UNITED STATES DISTRICT COURT DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v.

Civil No. 08-cv-358-JL Opinion No. 2010 DNH 130

Mutual Pharmaceutical
Company, Inc.

MEMORANDUM OPINION

Defendant Mutual Pharmaceutical Company has moved for reconsideration of this court's order denying Mutual's summary judgment motion in part and granting it in part. See Bartlett v. Mut. Pharm. Co., 2010 DNH 112 ("Order"). Mutual argues that this court made a manifest error of law in ruling that Bartlett could prevail on her strict products liability claim by proving that the product at issue, the prescription drug Sulindac, was "defective because its safety risks outweigh its medical benefits, making it an unreasonably dangerous product," id. at 23 (footnote omitted), without having to prove that the product had some other "defect" in design.

While language in the New Hampshire Supreme Court's opinion in <u>Buckingham v. R.J. Reynolds Tobacco Co.</u>, 142 N.H. 822 (1998), arguably supports Mutual's view, its subsequent decision in Vautour v. Body Masters Sports Industries, Inc., 147 N.H. 150

¹Document no. 243.

(2001), expressly holds that a plaintiff can prevail on a strict products liability claim by proving that a product was "unreasonably dangerous pursuant to the risk-utility balancing test," without also having to prove "a safer, alternative design," id. at 157. Mutual's motion does not address Vautour's holding and, indeed, barely mentions the case.

Accordingly, as fully explained <u>infra</u>, Mutual's motion to reconsider fails to demonstrate a "manifest error of fact or law," L.R. 7.2(e)," or, so far as the court is concerned, any error at all. The motion is therefore denied.

I. <u>Background</u>

The facts relevant to Mutual's motion for summary judgment are set forth throughout the Order and need not be repeated here. Essentially, Bartlett claims that she suffered a painful and life-threatening condition known as Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis, or "SJS/TEN," from taking Sulindac, a generic prescription drug manufactured by Mutual and prescribed by her doctor. In moving for summary judgment, Mutual argued principally that it adequately warned the doctor of the risk of SJS/TEN but that, even if it had not, any failure to warn was not the cause of Bartlett's injuries because her doctor admitted that he had not read Sulindac's warning label before

prescribing it to her. Mutual argued that those flaws were fatal not only to Bartlett's failure-to-warn claims, but also to her strict products liability claim based on defective design, because "the primary allegation [she] relies upon to support [it] is [her] erroneous contention that Sulindac was defective because it lacked an adequate warning."

In support of her strict products liability claim, though, "Bartlett also alleges that Sulindac is defective because its safety risks outweigh its medical benefits, making it an unreasonably dangerous product"--as this court ultimately observed in the Order. Thus, following oral argument on Mutual's summary judgment motion, the court ordered both parties to brief whether Bartlett's inability to prove causation on her failure-to-warn claims was also fatal to her strict products liability claim based on defective design.

Mutual maintained that it was, because "the New Hampshire Supreme Court would recognize that in actions involving pharmaceutical products, whether a product is defective in design turns on whether the product was accompanied by an inadequate warning." According to Mutual, that proposition followed from New Hampshire's embrace of comment k to the Restatement (Second) of Torts § 402A (1965), which, Mutual said, provides that "an unavoidably unsafe product is defective in design only if it is

not accompanied by a proper warning." Because "[w]here a product design cannot be made safer, it is judged by the adequacy of its warnings," Mutual argued that a causal link between an allegedly inadequate warning and the plaintiff's injury was essential to a strict liability claim based on an unavoidably unsafe product.

This court accepted Mutual's premise -- that New Hampshire would not hold the manufacturer of an important and unavoidably unsafe product strictly liable so long as it was accompanied by an adequate warning, see Order at 24-25--but rejected Mutual's conclusion that Bartlett's strict liability claim therefore failed for want of proof that the allegedly inadequate warning caused her injury, id. at 23-24. Instead, the court ruled, if Bartlett could prevail at trial on "whether Sulindac is unreasonably dangerous and whether that defective condition caused her injuries . . . Mutual might nonetheless be able to avoid liability for defective design if it can prove, as an affirmative defense, that Sulindac is unavoidably unsafe and had an adequate safety warning." Id. at 26. The court refused to enter summary judgment for Mutual based on that defense, however, because "the adequacy of Sulindac's safety warning is a matter of genuine dispute on this record." Id.

II. Analysis

As noted above, Mutual now argues that—quite apart from the adequacy of the warning—Bartlett's strict products liability claim fails because she cannot prove "a defect in the product." Proving that Sulindac's safety risks outweigh its medical benefits, making it unreasonably dangerous, is not enough, Mutual maintains.² Instead, Mutual says, Bartlett must also prove that Sulindac was "defective"—a concept that Mutual does not attempt to define, but which it insists cannot be proven here, because Sulindac "contains a single active ingredient" and therefore "cannot be made safer, as one would expect of a product containing a design defect."

There are a number of problems with this argument, but the first (and most glaring) is that the New Hampshire Supreme Court expressly rejected it in <u>Vautour</u>. There, the plaintiffs appealed from a directed verdict entered against them on their strict

²In a footnote, Mutual suggests that Bartlett cannot prove even that, because her expert witnesses "do not compare the utility of Mutual's Sulindac to any other medications with respect to their ability to relieve pain and inflammation or to treat patients with . . . any other condition" and "have not even addressed those benefits with respect to Sulindac itself." Because Mutual is not urging reconsideration on this point (and in fact did not even make this argument in support of its summary judgment motion), the court need not consider it here—but will do so at the appropriate point in the proceedings.

products liability claim, arguing that "the superior court erred by requiring them to prove an alternative design as an additional element in the case." 147 N.H. at 153. The defendant, however, urged the court "to adopt the Restatement (Third) of Torts § 2(b) (1998), which requires a plaintiff in a design defect case to prove that the risks of harm posed by the product could have been reduced or avoided by a reasonable alternative design." Id. at 154. The court declined, reasoning that "while proof an alternative design is relevant in a design defect case, it should be neither a controlling factor nor an essential element that should be proved in every case." Id. at 156. Instead, the court concluded, "the risk-utility test as currently applied protects the interests of both consumers and manufacturers in design defect cases." Id.

Under that test, the court explained, "a product is defective as designed 'if the magnitude of the danger outweighs the utility of the product.'" Id. at 154 (quoting William Prosser et al., Prosser and Keeton on the Law of Torts § 99, at 699 (5th ed. 1984)). Thus, because the "plaintiffs presented sufficient evidence that the [product at issue] was unreasonably dangerous pursuant to the risk-utility balancing test," the superior court "erroneously granted the defendant's motion for directed verdict upon the plaintiffs' strict liability, design

defect claim. Under New Hampshire law, the plaintiffs' evidence was sufficient to establish a prima facie case." Id. at 157.

Mutual's argument flies in the face of this explicit holding, which the motion for reconsideration simply ignores. Indeed, its only references to the case, express or implied, are in (1) a string citation with a parenthetical that describes the case as "involving [the] question of whether location of safety stops constituted a defective condition making equipment unreasonably dangerous" and (2) a footnote that, in what appears to be a tacit acknowledgment of Vautour, states that "[e]ven though plaintiff might not be required to establish that a safer alternative design exists, she must still prove that a defect exists." First, while Vautour certainly "involved" the question of the location of the safety stops on a leg press machine, the plaintiff presented no evidence that changing the location of the stops would have prevented his injury. 147 N.H. at 153. Hampshire Supreme Court, however, specifically ruled that no such evidence was necessary because, again, "the plaintiffs presented sufficient evidence that the leg press machine was unreasonably dangerous pursuant to the risk-utility test." Id. at 157. Vautour requires the rejection of Mutual's argument that, even if Bartlett can adduce sufficient evidence that Sulindac's risks outweigh its benefits, her strict products liability claim still

fails because she cannot prove that "a change in design would have avoided the injury" she suffered.

Second, Mutual does not attempt to reconcile its view that a plaintiff must prove that a product is "defective" -- and cannot do so by proving only that its risks outweigh its benefits -- with its concession that a plaintiff "need not prove that a safer alternative design exists." This cries out for an explanation as to how else a plaintiff proves that a product is defective in design. Mutual offers none. Vautour, however, does. Again, it expressly states that "a product is defective as designed if the magnitude of the danger outweighs the utility of the product." 147 N.H. at 154 (quotation omitted). That is precisely how this court articulated Bartlett's strict liability claim in the summary judgment Order--"Sulindac is defective because its safety risks outweigh its medical risks." Order at 23. So Mutual's request for reconsideration rings hollow, particularly in the absence of any effort to meaningfully address the Vautour decision.3

³This court also notes that Mutual's view appears to be inconsistent with comment k of the Restatement (Second) of Torts § 402A (1965), which allows manufacturers to avoid strict liability for defective design if they can prove that their product is important, unavoidably unsafe, and had an adequate warning. See Order at 24-26. There would be no need for comment k if, as Mutual argues, the fact that a product cannot be more safely designed is itself fatal to a strict products liability

In fairness to Mutual, the case on which it relies, Buckingham, did reject the argument that "'defect' is not a 'separate and distinct element of proof' from the 'unreasonably dangerous' element" in affirming the dismissal of a plaintiff's strict products liability claim against cigarette manufacturers. 142 N.H. at 825. The court reaffirmed that it recognizes "the tort of strict liability as set out in the Restatement (Second) of Torts § 402A," which "imposes liability for selling 'any product in a defective condition unreasonably dangerous to the user or consumer' when the product causes injury to the user or consumer." Id. The court reasoned that if "a product is per se defective if it is unreasonably dangerous, then it would be redundant for section 402A to include both the terms 'defective' and 'unreasonably dangerous.'" Id. at 826. The court found further support for this reading in comment i to § 402A, which states that it applies "'only when the defective condition of the product makes it unreasonably dangerous to the user or consumer'" and "cites several products, such as tobacco, whiskey, and

claim for defective design under New Hampshire law (regardless of the product's importance or the adequacy of its warning). Despite the fact that Mutual argued in moving for summary judgment that "New Hampshire courts evaluate a design defect claim involving a pharmaceutical product under comment k," its motion for reconsideration does not address this apparent inconsistency or mention comment k.

butter, that may be dangerous in their intended form . . . but liability will not be imposed absent an additional ingredient which the ordinary consumer would not expect to be present." Id.

Thus, the court ruled, "because the plaintiff has failed to allege separately that cigarettes are 'defective' and 'unreasonably dangerous,' he has failed to state a claim upon which relief may be granted."4 Id. Mutual, however, makes no attempt to reconcile this holding with the New Hampshire Supreme Court's subsequent decision in Vautour, which, again, specifically held that a product is defective if its risks outweigh its benefits so as to make it unreasonably dangerous. 147 N.H. at 154. A federal court exercising diversity jurisdiction over a state-law action, like this court here, "must apply the most recent statement of state law by the state's highest court." Vitkus v. Beatrice Co., 127 F.3d 936, 941-42 (10th Cir. 1997); see also, e.g., Brunner v. Hampson, 441 F.3d 457, 465 (6th Cir. 2006); Lamarque v. Mass. Indem. & Life Ins. Co., 794 F.2d 194, 196 (5th Cir. 1986); Middle Atl. Utils. Co. v. S.M. Dev. Corp., 392 F.2d 380, 384 (2d Cir. 1968); cf. Smith v.

⁴To like effect is the decision by another judge of this court in <u>Gianitsis v. Am. Brands, Inc.</u>, 685 F. Supp. 853, 856-57 (D.N.H. 1988) (Loughlin, D.J.), cited by both the New Hampshire Supreme Court in <u>Buckingham</u> and Mutual here. Like <u>Buckingham</u>, however, <u>Gianitsis</u> was decided prior to <u>Vautour</u>.

F.W. Morse & Co., 76 F.3d 413, 429 (1st Cir. 1996) (following the more "recently decided" New Hampshire Supreme Court case that "speaks directly to the question," rather than an older opinion). Insofar as Buckingham and Vautour are in conflict, then—a point on which, again, Mutual offers no argument at all5—this court must follow Vautour, as the New Hampshire Supreme Court's more recent articulation of its strict products liability rule. See also Kelleher v. Marvin Lumber & Cedar Co., 152 N.H. 813, 831 (2005) ("'a product is defective as designed if the magnitude of the danger outweighs the utility of the product'") (quoting Vautour, 147 N.H. at 154).6

⁵Mutual does not argue, for example, that <u>Buckingham</u>, rather than <u>Vautour</u>, applies here.

⁶Moreover, even assuming (contrary to the express holding of Vautour, as followed in the Order and again here) that New Hampshire law required Bartlett to prove a safer alternative design, this court is skeptical of Mutual's argument, raised repeatedly throughout this litigation, that because Sulindac is a single "molecule and the molecule cannot be changed," no safer alternative design could possibly exist. <u>See, e.g., Brown v.</u> <u>Super. Ct.</u>, 751 P.2d 470, 478 (Cal. 1988) (expressing "serious[] doubt" about such an argument, despite ruling as a matter of California public policy that drug manufacturers should be shielded from strict liability based on defective design). Even in such cases, a plaintiff "might be able to prove that other, less harmful drugs were available to prevent" the indicated condition (here, for example, other NSAIDs), so "the benefit of such alternate drugs could be weighed against the advantages of [the defendant's drug] in making the risk/benefit analysis." That has been one of Bartlett's main arguments from the beginning.

III. Conclusion

New Hampshire law allows a plaintiff to recover in strict products liability by showing that a product is defective in design because its risks outweigh its benefits, and that the plaintiff suffered injury as a result. See Vautour, 147 N.H. at 154. As our court of appeals has observed, this test applies not just to "mass-produced items sold over the counter," but also to prescription drugs. Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 655 (1st Cir. 1981) (applying New Hampshire law). That is the law this court applied in the summary judgment Order, and will continue to apply here. For the foregoing reasons, Mutual's motion for reconsideration is DENIED.

SO ORDERED.

Joseph N. Laplante

United States District Judge

Dated: July 30, 2010

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⁷Document no. 263.

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