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This Week's Feature
Published 8-30-17 by DRI

Trejo v. Johnson & Johnson: The Death of Design Defect in California?

by Amanda Villalobos and Nick Janizeh

Product liability lawyers in the medical device and pharmaceutical sphere know all too well which causes of action will likely be brought against their defendant-manufacturer clients—claims for failure to warn, manufacturing defect, design defect, breach of warranty, fraud—the list goes on. But thanks to a recent appellate decision out of California, that list might just get a little shorter. With *Trejo v. Johnson & Johnson*, a California Court of Appeal put what could possibly be the final nail in the coffin for design defect-based claims.

In *Trejo v. Johnson & Johnson*, 220 Cal. Rptr. 3d 127 (Cal. Ct. App. June 30, 2017), a plaintiff sued McNeil Consumer Healthcare (McNeil) and Johnson & Johnson after he developed Stevens-Johnson syndrome—a rare skin disorder thought to be triggered by an allergic reaction to medication—which he alleged was caused by his use of Motrin, an over-the-counter ibuprofen medication manufactured and sold by McNeil. *Id*. at 136. The plaintiff claimed, among other allegations, that the defendants were liable under strict liability and negligent design-defect theories because the defendants should have withdrawn Motrin from the market and sold a product that contained dexibuprofen—an alternative active ingredient with fewer side effects. *Id*. at 153–54. At trial, the jury found McNeil liable for both negligent and strict liability design defect and negligent failure to warn and awarded the plaintiff over $31 million in compensatory damages and over $15 million in punitive damages. *Id*. at 138.

Addressing the design-defect claims on appeal, the court applied *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), and *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 808 F.3d 281 (6th Cir. 2015), to find that the plaintiff's design-defect claims were preempted by federal law. *See id.* at 158–165. Under the plaintiff's theory, the design of

Motrin was inherently defective because the defendants used ibuprofen instead of dexibuprofen. *Id*. at 163. But the appellate court rejected that theory, concluding that federal law prevented the defendants "from changing the design of Motrin by selling dexibuprofen without prior FDA approval." *Id*. As the *Trejo* court noted, developing an alternatively designed version of Motrin that substituted dexibuprofen for ibuprofen would have resulted in a new drug, which would have therefore required both that (1) McNeil submit a New Drug Application for the alternatively designed product, and (2) the FDA approve the alternate product. *See id.* at 163–64. Under these circumstances, it would have been impossible for the defendants to comply simultaneously with both a state law duty to change the formulation of Motrin and with federal drug law. *Id*. at 164. The court similarly rejected the notion that McNeil should have stopped selling Motrin to avoid liability, explaining that *Bartlett* rejected the reasoning that the manufacturer could escape the impossibility of complying with both its federal- and state-law duties by choosing not to make the drug at all. *Id*. at 161.

Before *Trejo*, California law barred design-defect claims only for prescription drugs. *See Brown v. Superior Ct.*, 751 P.2d 470, 484 n.14 (Cal. 1988). In *Brown*, the highest court in California reasoned that public policy militates against holding prescription drug manufacturers liable for strict liability design defect. *See id.* ("[P]rescription drugs are not subject to strict liability for design defects."). The court specifically pointed to the likelihood that they would be "reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial" for "fear of large adverse monetary judgments." *Id*. at 479. In addition, drug manufacturers would face "the additional expense of insuring against such liability . . . and of research programs to reveal possible dangers not detectable by available scientific methods[, which] could place the cost of medication beyond the reach of those who need it most." *Id*.

Trejo is the first California case to extend the protections afforded by *Brown* to over-the-counter medications. The court's reasoning in *Brown* had previously only been extended to implanted medical devices. *See, e.g.*, *Hufft v. Horowitz*, 5 Cal. Rptr. 2d 377, 379–84 (Cal. Ct. App. 1992) (penile prostheses); *Plenger v. Alza Corp.*, 13 Cal. Rptr. 2d 811, 817–19 (Cal. Ct. App. 1992) (intrauterine devices); *Artiglio v. Superior Ct.*, 27 Cal. Rptr. 2d 589, 592 (Cal. Ct. App. 1994) (breast implants).

In short, *Trejo* delivered what is likely a killing blow to design defect-based claims in California. It makes clear that plaintiffs are precluded from pursuing design-defect claims premised on the theory that a defendant manufacturer should have utilized a safer alternative formulation when designing over-the-counter and prescription drugs. And we expect that the analysis in *Trejo* will have far-reaching implications beyond California as additional courts address the issue of whether *Bartlett*'s impossibility analysis should apply outside the prescription drug context.

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