UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 20-2139

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MELISSA EBERT,
Appellant

v.

C.R. BARD, INC.; BARD PERIPHERAL VASCULAR INC.,
a subsidiary and/or division of Defendant C.R. Bard, Inc.

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On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. No. 5-12-cv-01253)
District Judge: Hon. Gerald J. Pappert

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Submitted Pursuant to Third Circuit L.A.R. 110.1
March 4, 2021

Before: KRAUSE, PHIPPS, and FUENTES, *Circuit Judges*

(Filed: June 24, 2021)

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PETITION FOR CERTIFICATION OF QUESTIONS OF STATE LAW

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This matter came before the United States Court of Appeals for the Third Circuit on appeal from an order of the United States District Court for the Eastern District of Pennsylvania granting summary judgment in favor of Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard"). *See Ebert v. C.R. Bard, Inc.*, 459 F. Supp. 3d 637, 641 (E.D. Pa. 2020). It calls on us to predict two open questions of Pennsylvania

tort law: First, what standard the Pennsylvania Supreme Court would apply to negligent design claims against prescription medical device manufacturers, and second, whether prescription medical device manufacturers are categorically subject to strict liability under Pennsylvania law or may instead be immune from strict liability in certain circumstances.

This panel (Krause, Phipps, and Fuentes, JJ.), having read the briefs and submissions of the parties and having reviewed the applicable decisions of the Pennsylvania courts, believes that both questions represent important and unresolved issues of state products liability law appropriate for certification. We therefore respectfully request that the Supreme Court of Pennsylvania accept this certification.[1]

## I. Background

In 2008, Plaintiff Melissa Ebert was diagnosed with a deep vein thrombosis—in plain terms, a blood clot that could have potentially life-threatening complications. To catch any blood clots before they could reach Ebert's heart or lungs, her treating physician, Dr. Michael Ringold, implanted in her inferior vena cava a filter manufactured by Bard, known as a G2 IVC filter.[2] The safety of that G2 filter is the subject of this appeal.

About three years later, Dr. Ringold removed the filter, but there was a complication: In the course of the procedure, he discovered that one of the G2's struts had

[1] We certify pursuant to 3d Cir. L.A.R. 110.1 (2011), 3d Cir. I.O.P. 10.9 (2018), Pa. R. App. P. 3341 (2020), and Pa. Sup. Ct. I.O.P. 8 (2019). If the Court accepts this certification, we recommend that Melissa Ebert be designated as the appellant and Bard as the appellee.

[2] Dr. Ringold initially implanted an IVC filter manufactured by Cook Medical, but it penetrated the wall of Ebert's inferior vena cava and had to be removed.

fractured and grown into the wall of Ebert's inferior vena cava. Given the risks associated with removing that strut, Dr. Ringold decided to leave it undisturbed. But over the next seven months, the strut migrated into a branch of the pulmonary artery in the lower lobe of Ebert's left lung, requiring an endovascular procedure to remove it. Although tests following that procedure indicated that her heart and lungs were working normally, Ebert proceeded to sue Bard in federal court, claiming, among other things, negligent design and strict liability and seeking both compensatory and punitive damages.

In support of her claims, Ebert presented evidence of flaws in the G2 filter's design and of feasible alternative designs. Dr. Ringold testified that he no longer uses Bard IVC filters because of their problems with fracturing, and multiple experts' reports reflected that safer alternative designs were feasible at the time when Bard manufactured the G2. One such expert, Dr. McMeeking, offered a specific alternative design for the G2 that purportedly would have "reduc[ed] the risk of fracture." *Ebert*, 459 F. Supp. 3d at 646. Another, Dr. Freeman, concluded that both the G2 filter and Bard's earlier Recovery filter model—which was the basis for the G2's design—had fractured and migrated at greater rates than other IVC filters that were on the market at the time when Bard designed, manufactured, and sold the G2. *Id.* at 642; JA 225–26, 271–72. Because one of the models that failed at lower rates was Bard's own SNF filter, Dr. Freeman opined that "Bard had knowledge of a reasonable alternative design" and knew of the G2's "relatively high[er] rate[s]" of failure at the time when the G2 filter was implanted in Ebert. JA 226; *see Ebert*, 459 F. Supp. 3d at 642.

After being consolidated with other cases for pretrial proceedings by the Judicial Panel on Multidistrict Litigation, Ebert's suit was transferred back to the Eastern District of Pennsylvania, where the District Court granted summary judgment for Bard on all counts. On appeal to this Court, Ebert challenged that ruling, *see* Appellant's Br. 1–3, and requested that we certify the questions of state law governing her negligent design and strict liability claims to the Pennsylvania Supreme Court, *see* Reply Br. 3–8.[3] Bard opposed that request. *See* Appellee's Supp. Br. 1. Upon consideration of the parties' arguments and our own evaluation of Pennsylvania tort law, this panel has unanimously agreed to certify the questions of law raised by Ebert's negligent design and strict liability claims.[4]

## II. Discussion

Ebert argues that Bard is liable for harms caused by the G2 filter under both a negligent design theory and a strict liability theory. Both claims, however, hinge on unresolved questions of Pennsylvania law with significant ramifications for public policy in the Commonwealth. First, with regard to negligent design, it is unclear what standard of care should be applied to implantable medical devices like the G2 filter under the Court's decision in *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014). Second, with regard to strict liability, it is unclear whether and in what circumstances an implantable medical device like the G2

[3] The District Court had jurisdiction under 28 U.S.C. § 1332 and we have jurisdiction under 28 U.S.C. § 1291.

[4] Ebert also brought a negligent failure to warn claim and has appealed the District Court's summary judgment order in favor of Bard, *see* Appellant's Br. 30–37, but that claim is not raised in this petition.

filter is subject to strict liability under *Hahn v. Richter*, 673 A.2d 888 (Pa. 1996), and *Tincher v. Omega Flex, Inc.*, 104 A.3d 328 (Pa. 2014). We respectfully request clarification of both issues, as discussed in more detail below.

**A. Negligent Design**

Ebert first argues that Bard negligently designed the G2 filter. *See* Appellant's Br. 18–23. The parties agree that implantable medical devices like the G2 are subject to negligent design claims under Pennsylvania law, but they dispute the precise standard of care that applies to such claims. That question raises significant "social policy" concerns regarding the scope of "fault-based liability in Pennsylvania." *Lance*, 85 A.3d at 456. Resolving it turns on how we interpret the Supreme Court's holding *Lance*.

In that case, addressing a prescription drug that had been recalled by the Food and Drug Administration (FDA), the Court held, as a matter of first impression, that a plaintiff may bring a negligent design claim against a prescription drug manufacturer. *Id.* at 436–37, 453. Although prescription drugs are immune from strict liability under Pennsylvania law, the Court explained, they remain subject to the "other governing aspects of Pennsylvania tort law," including "negligent design defect claims." *Id.*at 453, 461. The Court therefore concluded—relying in part on § 6(c) of the Restatement (Third) of Torts—that "pharmaceutical companies violate their duty of care if they introduce a drug into the marketplace, or continue a previous tender, with actual or constructive knowledge that the drug is too harmful to be used by anyone." *Id.* at 459, 461 (citing RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) (1998)).

The question raised by this appeal is whether *Lance* means that a plaintiff may prevail in a negligent design claim against a medical device manufacturer *only* by showing that the device was "too harmful to be used by anyone," *id.* at 461, or whether such a plaintiff may also prevail on another theory of negligent design—here, for example, that there was "an alternative safer design" that was feasible at the time, *id.* at 447. Put simply, does *Lance* set the floor or the ceiling for negligent design claims against prescription medical devices?

Courts in Pennsylvania have divided over that question. Some, like the District Court here, hold that *Lance* requires a plaintiff to prove that a prescription medical device is "too harmful to be used by anyone." *Ebert*, 459 F. Supp. 3d at 646 (quoting *Lance*, 85 A.3d at 461); *see also Keen v. C.R. Bard, Inc.*, 480 F. Supp. 3d 624, 637–39 (E.D. Pa. 2020). These courts point out that *Lance* itself applied that standard, 85 A.3d at 461, and that § 6(c) of the Restatement (Third) of Torts, on which *Lance* relied, *id.* at 459, provides that "[a] prescription drug *or medical device* is not reasonably safe due to defective design" if reasonable doctors "would not prescribe the drug *or medical device* for *any class of patients*," RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(c) (emphasis added); *see also Pa. Suggested Standard Civil Jury Instructions* § 23.40 (5th ed. 2020) ("A . . . [medical device] [company] . . . that supplies a . . . [medical device] that it knew or reasonably should have known is too dangerous to be used by anyone, violates its duty of care." (brackets in original) (citing *Lance*, 85 A.3d 434)). Thus, in this case, Bard contends that *Lance* is dispositive and that because the G2's design is appropriate for some class of patients, Ebert's negligent design claim is meritless. Appellees' Br. 26; *see also* Amicus

Prod. Liab. Advisory Council, Inc. Br. 7–13 (arguing that *Lance* limits negligent design claims against prescription medical devices to those that are too harmful to be used by anyone).

Other courts, however, read *Lance* as leaving open additional theories of liability. *See, e.g.*, *Crockett v. Luitpold Pharms., Inc.*, 2020 WL 433367, at *11 (E.D. Pa. Jan. 28, 2020); *Krammes v. Zimmer, Inc.*, 2015 WL 4509021, at *6 (M.D. Pa. July 24, 2015); *Runner v. C.R. Bard*, 108 F. Supp. 3d 261, 271 (E.D. Pa. 2015). These courts highlight the Supreme Court's statement in *Lance* that "it is axiomatic that the holding of a judicial decision is to be read against its facts," 85 A.3d at 453, and perceive the standard applied in *Lance* as limited to the unique context of prescription drugs, where "proof of a reasonable alternative design" is "not an easy fit" because a court can only "speculat[e]" about "whether FDA approval could ever be had for a new 'design,'" *id.* at 458–59. As these courts read *Lance*, the fact that a prescription-device plaintiff may rely on a too-harmful-for-anyone theory when the "typical" proof of "a reasonable alternative design" is unavailable, *id.* at 458, does not preclude recourse to that proof for negligent design claims when it is available, *see Crockett*, 2020 WL 433367, at *10–11.

Certain other language in *Lance* supports this more expansive interpretation. *Lance* framed its holding as a rejection of the defendant's argument that "an alternative safer design [is] an absolute prerequisite to any and all design-based claims," *id.* at 458 n.36, which may suggest that *Lance* was expanding, not contracting, the acceptable theories of negligent design. The Court also noted "the potential for a plaintiff to refer to other existing medications . . . or interventions as a substitute for a drug" and cited academic articles

discussing "the potential role of substitutability in design-defect analysis relative to prescription drugs," *id.* at 459 (citations omitted), which may imply that in cases where allegedly safer medical devices are on the market, a plaintiff can base a negligence claim on those alternative designs. And the Court observed that "proof of a reasonable alternative design is a typical device used to establish defect," *id.* at 458, and that "the entire continuum" of duties under "the law of negligence," including all "governing aspects of Pennsylvania tort law" except for strict liability, still applies to prescription drugs, *id.* at 453, 459–60. These statements may indicate that an alternative design theory, and perhaps other theories, are still cognizable as a basis for liability after *Lance*.[5]

The Court's resolution of this issue will have a direct consequence for this appeal. Ebert's expert reports opined, among other things, "that an alternative design was both technologically and economically feasible at the time Bard manufactured the G2 filter," *Ebert*, 459 F. Supp. 3d at 646; that Bard possessed data showing "relatively high rate[s]" of failure in the Recovery filter and the G2 filter "within a matter of months of their release on the market," JA 226, after they were approved by the FDA in 2003 and 2005, respectively, *Ebert*, 459 F. Supp. 3d at 642; and that "Bard had knowledge of a reasonable

[5] *Lance* also emphasized that the Pennsylvania Supreme Court "has rather roundly endorsed the substantive principles reflected in both Sections 395 and 398 of the Restatement Second." 85 A.3d at 445 n.13. Those provisions, respectively, hold manufacturers liable for "fail[ure] to exercise reasonable care in the manufacture of a chattel which, unless carefully made, [they] should recognize as involving an unreasonable risk of causing physical harm," RESTATEMENT (SECOND) OF TORTS § 395 (1965), and for "physical harm caused by [their] failure to exercise reasonable care in the adoption of a safe plan or design," *id.* § 398. Proof of an alternative safer design for implantable medical devices would appear to be at least one viable theory of liability under the "substantive principles" articulated in those two provisions. *Lance*, 85 A.3d at 445 n.13.

alternative design . . . at the time it designed manufactured and sold the G2 filter which fractured" in Ebert's inferior vena cava, JA 226. Thus, depending on which is the proper reading of *Lance*, this record may be sufficient to defeat Bard's motion for summary judgment on Ebert's negligent design claim. Because the answer implicates an open question of Pennsylvania products liability law and involves "weighty and consequence-laden policymaking judgments impacting a traditional, state-law . . . remedial scheme," *Lance*, 85 A.3d at 461–62, this panel believes the Pennsylvania Supreme Court is best positioned to resolve this question.

**B. Strict Liability**

The second open question of state law raised by this appeal relates to strict liability. Ebert argues that Bard should be strictly liable for harms caused by the G2 filter, *see* Appellant's Br. 23–30, while Bard contends that the G2 filter should be immune from strict liability under comment k of the Restatement (Second) of Torts § 402A (1965), *see* Appellees' Br. 27–38. This issue implicates "significant interests central to the public policy justifying the strict liability cause of action" in the Commonwealth, *Tincher*, 104 A.3d at 387, and resolving it depends on how we interpret two other Pennsylvania Supreme Court cases: *Hahn* and *Tincher*.

In *Hahn*, the Court applied comment k of the Restatement (Second) of Torts § 402A to hold that prescription drugs are categorically immune from strict liability because they are "[u]navoidably unsafe" but are nonetheless justified for some patients. 673 A.2d at 889–91 (quoting RESTATEMENT (SECOND) OF TORTS § 402A cmt. k). Two decades later in *Tincher*, however, the Court rejected "[c]ategorical exemptions from liability" on

the ground that only the state legislature can properly make such categorical policy decisions.[6] 104 A.3d at 396–97. The Court therefore held that "the presumption is that strict liability may be available with respect to any product." *Id.* at 386. *Tincher* also repeatedly cited *Hahn* as a "but see" authority, *id.* at 382, 396, which could indicate that *Hahn* is limited to prescription drugs and does not categorically immunize implantable medical devices from strict liability. That conclusion finds some support in *Beard v. Johnson & Johnson, Inc.*, 41 A.3d 823 (Pa. 2012), where the Court clarified the strict liability standard for surgical devices and appeared to assume that "a strict-liability, design-defect theory" was applicable to "a medical-device product liability action," *id.* at 824.[7] *But see* Amicus Prod. Liab. Advisory Council, Inc. Br. 13–26 (arguing that prescription medical devices are categorically immune from strict liability under Pennsylvania law).

Courts are divided over this question, too. The Pennsylvania Superior Court has ruled that *Hahn* immunizes all medical devices from strict liability because there is "no reason why the same rational[e] applicable to prescription drugs [under *Hahn*] may not be applied to medical devices," *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006), and the Pennsylvania Court of Common Pleas has also suggested that prescription medical devices are immunized under *Hahn*, *see Lawrence v. Synthes Inc.*, No. 94-07627,

[6] *Tincher* also modified the standard for strict liability and held that a plaintiff may prevail on a strict liability claim by showing either that a reasonable person would conclude that the product's risks outweigh its utility or that the product would not meet an ordinary consumer's expectations about minimum safety standards. 104 A.3d at 387–89, 406.

[7] *Beard* does not resolve the strict liability issue in this appeal because a surgical tool is meaningfully different from an implantable medical device, but *Beard* does suggest that medical devices in general are not categorically immune from strict liability.

2003 WL 23914540, at *5 (Pa. C.P. Aug. 15, 2003).[8] Some federal district courts have likewise applied comment k to immunize all prescription medical devices from strict liability. *See, e.g.*, *Keen*, 480 F. Supp. 3d at 637; *Rosenberg v. C.R. Bard, Inc.*, 387 F. Supp. 3d 572, 576–78 (E.D. Pa. 2019).

Other federal courts, however, have predicted that Pennsylvania would not "extend *Hahn* to prescription medical devices," *Gross v. Coloplast Corp.*, 434 F. Supp. 3d 245, 248, 250–52 (E.D. Pa. 2020), and would instead "permit strict liability claims to proceed against a medical device manufacturer," *Bernard v. Johnson & Johnson*, 2020 WL 5407818, at *3 (E.D. Pa. Sept. 9, 2020); *see also Schrecengost v. Coloplast Corp.*, 425 F. Supp. 3d 448, 452, 465–66 (W.D. Pa. 2019). Two recent Court of Common Pleas decisions similarly permitted strict liability claims to proceed against implantable medical device manufacturers, and both were appealed to the Superior Court, but both appeals have now been withdrawn, depriving the Supreme Court of a potential vehicle in the state court system to resolve this question. *See Ebert*, 459 F. Supp. 3d at 652 n.8; *Ebaugh v. Ethicon, Inc.*, No. 463 EDA 2018 (Pa. Super. Ct. appeal withdrawn Nov. 19, 2020); *Emmet v. Ethicon, Inc.*, No. 1078 EDA 2019 (Pa. Super. Ct. appeal withdrawn Dec. 7, 2020); Amicus Ella Ebaugh & Suzanne Emmet Br. 1–3; Reply Br. 2–4. The District Court here took yet another approach, predicting that under *Tincher*, Pennsylvania would not categorically

[8] As the District Court pointed out here, *Creazzo* was decided before *Tincher*, and *Tincher*'s rejection of categorical approaches to tort immunity may undermine *Creazzo*'s reasoning. *See Ebert*, 459 F. Supp. 3d at 651–52. *But see* Amicus Prod. Liab. Advisory Council, Inc. Br. 16–18 (defending *Creazzo* as "the only result consistent with" Pennsylvania law).

immunize implantable medical devices but would still use comment k to immunize some such devices on a case-by-case basis. *Ebert*, 459 F. Supp. 3d at 652–53.

These cases suggest three alternative ways to analyze strict liability in this context: (1) implantable medical devices could be categorically subject to strict liability under *Tincher*'s holding that "the presumption is that strict liability may be available with respect to any product, provided that the evidence is sufficient to prove a defect," 104 A.3d at 382; (2) implantable medical devices could be categorically immune from strict liability under *Hahn* on the ground that prescription medical devices are legally indistinguishable from prescription drugs and therefore fall within the scope of *Hahn*'s holding; or (3) implantable medical devices could be immunized under comment k on a case-by-case basis.

Moreover, if this third alternative is the proper approach, there are also two possible methods for that case-by-case analysis. One method would focus on the general type of device at issue. Here, for example, the District Court ruled that because "every IVC filter . . . carries risks of fracture, migration and perforation" and because "it is impossible to design an implantable medical device with zero risk of failure," the G2 filter is "unavoidably unsafe" and therefore immune under comment k. *Ebert*, 459 F. Supp. 3d at 653 (citation omitted). The other method would focus on the specific model of the device at issue and would ask if that model is unavoidably unsafe, in which case a plaintiff could defeat a defendant's claim to immunity under comment k by presenting evidence of a feasible alternative safer design.

Here again, the Court's resolution of the issues would directly affect the disposition of this appeal. Ebert presented evidence of an alternative safer design and testimony from

Dr. Ringold that he no longer uses Bard filters because of their problems with fracturing. *Ebert*, 459 F. Supp. 3d at 645–46; *see* JA 225–26, 271–72, 334–35. That record may be sufficient to defeat Bard's summary judgment motion with regard to Ebert's strict liability claim if either (1) implantable medical devices are categorically subject to strict liability or (2) implantable medical devices are immune from strict liability on a case-by-case basis but evidence of a safer alternative design can defeat a defendant's claim to immunity under comment k. Because the applicable standard is an open question in Pennsylvania law and because "[s]trict liability in tort for product defects is a cause of action which implicates the social and economic policy of th[e] Commonwealth," *Tincher*, 104 A.3d at 381, we believe the resolution of this question, too, properly belongs with the Pennsylvania Supreme Court.

## III. Conclusion

Both the negligent design and the strict liability issues in this appeal raise questions of first impression under state law with significant public importance, but we are unable to predict how the Pennsylvania Supreme Court would rule on those questions. NOW THEREFORE, the following questions of law are certified to the Pennsylvania Supreme Court for disposition according to that Court's rules:

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?

We shall retain jurisdiction over the appeal pending resolution of this certification.

By the Court,

s/ Cheryl Ann Krause
Circuit Judge