SOMETIMES A GOOD DEFENSE IS THE BEST OFFENSE:

A Summary of Certain Useful Product Liability Affirmative Defenses

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Most product liability litigators are well aware of many of the standard affirmative defenses to raise at the responsive pleading stage. Statute of limitations, statute of repose, comparative fault or contributory negligence, and superseding cause are all common defenses used liberally in product liability—and other—litigation. *See generally* Fed. R. Civ. P. 8(c) (stating that "[i]n responding to a pleading, a party must affirmatively state any avoidance or affirmative defense" and enumerating several such defenses). This article, however, outlines a handful of less familiar, and perhaps underutilized, product liability affirmative defenses, to serve as a reminder that these defenses exist and may be applicable, depending on the unique facts and applicable law in your case. The defenses described below may not be as widely used as their more common counterparts, but they can be every bit as viable and effective.

THE COMPONENT SUPPLIER DEFENSE

In general, this defense provides that the manufacturer of a nondefective component is not liable for injuries sustained from the use of a larger defectively designed product into which the component is integrated. *See, e.g.*, *Restatement (Third) of Torts (Product Liability)* § 5. The common rationale for application of this defense is twofold. First, courts note that a fundamental requirement of strict liability theory is that the product malfunctions. *See, e.g.*, *Crossfield v. Quality Control Equip. Co., Inc.*, 1 F.3d 701, 704 (8th Cir. 1993). In cases where the component supplier defense is applicable, however, the component part is not defective and operates as it is intended. The part becomes hazardous only when incorporated into the larger machine system. Thus, the danger arises from the design or manufacture of the larger machine, not the component part. Accordingly, the designer of the machine is in the best position to know of these dangers and prevent them from causing injury. *See Crossfield*, 1 F.3d at 704.

The second common rationale used by courts is that the component supplier has no duty to warn end users because the supplier has no control over the design and function of the machine into which its product is integrated. *See, e.g.*, *Childress v. Gresen Mfg. Co.*, 888 F.2d 45, 49 (6th Cir. 1989); *Fleck v. KDI Sylvan Pools, Inc.*, 981 F.2d 107, 118 (3d Cir. 1992); *Jacobini v. V. & O. Press Co.*, 588 A.2d 476, 479 (Pa. 1991); *Zaza v. Marquess and Nell, Inc.*, 675 A.2d 620, 628 (N.J. 1996). Courts find that imposing liability upon the component supplier would unreasonably extend liability because it would require the supplier to have expert knowledge in the integrated product. *See Travelers Ins. Co. v. Chrysler Corp.*, 845 F. Supp. 1122, 1126 (M.D.N.C. 1994); *Crossfield*, 1 F.3d at 704. Indeed, imposing liability "would mean that suppliers would be required to hire machine design experts to scrutinize machine systems that the supplier had no role in developing. Suppliers would be forced to provide modifications and attach warnings on machines which they never designed nor manufactured." *Id.*

To the extent you can establish facts showing that the product you supplied was not defective or that you had no control over, or input into, the design of the larger machine system, you may have a viable defense to liability.

THE LEARNED INTERMEDIARY/SOPHISTICATED USER DOCTRINE

The learned intermediary doctrine, also often referred to by courts as the "sophisticated user doctrine," provides that a manufacturer may rely on a sophisticated and knowledgeable customer to warn the end user of the risks of the product. *See, e.g.*, *West v. Searle & Co.*, 806 S.W.2d 608, 613 (Ark. 1991); *Restatement (Third) of Torts (Product Liability)* § 6. While the rule typically arises in product liability actions brought against prescription drug manufacturers, the rule has been applied to other products as well. *See Singleton v. Manitowoc Co.*, 727 F. Supp. 217, 225 (D. Md. 1989) (eliminating manufacturer's duty to warn of risks of crane, under sophisticated user doctrine, where purchaser was a knowledgeable user of cranes); *Portelli v. I.R. Constr. Prod. Co.*, 554 N.W.2d 591, 601 (Mich. Ct. App. 1996) (finding manufacturer of door had no duty to warn ultimate user when purchaser was a sophisticated user); *Restatement (Second) of Torts* § 388, cmt. n (listing factors to consider in determining whether warning to intermediary discharges manufacturer's duty to warn). Whether a party is a "learned" intermediary is a fact-intensive question that will hinge on the party's degree of knowledge, experience, and sophistication with the particular product at issue. *See In re TMJ Implants Prod. Liab. Litig.*, 872 F. Supp. 1019, 1029–30 (D. Minn. 1995).

There are several reasons for applying the learned intermediary rule. First, it may be virtually impossible for a manufacturer that does not interact directly with the ultimate user to warn that person. *See West*, 806 S.W.2d at 613; *Hill v. Searle Labs.*, 884 F.2d 1064, 1070 (8th Cir. 1989). Indeed, requiring manufacturer's warnings to be given to the ultimate user might be futile because the manufacturer cannot guarantee that warnings emblazoned on its packages will remain intact until reaching the ultimate user. *See In re TMJ Implants Prod. Liab. Litig.*, 872 F. Supp. at 1029. Accordingly, the intermediary is usually in the best position to warn the user of the product. *See Singleton*, 727 F. Supp. at 227. Second, in the context of pharmaceuticals, application of the learned intermediary doctrine helps preserve the doctor-patient relationship. *West*, 806 S.W.2d at 613. The rule ensures that the doctor is the patient's source for a consistent warning regarding product risks. *See In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d 272, 288 (S.D.N.Y. 2001). Requiring the manufacturer to warn the patient, on the other hand, would threaten to undermine the patient's adherence to his physician's informed opinion regarding the patient's medical care. *Id.*

In the pharmaceuticals context, there is one key exception to the learned intermediary rule that may apply in your jurisdiction. According to the "mass immunization" exception, a drug manufacturer whose product is distributed to patients en masse, and not as a prescription drug, may have a duty to directly warn patients of the dangers of its product. *See Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977) (finding manufacturer is required to warn patient when it has knowledge that vaccine is administered with little independent medical judgment about the patient); *Mazur v. Merck & Co.*, 742 F. Supp. 239, 255–56 (E.D. Pa. 1990) ("[T]he mass immunization exception to the learned intermediary rule recognizes that there may be circumstances when by reason of the very size of a program, a manufacturer will know or should know that its product will not be dispensed as a prescription drug; in short the manufacturer can foresee that there will be no individualized balancing of the medical benefits and risks."); *see also Restatement (Third) of Torts (Product Liability)* § 6, cmt. c.

Thus, to the extent a manufacturer can demonstrate that it has little or no control over the communication of a warning to the ultimate user, and that the person who interacts directly with the ultimate user is knowledgeable about the risks of the product, the manufacturer may have a strong defense to liability.

THE GOVERNMENT CONTRACTOR DEFENSE

The government contractor defense may preclude state tort liability for manufacturers when the following three-part test is met: (i) The United States approved "reasonably precise specifications"; (ii) the "equipment conformed to those specifications"; and (iii) the "supplier warned the government about the dangers" associated with the use of the equipment that were known to the supplier, but not to the government. *Boyle v. United Technologies Corp.*, 487 U.S. 500, 512 (1988). Whether this defense applies to claims other than product liability claims, such as intentional torts, is unclear. *See, e.g.*, *In re "Agent Orange" Product Liability Litigation*, 373 F. Supp. 2d 7, 18 (E.D.N.Y. 2005) ("the government contractor defense does not apply to violations of human rights, norms of international law and related theories"); *but see Ibrahim v. Titan Corp.*, 2007 U.S. Dist. LEXIS 81794, *8–9 (D.D.C. Nov. 6, 2007) (finding that the government contractor defense may preempt common-law tort claims against contractors performing combatant activities if the "[contractor's] employees were acting under the direct command and exclusive operational control of the military chain of command"). At least one court, however, has extended the defense to contracts for services, rather than simply to procurement contracts. *See Hudgens v. Bell Helicopters*, 328 F.3d 1329, 1334 (11th Cir. 2003) (holding that government contractor defense applied to claims that defendant negligently maintained or repaired military helicopter).

THE SEALED CONTAINER DEFENSE

This statutory defense shields sellers from product liability claims if the "product was acquired and then sold or leased by the seller in a sealed container or in an unaltered form" and the seller had no knowledge of, nor could it discover, the defect. Maryland Code Ann. § 5-405; *see also, e.g.*, N.C. Gen. Stat. § 99B-2; Tenn. Code Ann. § 29-28-106; Del. Code Ann. 18 § 7001. In some jurisdictions, the defense is not strictly limited to products entirely enclosed or "sealed" at the time of sale, but rather covers any product that is sold in a "box, container, package, wrapping, encasement, or housing of any nature that covers it" or "unpackaged products that [are] sold in an unaltered form." *See* Maryland Code Ann. § 5-405*; see also Quirk v. Home Depot U.S.A.*, 2005 WL 3448039, at *1 (D. Md. Dec. 15, 2005); N.C. Gen. Stat. § 99B-2(a) ("No product liability action, except an action for breach of express warranty, shall be commenced or maintained against any seller when the product was acquired and sold by the seller in a sealed container or … *under circumstances in which the seller was afforded no reasonable opportunity to inspect the product*") (emphasis added).

In order to invoke the defense, a seller must typically establish that (i) the product was acquired and subsequently sold in either a sealed container or unaltered form; (ii) it was unaware of the defect and could not have discovered such defect; (iii) it did not designate or otherwise create specifications for the defective product; and (iv) it did not alter, modify, or mishandle the product prior to sale. *See, e.g.*, Maryland Code Ann. § 5-311(b); Del. Code Ann. 18 § 7001. Indeed, where these elements are present, product liability claims against sellers—and, in most cases, wholesalers, distributors, or retailers—may be barred.

CONCLUSION

As always, defendants facing product liability claims must develop defense strategies early in the case. Any strategy should include a thorough determination as to what, if any, affirmative defenses, such as those summarized above, apply. In certain situations, raising these affirmative defenses may not only underscore important litigation themes but could also result in a favorable dispositive ruling prior to trial. *See Hudgens*, 328 F.3d at 1345 (finding that the defendant "demonstrated the absence of any genuine issue of material fact regarding its entitlement to the [government contractor defense]" and affirming summary judgment on its behalf). ■

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