Schnader
ATTORNEYS AT LAW

Schnader Harrison Segal & Lewis LLP

NEW YORK PENNSYLVANIA CALIFORNIA WASHINGTON, D.C. NEW JERSEY DELAWARE

PRODUCT LIABILITY ALERT

JULY 2013

DOES *MUTUAL PHARMACEUTICAL CO., INC. V. BARTLETT* HERALD THE DEMISE OF THE "FAILURE-TO-WITHDRAW" THEORY?

By Carl J. Schaerf and Kerry C. O'Dell

In most states that use a "risk utility" test to determine whether a product is "not reasonably safe" (i.e. defective) as designed, an alternative design for the product is generally considered to be a critical element of the plaintiff's proof. *See, e.g.*, Restatement (Third) of Torts, § 2; *Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 108, 7462 N.Y.S.2d 398, 402-03, 450 N.E.2d 204 (1983) (outlining New York's risk utility approach). Where an alternative design cannot be claimed or argued, the argument is typically failure to warn. *See, e.g., Liriano v. Hobart Corp.*, 92 N.Y.2d 232, 677 N.Y.S.2d 674, 700 N.E.2d 303 (N.Y. 1998) (manufacturers can be liable for failure-to-warn even if the substantial modification defense would preclude liability for design defect).

Where a plaintiff can argue neither alternative design nor failure to warn, one fall back position is that the product is so dangerous, and its danger so far exceeds its utility, that it ought not have been marketed at all. This theory, often called "failure-to-withdraw" or "stop-selling" theory, is typically an unappealing one for a plaintiff. Products enter the stream of distribution, and become successful, because of their utility. Presumably the plaintiff, plaintiff's employer, or plaintiff's doctor found the product to be useful, which is why the product was used. The more remote a plaintiff's argument of danger or defect is, the less likely any court or jury is to allow for a liability finding. It is, in short, a big pronouncement for a court or jury to say, without proof of a feasible alternative design or a viable warning theory, that a product should be outright withdrawn from distribution. This fringe theory has been advanced as to certain types of guns, tobacco products, alcoholic beverages and, pertinent to this *Alert*, generic drugs.

The maker of a generic drug, in order to receive federal approval, must show that the drug has the same active ingredients, route of administration, dosage form, strength, and labeling as its brand-name equivalent, i.e., an identical design and label. 21 U.S.C. §§ 355(j)(2)(A)(ii) and (iii). Federal law prohibits generic pharmaceutical manufacturers from independently changing their drugs' labels. *PLIVA v. Mensing*, 131 S. Ct. 2567, 180 L.Ed. 2d 580 (2011) (failure-to-warn claims against generic manufacturers are pre-empted by the FDCA's prohibition on changes to generic drug labels). In *Mensing*, the Eighth Circuit held that the manufacturers of metoclopramide, or generic Reglan, could have "simply stopped selling the product" after learning that patients were developing tardive dyskinesia. *See Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009), rev'd, 131 S. Ct. 2567, 180 L.Ed. 2d 580 (2011). The Supreme Court reversed *Mensing* without specifically addressing the "failure-to-withdraw" theory, and on remand, the Eighth Circuit vacated that portion of its opinion. *See Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011).

Afterwards, most federal courts determined that *Mensing* held that "failure-to-withdraw" claims were pre-empted. *See, e.g., Smith v. Wyeth, Inc.*, 657 F.3d 420, 424 (6th Cir. 2011); *Gardley-Starks v. Pfizer, Inc.*, No. 4:10-cv-0099, 2013 U.S. Dist. LEXIS 3966, at *26 (N.D. Miss. Jan. 10, 2013); *Jacobsen v. Wyeth, LLC*, 2012 WL 3575293, at *9-11 (E.D. La. Aug. 20, 2012); *Cooper v. Wyeth*, No. 09-929-JJB, 2012 WL 733846, at *6 (M.D. La. Mar. 6, 2012); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 2012 WL 718618, at *2-3 (E.D. Ky. Mar. 5, 2012) ("*Darvocet*"); *Moretti v. Mutual Pharm. Co.*, 852 F. Supp. 2d 1114, 1118 (D. Minn. 2012); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 658-59 (D. Md. 2011). The "failure-to-withdraw" theory was ridiculed as "invalid," *Strayhorn v. Wyeth Pharms. Inc.*, 887 F. Supp. 2d 799, 820 (W.D. Tenn. 2012) and an "oversimplified solution." *Darvocet*, 2012 WL 718618, at *2-3.

The First Circuit Court of Appeals, however, distinguished *Mensing* and reasoned that generic manufacturers could simply "choose not to make the drug at all." *See Bartlett v. Mutual Pharm. Co., Inc.*, 678 F. 3d 30, 37 (1st Cir.

(continued on page 2)

(continued from page 1)

2012), rev'd, 133 S. Ct. 2466, 186 L.Ed. 607 (2013). Karen Bartlett was prescribed Clinoril, was given generic sulindac by her pharmacist, and suffered an extremely severe case of toxic epidermal necrolysis.[1] She brought a lawsuit in New Hampshire, which was removed to federal court. Bartlett's failure-to-warn claims were dismissed by the trial court based on the doctor's admission that he had not read the package insert. A jury found Mutual liable, and the First Circuit affirmed. 678 F.3d. 30.

In overturning the First Circuit, the Supreme Court reiterated its prior holding that state law design-defect or labeling claims against generic manufacturers are pre-empted because any feasible alternative design or label would require a new federal approval. *See Mutual Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. at 2476.[2]

The Supreme Court expressly rejected[3] the "failure-to-withdraw" theory which was relied upon by the trial court and the First Circuit:

> Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be "all but meaningless."
>
> The incoherence of the stop-selling theory becomes plain when viewed through the lens of our previous cases. In every instance in which the Court has found impossibility pre-emption, the "direct conflict" between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting.

133 S. Ct. at 2477.

Within days of the Supreme Court's holding in *Bartlett*, New Jersey Superior Court Judge Carol Higbee held that plaintiffs' "failure to suspend" argument, if successful, "would render impossibility preemption largely meaningless" and "goes beyond the duties and remedies that have ever been applied in state courts." *In re Isotretinoin Litig.*, No. ATL-L-1321-09, 2013 N.J. Super. Unpub. LEXIS, at *23-24 (N.J. Sup. Ct. Jun. 28, 2013) (holding that products liability claims against manufacturers of generic Accutane were pre-empted) ("*Isotretinoin*").

Bartlett made clear that the "failure-to-withdraw" theory is dead on arrival in litigation involving generic drugs. More importantly, *Bartlett* reiterated that state laws cannot act to ban federally-approved products, a conclusion reached by many other courts. *See Gross*, 825 F. Supp. 2d at 659 ("no state law duty that would compel generic manufacturers to stop production of a drug" could "exist, as it would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce"); *see also Ramirez v. Plough, Inc.*, 25 Cal. Rptr. 2d 97, 108-09, 6 Cal. 4th 539, 863 P.2d 167 (Cal. 1993) (finding no liability under California law for failing to withdraw OTC children's aspirin in early 1986 when FDA concluded product warnings about Reye's syndrome at that time were adequate); and *see FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 137-38, 120 S. Ct. 1291, 146 L.Ed.2d 121 (2000) ("Congress, however, has foreclosed the removal of tobacco products from the market."). Liability for "failure-to-withdraw" is essentially such a ban, and as such, is pre-empted.

Bartlett may ultimately extend further. In many jurisdictions, the availability of an alternative design is only a single factor in the risk utility test for design defect, though

(continued on page 3)

1. "In 1978, the FDA approved a nonsteroidal anti-inflammatory pain reliever called 'sulindac' under the brand name Clinoril. When Clinoril's patent expired, the FDA approved several generic sulindacs, including one manufactured by Mutual Pharmaceutical … In a very small number of patients, NSAIDs — including both sulindac and popular NSAIDs such as ibuprofen, naproxen, and Cox2-inhibitors — have the serious side effect of causing two hypersensitivity skin reactions characterized by necrosis of the skin and of the mucous membranes: toxic epidermal necrolysis, and its less severe cousin, Stevens-Johnson Syndrome." 133 S. Ct. at 2471-72.

2. *Bartlett* is concerned primarily with conflict pre-emption and impossibility pre-emption — when compliance with both federal and state law is impossible. This article does not address the principles of pre-emption announced in *Bartlett*, nor do we endeavor to mediate between the majority and the dissent over what issues were really at stake and preserved in the underlying litigation. For purposes of this *Alert*, we assume the majority's recitation of the facts and record to be accurate.

3. Footnote 3 of the decision acknowledges "the rare case in which state or federal law actually requires a product to be pulled from the market" but offers no reason why such a claim would be "pre-empted" under federal law, particularly a federal law disclaiming pre-emptive effect.

(continued from page 2)

certainly an important factor and typically a decisive one. *Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 108, 7462 N.Y.S.2d 398, 402-03, 450 N.E.2d 204 (1983). Now, if "failure-to-withdraw" is considered dead letter beyond the generic drug context (and there is no reason to believe that the Court's rationale is limited to generic drugs), an alternative design or feasible alternative warning claim will truly be a requirement in product litigation. This is a new wind in product liability, and one that defense counsel can try to expand. It means that Courts are less able to leave a case alive for trial, and potentially gives real meaning to the risk utility standard from a defense perspective.

Adamo v. Brown & Williamson Tobacco Corp., 11 N.Y.3d 545 (2008) involved the risks and utilities involved with light as opposed to regular cigarettes. The plaintiffs' case failed due to a failure to show equivalent taste between light and regular cigarettes:

> It is not necessary in every product liability case that the plaintiff show the safer product is as acceptable to consumers as the one the defendant sold; but such a showing is necessary where, as here, satisfying the consumer is the only function the product has. A cigarette is a different kind of product from the circular saw in *Voss*, whose function was to cut wood, or the molding machine in *Robinson v Reed-Prentice Div. of Package Mach. Co.* (49 NY2d 471 [1980]), whose function was to melt and form plastic.

The argument that cigarettes should not be sold at all hovered over the case as shown by this comment:

> Of course we are conscious, as everyone must be, of the irony in speaking of cigarettes' 'utility.' A strong argument can be made that, when the pleasure they give smokers is balanced against the harm they do, regular cigarettes are worse than useless. But it is still lawful for people to buy and smoke regular cigarettes, and for cigarette companies to sell them. To hold, as plaintiffs ask, that every sale of regular cigarettes exposes the manufacturer to tort liability would amount to a judicial ban on the product. If regular cigarettes are to be banned, that should be done by legislative bodies, not by courts.

In a sense, the Supreme Court is looking at the "failure-to-withdraw" in a similar way as the New York Court of Appeals did in *Adamo*. If it is feasible to make a better product with the same utility, the decision is for the Court and jury. If it is not feasible, there is no claim.

Bartlett was lost in the shuffle of a lot of other important decisions on voting rights and DOMA. Over time, it may be viewed as a watershed event in product liability. It is bound to have an influence, and be extremely useful to defendants and defense counsel even outside of the generic drug realm. ◆

For more information about Schnader's Product Liability Practice Group or to speak with a member of the Firm, please contact:

Matthew S. Tamasco, Co-Chair
212-973-8105
mtamasco@schnader.com

Keith E. Whitson, Co-Chair
412-577-5220
kwhitson@schnader.com

Carl J. Schaerf
212-973-8005
cschaerf@schnader.com

Kerry C. O'Dell
202-419-4206
ko'dell@schnader.com