









RX for the Defense

The Newsletter of the Drug and Medical Device Committee

Volume 19 Issue 2 Published October 2011 by DRI

It May Have Been Defective (But Now It's Gone): Proof of Manufacturing Defect When the Product Is Lost or Destroyed by Rebecca A. Lefler

Product liability cases often lack a critical piece of evidence: the product. Plaintiffs allege a drug or medical device was defectively manufactured, but when the surgical device was lost after surgery, the pill was swallowed, or the implant was discarded, the product cannot be examined to determine how it was defective or what caused it to malfunction.

The use of circumstantial evidence to prove a manufacturing defect in such circumstances is widely accepted, but it has important limitations. Some states specifically allow for a presumption of defect when a malfunction occurs, others require stronger circumstantial evidence before such a conclusion may be reached. The limits of acceptable circumstantial evidence, therefore, can have a profound impact on a case. Below are some of the issues that define the scope of acceptable circumstantial evidence when a product is lost or destroyed.

Presumptions of Negligence Versus Presumptions of Defect

The res ipsa loquitur doctrine allows for a determination of negligence when direct proof of negligence is lacking, so long as the instrumentality that caused the plaintiff's harm remained in the exclusive control of the defendant and the harm would not normally occur in the absence of negligence. Through the development of strict product liability, some courts have expanded this doctrine to circumstances in which the instrumentality was no longer in the defendant's control.

In most jurisdictions however, courts still do not allow for a presumption of *defect*—a distinction that can be important when an allegedly defective product has been lost. In products liability cases, however, the line between res ipsa loquitur and strict products liability can be blurred. As the Texas Court of Appeals held, for example, "The doctrine of res ipsa loquitur can apply to both negligence and strict liability cases to provide a presumption of product defect and causation." *Parsons v. Ford Motor Co.*, 85 S.W.3d 323, 331 (Tex.App.-Austin,2002). The Ninth Circuit has come to a similar conclusion under Hawaii law: "[N]othing bars application of the res ipsa loquitur theory to strict liability." *Jenkins v. Whittaker Corp.*, 785 F.2d 720, 733 (9th Cir.1986).

Even where res ipsa itself is not relied upon to allow for a presumption of defect, similar principles have been expanded to situations in which direct proof of defect is lacking. The Restatement (Third) of Torts: Products Liability, for example, uses the res ipsa doctrine as the basis for Section 3, "Circumstantial Evidence Supporting Inference of Product Defect":

It may be inferred that the harm sustained by the plaintiff was caused by a product defect existing at the time of sale or distribution, without proof of a specific defect, when the incident that harmed the plaintiff:

- (a) was of a kind that ordinarily occurs as a result of product defect; and
- (b) was not, in the particular case, solely the result of causes other than product defect existing at the time of sale or distribution.

Comment b to Section 3 explains, "[W]hen the product unit involved in the harm-causing incident is lost or destroyed in the accident, direct evidence of specific defect may not be available. Under that circumstance, this Section may offer the plaintiff the only fair opportunity to recover."

New Jersey has officially adopted the test from Section 3, which it called the "indeterminate product defect test." *Myrlak v. Port Authority of New York and New Jersey*, 157 N.J. 84, 106, 723 A.2d 45, 56 (1999). The Section 3 standard has also been cited with approval by the Minnesota Supreme Court in *Schafer v. JLC Food Systems, Inc.*, 695 N.W.2d 570, 576 (Minn.,2005), and the Court of Appeals of New York in *Speller ex rel. Miller v. Sears, Roebuck and Co.*, 100 N.Y.2d 38, 41-42, 790 N.E.2d 252, 25, 760 N.Y.S.2d 79, 82 (N.Y.,2003).

Not all courts have adopted the standards of the Restatement (Third). Justice Hecht of the Texas Supreme Court, for example, criticized Section 3 as "res ipsa lite" and noted that although it can be proper to use circumstantial evidence to prove a defect, Section 3 offers little information about when such evidence is appropriate: 'It may be inferred' really means 'it is sometimes proper to infer', but while this reading makes the rule stated in section 3 accurate, it also makes the rule not very helpful." Ford Motor Co. v. Ridgway, 135 S.W.3d 598, 603 (Tex.,2004) (Hecht, J., concurring). The Wisconsin Supreme Court, in a divided opinion, also rejected the standard from Section 3 of Restatement (Third) in Godoy ex rel. Gramling v. E.I. du Pont de Nemours and Co., 319 Wis.2d 91, 107, 768 N.W.2d 674, 681 (Wis.,2009), choosing instead to follow the strict liability elements in Restatement (Second) of Torts, section 402A.

The Malfunction Theory

Many jurisdictions rely on the "malfunction theory" to determine defect when the product is missing or destroyed. Under this theory, the plaintiff can establish a prima facie product liability case by showing that the product unexpectedly malfunctioned while being used normally. In Florida, for example, plaintiffs are entitled to a "Cassisi inference" in which "the plaintiff's testimony regarding a malfunction is sufficient circumstantial evidence...to reach the jury, and the plaintiff is not required to pinpoint the defect and exclude all other possible explanations for the malfunction." *Ainsworth v. KLI, Inc.*, 967 So.2d 296, 302 (Fla.App. 4 Dist.,2007), citing *Cassisi v. Maytag*, 396 So.2d 1140, 1150-1151 (1981). The extent to which a plaintiff must exclude other causes of the malfunction differs across jurisdictions.

Most cases discussing the malfunction theory point out that an accident itself is not proof of a defect, but the circumstances of the accident can be circumstantial evidence of a defect. The Connecticut Supreme Court recently held in *Metropolitan Property and Cas. Ins. Co. v. Deere and Co.*, 2011 WL 3505226, *6 (Conn.,2011): "Although the malfunction theory is based on the principle that the fact of an accident can support an inference of a defect, proof of an accident alone is insufficient to establish a manufacturer's liability." Pennsylvania is in accord, holding, "The mere fact that an accident happens, even in this enlightened age, does not take the injured plaintiff to the jury." *Dansak v. Cameron Coca-Cola Bottling Co.*, 703 A.2d 489, 496 (Pa.Super.1997). Thus to establish a defect in most jurisdictions, the accident alone is not enough.

Stacking Inferences

Without direct evidence of a defect, plaintiffs may attempt to "stack" or "pyramid" inferences by using one inference as the basis for a second inference. In general, inference stacking in an unacceptable form of proof, as set forth by the Court of Appeals of North Carolina: "Inferences must be based on established facts, not upon other inferences, and in other words, a jury may draw an inference from a set of facts, but may not then use that inference to draw another inference." *Thompson v. Wal-Mart Stores, Inc.*, 138 N.C.App. 651, 654, 547 S.E.2d 48, 49 (N.C. Ct. App. 2000).

But many courts have rejected the prohibition on inference stacking, finding such a rule to be unworkable and impractical. The Michigan Supreme Court, for example, overturned the ban on stacked inferences in 2002, stating, "It appears that the doctrine forbidding the piling of an inference upon an inference arose from the intuitive view that circumstantial evidence was less probative or reliable than direct evidence. Despite its initial appeal, this view is hard to justify as a logical proposition and has accordingly been assailed by legal scholars." *People v. Hardiman*, 466 Mich. 417, 424-425, 646 N.W.2d 158, 163 (Mich. 2002). In 1992, the Court of Appeals of Arizona held that "the inference upon inference rule has no further validity in Arizona. As stated by Wigmore, 'the drawing of inferences from inferences is the natural and inevitable course of things." *Lohse v. Faultner*,176 Ariz. 253, 259, 860 P.2d 1306, 1312 (Ariz.App. Div. 1,1992) (citing 1A John Henry Wigmore, Evidence in Trials at Common Law § 41 n.3, 1112 (Peter Tillers rev., 1983)).

Thus the accusation that plaintiff has stacked inferences may not be sufficient to make the point that the plaintiff's conclusions or the opinions of their experts are too far removed from the evidence. Nonetheless, the limitations on circumstances in general still apply, and conclusion not based on reliable evidence should be challenged as unsupported.

Conclusion

As the California Court of Appeal has said, "The absence of critical evidence does not give rise to an inference that the missing evidence exists; rather, it indicates a failure of proof." *Collin v. American Empire Ins. Co.*, 21 Cal.App.4th 787, 808 (1994). This can be a helpful defense mindset when the allegedly defective product is lost or destroyed. Although circumstantial evidence can be reliable and admissible, any conclusion about a product defect that strays too far from the evidence should be challenged. Defense counsel should look for ways to make it clear to the court that a presumption of defect is allowed only under limited circumstances, and lack of evidence is a failure of proof.

Rebecca Lefler is counsel in the Los Angeles office of Tucker Ellis & West, where she is a member of the Appellate & Legal Issues Group. She works closely with the Medical & Pharmaceutical Liability Group doing motions and briefing in trial and appellate courts, and working on legal strategy and analysis for local and nationwide drug and device litigation.

To learn more about DRI, an international membership organization of attorneys defending the interests of business and individuals in civil litigation, visit www.dri.org.