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PRACTICE TIP

A Primer on Preserving Statute Of Repose Defenses

By Doug Pfeifer

From the first year of law school, attorneys know that one of the first things they must determine when responding to a complaint is whether the claims are time-barred, either by an applicable statute of limitation, or statute of repose. Most attorneys are familiar with equitable tolling of limitation periods, but product liability attorneys and their clients are often less acquainted with tolling or revival of periods of repose through post-sale actions by the manufacturer or seller of the product at issue. Statutes of repose, like statutes of limitation, vary from state to state, but generalities about the effect of post-sale manufacturer or seller conduct have emerged. This article discusses the emerging law and concludes with some advice on how to foresee and deal with that law.

What Is a Statute of Repose?

A statute of repose differs from a statute of limitations. Where a statute of limitations establishes the time period within which a lawsuit must be commenced after a cause of action accrues, a statute of repose extinguishes the cause of action after a fixed time period, usually measured from the delivery date of the product, regardless of when the

continued on page 6

Proactive Preparation of Defense of Post-Recall Litigation

By Lori Cohen and Christiana C. Jacxsens

In the present environment, it is not surprising that a pharmaceutical or medical device recall may lead to litigation. Recalls often generate a large amount of media attention. In addition, attorneys representing plaintiffs frequently monitor the Food and Drug Administration (FDA) Web site for new recall information to solicit clients. After a pharmaceutical or medical device manufacturer initiates a recall, its duties pursuant to FDA laws and guidelines do not end there. The FDA has set out certain responsibilities and steps that a manufacturer must or should follow after initiating a recall. Pharmaceutical and medical device manufacturers, however, can effectively combine their post-recall duties and responsibilities with a proactive preparation of a defense of potential litigation.

Recalls Generally

The FDA assigns a classification to recalls of pharmaceutical and medical devices based on the relative degree of health hazard of the product being recalled: Class I, Class II, and Class III recalls, with a Class I recall having the highest degree of health hazard. *See* 21 C.F.R. § 7.41(b). A Class I recall is defined as "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." 21 C.F.R. § 7.3(m)(1). A Class II recall is defined as "a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." 21 C.F.R. § 7.3(m)(1). Finally, a Class III recall is defined as "a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences." 21 C.F.R. § 7.3(m)(1).

Most pharmaceutical and medical device recalls are voluntarily initiated by manufacturers either on their own or by FDA request. Indeed, the FDA is only authorized to order a recall and determine its scope and extent in certain situations

continued on page 2

In This Issue

Rule 502

continued from page 5

counsel reviews responses to complaints or provides other privileged input, that information should be copied from the database and segregated from the general document collection at the beginning of the collection phase.

Counsel and the client should collaborate to cull privileged documents from the relevant documents previously identified through a relevancy word search. If incident reports, complaints, or discussions of product problems have been tracked in a database as noted above, segregation of privileged material residing in the database may be straightforward. If, on the other hand, such reviews were recorded and discussed via e-mail — in so-called "unstructured data" — the records must be identified through privilege search terms and other strategies, pulled from the relevant document set and subjected to close scrutiny for privilege through careful review by senior lawyers. The "non hits" — which will comprise the vast bulk of the data set — should then be reviewed by junior lawyers or other legal professionals who receive training in the identification of privileged documents.

Counsel should conduct sampling in the "non-hits" — the document set that remains after the privileged "hits" have been removed.

Counsel should conduct sampling in the "non-hits" — the document set that remains after the privileged "hits" have been removed. This is the step that lawyers skipped in *Victor Stanley* and *Rhoads*, and there is no excuse for this omission. Neither case specifies the requirements of such sampling, such as what proportion of documents must be sampled, but common sense dictates that a sample should be randomly selected; for example, one in every 100 documents.

Conclusion

Litigants today struggle with the review of large volumes of electronic documents. It is difficult and expensive to identify relevant and responsive documents, and the fear of inadvertently disclosing privileged documents compounds the difficulty. Federal Rule of Evidence 502(d) allows parties to "claw back" privileged documents pursuant to a court-approved agreement. However, this provision may provide small comfort to a party whose privileged communications have been read by its adversary. Although Rule 502 appears to relieve parties of the obligation of conducting any privilege review whatsoever, the prudent lawyer will not forego this step, and will follow the methods outlined in *Victor Stanley* that demonstrate "reasonableness." Even though, under Rule 502(d), reasonableness is not required, it is reasonableness that keeps privileged documents out of the adversary's hands.

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Practice Tip

continued from page 1

cause of action accrues. *Stuart v. American Cyanamid Co.*, 158 F.3d 622, 627 (2nd Cir. 1998). Thus, a statute of repose bars a claim even if the statute of limitation does not. The policy underlying statutes of repose posits that prohibiting claims after a certain period of time allows manufacturers to plan their affairs with a degree of certainty unburdened by unknown potential liability. *See Reese v. Nat'l Mine Serv. Co.*, 672 F. Supp. 1116, 1118 (S.D. Ill. 1987); *Black v. Henry Pratt Co.*, 778 F.2d 1278, 1284 (7th Cir. 1985).

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Though many states have statutes of repose that apply in the product liability context, the majority of states do not. Nonetheless, a statute of repose, where applicable, can in some cases offer a complete defense. Among the states that do have statutes of repose, the repose periods can differ greatly. Illinois, for example, has a twelve-year period of repose, see 735 Ill. Comp. Stat. 5/13-213(b)), while North Carolina has a six-year period of repose, *see* N.C. Gen Stat. § 1-50(6). Nebraska has a ten-year period of repose for products manufactured in Nebraska, but borrows the applicable repose period for products manufactured elsewhere as long as the period is not less than ten years. Neb. Rev. Stat. § 25-224. The General Aviation Revitalization Act ("GARA"), which was signed into law in 1994, created an 18-year federal statute-of-repose for the general aviation industry. Cases decided under GARA will not be included in this article due to their specific nature.

What Actions by a Manufacturer or Seller Will Toll or Restart the Statute?

Post-sale actions by a manufacturer or seller can toll or revive periods of repose, depending upon the nature and extent of the actions. The period of repose will probably toll or revive if the manufacturer or seller regains control of the product and makes significant changes to the product, but not when simple maintenance of the product is all that is involved. The more the manufacturer or seller is involved, the greater the tendency of courts to hold that their conduct tolls or revives the period of repose. Conduct by someone other than the manufacturer or seller, not acting on behalf of the manufacturer or seller, will not arrest the running of the repose period. *See Masters v. Hesston Corp.*, 291 F.3d 985, 989-90 (7th Cir. 2002). Even then, absent conduct tantamount to an overhaul, ordinary

continued on page 9

Food Safety

continued from page 8

and safety of industrially produced food." *Id*. at 952. If that challenge is met, nothing prevents any of us from planting our own organic garden or buying from local farms we know and trust. Some good, specific recommendations Maki makes include the following:

- Expand FoodNet;
- Monitor more efficiently;
- Research;
- Require traceability;
- Address antibiotics;
- Focus on food preparation facilities; and
- Food irradiation.

Interestingly, Maki closes with the ultimate food safety recommendation, that is already implemented by meat producers and approved for certain produce — irradiation of food. This is thought to be safe because the low dose of ionized radiation needed to eliminate pathogens is too low to make the food radioactive or dangerous to human consumption. Maki notes, "Research has shown that irradiation kills pathogens or markedly reduces pathogen counts without impairing the nutritional value of food or making it toxic, carcinogenic, or radioactive." *Id*. at 953. *See also* Michael T. Osterholm, Ph.D., M.P.H. and Andrew P. Norgan, The Role of Irradiation in Food Safety, 350 *New Eng. J. Med.*, Apr. 2004, at 1898.

Agencies that have endorsed the radiation of food include the FDA, the CDC, the USDA, the American Medical Association, the World Health Organization and the European Commission's Scientific Committee on Food. Irradiation of fresh meat has been allowed in the United States since 1997, and in 2008, the FDA approved irradiation of iceberg lettuce and spinach. Maki writes that "The CDC has estimated that irradiation of high-risk foods could prevent up to a million cases of bacterial food borne disease each year in North America." *Id*.

CONCLUSION

As Congress and the Obama administration attempt to toughen up food safety measures in the United States, policymakers will be well served to be attentive to Dr. Maki's recommendations and include within the program a public relations campaign to help the public accept the concept of irradiation of high-risk foods. The proposed legislation, coupled with Maki's suggestions, has the potential to make peanuts, peppers, pistachios, and all high-risk foods safer to eat.

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Practice Tip

continued from page 6

maintenance by or on behalf of a manufacturer or seller will not toll or restart a statute of repose. *Hayes v. Otis Elevator Co.*, 946 F.2d 1272, 1277 (7th Cir. 1991).

Thus, the question becomes, when do the actions of a manufacturer become more than ordinary maintenance? Examination of a number of cases in the 1980s and early 1990s began to flesh out an answer to this question.

In 1983, the United States District Court for the Southern District of Indiana denied summary judgment for the manufacturer of a 15-year-old printing press where the press had been reconditioned by the manufacturer's successor four years prior to the plaintiff's injury. *Denu v. Western Gear Corp.*, 581 F. Supp. 7, 8 (S.D. Ind. 1983). Though the court did not have enough information to determine what changes, if any, had been made to the press, the court held that "The extent and nature of the manufacturer's alterations, modification or reconditioning of the product are certainly material questions of fact which have a bearing on whether the manufacturer has introduced a 'new' product into commerce and whether he should be held liable for defects in that product."

In *Fugate v. AAA Mach. & Equip. Co.*, 593 F. Supp. 392, 393 (E.D. Tenn. 1984), the court held that "a piece of machinery that is substantially rebuilt or reconditioned becomes a 'new' product for the purpose of a products liability action and that a statute of [repose] begins to run from the date of its sale." Therefore, it was a fact question whether the grinding wheel at issue qualified as a "new" product based on its reconditioning.

Courts have recognized, however, that changes to a product must be proximately related to the injury. "[P]ermitting the sale of replacement parts to extend or toll the statute of limitations would subject a manufacturer to virtually perpetual liability for unreasonably dangerous conditions and defects existing in a product as originally delivered." *Black v. Henry Pratt Co.*, 778 F.2d 1278, 1284 (7th Cir. 1985) (holding the sale of a replacement part unrelated to the alleged defect or unreasonably dangerous condition for the original product does not extend or toll the statute of limitations); *Hinds v. Compair Kellogg*, 776 F. Supp. 1102, 1107 (E.D. Va. 1991) (holding that replacement of two components did not constitute a new introduction into commerce where the subject air compressor never went through any substantial overhaul or reconditioning, and the manufacturer never reacquired possession, custody, or control of the air compressor after it was sold).

In 1993, the Seventh Circuit synthesized these cases and described the circumstances under which a period of repose will restart. *Richardson v. Gallo Equip. Co.*, 990 F.2d 330 (7th Cir. 1993). First, the court explained, "any reconstruction or reconditioning (as distinct from a mere repair — a familiar distinction in other areas of law, *see, e.g., Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 81 S. Ct. 599, (1961)) which has the effect of lengthening the useful life of a product beyond what was contemplated when the product was first sold starts the statute of repose running 'new.'" The court noted that, without this rule, a statute of repose would create the incentive for manufacturers to reconstruct or recondition old products rather than build new ones. *Aro*, cited by the *Richardson* court as defining the different between repair and reconstruction or reconditioning, was a patent case that held that "reconstruction of a

continued on page 10

Practice Tip

continued from page 9

patented entity, comprised of unpatented elements, is limited to such a true reconstruction of the entity as to 'in fact make a new article,' after the entity, viewed as a whole has become spent." *Aro*, 365 U.S. at 346, 81 S. Ct. at 604 (citations omitted). Second, the court explained, "by incorporating a defective component into an old product the incorporator cannot obtain the protection from suit that the statute of repose gave the old product."

A later decision from the Nebraska Supreme Court further expounded on *Richardson* and illustrates how the law that has developed in this area applies when one entity refurbishes a product manufactured by a separate entity. *Divis v. Clarklift of Nebraska, Inc.*, 590 N.W.2d 696 (Neb. 1999). In 1979, Clark Material Handling Company ("Clark") shipped a forklift to Christy Equipment Company, the predecessor to Clarklift of Nebraska ("Clarklift"). Later that year, Clarklift sold the forklift to another company. In 1992, Wahoo Concrete, Divis's employer, sought to purchase a used forklift from Clarklift. Clarklift repurchased the forklift for resale to Wahoo. Prior to delivering the forklift to Wahoo, Clarklift substantially refurbished the forklift and also installed a side-shifter. Clarklift further provided a warranty on the drive train for the forklift. Clark, the original manufacturer, approved the addition of the side-shifter as part of its standard procedure regarding its forklifts, but did not approve the refurbishment. In 1994, Divis was assisting with the manufacture of concrete slabs when a weld broke on the forklift and Divis was injured. Divis sued both Clark and Clarklift. Both companies moved for summary judgment on the basis that the claims were barred by Nebraska's ten-year statute of repose. Because all parties agreed that the weld failure could be traced back to the time of manufacture in 1979, the district court ruled in favor of the defendants. Divis appealed claiming that: 1) the statute of repose began anew when Clarklift reconditioned and refurbished the forklift, which Clark approved and authorized; 2) the statute of repose did not apply to the allegations of negligence; and 3) a factual issue existed regarding whether the warranty fell under exceptions to the statute of repose.

In affirming the lower court's decision, the Nebraska Supreme Court first noted that courts have employed a two-part test to determine whether the statute of repose should recommence when a product has been refurbished.

First, courts must determine whether the refurbishment resulted in a "new product."

First, courts must determine whether the refurbishment resulted in a "new product." To determine whether the product should be considered "new," courts must inquire whether the refurbishing has lengthened the product's useful life beyond what was contemplated when the product was first sold. Second, if the product is considered "new," the suit will still be time barred unless the refurbishing was defective and proximately caused the injury. *Id*. at 700 (citations omitted).

Using this analysis, the court held that the action against Clark was time-barred because even though Clark had approved the addition of the side-shifter, the side-shifter did not extend the useful life of the forklift or was not the proximate cause of the injury.

In regard to Clarklift, the court assumed that the refurbishment, together with the addition of the side-shifter, did extend the useful life of the forklift. However, since neither the refurbishment nor the side-shifter was the proximate cause of the injury, the claim against Clarklift was also time barred. Likewise, the negligence claim against Clarklift also failed on proximate cause as did the warranty claim because the warranty had expired and there was no evidence that the drive train (the subject of the warranty) was at all related to the latent defect in the weld. (Note: some statutes of repose expressly provide that the statute will not bar a claim if the product is warranted for a period longer than the repose period. *See, e.g.*, 735 Ill. Comp. Stat. 5/13-213(b); Conn. Gen. Stat. § 52-577a(d)).

In addition to the above, some case law suggests that replacing a defective component with a component of the same design will not restart a statute of repose. *See In re Air Disaster at Ramstein Air Base, Germany v. Lockheed Corp.*, 81 F.3d 570, 573 n. 5 (5th Cir. 1996) (citing *Butchkosky v. Enstrom Helicopter Corp.*, 855 F.Supp. 1251, 1257 (S.D.Fla. 1993) (modification must change original design of critical component that is alleged to have cause the injury)); *Hayes v. Otis Elevator Co.*, 946 F.2d 1272, 1277 (7th Cir. 1991). Further, supplemental materials provided separately from the product will not necessarily restart the period of repose, but may actually trigger a separate statute of repose. In *Driver v. Burlington Aviation, Inc.*, 430 S.E.2d 476 (N.C. Ct. App. 1993), the plaintiff was injured when a Cessna aircraft in which he was a passenger crashed, due to carburetor icing. The plaintiff did not allege that the aircraft was defective, but rather alleged that the manual, which had been sold separately, contained inadequate warnings related to icing. The court of appeals held that the defective product at issue was indeed the manual and that the date of sale for the manual, not the aircraft, would trigger the statute of repose.

Conclusion

Understanding when a statute may be tolled or restarted is an important step in evaluating a product liability claim. As shown by the above discussion, general repairs and maintenance will not restart a statute of repose. Rather, the service to the product must either: 1) be intended to lengthen the useful life of the product beyond that originally contemplated and introduce a defect into the product; or 2) an alteration must have been made that changes the specifications of the product and introduces a defect.

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