FALL 2011 NEWSLETTER

PRODUCTS LIABILITY UPDATE

By Rocky Little

1. *BIC Pen Corp. v. Carter,* 54 Tex. Sup. J. 1168, June 17, 2011.

Six-year-old Brittany Carter was burned when her five-year-old brother accidentally set fire to her dress with a BIC lighter. The Texas Supreme Court previously held that the design defect claim was preempted by federal law, because the CONSUMER PRODUCT SAFETY ACT created the Consumer Product Safety Commission ("CPSC") which promulgated regulations requiring a specific testing protocol. More specifically, the design defect claim was preempted because the design of the BIC lighter was properly certified according to federal protocol, and state law imposing a higher common law standard for child resistance would conflict with federal regulations.

The manufacturing defect claim, on the other hand, was not preempted by federal law because Plaintiff's allegation is that BIC failed to manufacture the lighter to the specifications submitted to the Consumer Product Safety Commission. The court noted that a manufacturing defect exists "when a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous." The court held that there was legally sufficient evidence that the lighter did not meet the manufacturing specifications. In order to recover, however, the plaintiff was also required to prove that the deviation from manufacturing specifications was a producing cause of the injury. A producing cause must be a cause in fact, that is, it must be a substantial factor in bringing about the injury, and a cause without which the injury would not have happened. Expert testimony is generally required in manufacturing defect cases to prove that the specific defect caused the accident. Proof other than expert testimony will constitute some evidence of causation only when a lay person's general experience and common understanding would enable the lay person to determine with reasonable probability the causal relationship between the event and the condition.

The BIC lighter at issue has five features that combine to make it child resistant. The post-accident testing showed small deviations in two of those features. The court held that it would not be within a lay juror's general experience and common understanding as to how the lighter with those small deviations in two of the five features would have functioned in the hands of a child. Even a lighter that meets CPSC child resistant specifications is not intended to be completely inoperable by children. The specifications contemplate that some children less than five years old will be able to operate a lighter certified as child resistant. Therefore, the plaintiff had the burden to prove that the child probably would not have operated the lighter but for the manufacturing defects. In other words, evidence was required to show that, but for those two deviations, the child probably would not have been able to operate the lighter.

The court contrasted the evidence necessary to prove causation in this case with certain types of toxic tort cases which can rely on epidemiological studies. In those cases, specific

causation may be proved by epidemiological studies showing increased risk following exposure. However, the court declined to adopt this type of analysis as to causation for a lighter because a different type of testing is more appropriate. Therefore, the court held that there was legally insufficient evidence to support the jury's finding that manufacturing defects were a cause in fact of the plaintiff's injuries.

2. *Merck & Co. v. Garza*, 54 Tex. Sup. J. 1697, August 26, 2011.

Leonel Garza had a long history of heart disease before his death at age 71. Mr. Garza's statutory beneficiaries ("Garza") contend that his death was the result of a heart attack in which the producing cause was the ingestion of Vioxx 25 mg pills over a period of 25 days. In *Merrell Dow Pharmaceuticals, Inc. v. Havner*, the Texas Supreme Court set out requirements for determining whether epidemiological evidence is scientifically reliable to prove causation. The court explained that causation, in this context, has two components: general and specific. General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual's injury. While causation can sometimes be proved directly, it often can be proved only indirectly with epidemiological studies. In other words, claimants may demonstrate that exposure to a substance increased the risk of their particular injury. Allowing such proof concedes that science cannot tell us what caused a particular plaintiff's injury. Rather, it is based on a policy determination. When the incidence of a disease or injury is sufficiently elevated due to exposure to a substance, someone who was exposed to that substance and exhibits the disease or injury can raise a fact question on causation.

The generally accepted methodology among epidemiologists is that studies finding a doubling of the risk are statistically significant at the 95% confidence level. Therefore, when parties attempt to prove general causation using epidemiological evidence, a threshold requirement of reliability is that the evidence must demonstrate a statistically significant doubling of the risk. Additionally, a plaintiff must show that he or she is similar to the subjects in the studies and that other plausible causes of the injury or condition are excluded with reasonable certainty. The court also requires that the threshold requirements of reliability are met in at least two properly designed studies. Thus, a plaintiff must first pass the primary reliability inquiry by meeting *Havner*'s threshold requirements of general causation. Then, courts must conduct the secondary reliability inquiry that examines the soundness of a study's findings using the totality of the evidence test. The totality of the evidence cannot prove general causation if the evidence does not meet the standards for scientific reliability established by *Havner*. In other words, plaintiff cannot prove causation by presenting different types of unreliable evidence. Because the Garzas did not present reliable evidence of general causation, they are not entitled to recover.