The Sophisticated User Defense: It’s Not Just for Drug Companies Anymore

by Andrew M. Thompson

The sophisticated user defense, also known as the learned intermediary doctrine, has been widely used by drug manufacturers in defending against failure to warn claims in products liability lawsuits. Although less well known, Georgia courts have also applied the sophisticated user defense outside the pharmaceutical drug context. Recently, in Parker v. Schmiede Machine & Tool Corp., the U.S. Court of Appeals for the 11th Circuit relied on the sophisticated user defense in affirming a district court’s grant of summary judgment to the defendants in a case in which employees at Lockheed Martin’s Marietta, Ga., facility alleged that they developed illnesses as a result of exposure to beryllium.

This article will discuss the origins of the sophisticated user defense in Georgia cases outside the pharmaceutical drug context, the application of the defense by the federal district court and 11th Circuit in the Parker case and the use of the defense in future toxic tort cases. Based upon the decisions of the district court and the 11th Circuit in Parker and the well-recognized basis for the sophisticated user defense in Georgia law, it is expected that practitioners will increasingly use the sophisticated user defense in defending toxic tort claims against manufacturers and suppliers of allegedly hazardous products.

The Origins of the Sophisticated User Defense Under Georgia Law

In products liability and toxic tort lawsuits, plaintiffs frequently allege that the manufacturer of a product
failed to properly warn the end user of the product’s risks or hazards. For a plaintiff to prevail on a claim for failure to warn under Georgia law, a plaintiff must show that the defendant had a duty to warn, that the defendant breached that duty and that the breach proximately caused the plaintiff’s injury. The “sophisticated user” or “learned intermediary” defense relieves a product supplier of the duty to warn an ultimate consumer or user of a known hazard if there is an intermediary with knowledge of the hazard. In the pharmaceutical drug context, the rationale for the defense is that a patient’s treating physician is in a better position than the manufacturer to warn the patient of a drug’s risks. Similarly, in the toxic tort context, the rationale for the defense is that a sophisticated employer with a history of using a particular product or substance and specific knowledge of how the particular product or substance will be used in the employer’s production process, is likewise in a better position than the product manufacturer to warn its employees of the product’s dangers. If a learned intermediary has actual knowledge of the dangers of a product or substance, yet would have taken the same course of action even with the information the plaintiff contends the manufacturer should have provided, then courts typically conclude that the sophisticated user or learned intermediary defense applies and the plaintiff cannot recover.

The defense appears to have been first recognized in Georgia outside the pharmaceutical drug context in Eyster v. Borg-Warner Corporation, in which residents who were injured in a house fire brought a lawsuit against the manufacturer of an HVAC unit, alleging that the manufacturer failed to warn the installer/distributor of the HVAC unit of the risks associated with an aluminum-copper connection in the unit. In affirming the trial court’s grant of a directed verdict in favor of the manufacturer because the danger of an aluminum-copper connection was com-
mon knowledge to those engaged in the installation of HVAC units, the Court of Appeals of Georgia held that “[w]here the product is vended to a particular group or profession, the manufacturer is not required to warn against risks generally known to such group or profession.”

Twenty years ago, in Stuckey v. Northern Propane Gas Company, the U.S. Court of Appeals for the 11th Circuit issued its first decision addressing the scope of Georgia’s sophisticated user/learned intermediary defense outside the pharmaceutical drug context. In Stuckey, a plaintiff who was burned in a propane gas explosion at a house owned by his parents sued a supplier that had distributed propane to a company that then sold and delivered the propane to the house. The plaintiff alleged that the supplier failed to warn him about the tendency of the odorant added to propane gas to fade over time. In appealing the trial court’s denial of its motion for directed verdict, the propane supplier argued that the seller’s actual knowledge of odor fade satisfied the supplier’s duty to warn. Although the 11th Circuit affirmed the trial court’s denial of the supplier’s directed verdict motion because the propane supplier was unable to establish that the seller of the propane had actual knowledge of odor fade, the court in Stuckey explained the scope of the learned intermediary defense under Georgia law. Relying on comment n to the Restatement (Second) of Torts § 388 (1965), the 11th Circuit held that “a supplier’s duty to warn a consumer does not turn on whether a warning was actually given to an intermediary, but on whether the intermediary’s knowledge was sufficient to protect the ultimate consumer.” In other words, and as explained by subsequent courts, if a learned intermediary “has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided, courts typically conclude that the learned intermediary doctrine applies or that the causal link has been broken and the plaintiff cannot recover.”

Since Eyster and Stuckey, federal courts in Georgia have granted summary judgment to manufacturers based on the sophisticated user defense and those decisions have been affirmed by the 11th Circuit. For example, in Argo v. Perfection Products Company, the district court applied the sophisticated user defense in a lawsuit by the intermediary’s employees who were injured in an explosion relating to an industrial heater. In granting summary judgment to the heater manufacturer and a component-part manufacturer, the court found that the plaintiffs’ employer was a sophisticated industrial user, that knew or should have known how to operate and maintain the product it purchased and, “[u]nder Georgia law, when a product is sold to a particular group or profession, a manufacturer has no duty to warn against the risks generally known to that group or profession.”

In addition, although the sophisticated user defense is usually based upon an intermediary’s actual knowledge, the defense can also be applied to protect a supplier or manufacturer from liability for failure to warn if the intermediary is charged by law with knowledge of the hazards of a particular substance or product. For example, in Stiltjes v. Ridco Exterminating Company, the resident of an apartment complex sued the manufacturer of a pesticide that had been supplied to a licensed pest control operator for application at the plaintiff’s apartment complex. The Court of Appeals of Georgia held that the pesticide manufacturer had no duty to warn the plaintiff because the manufacturer was entitled to rely on the laws charging licensed commercial applicators with knowledge of pesticide toxicity and safe methods of application. Thus, in Georgia, if an intermediary is charged by law with knowledge that a supplier would otherwise have a duty to communicate to the eventual consumer or user, then the supplier need not communicate the warning to the consumer or user, can rely on the learned intermediary and any failure to warn claim against the supplier is barred by the sophisticated user defense.

The Lengthy Saga of the Parker and Berube Beryllium Cases

In 2004, a number of current and former employees of Lockheed Martin’s Marietta, Ga., facility filed a putative class action against eight defendants alleging that the plaintiffs and members of the putative class had developed beryllium sensitization and/or “sub-clinical, cellular and sub-cellular damage” from exposure to beryllium-containing products utilized at the Lockheed facility for more than 40 years. In two orders issued in March 2005 and March 2006, the federal district court dismissed the plaintiffs’ claims for alleged sub-clinical, cellular and sub-cellular damage, dismissed plaintiffs’ claims for emotional distress and for medical monitoring costs, and concluded that the plaintiffs’ claims for beryllium sensitization did not constitute an actionable injury under Georgia law. The plaintiffs appealed the district court’s rulings to the U.S. Court of Appeals for the 11th Circuit and in an April 2007 opinion, the 11th Circuit affirmed the district court’s dismissal of the plaintiffs’ claims for “sub-clinical, cellular and sub-cellular damage” and for emotional distress and medical monitoring costs, but reversed the district court’s grant of summary judgment on the claims of the plaintiffs who alleged beryllium sensitization. Based on the 11th Circuit’s 2007 opinion, the plaintiffs’ class allegations were defeated and the Parker case was limited to four plaintiffs alleging beryllium sensitization and/or chronic beryllium disease. In 2008, the Parker case was consolidated for discovery purposes with Timothy Berube v. Brush Wellman, Inc., a very similar case involving eight additional plaintiffs alleging beryllium sensitization and/or chronic
beryllium disease from exposure to beryllium-containing products at Lockheed’s Marietta facility.

After the close of over a year-and-a-half of extensive discovery in the Parker and Berube cases, the claims of the 12 remaining plaintiffs were limited to failure to warn claims against four remaining defendants who were alleged to have supplied beryllium-containing products used at the Lockheed Martin facility. In September 2010, the district court granted summary judgment to the four remaining defendants based upon (1) the record evidence that the plaintiffs’ employer Lockheed Martin was a sophisticated user of copper-beryllium and aluminum-beryllium alloys and thus the plaintiffs’ failure to warn claims were barred under Georgia law; and (2) exclusion of the plaintiffs’ causation expert because the expert’s opinions were scientifically unreliable under the prevailing standard for admissibility of expert testimony and without expert causation testimony, the plaintiffs’ claims failed as a matter of law.21

The 11th Circuit’s October 2011 Decision

In an Oct. 21, 2011, opinion, the 11th Circuit affirmed the grant of summary judgment to the defendants, discussed its prior decision in Stuckey and the Georgia law applying the sophisticated user and learned intermediary defense and explained that “the ‘sophisticated user’ or ‘learned intermediary’ doctrine relieves a product manufacturer or supplier of this duty to warn the ultimate user where there is an intermediary with knowledge of the hazard.”22 The 11th Circuit declined to decide the specific standard to apply in evaluating the record evidence on sophisticated user, but rather assumed arguendo that the following standard proposed by the plaintiffs was a correct statement of the law:

if the plaintiffs here adduce evidence from which the jury could conclude that (1) the defendants possessed information, which Lockheed did not possess, regarding a particular danger associated with beryllium, and (2) the defendants failed to warn Lockheed of that danger, then summary judgment based on the sophisticated user or learned intermediary doctrine would be inappropriate.23

The 11th Circuit concluded that the plaintiffs “fail to adduce any evidence to satisfy this standard” and that “the defendants have established that Lockheed is a sophisticated user of beryllium and a learned intermediary between its employees and the manufacturers of beryllium products.”24 Specifically, the court explained that the Lockheed facility had produced aircraft containing beryllium parts for almost 60 years, had utilized a 1966 Department of Defense

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publication as a standard reference guide regarding the dangers inherent in the use of beryllium, had issued its own “Safety & Industrial Hygiene Standard” in 1983 that addressed actions that could lead to the generation of beryllium dust, and employed a team of industrial hygienists and toxicologists who had studied beryllium and its health effects and developed Lockheed’s own internal warnings regarding the hazards of beryllium.  

In addition, the 11th Circuit expressly declined the plaintiffs’ invitation to rely on the decision in Generexx v. American Beryllia Corp., in which the 1st Circuit relied on Massachusetts law in concluding that a court considering a sophisticated user defense “must analyze the particular dangers to be guarded against” and engage in a detailed fact-specific analysis of whether the intermediary had sufficient knowledge of each and every particular danger of the allegedly hazardous substance. In contrast, Georgia law regarding the sophisticated user defense requires that an intermediary possess only general knowledge of the dangers associated with a product’s use.  

In another important aspect of its decision, the 11th Circuit concluded that a plaintiff cannot avoid application of the sophisticated user defense simply by showing that the intermediary failed to take measures to protect adequately against a certain hazard; rather, plaintiffs must show that the intermediary lacked actual knowledge of the hazard. Thus, the inquiry is focused on the intermediary’s knowledge, not on the adequacy of the intermediary’s implementation of its knowledge or the intermediary’s failure to act on its knowledge.

The Future of the Sophisticated User Defense in Toxic Tort Cases

The decisions by the district court and 11th Circuit in Parker demonstrate the continuing viability of the sophisticated user defense in toxic tort cases in Georgia in which plaintiffs allege that the supplier or manufacturer of a product failed to sufficiently warn the end user of the hazards of the product. Although the applicability of the defense is frequently very fact- and case-specific, Georgia courts have made it clear that it is an issue that is appropriately resolved at the summary judgment stage based upon the record evidence. In addition, by (1) reaffirming the principle that an intermediary need possess only general knowledge of the hazards associated with a product, and (2) making it clear that the relevant inquiry is focused on the intermediary’s actual knowledge and not on the adequacy of the supplier’s warnings or on the intermediary’s failure to act on its knowledge, the decisions by the 11th Circuit and the district court in Parker foreclose two relatively common means by which plaintiffs may seek to create disputed factual issues and avoid applicability of the sophisticated user defense.

Although not expressly addressed by the courts in the Parker decisions, the case also demonstrates how the timing of when an intermediary obtained its knowledge can impact the application of the sophisticated user defense in a case involving a lengthy alleged exposure period. In Parker, the plaintiffs alleged that they were exposed to beryllium for more than a 40-year period and the state of the art of knowledge of beryllium and its health risks had evolved over that time, but the record evidence was clear that Lockheed was always at the forefront of possessing knowledge regarding beryllium and its health risks. Nevertheless, it is not difficult to imagine a scenario in which a plaintiff could attempt to create a fact issue in regard to the sophisticated user defense by arguing that a particular intermediary was not a sophisticated user of a hazardous product during the early portion of the plaintiff’s alleged period of exposure to the product and thus the intermediary’s subsequent sophistication should not bar the plaintiff’s failure to warn claim against the suppliers of the product. In such a scenario, it will be important for courts to compare the respective knowledge of the industry and the intermediary at comparable time periods and not fall into an “apples to oranges” comparison of the current state of the art regarding a product’s hazards to what was known about the product during earlier time periods.

Parties seeking to avoid application of the sophisticated user defense may also attempt to limit the impact of the Parker decision by arguing that the learned intermediary at issue in the case was Lockheed Martin, one of the world’s largest defense contractors who employed a team of toxicologists, industrial hygienists and PhDs. However, the Georgia sophisticated user cases relied on by the 11th Circuit and the district court in the Parker decisions involved significantly smaller intermediaries with substantially less obvious sophistication, including the installer/distributor of an HVAC unit in Eyster and the installer of residential kitchen tiles in Whirlpool. Thus, the sophisticated user defense is by no means limited to cases involving large intermediaries.

Conclusion

In light of the fact that employees allegedly exposed to toxic substances or hazardous products in the workplace are barred by the Georgia’s Workers’ Compensation Act from recovering damages from their employers, it is commonplace for such employees to name manufacturers, suppliers and distributors of allegedly hazardous products as defendants in toxic tort and products liability lawsuits. However, as demonstrated by the 11th Circuit’s decision in Parker and the Georgia cases cited therein, summary judgment is available to manufacturers and suppliers on the basis of the sophisticated user defense when the plaintiffs’ employer possessed general knowledge of the hazards associated with the substance or product at issue and thus any alleged failure
to warn by the manufacturer/supplier would not constitute the proximate cause of the plaintiff's injury. It is reasonable to expect that the use of the sophisticated user defense will increase as society becomes more regulated, which imputes knowledge to the regulated community and creates more "learned intermediary," and information regarding hazardous substances and products becomes more readily available leading to more sophisticated users of hazardous products.

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Endnotes
1. See Dietz v. Smithkline Beecham Corp., 598 F.3d 812, 816 n.2 (11th Cir. 2010) (affirming summary judgment in products liability case against pharmaceutical company based on "Georgia's long-recognized, unwavering use of the learned intermediary doctrine.")


5. Wheat, at 1363.


7. Id. at 670 (citing a New York case and two treatises on products liability and tort law).

8. 874 F.2d 1563 (11th Cir. 1989).

9. Id. at 1568-1569.

10. Id. at 1568 (emphasis added).


13. Id. at 1118-1119 (emphasis added) (citing Eyster); see also Powell Duffryn Terminals, Inc. v. Calgon Carbon Corp., 4 F. Supp. 2d 1198, 1203 (S.D. Ga. 1998) ("There is no duty to warn when the person using the product `should know of the danger, or should in using the product discover the danger' . . . Ordinarily, there is no duty to give warning to the members of a profession against generally known risks.").


15. 343 S.E.2d at 719.


17. Beryllium is a light metal with extreme hardness and a high melting point that makes it very desirable for use in a number of industries, particularly the aerospace industry and in the production of nuclear energy and weapons. In certain individuals, exposure to beryllium can result in beryllium sensitization, which is similar to an allergy and can be a precursor to the development of chronic beryllium disease, a respiratory illness.


20. Out of the eight original defendants, three were voluntarily dismissed by the plaintiffs and Brush Wellman entered into a confidential settlement. Lockheed Martin was one of the original defendants, but once the plaintiffs' class claims were defeated and the only plaintiffs were employees of Lockheed Martin, the plaintiffs voluntarily dismissed Lockheed Martin because their claims against Lockheed were barred under the Georgia Workers' Compensation Act, O.C.G.A. § 34-9-11.


23. Id. at *3.

24. Id.

25. Id.

26. 577 F.3d 350 (1st Cir. 2009).


28. See Powell Duffryn Terminals, Inc. v. Calgon Carbon Corp., 4 F. Supp. 2d 1198, 1203-04 (S.D. Ga. 1998) (holding that, if a user knows or should know of a general danger, then it is incumbent upon that user to investigate more particular dangers); Whirlpool Corp. v. Hurlbut, 166 Ga. App. 95, 101, 303 S.E.2d 294, 288 (1983) ("It is not important whether he knew the precise, physical nature of the hazard presented by his 'use' of the product; it is sufficient if he is aware generally that the 'use' being made of the product is dangerous.").

29. Parker, 2011 WL 5025135 at *5 n.8 ("Even if the Plaintiffs could prove that Lockheed did not employ the proper [beryllium] control devices, that proof would not be enough to rebut the evidence that Lockheed had actual knowledge of the need for such controls.").