, confusing the issues, or misleading the jury. The Court further found there was insufficient evidence that the two accidents were in fact substantially similar, lessening the relevance of the video of the Donner Pass accident.

However, the Court found relevance remained in showing the video for the purpose of explaining the science behind the accident. The Court held the Defendant would be allowed to show the Donner Pass accident at trial for purposes of showing the general mechanics and physics of a tractor-trailer rollover.

FLORIDA

The Constitutionality and Viability of the Florida Asbestos and Silica Compensation Fairness Act

The Florida Asbestos and Silica Compensation Fairness Act ("FASCFA" or "Act") was passed in 2005 as an attempt to stop mass filings by creating medical criteria requirements in order to maintain an asbestos/silica suit. Specifically, Plaintiffs were required to plead and prove an existing malignancy or actual physical impairment for which asbestos was a substantial contributing factor. Due to its reform nature, the Act was intended to be applied retroactively. However, the appellate districts were conflicted as to the constitutionality of retroactive application. *DaimlerChrysler Corp. v. Hurst, 949 So.2d 279 (Fla. 3d DCA 2007)" ("retroactive application of the Act is constitutionally permissible"); *Williams v. American Optical Corp., 985 So.2d 23 (Fla. 4th DCA 2008)" ("the Act in its entirety can not constitutionally be applied retroactively").

Given the conflict in the appellate districts, the *Williams* decision was consolidated with *American Optical v. Spiewak*, 73 So.3d 120 (Fla. 2011) and went up on appeal to the Florida Supreme Court. In
affirming the *Williams* decision, the Court struck down FASCFA as unconstitutional as applied to Plaintiffs who had filed actions prior to the adoption of the Act for damages "based on various degrees of asbestosis." *Williams*, 985 So.2d at 25. The *Spiewak* opinion addressed two primary issues: (1) whether the right to sue in the absence of physical impairment was a vested property right at the time of the passage of the Act; and (2) whether as a vested property right a plaintiff's ability to sue could be taken away retroactively.

In reaching its conclusion, the Court focused extensively on the Act's requirement of a "physical impairment" as set forth in various sections, including section 774.204(1), Fla. Stat., which provides that "[physical impairment of the exposed person, to which asbestos… exposure was a substantial contributing cause" is an essential element of an asbestos claim. Acknowledging that a cause of action is a property right protected by the Constitution, the Court concluded that appellees had enjoyed a right to pursue an asbestos-related cause of action under existing Florida common law prior to FASCFA irrespective of physical impairment. This right arose "when the accumulated effects of the substance manifest in a way which supplies some evidence of the causal relationship to the manufactured product." *Spiewak*, 73 So.3d at 126. The Court determined that common law "did not require any particular symptoms to constitute 'manifestation' in connection with asbestos injuries" and that the development of 'particular impairment symptoms' was never required to open the courthouse doors." *Id.* at 127. Thus, the inhalation of asbestos fibers which would become imbedded in the lungs constituted an actual injury regardless of the level of impairment and regardless of whether symptoms were manifest. *Id.* at 126. Accordingly, the majority held that under Florida common law an asbestos claimant has a cognizable claim even in the absence of any physical impairment or symptoms but merely with evidence of exposure and that FASCFA was intended to reverse years of common law precedent" and thus acted to deprive appellees or those similarly situated of a vested right constituting a property interest. *Id.* 130.

Although the Act expressly states that it is to apply retroactively, the Court held that retroactive application would violate the Florida Constitution by destroying the vested rights of those claimants diagnosed with asbestos-related disease who could not satisfy the impairment criteria of the Act. Notably, it is not entirely clear from the opinion whether the Florida Supreme Court struck down the Act only as to claimants whose claims accrued prior to its effective date or also as to claimants whose claims accrued after its effective date. For example, the opinion when closely read is limited to the class of claimants represented by those who had vested property rights prior to the passage of FASCA and then had those rights taken away by the enactment of the Act. In fact, the Court expressly states that "...the Act cannot be constitutionally applied as to them [the Appellees]." *Id.* at 133.

Nevertheless, the extent of the *Spiewak* opinion will prove to form a bone of contention among litigants. This is particularly due to a footnote found in dicta that "although not argued by the parties, we agree with the analysis of the Fourth District…that the unconstitutional portions of the Act cannot be severed from the remainder, and that the Act as a whole must fail as applied to the Appellees." *Id.* The plaintiffs' bar will attempt to apply this footnote expansively and contend that it rejects the severability clause of the Act and holds that it is unconstitutional in its entirety. However, a narrow reading potentially belies this point in that the Court repeats the limitation language in the subject footnote by stating "as applied to the Appellees."

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ILLINOIS

Illinois Supreme Court Examines the “Risk-Utility” Test and Post-Sale Duty to Warn in Design Defect Cases

Jablonski v. Ford Motor Co., 2011 Ill. LEXIS 1136 (Ill. 2011)

In an Illinois case of major significance, Jablonski v. Ford Motor Co., 2011 Ill. LEXIS 1136, the Illinois Supreme Court examined the “risk-utility” test and the question of a manufacturer’s post-sale duty to warn. Jablonski involved the collision of a 1993 Lincoln Town Car in which plaintiffs were riding. When their car came to a stop in a highway construction zone, it was struck from behind by another car traveling at a high rate of speed. A large pipe wrench in the trunk of the Jablonskis’ Town Car penetrated the trunk, puncturing the back of the car’s fuel tank and causing the Town Car to burst into flames, resulting in severe burns and permanent disfigurement to Mrs. Jablonski and the death of her husband.

Plaintiffs sued Ford Motor Company under theories of strict tort liability and negligence, alleging design defects associated with the location of the Town Car’s fuel tank. At the close of the evidence, plaintiffs dismissed their strict liability claim against Ford and the case was submitted to the jury on theories of negligent design and willful and wanton misconduct. Over Ford’s objection, plaintiffs were also allowed to instruct the jury on another claim of negligence not previously pled, i.e. the breach of an alleged post-sale duty to warn related to a post-sale design modification that cured the alleged defect, implemented after the sale of the subject vehicle but before the accident. Ford’s alleged failure to advise its customers of the existence and availability of the design fix was the crux of the plaintiffs’ post-sale duty to warn case.

In reversing a multi-million dollar verdict for plaintiffs, the Illinois Supreme Court found that the key question of whether the manufacturer exercised reasonable care in the design of the product “encompasses a balancing of the risks inherent in the product design with the utility or benefit derived from the product, . . . .” so that “[w]hen the risk of harm outweighs the utility of a particular design, there is a determination that the manufacturer exposed the consumer to a greater risk of danger than is acceptable to society.” 2001 Ill. LEXIS 1136 at pp.36-37.

The Court noted that the same factors that are relevant to a risk-utility analysis in a product liability case founded upon strict tort liability are also pertinent to a design defect case based on negligence, including the existence of alternative and feasible designs at the time of the subject product’s manufacture; conformance or non-conformance of the design to applicable industry standards or governmental regulations; the overall utility of the product both to its user and the public examined in the light of the likelihood of injury and the probable seriousness thereof; and the ability of the manufacturer to design out the unsafe characteristics of the product without impairing its usefulness or making it cost-prohibitive to the consumer. Such factors must first be balanced by the court in order to determine if the case is submissible to a jury for consideration of these and other relevant factors in the risk-utility analysis.

Applying the risk-utility analysis to the facts of the case, the Supreme Court said that it was incumbent upon the plaintiffs to introduce evidence that the defendant’s conduct in designing the placement of the fuel tank was unreasonable, by demonstrating that the foreseeable risks of the adopted design outweighed its associated benefits and utility. Such proof cannot be satisfied by an alternative design which the evidence showed would introduce other risks of an equal or greater magnitude than the challenged design. Based on the evidence
presented, the Court found that plaintiffs had not sustained their burden in that regard.

Turning to the post-sale duty to warn issue, the Court characterized Illinois precedent regarding a manufacturer’s duty to warn as follows: “[W]hen a design defect is present at the time of sale, the manufacturer has a duty to take reasonable steps to warn at least the purchaser of the risk as soon as the manufacturer learns or should have learned of the risk created by its fault” (see 2011 Ill. LEXIS 1136 at p.52, emphasis added), but went on to cite other Illinois cases in which the existence of a post-sale duty to warn was flatly rejected. (See, e.g., Carrizales v. Rheem Mfg. Co., 226 Ill.App.3d 20, 34, 589 N.E.2d 569, 579 (1981); Modelski v. Navistar Int’l Trans. Corp., 302 Ill.App.3d 879, 890, 707 N.E.2d 239, 247 (1999); Collins v. Hyster Co., 174 Ill.App.3d 972, 977, 529 N.E.2d 303, 306 (1988)).

Plaintiffs urged adoption of a post-sale duty to warn, such as that in Section 10 of the Restatement (Third) of Torts: Product Liability (1982), citing certain factors in automotive litigation that circumstantially support a post-sale duty to warn, such as the ability of the car manufacturer to pass along a warning or the like to consumers by tracking vehicle owners Vehicle Identification Number information. However, since no such evidence regarding the means or methods of contacting consumers had been presented at trial, the Court declined, at least for now, the creation of a post-sale duty to warn in Illinois.

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KANSAS

Kansas Supreme Court’s Silence on Economic Loss Doctrine as it Relates to Product Liability Creates Inference of Endorsement


Before the very recent case of David v. Hett, the Kansas Supreme Court had never previously considered the economic loss doctrine in any context. Consequently, whatever we can glean from the Court in David is beneficial, because it is the only mention the Kansas Supreme Court has ever given the economic loss doctrine.

In David, the plaintiffs brought suit against the defendant for various claims after they experienced problems with their home on which defendant had performed construction work. Id. at *2. The trial court held, and the Court of Appeals affirmed, that the economic loss doctrine prevents plaintiffs from bringing a claim in tort when it is based in contract. Id. at *3. Thus, under this ruling, in the context of residential construction defect cases, courts should continue to apply the economic loss doctrine as it had previously been applied. Prendiville v. Contemporary Homes, Inc., 32 Kan. App. 2d 435 (Kan. Ct. App. 2004). In other words, the economic loss doctrine acted to bar claims brought in tort when such claims were based in contract, even in the context of residential construction defect cases.

The Kansas Supreme Court granted review solely to analyze the applicability, or lack thereof, of the economic loss doctrine in a construction defect context. David, 2011 WL at *3. The Court undertook a lengthy analysis and summation of the economic loss doctrine in the product liability context. Then, the Court overruled Prendiville and specifically stated that the economic loss doctrine does not apply in a residential construction defect case. Id. at *16.

In this, its inaugural treatment of the economic loss doctrine, the Court did not express any disfavor with the economic loss doctrine in the product liability context. Instead the Court simply stated
that “we reject the Prendiville court’s determination that the same reasons justifying the economic loss doctrine’s limitation in product liability lawsuits apply with equal force against a service contractor in the residential construction context.” *Id.* Ultimately, one can infer from the court’s language, an endorsement of the economic loss doctrine as it applies to product liability in its first, albeit tangential, treatment of the rural.

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KENTUCKY

Kentucky Law Adopts the Economic Loss Rule and Extends it Beyond Negligence and Strict Liability Claims, to Include Negligent Misrepresentation Claims as Well

*Giddings & Lewis, Inc. v. Industrial Risk Insurers*, 348 S.W.3d 729 (Ky. 2011)

In *Giddings*, Ingersoll Rand (“Ingersoll”) purchased from Giddings & Lewis (“Giddings”), a large lathe, known as a Diffuser Cell system, which consisted of a vertical turning lathe, two vertical machining centers, and a material handling system. This system was used to cut and shape metal parts. The purchase contract contained an express warranty, which provided that the goods sold were “the best quality of their respective kinds, and … free of defects in design, workmanship, or material.” *Id.* at 734.

After seven years of almost continuous use, by which time the warranty had expired, one of the pieces of the vertical turning lathe flew off in a sudden event. This caused great damage to the machine. Other than the damage to the machine, nothing else in Ingersoll’s workspace was damaged. Ingersoll’s insurers engaged Giddings to repair and rebuild the system, at a cost of $2,798,742.00.

Ingersoll’s insurers then sued Giddings to recover the amount paid, arguing breach of implied warranty, breach of contract, negligence, strict liability, negligent misrepresentation, and fraud by omission. Giddings moved for summary judgment. Eventually, the trial court granted Giddings’ motion for summary judgment, ruling that the implied warranty claim was barred by the statute of limitations, and that the economic loss rule, which was implicitly adopted by the Kentucky Court of Appeals in *Falcon Coal Co. v. Clark Equip. Co.*, 802 S.W.2d 947 (Ky. App. 1990), barred the tort claims, including the claims for fraud and negligent misrepresentation. The trial court considered, but rejected, the “calamitous event” exception to the economic loss rule. The trial court also held that the product consisted of the vertical turning lathe, the material handling system, and the two vertical machining systems, which prevented Ingersoll’s insurers from recovering for damage to any part of the Diffuser Cell system.

The Court of Appeals reversed the trial court’s ruling, in part, holding that the economic loss rule did not bar Ingersoll’s insurer’s negligent misrepresentation and fraud claims, because “they arose in tort, independent of any contractual duty.” *Id.* at 735. The Court of Appeals also held that whether the Diffuser Cell System constituted one product or several individual products was a question of fact for the jury.

The Kentucky Supreme Court granted discretionary review. In reversing the Kentucky Court of Appeals, Justice Abramson laid out the Court’s entire ruling in a concise statement, whereby it formally adopted the economic loss rule, rejected the “calamitous event” exception to the economic loss rule, described what constitutes a product for purposes of the economic loss rule, and extended the rule beyond negligence and strict liability, to include negligent misrepresentation claims:

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Today, we hold that the economic loss rule applies to claims arising from a defective product sold in a commercial transaction, and that the relevant product is the entire product bargained for by the parties, and placed in the stream of commerce by the manufacturer. Further, the economic loss rule applies regardless of whether the product fails over time or destroys itself in a calamitous event, and the rule’s application is not limited to negligence and strict liability claims, but also encompasses negligent misrepresentation claims.

*Id.* At 733.

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**LOUISIANA**

The Louisiana Supreme Court Clarifies Definition of “Reasonably Anticipated Use” in a Product Liability Case

*Payne v. Gardner*, 2010-2627 (La. 02/18/11); 56 So. 3d 229

Under the Louisiana Products Liability Act (“LPLA”),

“reasonably anticipated use” is to be ascertained from the point of view of the manufacturer at the time of manufacture. The intent of the LPLA definition is to discourage fact-finders from using hindsight in making this analysis. La. Rev. Stat. 9:2800.54(A) provides:

The manufacturer of a product shall be liable to a claimant for damages proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use of the product by the claimant or another person or entity.

La. Rev. Stat. 9:2800.53(7) provides the statutory definition of “reasonably anticipated use”, as follows:

“Reasonably anticipate use” means a use or handling of a product that the product’s manufacturer should reasonably expect of an ordinary person in the same or similar circumstances.

In *Payne*, the Louisiana Supreme Court clarified the meaning of the “reasonably anticipate use” definition. The case involved a thirteen year old boy, Henry Goudeau, who climbed onto the moving pendulum of an oil well pump attempting to ride the pendulum. His pants became entangled in the pump, resulting in severe injuries. Henry’s mother filed suit against Lufkin Industries, Inc. (“Lufkin”), the company that had designed and manufactured the oil well pump in the 1950s. Lufkin filed a motion for summary judgment arguing that at the time it had designed and manufactured the pump it did not “anticipate” that it would be used for recreational purposes. Henry’s mother argued that there existed a foreseeable risk that children would attempt to play on the pump.

The trial court granted Lufkin’s motion, finding that Henry’s mother “failed to allege any facts that the pump was unreasonably dangerous in itself and for the purpose for which it was intended”. The court determined that because Henry was 13 years of age, he should have known not to attempt to ride the pump (a reasonable person standard). The court also observed that the well was not unreasonably dangerous because it’s anticipated use was for pumping oil, not riding.

On appeal, the Court of Appeal, Third Circuit, reversed the trial courts ruling finding that it could not “conclude that the scintilla of direct evidence presented by Ms. Payne was insufficient to allow a reasonable juror to conclude Lufkin…should have expected an ordinary person in the same or similar circumstances to use or handle the pumping unit in this way”.

The Louisiana Supreme Court reversed the appellate decision.

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and reinstated the judgment of the trial court granting Lufkin’s motion for summary judgment. In doing so, the Louisiana Supreme Court analyzed what “reasonably anticipated use” meant under the LPLA.

The Court noted that the definition contained in the LPLA (which came into effect in 1988) was narrower than the pre-LPLA counterpart of “normal use” which included “all reasonably foreseeable uses and misuses”. Next, the Court noted that what constitutes a reasonably anticipated use is to be ascertained from the point of view of the manufacturer at the time of manufacture and that the more narrow language of the LPLA was intended to discourage fact-finders from using hindsight.

With the correct analysis defined, the Court held that in order to avoid summary judgment, plaintiff would have to make a showing that, back in the 1950s, when Lufkin designed and manufactured the pump, it should have reasonably expected that an ordinary consumer or user of its product would use it as a ride. Lufkin presented the deposition testimony of its owner that the pump was manufactured solely for the pumping of oil. Plaintiff’s support came from other case decisions outside of Louisiana indicating that riding could be considered a reasonably anticipated use. However, because those decisions where well after the 1950s when Lufkin designed and manufactured this pump, the court concluded that the plaintiff had failed to produce sufficient factual support show that she would be able to carry her burden of proof at trial. Specifically, the Court determined on the record that reasonable persons would conclude that riding the pump was not a reasonably anticipated use.

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MARYLAND

Claims Against Generic Drug Manufacturers Fail in Light of Supreme Court’s Decision in Pliva, Inc. v. Mensing (two decisions)


In a recently issued opinion from the U.S. District Court for the District of Maryland, the claims of the Plaintiff were dismissed pursuant to Defendant Pliva USA, Inc.’s (“Pliva”) Motion for Judgment. The Court held that Plaintiff’s claims against Pliva were preempted by federal law in light of the Supreme Court’s June 2011 decision in Pliva, Inc. v. Mensing, 564 U.S. ----, 131 S. Ct. 2567 (2011).

Plaintiff filed suit against pharmaceutical manufacturers Pliva, Pfizer, Wyeth, and Schwartz, alleging she sustained injuries from taking the prescription drug metoclopramide, which is used to treat patients with slow emptying of the stomach or intestinal tract often caused by cancer treatment or surgery. The Complaint sought damages on theories of negligence, breach of warranty, strict liability, and misrepresentation. The claims against Pfizer, Wyeth, and Schwartz were previously dismissed, as those companies manufactured “Reglan,” the brand-name form, as opposed to the generic version of the drug, “metoclopramide,” which Plaintiff took and Pliva manufactured.

In April 2011, the Court stayed the proceedings in Gross in light of the pending Supreme Court decision in Mensing, a case with substantially similar facts. The Supreme Court was considering a state tort law claim based on the alleged failure of a manufacturer to provide adequate warning labels for generic metoclopramide. Mensing, 131 S.Ct. at 2572. The Supreme Court held in Mensing that state law concerning labeling was preempted by federal regulatory law. The District Court in Gross described the Supreme Court’s holding in Mensing:
Under the Food and Drug Administration (“FDA”) regulations, generic drug manufacturers are required to make their warning labels identical to those provided by the brand-name manufacturers. Id. at 2577. Because FDA regulations do not allow generic manufacturers to independently change or strengthen their product labeling, the Court found that it would be impossible for a generic manufacturer to comply with both federal law and state tort law. Id. at 2578. As a result, the Court held that the federal regulations preempt state law failure to warn claims, reversing decisions by the Fifth and Eighth Circuit Courts of Appeals which found otherwise. Id.

2011 WL 5865367, at *1.

In light of the Supreme Court’s opinion in Mensing, Pliva sought dismissal of Plaintiff’s claims on the pleadings pursuant to Rule 12 of the Federal Rules of Civil Procedure. Pliva argued that all of Plaintiff’s state tort law claims were preempted by federal drug regulation and as such the case should be dismissed.

Plaintiff argued that Mensing only preempted failure to warn claims and that she was entitled to pursue claims that Pliva was negligent for continuing to sell metoclopramide with an inadequate label, continuing to put a dangerous product into the stream of commerce, and negligent in concealing safety information. The Court rejected Plaintiff’s contention that her case was not entirely preempted, noting that the Supreme Court itself had rejected similar arguments.

Specifically, the Court noted that under Maryland law product liability claims must be based on a design defect, a manufacturing defect, or a failure to warn. There was no claim of manufacturing defect, and “[d]esign defect claims are generally incompatible with actions concerning prescription medications because these medications are thought to be ‘unavoidably unsafe.’” 2011 WL 5865267, at *3 (quoting from King v. Pfizer Pharm. Co., Inc., 2011 WL 3157305, at *2 (D. Md. Jul. 25, 2011)). Therefore, the Court held that Plaintiff’s allegations regarding the continued sale of the generic drug must come under the failure to warn umbrella. As such, the claims were preempted by federal drug regulation.

The Court then briefly addressed the unfortunate nature of Plaintiff’s position of no redress and stated: “[F]ederal drug regulations have foreclosed Plaintiff’s means of seeking a judicial remedy in the instant action, and legislative action remains the most appropriate means of redress at this juncture.” 2011 WL 5865267, at *5.

Grinage v. Mylan Pharmaceuticals, Inc.

Plaintiff sued Mylan Pharmaceuticals, Inc. and its parent company Mylan, Inc. (collectively, “Mylan”) after her husband developed a fatal skin disease from taking Allopurinol, a Mylan manufactured-product. Allopurinol is a generic form of Zyloprim, a brand-name drug approved by the FDA. Federal labeling laws require generic drugs to contain the same warnings as brand-name drugs. Therefore, the warning label for Allopurinol was substantially identical to the warning label of Zyloprim. Both labels warned that skin reactions, sometimes fatal, could occur. The labels cited one study that found that 3% of patients had skin reactions, but they further noted that “with current usage, skin reactions have been observed less frequently than 1%.” Plaintiff alleged that Mylan knew or should have known that the risk of the skin diseases were greater than the 1% referenced on the label based on more recent studies. Therefore, Plaintiff contended, Mylan was negligent in failing to report published articles and scientific evidence regarding same. The Complaint sounded in negligence, strict liability, fraud, and breach of implied warranty.

Mylan filed a Rule 12(b)(6) Motion to Dismiss for failure to
state a claim, based on *Pliva, Inc. v. Mensing*, 564 U.S. ----, 131 S. Ct. 2567 (2011). Addressing Mensing, the Court noted that the Supreme Court was relying on statutory law:

The statutory language and regulations related to the Drug Price Competition and Patent Term Restoration Act (“Hatch-Waxman”) and the FDA’s interpretation of these rules “require that the warning labels of a brand-name drug and its generic copy must always be the same – thus, generic drug manufacturers have an ongoing federal duty of sameness.” *Id.* at 2574-75 (citing 57 Fed.Reg. 17961 (1992)); see also 21 U.S.C. §§ 355(j)(2)(A)(v), 355(j)(4)(G); 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7). So even if a generic manufacturer had new information about side effects, it could not change its label unless the brand-name manufacturer did so first, or unless the FDA instructed all manufacturers to do so. As a result, pursuant to impossibility pre-emption doctrine, federal law pre-empts any state law tort action that creates liability for generic manufacturers who fail to take independent action to change their labels. *Mensing*, 131 S.Ct. at 2577-81.

2011 WL 6951962, at *2.

The Court held that Plaintiff’s negligent warning, defective design, and breach of warranty claims failed under both *Mensing* (as to preemption), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (as to the failure to allege more than speculative claims). Moreover, Plaintiff’s fraud claim failed, because Plaintiff failed to plead with particularity, as required under the heightened pleading standards required for such an allegation. Therefore, the Court granted the Motion to Dismiss and ordered that the case be closed.

**MASSACHUSETTS**

**Feasible Alternative Designs**

*Osorio v. One World Technologies, Inc.*, 659 F.3d 81 (1st Cir. 2011)

Defendants have to be prepared to defend against evidence of a feasible alternative design, as such evidence may be sufficient to support significant jury awards. In *Osorio v. One World Technologies, Inc.*, 659 F.3d 81 (1st Cir. 2011), the First Circuit affirmed a $1.5 million dollar jury verdict against the manufacturing defendant finding the verdict was sufficiently supported by evidence of a feasible alternative design.

Although the use of an alternative design has long been used by Massachusetts plaintiffs, the *Osorio* decision arguably lessens the burden plaintiffs now have in proving all “factors” of such an alternative design.

In the case, plaintiff was injured when his hand got caught in a benchtop table saw’s blade. During the trial against the manufacturer, the plaintiff presented the inventor of a flesh sensing device called the “StopSaw,” which, when triggered, stops a saw’s blade. The plaintiff thus argued that there had been a feasible alternative design, despite the fact that at the time, no similar saw was using such a device. After hearing the evidence, the jury found for the plaintiff.

In Massachusetts, like many jurisdictions, manufacturers must design products that are “fit for the ordinary purposes for which such good are used.” Thus, a product must have safeguards to prevent against reasonably foreseeable risks. In evaluating whether a design presents an unreasonable risk, a jury can consider the following factors: (1) the dangers posed by the current design, (2) the likelihood of injury, (3) the feasibility of a safer alternative design, (4) the cost of an
improved design; and (5) the consequences to either the product or consumer from using an alternative design. *Back v. Wickes Corp.*, 375 Mass. 633 (1978).

In *Osorio*, the First Circuit determined that the evidence was sufficient for a jury to find a feasible alternative design and this was not a case of “categorical liability.” Despite the manufacturer’s argument that plaintiff had failed to show an alternative design that considered weight, cost and features particular to the specific saw, the First Circuit stated “It is the province of the jury to determine whether the relevant factors, properly balanced, suggest that a product’s design is unreasonable.” The Court thus determined that a plaintiff does not need to meet all of the *Back* factors to succeed, but rather, a jury can balance these factors in any way it chooses.

The First Circuit further ruled that this was not a case of categorical liability. Categorical liability claims are those in which plaintiffs attempt to hold manufacturers accountable for an entire category of products. Such claims have been made with regard to products such as guns or particular automobiles. More specifically, in categorical liability claims, plaintiffs’ argue that although the products at issue in the lawsuits have no manufacturing defect, have proper warnings and have no feasible alternative design, the manufacturers should be held liable as the products are simply inherently dangerous. Here, due to the significant amount of time spent during the trial arguing whether there was a reasonably alternative design, the First Circuit refused to find this to be case of categorical liability.

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**MICHIGAN**

**Michigan’s Product Liability Immunity Statute, MCL 600.2946(5), Bars a Medicaid Fraud Claim**

**A. Overview.**

MCL 600.2946(5) states, in pertinent part:

“In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States Food and Drug Administration, and the drug and its labeling were in compliance with the United States Food and Drug Administration’s approval at the time the drug left the control of the manufacturer or seller.”

The Michigan Supreme Court in *Taylor v Smithkline Beecham Corp.*, 468 Mich 1, 658 NW2d 127 (2003), upheld §600.2946(5) as a proper legislative determination, noting that where “the Legislature has determined that a drug manufacturer or seller that has properly obtained FDA approval of a drug product has acted sufficiently prudently so that no tort liability may lie.” *Id* at 7, 658 NW2d at 131.

**B. The Scope of Immunity Under the Statute.**

In *Attorney General v Merck, Sharp & Dohme Corp.*, 292 Mich App 1; _____ NW2d _____; 2011 WL 921669 (2011), the Michigan Court of Appeals held that MCL 600.2946(5) barred the State of Michigan from suing to recover Medicaid funds paid because of a drug manufacturer’s alleged fraudulent representations about its product. The Michigan Attorney General asserted that the manufacturer of the nonsteroidal anti-inflammatory drug (NSAID) Vioxx misrepresented the safety and efficacy of the drug and claimed that Michigan would not have incurred some or all of the cost of Vioxx prescribed to Medicaid recipients but for the manufacturer’s alleged fraudulent representations.
activity. In 2008, the State filed an action against the manufacturer to recover damages under Michigan’s Medicaid False Claims Act, MCL 400.601 et seq.

The manufacturer filed a motion for summary disposition arguing that the action was a “product liability action” within the meaning of the Michigan statute, MCL 600.2945(h), and, as such, was barred under MCL 600.2946(5) which provides immunity from product liability claims against manufacturers of drugs which are approved for safety and efficacy by the Federal Drug Administration and labeled in compliance with FDA standards. The Michigan Trial Court denied the motion for summary disposition. The Michigan Court of Appeals reversed, in a 2-1 decision, holding that the action was a “product liability action” under the immunity statute because the State had asserted legal and equitable theories of liability or damage to property, monetary loss, resulting from the production of a product. The Court of Appeals then held that MCL 600.2946(5) is not limited in its application to claims brought by consumers and was broad enough in scope to bar the claim under the Medicaid False Claims Act. The dissenting appellate judge asserted that “damage to property” under MCL 600.2946(5) “is properly interpreted as physical damage to property resulting from a defective or unreasonably dangerous product.” Plaintiff’s application for leave to appeal to the Michigan Supreme Court was denied on September 30, 2011. Attorney General v Merck, Sharp & Dohme Corp, 490 Mich 878; 803 NW2d 696 (2011).

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MINNESOTA

Eight Circuit Held that Under Minnesota Law, “Gross Negligence” and “Willful and Wanton Negligence” Are Separate Tort Theories of Recovery With Different Legal Standards.

Recently, in Block v. Toyota Motor Corp., --- F.3d ----, 2011 U.S. App. LEXIS 25081 (8th Cir. 2011), the Eighth Circuit Court of Appeals engaged in a robust construction of Minnesota’s “seller’s exception” statute, Minn. Stat. § 544.41, which can operate to provide a complete defense for product distributors and sellers against claims sounding in strict liability. Block arose on appeal from two personal injury and wrongful death product liability actions involving unintended acceleration of a 1996 Toyota Camry. Plaintiffs sued in state court both Toyota and the Minnesota dealership that sold the Camry. Toyota subsequently removed both cases to federal court, claiming that complete diversity of citizenship existed between the plaintiffs and Toyota, and that the dealership’s citizenship could be disregarded due to fraudulent joinder. Specifically, Toyota argued that the dealership could not be held liable because Section 544.41 provided the dealership with a complete defense to the strict liability claim since Toyota, the manufacturer, was subject to suit in Minnesota court. Both plaintiffs moved for remand based on Section 544.41, subdivision 3(b)’s exception to dismissal for sellers and distributors with “actual knowledge of the defect in the product”. Both the district court and the Eighth Circuit on appeal rejected this argument, concluding that the “actual knowledge” exception means what it says, and that a plaintiff seeking to invoke this exception must submit evidence showing that the seller/distributor indeed possessed “actual knowledge of the defect in the product”; and that the plaintiffs had not met this standard. A lesser showing, such as one indicating that the seller “should have known” of the product defect was insufficient.

Eighth Circuit Court of Appeals Engaged in Robust Construction of Minnesota’s “Seller’s Exception” Statute

Gage v. HSM Electronic Protection Servs., Inc., 655 F.3d 821 (8th Cir. 2011)

In Gage v. HSM Electronic Protection Servs., Inc., 655 F.3d 821 (8th Cir. 2011), the Eighth Circuit
held that under Minnesota law, “gross negligence” and “willful and wanton negligence” are separate tort theories of recovery with different legal standards that a plaintiff must satisfy. In that case, the plaintiff purchased a security alarm for her home from the defendant, and later sued the defendant for property damage arising from a wintertime burst pipe under the theory that the defendant failed to notify the plaintiff that a low-temperature alarm had sounded in the home several weeks before the pipe burst. The defendant argued, and the district court agreed in granting defendant summary judgment, that plaintiff’s claims were barred by an exculpatory clause in the parties’ purchase contract. The plaintiff argued that the exculpatory clause was unenforceable because the defendant’s conduct rose to the level of “willful and wanton negligence” – conduct that under Minnesota law, cannot be excused by an exculpatory clause. The district court disagreed, concluding that under Minnesota law, “willful and wanton negligence” was indistinguishable from “gross negligence”, and that, as a matter of law, defendant was not grossly negligent. On appeal, the Eighth Circuit reversed. It concluded that “gross negligence” and “willful and wanton negligence” were separate concepts: gross negligence is “very great negligence or absence of even slight care” whereas willful and wanton negligence “does not require a showing of malice, actual intent to injure the person, or even negligence of a grosser degree than lack of ordinary care” but instead arises where a plaintiff “suffers damage while in a position of peril[,] if the person causing the harm actually knew that the person harmed was in such a position and had sufficient time and ability to avert the harm but failed to use due care to do so.” The Eighth Circuit further concluded that on the record presented, genuine disputes of material fact existed as to whether defendant’s conduct amounted to willful and wanton negligence.

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MISSISSIPPI

The Mississippi Supreme Court Revives Common Law Actions of Product Liability Against “Non-Manufacturers” and “Non-Sellers”

**Lawson v. Honeywell International, Inc.,** 2011 Miss. LEXIS 506 (Miss. 2011)

In Mississippi, our products liability statute, commonly referred to as the MPLA, is relatively young. See Miss. CODE ANN. § 11-1-63 (2004). Like most statutes, the legislature often creates ambiguity, either through the words used or not used. The MPLA was once thought to replace any and all common law claims for negligence of defective products. However, in a recent 2011 opinion, the Mississippi Supreme Court dispenses with that conclusion. See **Lawson v. Honeywell International, Inc.,** 2011 Miss. LEXIS 506 (Miss. 2011). The primary issue in **Lawson** was whether a mere designer of a product fell under the term “manufacturer”. The **Lawson** court declined to include a mere designer, and thus dismissed the MPLA design defect claim against Honeywell. Id. at *11.

The MPLA addresses what plaintiffs must prove to hold “manufacturers” and “sellers” liable for damage caused by a product. Unfortunately, our legislature failed to define the words “manufacturer” and “seller”, and makes no reference to anyone outside those two generic categories. Prior to the MPLA, the Mississippi Supreme Court defined “manufacturer” in a 1995 opinion, **Scordino v. Hopeman Bros., Inc.,** 662 So. 2d 640, 645 (Miss. 1995). In **Lawson**, the court effectively confirms this definition,

> “the Restatement of Torts (Second) impliedly defined a manufacturer as a ‘person or company who regularly and in the course of their principal business, create(s), assemble(s) and/or prepare(s) goods for sales to the consuming public.’”

**Lawson**, at *10.

Based on the court’s textual analysis, the court concluded the MPLA does not allow claims against mere designers. The court did not stop there, however. Under the court’s rules for statutory interpretation, “a new statute will not be considered as reversing long-established

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principles of law and equity unless the legislative intention to do so clearly appears.” *Thorp Commercial Corp. v. Miss. Road Supply Co.*, 348 So. 2d 1016, 1018 (Miss. 1977). Based on a reading of the entire statute, the court concluded the statute makes no reference to “non-manufacturers” and “non-sellers”. Thus, while the MPLA abrogated common law claims against manufacturers and sellers, common law claims for “non-manufacturers” and “non-sellers” are still allowed.

The practical points of business often cause confusion when interpreting applicable statutes and case law. From the origin of the idea to the retail sale of a good, one product could easily have an idea man, designers, component manufacturers, importers, an assembler, and multiple retailers. Each job function could be done by one or any combination of different entities. The permutations of organization are limitless, and consequently can lead to great confusion when applying a statute. When faced with a products claim, be sure to analyze your business’ function in the development of a product early in litigation. Depending upon your conclusion, the elements of proof, damages, and applicable defenses could vary drastically under the MPLA and common law product claims.

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The Explorer when she was hit from behind by another vehicle. At impact, her seat collapsed backward and Ms. Moore’s head and shoulders hit the back seat, fracturing her T9 vertebra. Ms. Moore was rendered a paraplegic.

The Explorer had no warning or information telling its customers, like the plaintiff, that the seat was susceptible to breaking and collapsing in a mild to moderate impact when holding an occupant of Ms. Moore’s size and weight. There were no warnings that the seats were designed to collapse backward in a rear-impact collision. Ms. Moore and her husband testified that she paid attention to weight warnings when she purchased products and routinely read warnings, instructions and manuals if they involved something in which she was interested. Mr. and Mrs. Moore testified, without objection, that they would not have purchased the Explorer had they known the seats were not designed for people of her size.¹

Warnings Submissions In Missouri

A. How much to write and where to write it

Ford argued that the type of danger presented by its seats is not amenable to a simple warning because the seat is safe for use by people of Ms. Moore’s weight in normal driving conditions and in most accidents.

Moore v. Ford Motor Company, 332 S.W.3d 749 (Mo banc. 2011)

Introduction

The Missouri Supreme Court held that a plaintiff makes a submissible failure to warn case in a product liability action even if the jury finds the product was not unreasonably dangerous pursuant to a strict product liability theory.

In *Moore v. Ford Motor Company*, 332 S.W.3d 749 (Mo banc. 2011), the Missouri Supreme Court reversed the Circuit Court’s directed verdict for the defendant on the warning claim. Ironically, the case was submitted on a strict product theory and the jury returned a verdict for the defendant. However, on appeal, the Missouri Supreme Court held that even though a jury found the product was not defective, the manufacturer could still be liable for the failure to warn of an unreasonably dangerous seat.

Jeanne Moore was driving a 2002 Ford Explorer. Ms. Moore was six feet tall and weighed approximately 300 pounds. She was stopped to make a left turn in

**MISSOURI**

**The Ultimate Boot Strap: Missouri’s Heeding Presumption Requires Warning When Product is Found Safe**
Writing a warning for each accident scenario and anticipating the height and weight of all users would require Ford to write a warning that would be impossible to write. The Court side stepped this issue by commenting: “While the warning alleged to be needed here may take some thought to construct, in the absence of a showing that giving a warning simply would not be technically feasible, any remaining difficulty Ford might have in formulating the precise wording to use in the warning does not negate its need to warn but rather emphasizes the need to do so carefully.” (Id at 761) In a footnote, the Court commented “the Court holds only that where, as here, the evidence shows that Ford knew its design meant that its seats were more likely to collapse backward in rear-end collisions when used by persons of more than normal weight, subjecting them to the risk of serious injuries such as those sustained by Ms. Moore, a jury could find that it had a duty to warn the consumer of the increased risk so the consumer could make an informed choice whether to use the seats despite that danger.” (Id at 761, FN6)

B. What about causation? (Does anyone really read and follow all this stuff?)

The causation element of the submission requires proof that a warning would have altered plaintiff’s behavior. In the absence of any warning, whether a warning would have altered behavior, calls for pure speculation. It is difficult to make a submissible failure to warn case in the absence of any warning because the plaintiff has the dilemma of having to say what they “would have or should have done”.

To satisfy the causation requirement, the Court employed the heeding presumption. Proof of causation in a warning case is two fold: 1) Plaintiff must show causation in fact; a showing the product for which there was no warning caused the injuries and, 2) For proximate cause, the plaintiff must show that a warning would have altered the behavior of the individuals involved in the accident. This necessarily calls for speculation. This is where the heeding presumption comes in.

The court stated the rule: “If there is sufficient evidence from which a jury could find that the plaintiff did not already know the danger, there is a presumption that a warning will be heeded.” (Id. at 762) The term “presumption” is used here to mean “makes a prima facie case,” i.e., creates a submissible case that the warning would have been heeded. Such a presumption would make a prima facie case that had Ford given the Moores an adequate warning, the Moores would have heeded it. The Court commented: “As a matter of logic, to accomplish this [the benefit of the heeding presumption] a plaintiff must show that she did not have the information the warning would have imparted already and that if she had the information, it would have affected her conduct.” (Id. at 762) The court further commented, “Where, as here, the evidence is sufficient to show that the product was unreasonably dangerous for use by the plaintiff without the additional warning and that had the warning been given at the time of purchase or before use on the day of the accident, it would have been heeded, a submissible case is made.” (Id. at 764)

The plaintiff is not required to propose the wording of an adequate warning. This means, in this case, that even though the jury was not presented with any warning, the plaintiff makes a submissible case and gets past the causation hurdle by relying on the heeding presumption.

The dissent noted that Missouri originally relied on an Indiana case to adopt the presumption. However, Missouri has only adopted part of it. Indiana’s
heeding presumption includes shifting the burden to plaintiff to offer some evidence of the content or placement of a warning that would have prevented the danger proposed by the product in question.

**Warning required in a product the Jury Found not Defective**

The holding is at least ironic (some might say ludicrous) in that the jury returned a verdict finding no product defect. The Court commented that it has never specifically held that a finding of a product defect was a necessary predicate to a failure to warn action and further commented even though a product may be designed and manufactured properly, the lack of an adequate warning, in itself, may render a product defective or unreasonably dangerous within the meaning of the law. (Id. at 757)

**Evidence of Compliance with Standards in Strict Products Submissions.**

The case also seems to add some hope, ever so slightly, to the Missouri evidentiary rules in strict liability cases. It is well established in Missouri that evidence of compliance with industry standards is not admissible in cases that are submitted on strict liability theories. Compliance with industry and government standards is admissible when cases are submitted on negligent design and/or manufacturing theories. (In fact, this is one strong reason for removal from Missouri state courts.)

Normally, plaintiffs dismiss negligent product claims to prevent the defendant from introducing evidence of compliance with industry or governmental standards. Here, the Missouri Supreme Court found no error in the trial court’s allowing defendant’s expert testimony of industry standard compliance, because it rebutted the plaintiff’s evidence of the strength of seat backs compared to other vehicles. The trial court gave, at plaintiff’s request a limiting instruction and therefore the Supreme Court found there is no prejudice to the plaintiff.

¹Counsel undoubtedly was relying on authority found in *Arnold v. Ingersoll-Rand Co.*, 834 S. W. 2d 192 (Mo banc. 1992).

**NEW JERSEY**

**U.S. Supreme Court Reverses New Jersey’s Exercise of Personal Jurisdiction Over Foreign Manufacturer**


In *J. McIntyre Machinery, Ltd. v. Nicastro*, 131 S. Ct. 2780, 180 L. Ed. 2d 765, 2011 U.S. LEXIS 4800 (2011), the U.S. Supreme Court reversed the New Jersey Supreme Court’s decision that New Jersey courts could exercise personal jurisdiction over a foreign manufacturer defendant in a product liability action under a “stream of commerce” theory if, based on its nationwide distribution system, the manufacturer has reason to know that its product may end up in New Jersey.

Petitioner J. McIntyre Machinery, Ltd. (“J. McIntyre”), a United Kingdom company, manufactured recycling machines and sold them in the United States exclusively through an independently owned and operated distributor, McIntyre Machinery America, Ltd. (“McIntyre America”), based in Ohio. McIntyre America sold the recycling machine to Nicastro’s employer during a 1995 trade show in Las Vegas and shipped the machine to New Jersey. In

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October 2001, Nicastro was injured during a workplace accident involving the machine resulting in the loss of four fingers. Jurisdictional discovery revealed that: 1) J. McIntyre targeted the United States market as a whole by engaging McIntyre America to sell J. McIntyre’s machines throughout the country; 2) J. McIntyre attended annual scrap recycling industry trade shows with McIntyre America in the U.S. to advertise its machines; and 3) no more than four of J. McIntyre’s recycling machines ended up in New Jersey. There, however, was no evidence that J. McIntyre targeted New Jersey in any specific manner, or that McIntyre America was under J. McIntyre’s control.

The U.S. Supreme Court held that the proper analysis required a demonstration that the foreign manufacturer “purposefully availed itself of the privilege of conducting activities within the forum state, thus invoking the benefits and protections of its laws.” Because the foreign manufacturer did not advertise, sell its product, conduct business, or otherwise target the State of New Jersey, it was not subject to jurisdiction in New Jersey in the underlying products liability lawsuit.

The U.S. Supreme Court’s decision presents a significant victory for foreign manufacturers who distribute their products through an independent U.S. distributor. Although the Court did not produce a majority opinion, there was consensus among a majority that a “stream of commerce” theory alone cannot subject a foreign manufacturer to jurisdiction without additional evidence of purposefully targeting the forum State. In light of the ever changing global economy, Nicastro is unlikely to be the Court’s final word on jurisdiction over foreign manufacturers in products liability lawsuits. For the time being, however, foreign manufacturers will likely be able to avoid jurisdiction in New Jersey and elsewhere by utilizing an independent nationwide distributor that targets the entire U.S. market without specifically targeting any one State in particular.

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NEW YORK

New York’s Highest Court Clarifies a Latency Exception to the Statute of Limitations for Bringing Some Product Liability Tort Claims


Tim Bechler, a 23 year old pitcher fighting for a Baltimore Orioles roster spot during spring training of February 2003, took the dietary supplement Ephedra and tragically died of heatstroke the same day. In Giordano v. Market America., Inc., 15 N.Y.3d 590 (N.Y. 2010) the plaintiff claimed the news relating Ephedra to the ballplayer’s death caused him to consider, for the first time, a possible relationship between the supplement and strokes he suffered four years before and claimed application of the latency exception of CPLR 214-c to the three year statute of limitations. Id at 594. In the underlying federal action, plaintiff claimed he was entitled to an extension of the statute of limitations to bring his tort action, pursuant to CPLR 214-c(4), arguing that he could not have attributed the cause of several strokes to his ephedra use a day or two earlier until such information linking that substance with various health risks became known. Id. While the New York Court of Appeals in Giordano refrained from ruling on the
Merits of the underlying case, it did illuminate CPLR 214-c(4), perhaps both expanding and then ultimately narrowing the class of potential plaintiffs who will be able to benefit from that section’s latency extension. See Id.

Plaintiff sued the distributor of ephedra in July 2003 and his action was removed to the United States District Court for the Southern District of New York. The manufacturer was then added as a party. Both defendants moved to dismiss the case as barred by the applicable three-year limitation period on “an action to recover damages for a personal injury.” Id. quoting N.Y. C.P.L.R. 214(5). After a decision granting defendants’ motion to dismiss, a resulting appeal, a subsequent remand to the district court on other grounds, and one final appeal, the United States Court of Appeals for the Second Circuit, pursuant to NY Constitution, article VI, § 3(b)(9) and Rules of the Court of Appeals (22 NYCRR) § 500.27, certified the following questions to the New York Court of Appeals for review:

“1. Are the provisions of N.Y. C.P.L.R. § 214-c(4) providing for an extension of the statute of limitations in certain circumstances limited to actions for injuries caused by the latent effects of exposure to a substance?
2. Can an injury that occurs within 24 to 48 hours of exposure to a substance be considered ‘latent’ for these purposes?
3. What standards should be applied to determine whether a genuine issue of material fact exists for resolution by a trier of fact as to whether ‘technical, scientific or medical knowledge and information sufficient to ascertain the cause of [the plaintiff’s] injury’ was ‘discovered, identified or determined’ for N.Y. C.P.L.R § 214-c(4) purposes?” Id. at 596-7 quoting Giordan v. Market Am., Inc., 599 F3d 87 (2d Cir 2010).

At the outset, it is important to discuss the extension to the statute of limitations under discussion. Subdivision (4) of CPLR 214-c directs, in pertinent part, that:

“…where the discovery of the cause of injury [due to latent effects of exposure to a substance or combination of substances] is alleged to have occurred less than five years after discovery of the injury or when with reasonable diligence such injury should have been discovered, whichever is earlier, an action may be commenced or a claim filed within one year of such discovery of the cause of injury…”.

Essentially, what CPLR 214-c (4) provides for is a maximum six-year period running from the date of the discovery of the injury, during which plaintiff must discover the cause of the injury (this must be done in the first five years), and then properly commence a lawsuit (during the remaining year)---or be barred from doing so, notwithstanding any latency in the revelation of the injury causation.

Subdivision (4) further provides that if any such action is commenced or claim filed after the expiration of the applicable limitations period, measured from the earlier of the date of discovery of the injury or when injury should have been discovered with reasonable diligence “the plaintiff or claimant shall be required to allege and prove that technical, scientific or medical knowledge and information sufficient to ascertain the cause of his injury had not been discovered, identified or determined prior to the expiration of the period within which the action or claim would have been authorized and that he has otherwise satisfied the requirements of subdivisions two and three of this section.” N.Y. C.P.L.R. 214-c(4) (emphasis added). It is through a close reading of the language of these interrelated subdivisions that the Court comes to its conclusion as to the first question.

Plaintiff argued that, because the word “latent” does not actually appear in subdivision (4) of CPLR 214-c, the protections of the statute were not limited solely to
injuries caused by latent effects of exposure. The Court shrugged off this claim and answered the first certified question in the affirmative finding that the entire statute and the legislative history required latency. *Giordano*, 15 NY3d 590 at 597-8.

Moving on to the second question, the Court concluded, in an answer that was undoubtedly more pleasing to the plaintiff’s bar, that “even effects concealed for a few hours may be ‘latent’ within the meaning of the statute.” *Giordano*, 15 NY3d 590 at 597-8. Although legislative history showed that the statute was “concerned with long-term latency---with plaintiffs who were unaware that they had been injured ‘until after the limitations period had expired,’” the Court responded that that was not the sole concern of the statute. *Id.* at 599 quoting *In re New York County DES Litig.*, 89 N.Y.2d 506, 514 (N.Y. 1997) (internal citations omitted). In essence, the Court refused to only extend the benefits of CPLR 214-c(4) to those plaintiffs and claimants whose injuries cannot be discovered within the normal limitations period. *Giordano*, 15 NY3d 590 at 597-8. Although this answer does potentially grow the class of plaintiffs who will be able to benefit from the 214-c(4) toll, it is the third and final question upon which decisions in cases like these will ultimately hinge. Fortunately, in its answer to that question, the Court comes down on the side of the defense. Before responding to the third Question, the Court aptly noted that there are really two possible ambiguities imbedded in the question which must be addressed. Namely: (1) “Is it the plaintiff and his lawyers or the technical, scientific or medical community that must be able to ‘ascertain the cause of his injury’,” and (2) “What level of certainty is implied by the word ‘ascertain’”? *Giordano*, 15 NY3d 590 at 600-1.

Reaffirming what it previously said in *In re New York County DES*, the Court responded, with regards to the first of those questions, that it must be the “time when information is sufficient for the technical, scientific or medical community ‘to ascertain’ the cause of an injury,” which the statute is referring to, as it is “not reasonable to extend the statute of limitations until the time when a reasonable layperson or lawyer could ‘ascertain’ the cause without consulting an expert---in many cases that time might never come.” *Giordano*, 15 NY3d 590 at 600-1. (emphasis added). The Court further iterated “we see no unfairness in requiring that injured people who want to protect their rights seek out expert advice, rather than waiting for the media to bring a possible cause of the injury to their attention.” *Id.* (emphasis added).

Finally, with regards to the second of those questions, the issue of what level of certainty is necessary “to ascertain,” the Court essentially adopted a standard of a “probable causal relationship”, filtered through the *Frye v. United States* 293 F 1013 (DC Cir 1923), rendering that “the test is one of general acceptance of that relationship in the relevant technical, scientific or medical community.” *Giordano*, 15 NY3d 590 at 600-1. (internal citations omitted). Therefore, it can be said that “a causal relationship will be sufficiently ascertained for CPLR 214-c(4) purposes at, but not before, the point at which expert testimony to the existence of the relationship would be admissible in New York courts”. *Id.* at 602.

It is important to remember that while CPLR 214-c(4) does extend the time which plaintiffs have to timely institute an action against potential product liability defendants---adding, potentially, up to another three years of exposure to liability---it only does so for those plaintiffs whose injuries fall into that class for which the cause cannot be detected at the moment of injury, and then only for those plaintiffs who are able to prove that the cause of their injury remained undetected, or was not “generally accepted” by the relevant technical, scientific or medical community during the first three years following the discovery of
the injury. Additionally, plaintiffs only have five years maximum to discover the cause of their injuries, and then one additional year to commence a lawsuit. The Court’s determination that the discovery of the cause of the injury is not subjective to the lay plaintiff closes the door on a large, likely spurious class of claims, and has ensured that it will remain relatively difficult to extend the statute of limitations using CPLR 214-c. On the other hand, it may place a defendant manufacturer, seeking to avoid the application of the extension, in the posture of asserting that the potential of its product to cause latent harm has had long-term general scientific acceptance.

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New York Appellate Court Applies Frye Test to Exclude Expert Causation Opinions Not Based on New Science


In New York, which follows the Frye test, expert testimony is admissible only if the proffered opinions are based on “scientific principles, procedures or theories” which have “gained general acceptance in the relevant scientific field.” Ratner v. McNeill-PPC, Inc., 933 N.Y.S.2d 323, 329 (2d Dept 2011); See also Frye v. United States, 293 F. 1013 (D.C. Cir. 1923). Most frequently, the test’s application is necessary when determining the admissibility of opinions based on new science and/or novel techniques. Ratner, 933 N.Y.S.2d at 330; See also Selig v. Pfizer, Inc., 713 N.Y.S.2d 898, 902 (N.Y. Sup. Ct. 2000). In the recent case of Ratner v. McNeill however, which resulted in the exclusion of plaintiff’s claim that habitual use of Tylenol had caused the cirrhosis of her liver, a separate inquiry was necessary---one which was not concerned with whether the science behind the causation theory was “generally accepted”---but rather, whether the expert opinion was “properly founded on generally accepted methodology.” Ratner, 933 N.Y.S.2d at 334. Holding that plaintiff’s expert causation opinions, supported almost entirely by observational studies and case reports (as opposed to clinical studies) lacked proper foundation, the Court in that case laid the groundwork for future analysis of the admissibility of novel medical causation theories which do not rely on new tests or techniques. Id.

Ratner involved a female plaintiff who had begun taking Tylenol, as needed, for relief from migraines in 1985. Ratner, 933 N.Y.S.2d at 325. She claimed that her regular use of the medication was always in accordance with the package instructions and that this nonetheless caused cirrhosis and ultimately, a liver transplant. Id. Alleging, among other things, defective design, failure to warn and negligence, plaintiff sued the manufacturer of Tylenol for damages resulting from the alleged causal relationship between acetaminophen (the active ingredient in Tylenol) and her cirrhosis. Id.

Plaintiff disclosed several experts. The first was a gastroenterologist/hepatologist who would testify that “the toxic effects of acetaminophen could be seen at doses that were only slightly greater than the recommended therapeutic doses… [and that]… after ruling out other possibilities and analyzing the evidence using techniques consistent with those that he use[d] in his practice… plaintiff’s cirrhosis was caused or substantially contributed to by acetaminophen.” Ratner, 933 N.Y.S.2d at 334. Holding that plaintiff’s expert causation opinions, supported almost entirely by observational studies and case reports (as opposed to clinical studies) lacked proper foundation, the Court in that case laid the groundwork for future analysis of the admissibility of novel medical causation theories which do not rely on new tests or techniques. Id.

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hepatic fibrosis and liver cirrhosis.” Id. Finally, a pharmacologist, as well as a former FDA chief medical officer, would both address the allegations that the defendant manufacturer “failed to provide an adequate warning to consumers about the hepatotoxicity of acetaminophen,” and defectively designed the drug without including “methionine or other compounds” which would have effectively eliminated its hepatotoxicity. Id. In support of their opinions, plaintiff’s experts relied almost entirely on observational studies and case reports “of a lesser caliber than controlled clinical studies from which results can be reviewed and verified.” Id. at 333.

When discovery was complete, the defendant moved to “preclude the plaintiff’s expert testimony relating to the plaintiff’s theory of medical causation and for summary judgment dismissing the amended complaint”, arguing that the opinions averring acetaminophen’s potential to cause cirrhosis of the liver, or that it contributed to plaintiff’s cirrhosis, did not satisfy the standard for admissibility of scientific evidence, and should be excluded pursuant to the Frye test. Ratner, 933 N.Y.S.2d at 326. In support of the motion, defendant relied upon the opinion of a physician specializing in hepatology and cell biology, whose affidavit conceded acetaminophen’s hepatotoxicity in cases of overdose, but also insisted that “the theory that long-term acetaminophen use at therapeutic doses can cause cirrhosis [is] not generally accepted in the medical and scientific communities” and that “the literature that plaintiff’s experts relied upon consisted almost exclusively of case reports and animal studies about acetaminophen overdose…data [which] could not be extrapolated to explain the cause of plaintiff’s condition.” Id. In contrast with the plaintiff’s disclosures, his affidavit was “supplemented with, inter alia, two medical articles which concluded that acetaminophen was safe in therapeutic doses, even for individuals suffering from liver disease.” Id. at 327.

In opposition to the motion, plaintiff supplemented her previous disclosures with additional opinions—supported by, essentially, more case reports, observational data, and extrapolations. See Ratner, 933 N.Y.S.2d at 333. The trial court granted defendant’s motion in its entirety, determining that there was no evidence linking acetaminophen to cirrhosis.” Id. at 329. It further stated that “plaintiff was attempting to draw a medical parallel between…proper…and excessive doses” to prove her point, and held that she “failed to satisfy the evidentiary requirements of Frye.” Id.

On appeal, the Appellate Division, Second Department agreed with the plaintiff that, contrary to the typical Frye admissibility issue, “her proffered experts [did] not utilize any novel scientific techniques or evidence…rather… [they sought] to set forth the novel theory that therapeutic acetaminophen use caused plaintiff’s liver cirrhosis primarily based upon the fact that acetaminophen is a hepatotoxin and that certain case studies suggest a relationship between acetaminophen and cirrhosis.” Ratner, 933 N.Y.S.2d at 332. Additionally, the Court reiterated that as a general principle “deductive reasoning or extrapolation, even in the absence of medical texts or literature that support a plaintiff’s theory of causation under identical circumstances, can be admissible if it is based on more than mere theoretical speculation or scientific hunch.” Id. at 333; See also Zito v. Zabarsky, 28 A.D.3d 42 (2d Dept 2006) (emphasis added).

Nevertheless, the Court noted that “[it] may conclude that there is simply too great an analytical gap between the data and the opinion proffered.” Id. quoting GE v. Joiner, 522 U.S. 136, (U.S. 1997) (emphasis added).

Analyzing the specific angle of the admissibility issue before it and essentially declaring the traditional Frye analysis unnecessary when it comes to
expert opinions such as the plaintiff’s, the Court further instructed that “when an expert seeks to introduce a novel theory of medical causation without relying on a novel test or technique, the proper inquiry begins with whether the opinion is properly founded on generally accepted methodology, rather than whether the causal theory is generally accepted in the relevant scientific community.” Ratner, 933 N.Y.S.2d at 334 (emphasis added).

Finally, applying the facts of the case to that particularized standard, the Court ultimately affirmed the order, concluding that because “the methodology employed by the plaintiff’s experts, correlating long term, therapeutic acetaminophen use to the occurrence of liver cirrhosis, primarily based upon case studies, was fundamentally speculative… there was too great an analytical gap between the data and the opinion proffered,” and as such, plaintiff failed to meet her burden of demonstrating that the opinions proffered were properly founded on generally accepted methodology. See Ratner, 933 N.Y.S.2d at 334.

Ratner offers a new wrinkle in the application of the Frye standard concerning expert testimony on novel causation theories extrapolated from conventional science. Causation theories deduced from case reports and observational studies and not formal clinical analysis might be deemed more suspect by the Court. On the other hand, if an expert can, using standard methodology, refer to a large cohort clinical study and deduce an extension, even in the absence of research specific to the particular claim of causation, it may be sufficient to get by a motion for summary judgment.

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**NORTH CAROLINA**

**Products Liability**
**Plaintiffs Must Satisfy Burden That Cause of Action is Brought Within Statute of Repose Period**


In the products liability case of Robinson v. Bridgestone/ Firestone North American Tire, North Carolina’s Court of Appeals held that the Plaintiffs’ claims were barred because they failed to meet their burden of showing that their action was brought within the six-year statute of repose set out in N.C. Gen. Stat. § 1-50(a)(6).

Robinson arose out of a motor vehicle accident occurring on June 2, 2002. The Plaintiffs were Anthony Robinson; his wife, Edith Robinson; and Ms. Robinson’s daughters, Calizza Whitaker and Shondretta Whitaker. Shondretta Whitaker was a minor. Plaintiffs alleged that the Defendants’ defective tire caused them personal injuries. Plaintiff Anthony Robinson had purchased four used tires in late May 2002, unaware that one of the tires was the subject of a nationwide voluntary recall initiated by Firestone on August 9, 2000.

The Plaintiffs alleged that Defendants Bridgestone/Firestone North American Tire manufactured a defective tire, which they purchased used and installed on their vehicle. The Plaintiffs further alleged that the tire tread separated, causing Plaintiff Edith Robinson to lose control of the vehicle, which caused them personal injuries. The Defendants filed a motion for summary judgment as to all of Plaintiffs’ claims based on the six-year statute of repose set forth in N.C. Gen. Stat. § 1-50(a)(6). The trial court granted summary judgment in favor of all of the defendants. Plaintiffs appealed.

In determining whether the Plaintiffs satisfied the six-year...
statute of repose, the Court held that the Plaintiffs bear the burden of proving when the statute of repose began running. On appeal, the Plaintiffs challenged the general fairness of the statute of repose, including the statute’s requirement that plaintiffs bear the burden of proving when the statute of repose began running.

The Court found that the Plaintiffs had to show that the allegedly defective tire was initially purchased within six years of the filing of Plaintiffs’ complaint. Plaintiffs filed their complaint on May 27, 2005. Thus, the Plaintiffs had to show that the tire was purchased on or after May 27, 1999. The only evidence was that the tire was manufactured at a Firestone facility during the 35th week of 1995 based on the tire’s DOT identification number, well outside the statute of repose period.

The Court held that the analysis was different for Plaintiff Shondretta Whitaker, a minor. N.C. Gen. Stat. § 1-17(a) provides for the tolling of limitations periods during a person’s minority. If the product is over six years old at the time of injury, the statute of repose still operates as a total bar on that claim. However, if the claim accrues before the statute of repose time period expires, N.C. Gen. Stat. § 1-17(a) extends the time period within which a minor may bring suit. Therefore, under this statute, the minor Plaintiff still had to show that the accident occurred less than six years after the tire was initially sold. As a result, in order to be timely, the tire would have had to have been first sold no earlier than June 2, 1996, six years before the date of the accident.

The Court found that Plaintiffs failed to carry their burden of proof that the tire was initially sold on or after either May 27, 1999 for the adult plaintiffs and June 2, 1996 for the minor plaintiff. Plaintiffs contended that it was possible that the tire’s first sale was nine months after it was manufactured in the 35th week of 1995, bringing it within the statute of repose. However, the Court rejected this theory as mere speculation.

Therefore, since the Plaintiffs failed to show that the tires were sold within the six-year statute of repose time limit, the Court held that the Defendants were entitled to summary judgment.

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The Sixth Circuit Confirms that Plaintiffs in Toxic Tort Cases Must “Rule In” Exposure to Defendant’s Contaminant, and “Rule Out” Alternative Sources of Exposure

Pluck v. BP Oil Pipeline Co., 640 F.3d 671 (6th Cir. 2011)

In Pluck, homeowners Sue and Ray Pluck brought suit against BP Oil Pipeline Co. (“BP”) in the Northern District of Ohio, alleging BP’s gas-pipeline releases contaminated their well water and caused Mrs. Pluck’s Non-Hodgkins lymphoma (“NHL”). The Plucks offered evidence that benzene was detected in their well water twice over the course of the nine years that they lived in the home at issue. However, the benzene levels detected on those two occasions did not exceed the maximum permissible contaminant level for benzene established by the Environmental Protection Agency (“EPA”). Id. at 673-75.

BP moved for summary judgment, which the Northern District of Ohio granted, dismissing the Plucks’ case with prejudice. The court held that the Plucks failed to establish the “specific causation” element of
their claims -- i.e., that Mrs. Pluck was exposed to benzene from BP’s gas pipeline leaks and that the level of exposure was sufficient to induce her NHL. Id. at 675-76. No evidence existed for this element because the court excluded the Pluck’s medical causation expert opinion.

The district court excluded the specific-causation expert opinion, holding it was unreliable under the Daubert standard because it “suffered significant methodological flaws and was apparently based upon speculation and conjecture rather than evidence and data.” Id. at 675. In particular, the expert did not rely on any “exposure data, only having been told that [Mrs. Pluck] had been ‘heavily’ exposed to benzene in her water.” Id.

The Plucks appealed to the Sixth Circuit. While they agreed that their expert did not establish the dose of the contaminant, the Plucks argued the court erred in requiring such specificity because their expert had employed a “differential diagnosis methodology.” This methodology is a “standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated.” Id. at 678.

The Sixth Circuit rejected the Pluck’s argument and affirmed the district court’s exclusion of their expert’s opinion. Id. at 680. The Court opined that while a differential diagnosis can establish specific causation, the Plucks’ expert opinion was not conducted using reliable differential diagnosis methodology. Id. at 678-688. A differential diagnosis requires that the medical expert perform three steps: (1) accurately diagnose the nature of the disease; (2) “rule in” all of the possible causes of the disease; and (3) “rule out” the rejected causes of the disease. Id. at 678. The Court held that the Plucks’ expert failed both steps 2 and 3; the expert did not “rule in” benzene as the cause of Mrs. Pluck’s NHL, and he did not “rule out” alternative causes of her illness. Id. at 679-80.

First, the expert did not reliably “rule in” benzene as a possible cause of Mrs. Pluck’s NHL because he did not reliably determine plaintiff’s level of benzene exposure. Specifically, the expert did not: (i) ascertain the plaintiff’s particular level of benzene exposure, (ii) determine whether she was exposed to quantities of benzene exceeding EPA regulations, (iii) explain the methodology for his exposure calculations, or (iv) use a gasoline vapor concentration study that supported the conclusions he sought to draw from it. Id. at 679. The expert’s claims that chronic low-level exposure can and does cause NHL, that plaintiff “probably” had an exposure to benzene, and that there is “no safe level” for benzene in terms of causing cancer” were insufficient to “rule in” benzene as a cause of the plaintiff’s NHL. Id.

The Sixth Circuit stressed that “the mere existence of a toxin in the environment is insufficient to establish causation without proof that the level of exposure could cause the plaintiff’s symptoms.” Id.

Second, the Court found the expert’s failure to reliably “rule out” alternative causes of Mrs. Pluck’s illness problematic. Id. at 680. In deposition, the expert acknowledged that Mrs. Pluck was exposed to other sources of benzene, including from her “extensive smoking habit” and other “organic solvents.” But, he provided no basis for ruling out these exposures as potential causes of her NHL. Id.

The Pluck opinion is consistent with the Sixth Circuit’s recent decision in an asbestos case applying Kentucky law. See Moeller v. Garlock Sealing Technologies, LLC, 660 F.3d 950 (6th Cir. 2011). In Moeller, the Sixth Circuit, in a split-panel decision, reversed the district court’s denial of Garlock Sealing Technologies, LLC’s (“Garlock’s”) motion for judgment as a matter of law following a jury verdict against it. Id. at 951. The Sixth Circuit held that plaintiff had failed to establish that Garlock’s asbestos-containing gaskets were a “substantial cause” of the plaintiff’s mesothelioma as a matter of law. Id. at 955.
Although the Sixth Circuit did not use the same terminology as it did in Pluck, essentially the Court found plaintiff had failed to “rule in” Garlock’s gaskets as a possible cause of his mesothelioma, and also failed to “rule out” alternative causes. Like in Pluck, the plaintiff’s expert was unable to quantify the plaintiff’s exposure to asbestos from Garlock’s gaskets, but acknowledged that plaintiff had been exposed to large quantities of asbestos from other sources. Id. No evidence of substantial cause existed. As the Court explained: “saying that exposure to Garlock gaskets was a substantial cause of [the plaintiff’s] mesothelioma would be akin to saying that one who pours a bucket of water into the ocean has substantially contributed to the ocean’s volume.” Id.

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Texas Supreme Court Continues Trend of Highly Critical Review of Product Liability Verdicts, Addresses Interplay Between Federal Pre-Emption and Manufacturing Defect Claims

*BIC Pen Corp. v. Carter*, 346 S.W.3d 533 (Tex. 2011)

In a recent case involving a disposable lighter, the Texas Supreme Court demonstrated again that its reputation for closely scrutinizing adverse injury awards is well deserved. In doing so, the Court also clarified the interplay between a manufacturing defect claim and a pre-emption defense. *Carter* involves tragic facts and a convoluted history in the courts.

Six-year-old Brittany Carter was seriously burned when her then five-year-old brother (Jonas) set her clothing on fire with a BIC J-26 disposable lighter. Brittany’s parents sued BIC, alleging both design and manufacturing defects led to the incident. After a trial resulted in a multi-million dollar award for both actual and exemplary damages, BIC appealed, arguing Carter’s claims were pre-empted by CPSC regulations. In the original appeal, the intermediate appellate court upheld the verdict based on a finding of defective design. On initial appeal to the Texas Supreme Court, it held that Carter’s design defect claims were pre-empted by federal law and remanded to the court of appeals to consider the other aspects of BIC’s appeal from the trial court. *BIC Pen Corp. v. Carter*, 171 S.W.3d 657, 662 (Tex. App. – Corpus Christi 2005), rev’d, 251 S.W.3d 500, 511 (Tex. 2008). On remand, the intermediate appellate court found that Carter’s manufacturing defect claims were not pre-empted by federal law and that sufficient evidence supported the finding of a manufacturing defect being a cause of Brittany’s injuries. See, *BIC Pen Corp. v Carter*, 346 S.W.3d 569, 575 & 581 (Tex. App. – Corpus Christi 2008), rev’d, 346 S.W.3d 533 (Tex. 2011).

On its second appeal to the Texas Supreme Court, BIC argued that Carter’s manufacturing defect claims were pre-empted by federal law and that there was no evidence to prove (1) the lighter deviated from BIC’s specifications, (2) the lighter was unreasonably dangerous and/or (3) any alleged defect in the lighter was the cause of Brittany’s injuries. The CPSC’s investigation and regulation of lighters of this type, specifically the need for child-resistant designs, was closely examined, noting that the CPSC had adopted “performance-based” regulations requiring that manufacturers...
design and produce a lighter that passed a detailed certification procedure which, according to testing (per a detailed test protocol mandated by the CPSC), resulted in a lighter design that was incapable of operation by 85% of those tested (those tested were age five (5) and under). BIC chose to address these requirements with the interplay of five components in the design of the J-26 lighter – “(1) the distance that the shield over the sparkwheel must be pushed down, (2) the force required to move the shield; (3) the distance the fork must move to release butane; (4) the force required to depress the fork; and (5) the force required to produce a spark by rotating the sparkwheel.” The Texas Supreme Court correctly recognized that Carter’s manufacturing defect claims were not attempting to increase the requirements over federal law, but were simply focused on whether the lighter at issue actually met the specification that was certified by the CPSC. The Court held that there was no pre-emption of this type of claim. The Court also found sufficient evidence that the lighter arguably contained a manufacturing defect – defined by it as “when a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous. (quoting Cooper Tire & Rubber Co. v. Mendez, 204 S.W.3d 797, 800 (Tex. 2006)). The Court noted that BIC’s own testing of the lighter indicated that it failed to meet BIC’s design specifications in two of the five areas – fork force and sparkwheel force. Although the deviation was minimal in terms of force required, the Court noted the deviation was nonetheless present.

However, the Court also noted that more than a deviation is required to establish liability – there must also be competent evidence that the deviation caused the accident, or, more precisely, that the accident would not have occurred “but for” the deviation. The Court closely scrutinized the evidence and found there was none to support causation. The Court noted that there was no evidence admitted that proved that the two factors found lacking (fork and sparkwheel force) were, in and of themselves (as opposed to considered in combination with the other three facets of the design), sufficient to cause the child-resistant functionality to be sufficiently compromised to allow a finding of causation. Further, the Court placed great reliance on the fact that the CPSC certification did not result in a lighter where no child could operate it (i.e., it was not child-proof). The test criterion for certification itself assumed that up to 15% of children under the age of 5 would be able to operate the lighter, yet it would still be certified. On this issue, the Court noted that Carter had presented no evidence that Jonas Carter would not have been in the 15% that was able to operate the lighter, even had it complied with all manufacturing specifications that applied. As such, the Court found no evidence of causation and reversed and rendered judgment in BIC’s favor, after a long and winding road through the Texas justice system.

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Texas Supreme Court Clarifies and Reaffirms “Doubling of the Risk” Requirement and Other Factors Necessary for Epidemiological Evidence of Causation in Pharmaceutical Products Case

Merck & Co. v. Garza, 347 S.W.3d 256 (Tex. 2011)

Very few cases garnered as much interest and discuss as the Texas Supreme Court’s Landmark opinion regarding the reliability of epidemiological evidence in Merrell Dow Pharmaceuticals, Inc. v. Havner, 953 S.W.2d 706 (Tex. 1997). In the following years, Havner became the lynchpin for pre-trial challenges to expert causation opinion based on epidemiological evidence. Garza provided another opportunity for
Garza involved the death of 71-year-old Leonel Garza. At the time of his death, Garza had, for over twenty years, suffered from a number of heart related issues, included heart attack, quadruple bypass surgery, numerous cardiac catheterizations and placement of stents. In the month before his death, Garza had also begun taking Vioxx, a non-steroidal anti-inflammatory drug (NSAID), provided by his cardiologist in response to intermittent pain, numbing and weakness in Garza’s left arm. The drug was provided after tests revealed that Garza was not suffering a heart attack. Various other diagnostic tests were run which showed Garza to be stable from a cardiac perspective. Less than three weeks later, however, Garza died of “probably myocardial infarction”, less than thirty days after beginning to take Vioxx. Garza’s heirs sued Merck, alleging design and marketing defects in Vioxx. The jury returned a multi-million dollar award for both actual and punitive damages; however, the intermediate appellate court reversed the finding of a design defect and remanded for a new trial based on juror misconduct. As opposed to returning for a retrial, Merck continued its appeal to the Supreme Court, arguing that there was no reliable evidence of causation.

In Texas, the issue of causation in a case such as this requires a plaintiff to provide competent evidence of both general and specific causation. That is, a plaintiff must first show that the “substance is capable of causing a particular injury or condition in the general population” (general causation) and, second, that the “substance caused a particular individual’s injury” (specific causation). In this appeal, Merck argued that Havner required a plaintiff to produce “two independent epidemiological studies” showing at least a statistically significant doubling of the risk of injury for patients taking the drug under substantially similar circumstances. Garza’s heirs, however, argued that this was not necessary as Havner did not involve controlled clinical trials but, rather, dealt with uncontrolled observational studies of the potential effects of Bendectin on expectant mothers.

While recognizing that the clinical trials available on Vioxx were more reliable, and many showed an increased risk of cardiac complications, the Texas Supreme Court made clear that, regardless of the type of study at issue, Havner’s requirement of a statistically significant doubling of the risk applies to ALL types of epidemiological evidence. Even in the context of clinical trials, the Court will consider a study that does not show a doubling of the risk at a 95% confidence level to be unreliable and insufficient to prove causation.

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WASHINGTON

Product Sellers that Market Under their Brand Name Are Precluded from Allocating Fault to Upstream Manufacturers


In Johnson, the plaintiff alleged injuries arising from a bike accident. She sued the retailer although REI did not manufacture the bike. The plaintiff claimed that the bike was defective because of a component part manufactured by a foreign corporation. Plaintiff sued REI but not the component part manufacturer.
REI presented a partial motion for summary judgment requesting that it be allowed to allocate fault to the upstream component part manufacturer. Plaintiff responded that a retailer selling under its own brand name should not be permitted to allocate fault to an upstream component part manufacturer. The trial court agreed with plaintiff finding that the defendant as a retailer selling under its private brand has the same liability as that of a “manufacturer” and, would not be permitted to allocate fault to an upstream manufacturer.

Under Washington’s product liability law manufacturers are strictly liable where plaintiff’s injury is caused by a defective product. RCW 7.72.030. Product sellers, generally are only liable for negligence, breach of express warranties or intentional misrepresentations. RCW 7.72.040. A product seller assumes the liability of a manufacturer, however, if it sells the product under its own brand. The trial court reasoned that because a retailer had the same liability as that of a manufacturer it should not be permitted to allocate fault to other upstream manufacturers. The trial court did grant leave for the defendant to file a third-party action to enforce any contractual obligations for indemnity or other breaches. The trial court further indicated that such third-party action should not delay plaintiff’s trial and that it would take the issue up at a later time.

REI sought discretionary review from Washington’s Court of Appeals. The Court of Appeals held that to allow allocation to an upstream manufacturer would render meaningless the strict liability of a product seller where they are deemed to be a manufacturer. The court noted that under Washington’s product liability system, it presupposes that sophisticated commercial parties will contract to allocate the risk as between them. The Court of Appeals noted that REI and the upstream manufacturer would equally be strictly liable as manufacturers and, thus, allocation cannot be permitted. The Washington Supreme Court declined to review the Court of Appeals’ decision.

The Johnson decision confirms what has long been suspected, that is, retailers held to the standard of manufacturers would not be permitted to allocate fault to upstream component manufacturers. As between the plaintiff and the retailer, the courts will not permit allocation to empty chairs which would diminish plaintiff’s recovery. The decision also highlights the need for retailers selling products under their own name to take appropriate steps to control this risk by way of indemnity and additional insured provisions with upstream manufacturers. Going forward plaintiffs will likely not join other upstream manufacturers or component manufacturers as the threat of an empty chair defense has been removed.

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