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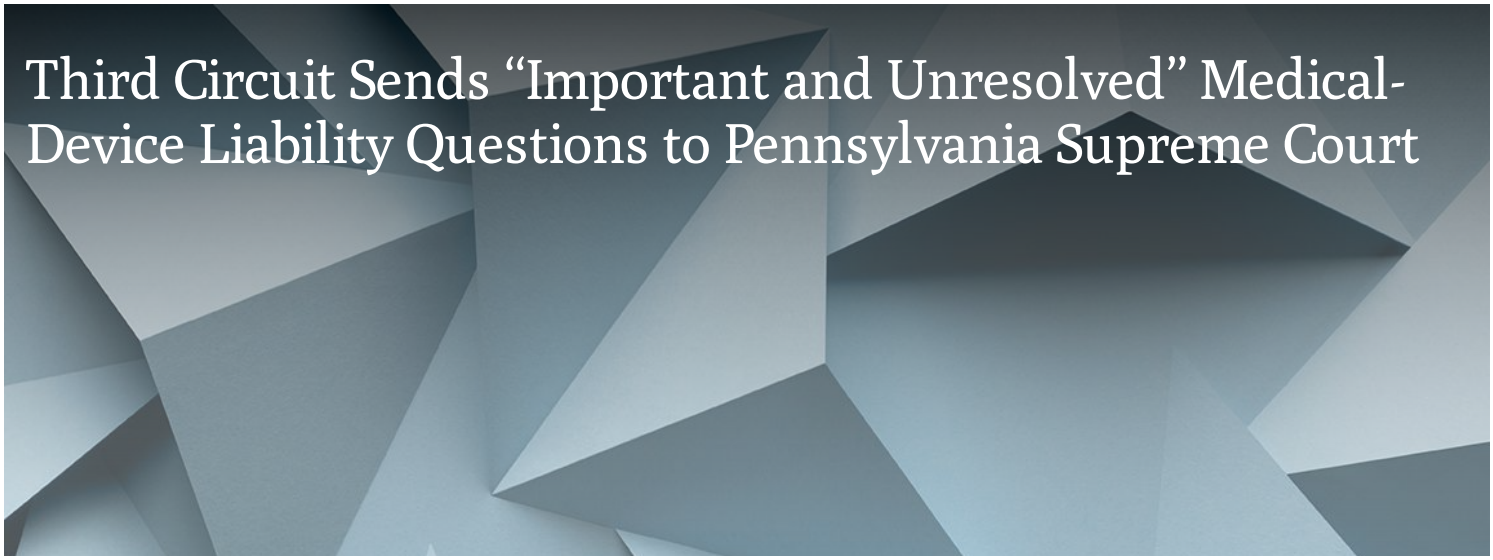
BLOG

Third Circuit Sends "Important and Unresolved" Medical-Device Liability Questions to Pennsylvania Supreme Court



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Recently, in *Ebert v. C.R. Bard, Inc.*, the Third Circuit considered two questions of medical-device liability left unresolved by Pennsylvania law. The first is whether a plaintiff claiming that a device was negligently designed must prove that the device was "too harmful to be used by anyone." The second is whether a strict liability claim involving a medical device is cognizable under Pennsylvania law. Finding these questions too important to be resolved by an *Erie* "guess," the Third Circuit asked the Pennsylvania Supreme Court to answer them instead. How that court does so will likely impact thousands of cases, including several active multi-district litigations.

The plaintiff in *Ebert* suffered from a deep vein thrombosis, a kind of blood clot "that could have potentially life-threatening complications." *Ebert v. C.R. Bard, Inc.*, No. 20-2139, 2021 WL 2656690, at *1 (3d Cir. June 24, 2021). To catch any further clots before they became pulmonary embolisms, Ebert's doctor installed in her inferior vena cava a device known as a G2 filter, which Bard manufactured. *Id.* Three years later, when the doctor tried to remove the device, he found that a piece of the filter had "fractured and grown into the wall of Ebert's inferior vena cava." *Id.*

Ebert sued Bard in the U.S. District Court for the Eastern District of Pennsylvania, alleging that the company was both negligent in designing a defective filter and strictly liable for its defective manufacture. *Id.* at *2. Each theory stemmed from a watershed decision by the Pennsylvania Supreme Court. In *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014), that court held that prescription drug manufacturers, though immune from strict liability, are subject to state-law negligence liability for design defects. The *Lance* court grounded this decision in Section 6(c) of the Restatement (Third) of Torts, which states that manufacturers are negligent if they introduce or market a drug "with actual or constructive knowledge that [it] is too harmful to be used by anyone." *Lance*, 85 A.3d at 459, 461 (citing Restatement (Third) of Torts: Prods. Liab. § 6(c) (1998)). Ebert argued that Section 6(c) did not foreclose alternative theories of design-defect liability—such as her theory which was that Bard could have chosen a "safer alternative design" for the G2 filter.

Ebert's strict liability claim rested on a novel interpretation of *Tincher v. Omega Flex, Inc.*, 104 A.3d 328 (Pa. 2014). There, the Pennsylvania Supreme Court rejected the notion that some products—aside from prescription drugs—should be exempted categorically from strict liability. Since *Tincher* did not speak with specificity to medical-*device* liability, Ebert argued that *Tincher* had stripped medical devices of their exemption from strict liability.

The district court granted summary judgment to Bard. *Ebert v. C.R. Bard, Inc.*, 459 F. Supp. 3d 637, 641 (E.D. Pa. 2020). Judge Pappert first rejected Ebert's contention that, under *Lance*, the existence of an "alternative safer design" could suffice as a theory of negligence. *Id.* at 644. Since accepting such an argument would require a court to speculate as to "whether FDA approval could be had for a new design," he determined that "the alternative design approach [was] not an easy fit measured against conventional design theory." *Id.* at 646 (citing *Lance*, 85 A.3d at 458–59). Thus, Ebert's design defect theory was not cognizable under Pennsylvania law. *Id.*

Judge Pappert also found Ebert's strict liability claim viable in theory and wanting in practice. He conceded that, under *Tincher*, Pennsylvania law might allow for strict liability for medical-device manufacturing defects. *Id.* at 652. And he predicted that the Pennsylvania Supreme Court would consider that question—and the applicability of the "unavoidably unsafe" exception—on a "case-by-case basis." *Id.* at 652–53. Applying those forecasts to the "fully developed factual record," however, Judge Pappert still found Bard's filter "unavoidably unsafe" and shielded from strict liability. *Id.* at 653.

On appeal, the Third Circuit declined to answer these "important and unresolved issues of state products liability law" without the advice of the state's highest court. *Ebert v. C.R. Bard, Inc.*, No. 20-2139, 2021 WL 2656690, at *1 (3d Cir. June 24, 2021). Writing for a unanimous panel, Judge Krause found that *Lance*'s "expansive language" fairly could be read to permit a design-defect theory sounding in the existence of a safer alternative design. *Id.* at *3–*4. And she concluded that *Tincher* had left available "three alternative ways to analyze strict liability" for prescription medical devices. *Id.* at *5. Left "unable to predict how the Pennsylvania Supreme Court would rule on those questions," the Third Circuit certified to that court two questions of law:

> "1. Under Pennsylvania law, must a plaintiff bringing a negligent design claim against a prescription medical device manufacturer prove that the device was too harmful to be used by anyone, or may the plaintiff also prevail on other theories of liability where appropriate?
>
> 2. Under Pennsylvania law, are prescription implantable medical devices categorically subject to strict liability, categorically immune from strict liability, or immune from strict liability on a case-by-case basis? If they are immune on a case-by-case basis, what test should a court apply to determine whether a particular device is immune?" *Id.*

Ebert likely will determine the degree to which medical-device manufacturers can be held liable for design and manufacturing defects in the nation's fifth-largest state, and may have reverberating effects in other jurisdictions.
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