United States Court of Appeals
For the First Circuit

No. 14-1927

MICHAEL J. TERSIGNI,

Plaintiff, Appellant,

v.

WYETH, a/k/a Wyeth, LLC, f/k/a American Home Products Corp.; AMERICAN HOME PRODUCTS, INC.; WYETH AYERST LABORATORIES; WYETH PHARMACEUTICALS, a/k/a Wyeth Pharmaceuticals, Inc., f/k/a Wyeth-Ayerst Pharmaceuticals, Inc.; f/k/a Ayerst Laboratories, Inc.; WYETH-AYERST PHARMACEUTICALS, INC.; AHP SUBSIDIARY HOLDING CORPORATION, f/k/a Wyeth-Ayerst Laboratories Company, a division of Wyeth; AYERST LABORATORIES, INC., a division of Wyeth, Wyeth-Ayerst Pharmaceuticals, Inc.,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Richard G. Stearns, U.S. District Judge]

Before

Lynch, Circuit Judge,
Souter, Associate Justice,*
and Stahl, Circuit Judge.

Louis M. Bograd, with whom Center for Constitutional Litigation, P.C., Gregory J. Bubalo, Paula S. Bliss, and Bubalo Goode Sales & Bliss, PLC were on brief, for appellant.

* Hon. David H. Souter, Associate Justice (Ret.) of the Supreme Court of the United States, sitting by designation.

Theodore V.H. Mayer, with whom William J. Beausoleil, Michael D. Tiger, Hughes Hubbard & Reed LLP, Peter L. Welsh, Jesse M. Boodoo, and Ropes & Gray LLP were on brief, for appellees.

March 23, 2016

STAHL, **Circuit Judge**. For a period of time in 1997, the appellant, Michael Tersigni, was prescribed Pondimin, a weight loss drug developed and sold by the appellee, Wyeth.[1] Tersigni later sued Wyeth, alleging that Pondimin caused him to develop a dangerous condition known as primary pulmonary hypertension ("PPH"). The district court entered summary judgment for Wyeth on most of Tersigni's claims, including his claim for negligent design, and allowed only a single claim for negligent failure to warn to go to trial. In separate rulings, the district court denied a pair of motions in limine in which Tersigni sought to exclude reference at trial to his past incarceration and use of cocaine.

The jury returned a verdict for Wyeth on Tersigni's surviving negligent failure to warn claim. In this appeal, Tersigni claims that the district court erred by entering summary judgment for Wyeth on the negligent design claim and by denying his motions in limine. After careful consideration, we AFFIRM.

I. Facts and Background

From 1989 until 1997, Wyeth marketed Pondimin as a medication to promote weight loss. In the mid-1990s, however, clinical research began to emerge linking Pondimin to an elevated

[1] "Wyeth" refers collectively to Wyeth and its many subsidiaries and other affiliates (and their current and former pseudonyms) listed in the case caption above.

risk for valvular heart disease and PPH.[2] Eventually, in July 1997, the Food and Drug Administration ("FDA") required Wyeth to warn doctors of these risks and to add a so-called "Black Box" warning to Pondimin's label. Soon thereafter, the FDA ordered that Wyeth withdraw Pondimin from the market entirely.

Tersigni was one of millions of Americans to receive a prescription for Pondimin. He was prescribed (and apparently took) the drug for an approximately six-month period beginning in early 1997, and ending in July 1997, when Tersigni's doctor learned of the FDA's required Black Box warning.

In 2011, several years after Tersigni stopped taking Pondimin, he was diagnosed with PPH. Thereafter, he sued Wyeth in federal district court in Massachusetts, asserting claims for, inter alia, negligent design[3] and negligent failure to warn. In effect, Tersigni's negligent design claim alleged that Wyeth knew,

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[2] Valvular heart disease refers to a group of conditions which cause a disruption in the normal structure and function of the heart valves. PPH is a disease affecting pulmonary circulation and is characterized by scarring and fibrosis of the pulmonary arteries. PPH is "relentlessly progressive" and "leads to death in virtually all circumstances." See Brown v. Am. Home Prods. Corp., (In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.), Nos. 1203, 99-20593, 2000 WL 1222042, at *16 (E.D. Pa. Aug. 28, 2000).

[3] Tersigni's negligent design claim has taken on many guises. For example, in his opening brief, Tersigni refers to this claim interchangeably as one for "negligent marketing," "negligent failure to discontinue marketing," and "negligent design." When pressed at oral argument, counsel clarified that Tersigni is, in fact, pursuing a claim for "negligent design."

or should have known, that Pondimin was unreasonably dangerous, but nonetheless continued to market it.

Wyeth moved for summary judgment on most of Tersigni's claims. The district court granted this motion, reasoning in relevant part that Massachusetts courts would not recognize a cause of action for the negligent design of a prescription drug. See Tersigni v. Wyeth-Ayerst Pharm., Inc., No. 11-10466-RGS, 2014 WL 7464759, at *1 (D. Mass. June 25, 2014). Following the entry of summary judgment, only Tersigni's claim for negligent failure to warn remained for trial.

Separately, Tersigni moved to preclude reference at the trial both to his previous incarceration in 2008 for non-payment of child support, and to his occasional use of cocaine several decades earlier. Wyeth opposed both motions, arguing that this evidence was relevant to the defense's theory that cocaine use and the stress associated with Tersigni's incarceration contributed to his cardiopulmonary symptoms. The district court denied Tersigni's motions, ruling that, subject to certain restrictions, evidence of the cocaine use and incarceration could be offered.

Following an eleven-day trial on Tersigni's negligent failure to warn claim, the jury found in Wyeth's favor, concluding that Wyeth had not negligently failed to warn Tersigni's doctor of the risks posed by Pondimin. Consequently, the jury did not reach

the separate question of whether Pondimin caused Tersigni to develop PPH. This appeal followed.

II. Analysis

A. Negligent Design

We review the district court's order granting summary judgment on Tersigni's negligent design claim de novo, assessing the record in the light most favorable to Tersigni and resolving all reasonable inferences in his favor. Bingham v. Supervalu, Inc., 806 F.3d 5, 9 (1st Cir. 2015). "In so doing, 'we are not bound by the district court's decisional calculus but, rather, may affirm the decision . . . on any ground made manifest by the record.'" Ocasio-Hernández v. Fortuño-Burset, 777 F.3d 1, 7 (1st Cir. 2015) (quoting Ruiz v. Bally Total Fitness Holding Corp., 496 F.3d 1, 5 (1st Cir. 2007)). The entry of summary judgment is appropriate where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Bingham, 806 F.3d at 9 (quoting Fed. R. Civ. P. 56(a)).

By way of background, Section 402A of the Restatement (Second) of Torts subjects to strict liability certain sellers of products which are "in a defective condition unreasonably dangerous to the user or consumer." Evans v. Lorillard Tobacco Co., 990 N.E.2d 997, 1011 (Mass. 2013) (quoting Restatement (Second) of Torts § 402A (1965)). However, Comment K to Section 402A ("Comment K") offers an exception and exempts from strict

liability the manufacturer of certain products (including drugs) that are highly beneficial but may carry known risks:

> There are some products which . . . are quite incapable of being made safe for their intended and ordinary use. . . . The seller of such products, . . . with the qualification that they are properly prepared and marketed, and proper warning is given, . . . is not to be held to strict liability . . . merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A cmt. k.

In granting summary judgment to Wyeth on Tersigni's negligent design claim, the district court reasoned that because the Supreme Judicial Court ("SJC") had previously adopted Comment K, Massachusetts courts would not recognize a negligent design claim where the product in question is a prescription drug. See Payton v. Abbott Labs, 437 N.E.2d 171, 189-90 (Mass. 1982) (adopting Comment K).

As both parties acknowledge, Massachusetts courts do recognize claims predicated on the negligent design of a variety of consumer products and other goods. For example, in Smith v. Ariens Co., 377 N.E.2d 954 (Mass. 1978), the SJC permitted a claim to go forward where the plaintiff sought to prove that the negligent design of a snowmobile had caused her to sustain injury. Id. at 957; see also Evans, 990 N.E.2d at 1010 (cigarettes); Vassallo v. Baxter Healthcare Corp., 696 N.E.2d 909, 912 (Mass.

1998) (silicone breast implants); McDonough v. Whalen, 313 N.E.2d 435, 440-41 (Mass. 1974) (septic system).

The parties dispute, however, whether Massachusetts courts would recognize a negligent design claim involving a prescription drug. This is a seemingly straight-forward question, but it lacks an obvious answer. On the one hand, as Wyeth points out, Massachusetts courts have yet to formally recognize such a claim.[4] But, on the other hand, as Tersigni fairly argues, neither has the SJC expressly ruled the claim out. In fact, in the context of claims for the negligent design of other products, the SJC has repeatedly cited not to Section 402A, involving strict liability, but to Restatement (Second) of Torts Sections 395 and 398, which pertain to the negligent design and manufacture of chattel. See Smith, 377 N.E.2d at 957-58; McDonough, 313 N.E.2d at 439 n.7. At a minimum, this raises the possibility that Massachusetts courts might consider a negligent design claim related to a prescription drug, notwithstanding the SJC's embrace of Comment K. See Toner

[4] Tersigni reaches far into the annals of Massachusetts jurisprudence and directs our attention to Norton v. Sewall, 106 Mass. 143 (1870), where an apothecary was found liable for the negligent sale of a deadly poison, which he had mistaken for a harmless medicinal tincture. Id. at 144. Norton, however, tells us little about how Massachusetts courts would treat a claim for the negligent design of a prescription drug. As an initial matter, the apothecary's liability was premised merely on his negligent sale, rather than his design or manufacture, of the poison. Id. Beyond that, Norton was decided more than a century prior to the SJC's adoption of Comment K, leaving open the question of whether Comment K would bar the claim Tersigni seeks to bring.

v. Lederle Labs., 732 P.2d 297, 311 (Idaho 1987) ("[C]omment [K] does not shield sellers of products from negligence claims."); see also Restatement (Second) of Torts § 402A cmt. a ("[Section 402A] does not preclude liability based upon the alternative ground of negligence . . . .").

It is thus quite uncertain whether Massachusetts courts would recognize Tersigni's negligent design claim. We need not decide this issue, however, because even if we were to assume that such a claim is cognizable under Massachusetts law, the claim would nonetheless fail based on Tersigni's inability to proffer evidence of a reasonable alternative design.[5] See Evans, 990 N.E.2d at 1024 ("In claims alleging negligence in the design of a product, . . . the plaintiff must show an available design modification which would reduce the risk without undue cost or interference with the performance of the product . . . ." (alterations, citations, and internal quotation marks omitted)); Gillespie v. Sears, Roebuck & Co., 386 F.3d 21, 26 (1st Cir. 2004) (applying Massachusetts law and finding that "[a]n essential element of . . . a design flaw claim is that there be a safer alternative design"); 1 Mass. Super. Ct. Civil Practice Jury Instructions § 11.2.3 (Mass. Continuing

[5] For the same reason, we acknowledge but need not consider the parties' dispute as to whether Tersigni's negligent design claim under state law is preempted by federal regulation of pharmaceutical drugs.

Legal Educ. 3d ed. 2014) (requiring plaintiffs to show an available design modification as an element of a negligent design claim).

Tersigni does not contend here, nor did he contend before the district court, that there exists a reasonable alternative design which would have made Pondimin less likely to cause PPH or otherwise safer. Rather, he argues first that Wyeth may be held liable because, at the time Pondimin was marketed, there were other, safer methods of weight loss available. This argument, however, misconstrues the focus of the reasonable alternative design inquiry, which requires the plaintiff to show that the product in question could have been more safely designed, not that a different product was somehow safer. See Evans, 990 N.E.2d at 1016, 1024 (noting that the plaintiff must offer proof of an available design modification of "the product" (emphasis added) (alteration omitted)); Caterpillar, Inc. v. Shears, 911 S.W.2d 379, 385 (Tex. 1995) ("A motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle.").

Tersigni also argues that Massachusetts courts would, on the basis of Restatement (Third) of Torts: Products Liability § 6(c) (1998) - which Massachusetts courts have not yet adopted - find that proof of a reasonable alternative design is not required where the product in question is a prescription drug. Thus, in effect, Tersigni asks us to assume, in the absence of any

applicable precedent, that Massachusetts courts would recognize his negligent design claim, and that having done so, those same courts would grant a heretofore unrecognized exception to the general requirement of proof of a reasonable alternative design. This is a bridge too far, and we decline to cross it.

As a federal court applying Massachusetts law, we are bound to apply state law as it exists, not as it may become, or as the plaintiff wishes it to be. See Ryan v. Royal Ins. Co. of Am., 916 F.2d 731, 744 (1st Cir. 1990). Here, we need not attempt to foretell whether Massachusetts courts will one day embrace a claim for the negligent design of a prescription drug. Rather, even assuming that they would, Tersigni's claim fails because he cannot offer proof of a reasonable alternative design, as Massachusetts law plainly requires. Thus, summary judgment properly entered in Wyeth's favor.[6]

[6] Tersigni urges that we certify to the SJC the question of whether his claim for negligent design is cognizable under Massachusetts law. See Mass. S.J.C. R. 1:03. We decline to do so. Tersigni chose to bring suit in federal court despite obvious uncertainty as to whether Massachusetts courts would recognize his cause of action. This undermines his request for certification. See Cantwell v. Univ. of Mass., 551 F.2d 879, 880 (1st Cir. 1977) ("[O]ne who chooses the federal courts in diversity actions is in a peculiarly poor position to seek certification. We do not look favorably, either on trying to take two bites at the cherry by applying to the state court after failing to persuade the federal court, or on duplicating judicial effort.").

B. Evidentiary Rulings

We turn next to Tersigni's claim that the district court erred by denying his motions in limine seeking to exclude evidence of his prior incarceration and cocaine use. Our review is for abuse of discretion. See Fryar v. Curtis, 485 F.3d 179, 182 (1st Cir. 2007). We may affirm in spite of an erroneous evidentiary ruling if the error was harmless, meaning that "it is highly probable that the error did not affect the outcome of the case." McDonough v. City of Quincy, 452 F.3d 8, 19-20 (1st Cir. 2006).

i. Incarceration

Tersigni moved to exclude reference to his past incarceration for non-payment of child support, evidence Wyeth argued was relevant to prove that Tersigni had undergone a stressful event which contributed to his cardiopulmonary symptoms. The district court denied Tersigni's motion, allowing testimony "limited to the fact of incarceration, the effect on [Tersigni's] blood pressure, and that the incarceration was based on a child support issue and not any crime of violence." During the ensuing eleven-day trial, the jury heard a total of four sporadic references to Tersigni's incarceration. Tersigni argues that this evidence should have been excluded because its prejudicial effect of undermining his character substantially outweighed its probative value. See Fed. R. Evid. 403.

We need not decide whether the district court abused its discretion by admitting this evidence because any error - if indeed there was one at all - was harmless. The jury was given a verdict form in which it was first asked to determine whether Tersigni had established that Wyeth negligently failed to warn his doctor of the risks associated with Pondimin. The jury answered this question in the negative. Consequently, the jury did not reach the second question, which asked whether Tersigni had established that he developed PPH as a result of taking Pondimin, a causation issue to which Tersigni's incarceration was arguably relevant.

In our view, evidence of Tersigni's incarceration likely had no effect on the jury's consideration of whether Wyeth negligently failed to warn physicians of Pondimin's risks, the only issue on which the jury was required to pass. See McDonough, 452 F.3d at 19-20. The nature of this inquiry simply left no room for consideration of Tersigni's reliability as a witness or his overall character. Thus, if an error occurred, it was harmless.

ii. Cocaine Use

Tersigni also sought to exclude evidence that, several decades earlier, he had occasionally used cocaine. Again, Wyeth claimed that this evidence was relevant to show alternative causes of Tersigni's symptoms. The district court denied Tersigni's motion, pending its "evaluation of expert testimony that the abuse of cocaine . . . is related to the issue of specific causation."

The district court, however, was not required to conduct any such evaluation because Tersigni's counsel chose to raise the cocaine use herself, referencing it twice during her opening statement and again during direct examination of two of Tersigni's witnesses.

We have previously held that a party which seeks to "remove the sting" by preemptively introducing damaging evidence thereby waives the right to appeal the admission of that evidence. See Gill v. Thomas, 83 F.3d 537, 541 (1st Cir. 1996); see also Ohler v. United States, 529 U.S. 753, 760 (2000). Tersigni tries to circumvent our holding in Gill by noting that it predated the amendment, in 2000, of Federal Rule of Evidence 103, which governs the manner by which parties must preserve claims of evidentiary error. This attempt cannot succeed, however, because the Advisory Committee Notes accompanying that amendment provide that the amendments "do[] not purport to answer whether a party who objects to evidence that the court finds admissible in a definitive ruling, and who then offers the evidence to 'remove the sting' of its anticipated prejudicial effect, thereby waives the right to appeal the trial court's ruling." Fed. R. Evid. 103 advisory committee's notes to 2000 amendment (citing, inter alia, Gill, 83 F.3d at 540). Thus, Gill remains good law and the admission of evidence of Tersigni's cocaine use does not merit reversal.[7]

[7] Tersigni argues that the cumulative effect of admitting evidence of both his incarceration and cocaine use requires

III. Conclusion

The judgment of the district court is AFFIRMED.

reversal. See United States v. Stokes, 124 F.3d 39, 43 (1st Cir. 1997) (discussing the cumulative error doctrine). Here, we have found that there was, at worst, one arguable error, and thus we need not consider its potential cumulative effect.