IADC COMMITTEE NEWSLETTER

DRUG, DEVICE AND BIOTECHNOLOGY

DECEMBER 2016

IN THIS ISSUE

In a recent, lengthy opinion, the Alabama Supreme Court explained the evidentiary standard necessary to establish the existence of a safer, practical alternative design in products liability cases alleging design defect. This article examines the Court's opinion and its implications for defense attorneys representing pharmaceutical and medical device manufacturers in cases applying Alabama law.

For Design Defect Cases, Alabama's Alternative Design Requirement Just Got Tougher

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The Drug, Device and Biotechnology Committee serves as an educational and networking resource for in-house counsel employed by pharmaceutical, medical device and biotech manufacturers and the outside counsel who serve those companies. The Committee is active in sponsoring major CLE programs at the Annual and Midyear Meetings as well as internal committee programs. The Committee also publishes a monthly newsletter that addresses recent developments and normally contributes two or more articles to the *Defense Counsel Journal* annually. Learn more about the Committee at www.iadclaw.org. To contribute a newsletter article, contact:

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Introduction

Unlike most states, Alabama's product liability law was judicially created rather than legislatively enacted. Dubbed the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD"), this common law concept of strict liability is, in fact, a hybrid version of strict liability in which the manufacturer may be liable for its negligence or wantonness in placing an unreasonably dangerous product in the market place.

When alleging design defect under the AEMLD, a plaintiff has the burden of proving the existence of a safer, practical alternative design by demonstrating that (1) the injuries inflicted would have less severe or eliminated by the use of the alternative design, and (2) the utility of the alternative design outweighs the utility of the design actually used.[1] Factors to be considered when determining whether the utility of the alternative design outweighed the utility of the design actually used include: the intended use of the product; its styling, cost, and desirability; its safety features; the foreseeability of the accident that occurred, along with the likelihood of injury and the seriousness of injury that would result from such an accident; the obviousness of the defect; and the manufacturer's ability to eliminate the defect.[2]

***Hosford* and the Alternative Design Requirement**

Although Alabama's product liability jurisprudence is generally well-defined, the Alabama Supreme Court recently examined the AEMLD's alternative design requirement, further defining the proof needed to establish the existence of an alternative design.

In *Hosford v. BRK Brands, Inc.*, 2016 Ala. LEXIS 91 (Ala. Aug. 19, 2016), the plaintiff's 4-year old daughter died in a slow, smoldering mobile home fire. The home was equipped with two BRK-manufactured smoke alarms, but only one activated during the fire.[3] Both smoke alarms relied on "ionization technology," which is less sensitive to smoke from smoldering fires than smoke from flaming fires.[4] By contrast, "photoelectric technology"-equipped smoke alarms are generally more sensitive to smoke from smoldering fires.[5]

Plaintiff alleged that had the alarm not been defectively designed, her daughter would have been alerted to the fire and escaped.[6] In support of her AEMLD claim, plaintiff proposed as an alternative design a "dual-sensor" smoke alarm incorporating both ionization and photoelectric technology. In fact, BRK manufactured a dual-sensor alarm

[1] *General Motors Corp. v. Jernigan,* 883 So. 2d 646, 662 (Ala. 2003); *see also* Ala. Pattern Jury Instructions 32.07 and 32.08.
[2] *Jernigan,* 883 So. 2d at 662.
[3] *Hosford,* 2016 Ala. LEXIS 91, *2.
[4] *Id.* at *2-3, 10.
[5] *Id.* at *10.
[6] *Id.* at *2-3.

that included both sensor types and redundant circuitry, but at a significantly higher cost. After a jury verdict in favor of BRK, plaintiff appealed. The central issue on appeal was whether plaintiffs had presented substantial evidence of a safer, practical alternative design under the AEMLD.

Affirming the trial court, the Alabama Supreme Court held that, as a matter of law, plaintiff's proposed alternative design—the dual-sensor smoke alarm—was not a safer alternative design to the ionization alarm; "rather, it is a design for a different product altogether."[7]

In explaining its holding, the Court analogized the case to pharmaceutical cases like the hormone replacement litigation. Indeed, the Court relied extensively on *Brockert v. Wyeth Pharm., Inc.*, 287 S.W.3d 760, 762 (Tex. App. 2009), where the plaintiff alleged that Wyeth's Prempro (a combination of estrogen and progestin) was defectively designed and caused her to develop breast cancer.[8] In support of her design defect claim, plaintiff alleged that estrogen alone was a safer, alternative design to Prempro.[9] However, Wyeth also manufactured Premarin, an estrogen-only HRT.[10]

Rejecting plaintiff's argument, the Texas Court of Appeals reasoned that "a safer alternative design must be one for the product at issue –here, Prempro."[11] In essence, plaintiff argued that "Prempro should have been a different product: its predecessor Premarin."[12] However, the court reasoned further that the plaintiff failed to "explain how Prempro could have been modified or improved."[13] Importantly, although Prempro and Premarin served "essentially the same purpose – to treat menopausal symptoms—the *Brockert* court" found as a matter of law that Premarin was not a safer, alternative design to Prempro because they were different products altogether.[14]

The *Hosford* Court also cited the risk-utility the trade-offs consumers make in purchasing safety devices. Specifically, the Court observed

> [Manufacturers are] not obligated to market only one version of a product, that being the very safest design possible. If that were so, automobile manufactures could not offer consumers sports cars, convertibles, jeeps, or compact cars … Personal safety devices, in particular, require personal choices, and it is beyond the province of courts and juries to act as

[7] *Id.* at *14. In so doing, the Court also held that the reasonableness of a safer, alternative design is generally a question of fact for the jury, noting that in cases like the one at bar, Alabama courts can appropriately find that a plaintiff has failed, as a matter of law, to present substantial evidence of an alternative design. *Id.* at *14.

[8] *Id.* at *14-15.
[9] *Id.* at *15-16.
[10] *Id.* at *16.
[11] *Id.* at *18.
[12] *Id*.
[13] *Id*.
[14] *Id.* at *18-19.

> legislators and preordain those choices.[15]

Applying that rationale in *Hosford*, the Court found that while the ionization smoke alarm and dual sensor smoke alarms "serve[] the same purpose,"[16] the dual-sensor alarm was "a design for a different product altogether."[17] Consequently, as a matter of law, the dual-sensor alarm was not a safer, alternative design for the ionization smoke alarm.[18] As such, the Court held that plaintiff's AEMLD claim could not "prevail in the absence of evidence of evidence establishing the existence of a safer, practical alternate design for the allegedly defective product …."[19]

Conclusion

For manufacturers of pharmaceutical products—and more broadly, manufacturers defending design defect claims of any kind—in Alabama, plaintiffs will now have an even more difficult time maintaining design defect claims in light of the clearly articulated evidentiary requirement necessary to establish the existence of a safer, practical alternative design.

[15] *Id.* at *20.
[16] *Id.* at *22
[17] *Id.* at *19.
[18] *Id.*
[19] *Id.* at *22.

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