2013 YEAR IN REVIEW

SIGNIFICANT DECISIONS IN 2013:
PRODUCTS LIABILITY UPDATE

By Rocky Little

***McKay v. Novartis Pharms. Corp.*, 2013 U.S. Dist. Lexis 47136, United States District Court for the Western District of Texas, El Paso Division, decided March 28, 2013.**

McKay was prescribed Aredia to treat osteoporosis, although the Food and Drug Administration (FDA) had not approved the drug for that purpose. After several years, McKay was also prescribed Zometa which, like Aredia, is manufactured by Novartis. McKay developed severe jaw and dental problems, including non-healing tooth extraction sites and exposed bones. He was diagnosed with osteonecrosis ("ONJ"), a condition marked by dead and dying bone in the jaw. McKay brought suit alleging products liability/strict liability based on an alleged failure to provide adequate warnings. The Court analyzed the application of Texas Civil Practice & Remedies Code §82.007, which pertains specifically to pharmaceutical products. Section 82.007 creates a rebuttable presumption that manufacturers are not liable with respect to an alleged failure to provide an adequate warning if the product and the accompanying warnings were approved by the FDA. However, §82.007 provides five means by which the non-liability presumption can be rebutted. One way to rebut the presumption of non-liability as provided in subsection (b)(1) is to show that the defendant withheld or misrepresented information from the FDA that was material and relevant to the performance of the product and was causally related to the alleged injury. This subsection is referred to as the "fraud on the FDA" rebuttal. However, the court held that the fraud on the FDA rebuttal is preempted by federal law and, therefore the FDA itself must find fraud. In this case, the FDA had not found that the Defendants withheld or misrepresented required information and therefore the alleged rebuttal is preempted by federal law, and not available to the plaintiff.

The Court also addressed another rebuttal provided by (b)(3)(A) of §82.007, which is sometimes referred to as improper or off-label marketing. This rebuttal to the non-liability presumption applies when a defendant recommends, promotes, or advertises a pharmaceutical product for an indication not approved by the FDA. In this case, McKay was prescribed Aredia for osteoporosis, although the FDA had not approved the drug for that purpose. However, plaintiff is required to provide evidence that recommendations, promotions, or advertisements by, or on behalf of, the manufacturer to use the pharmaceutical for off-label purposes reached and were relied on by the prescribing physician. Although the Plaintiff provided evidence that Dr. Berenson "marketed" Aredia to the prescribing physician, there was no evidence that there was any relationship between Novartis and Dr. Berenson. Therefore, there was a lack of evidence to support the allegation that the off-label promotion by Novartis reached the prescribing physician.

***Genie Indus. v. Matak*, No.13-11-00050-CV (Tex. App. -- Corpus Christi-Edinburg, December 6, 2012).**

Apprentice electrician, Walter Matak died from massive craniocerebral injuries caused when he crash-landed to the floor from a 40-foot, fully-extended AWP-40S aerial work platform manufactured by Genie. The AWP-40S is a lightweight portable single-person aerial lift with a work platform, or bucket, which is enclosed with a guardrail and telescopes up to forty feet. The base is supported by four outriggers at each corner, with foot pads supporting each outrigger. The lift's base has wheels which allow a single person to roll it around a worksite. The outriggers must be locked in place in order for the machine to elevate the bucket. However, it is possible to raise the outriggers, and roll the base, while the bucket is elevated.

Prior to his fall, each time Matak needed to reposition himself to work, he would lower the lift and exit the lift bucket. Then, he and a co-worker would raise the outriggers and move the lift to a new spot. However, a facility maintenance worker who had used the AWP-40S many times suggested that Matak did not need to lower himself, but rather he and Matak's co-worker could raise the outriggers and roll the lift while Matak remained elevated. While doing this, the lift fell over resulting in Matak's crash landing. Matak's estate brought a cause of action against Genie based on strict products liability for a defective design.

DESIGN DEFECT

To prevail in a products liability case alleging a design defect, a plaintiff must prove by a preponderance of the evidence that:

(1) the product was defectively designed so as to be unreasonably dangerous;
(2) a safer alternative design existed; and
(3) the design defect was the producing cause of the damages sought.

To determine whether a defectively designed product is "**unreasonably dangerous,**" Texas courts apply a **risk-utility analysis** which includes the following factors:

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

The Court noted that whether a product is unreasonably dangerous is generally a question of fact for the jury, rather than a question of law to be decided by the Judge. The Court also noted that the risk-utility analysis does not operate in a vacuum, but rather in the context of the

product's intended use and its intended users. The fact that the lift's utility is high and the risk of injury is low when the product is used as intended is but one consideration in the multitude of factors used in the risk-utility analysis. Also, the fact that a product's foreseeable risk of harm stems from a misuse of the product, rather than its intended use, is not an absolute bar to design defect liability. Misuse of the product is a factor that must be considered in allocating responsibility. In other words, product misuse is subject to comparative responsibility.

A "**safer alternative design**" is statutorily defined as a product design other than the one actually used that in reasonable probability:

(1) would have prevented or significantly reduced the risk of the plaintiff's injuries;
(2) without substantially impairing the product's utility; and
(3) was economically and technologically feasible when the product was manufactured or sold.

In this case, the plaintiff introduced evidence through a design engineer's expert witness testimony of four alternative designs that met the criteria for a safer alternative design. Therefore, the Court of Appeals upheld the jury's finding that the Genie AWP-40S lift was defectively designed so as to be unreasonably dangerous, which was a producing cause of Matak's injuries.