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Product Liability

by Franklin P. Brannen, Jr.*

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This Article surveys developments in Georgia product liability law between June 1, 2015 and May 31, 2017.¹ It covers noteworthy cases decided during this period by the Georgia Supreme Court, Georgia Court of Appeals, the United States Court of Appeals for the Eleventh Circuit, and the United States district courts located in Georgia.

I. ELEMENTS OF PRODUCT LIABILITY CLAIMS

A. *Definition of Manufacturer*

Georgia product liability law limits strict liability to the manufacturer of the product at issue.² Non-manufacturers in the sales chain may only be found liable under a negligence or breach of warranty theory. Defining

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1. For an analysis of product liability law during the prior survey period, see Franklin P. Brannen, Jr., P. Michael Freed & Jake C. Evans, *Product Liability, Annual Survey of Georgia Law*, 67 MERCER L. REV. 177 (2015).

2. O.C.G.A. § 51-1-11 (2017).

whether a defendant is or is not a manufacturer, therefore, is a critical issue in many product liability cases.

In *Williams v. Pacific Cycle, Inc.*,³ the Eleventh Circuit addressed the definition of “manufacturer.” The plaintiff in *Williams* suffered a brain injury when he fell off of his bicycle and struck his head on the pavement. At the time of the accident, the plaintiff was wearing a Pulsar model Schwinn bike helmet. Pacific Cycle, the owner of the Schwinn brand name, granted a license to PTI Sports (PTI) to sell helmets using the Schwinn brand.⁴ Then, Pacific Cycle purchased certain assets from PTI including an inventory of Schwinn bicycle helmets. The subject helmet had been manufactured by Strategic Sports Ltd. (Strategic). The plaintiff filed suit against Pacific Cycle seeking relief under several theories including strict liability for design defect, negligent design and manufacture, and negligent import, sale, and distribution. The district court granted summary judgment to Pacific Cycle on all of the plaintiff’s claims.⁵

The Eleventh Circuit considered whether certain actions on the part of PTI took Pacific Cycle out of the category of product seller and made it a manufacturer that could be subject to a strict liability claim.⁶ These actions included that PTI provided the instructional booklet and header card for the Pulsar, provided some design specifications, imported the Pulsar, and shipped the Pulsar to a retailer.⁷ The court also considered whether Pacific Cycle’s role as an importer, which required it to adhere to certain Consumer Product Safety Commission regulations, made it a manufacturer subject to strict liability claims under Georgia law.⁸

As to these two questions, the court held the actions attributable to Pacific Cycle were not sufficient to make it a manufacturer. Further, the fact that Pacific Cycle was a bicycle helmet importer subject to federal regulations did not make it a manufacturer under Georgia law.⁹ It was a product seller pursuant to section 51-1-11.1¹⁰ of the Official Code of Georgia Annotated (O.C.G.A.), which excluded it from strict liability.¹¹ The court also considered the question of whether Pacific Cycle was an “ostensible manufacturer” under Georgia law and may be held liable for

3. 661 F. App’x 716 (11th Cir. 2016).

4. *Id.* at 717.

5. *Id.* at 716–18.

6. *Id.* at 718.

7. *Id.* at 718–19.

8. *Id.* at 719.

9. *Id.* at 720–21.

10. O.C.G.A. § 51-1-11.1 (2017).

11. *Williams*, 661 F. App’x at 719.

negligent design and manufacture.¹² The court held that Pacific Cycle could not be held liable for negligent manufacture or design as an ostensible manufacturer because neither it nor its licensee designed or manufactured the helmet.¹³

In *Pfeil v. Mike's Golf Carts, LLC*,¹⁴ the United States District Court for the Middle District of Georgia also considered the question of what it means to be a product manufacturer.¹⁵ The plaintiffs brought a negligence and strict liability product claim for injuries sustained when part of a golf cart's suspension broke causing the cart to flip over. The defendant purchased a used 2002 Club Car limo golf cart and installed a cargo box, roll bar, dipped-camo body, cooler rack, winch, eleven-horsepower motor, 700-amp controller, heavy-duty F and R switch, ten-inch lift kit, clay basket, gun rack, as well as twelve-inch rims, six 8-volt batteries, and 27-inch tires. The parties disputed whether the customized golf cart was a "Beast Buggy model" or the accessories added were part of the defendant's "Beast Package."¹⁶ The court denied the defendant's motion for summary judgment holding that the defendant was not the manufacturer as a matter of law because the evidence conflicted as to whether the defendant assembled component parts into a single product and sold it under its own name (the Beast Buggy).¹⁷

In *Andrews v. Autoliv Japan, Ltd.*,¹⁸ the United States District Court for the Northern District of Georgia also addressed the definition of a product manufacturer.¹⁹ There, Andrews died when his head struck the steering wheel of his 2005 Mazda 3 after it left the road and struck some trees. Andrews's estate and surviving spouse filed suit against Autoliv Japan and others for damages contending that a defective seatbelt assembly was the cause of his death. The main issue was whether Autoliv designed the seatbelt assembly for the 2005 Mazda 3.²⁰ The evidence showed that Autoliv's role was limited to choosing the components appropriate for the Mazda 3 based on Mazda's specifications, while Mazda made the ultimate decision regarding the types of components to incorporate.²¹ The court granted Autoliv's motion for summary judgment,

12. *Id.* at 720.

13. *Id.*

14. No. 5:13-CV-434, 2015 U.S. Dist. LEXIS 121801 (M.D. Ga. Sept. 14, 2015).

15. *Id.*

16. *Id.* at *2-4.

17. *Id.* at *16-17.

18. 228 F. Supp. 3d 1340 (N.D. Ga. 2017).

19. *Id.* at 1343.

20. *Id.* at 1341-42.

21. *Id.* at 1347.

finding that it was not the designer of the seatbelt assembly and that this type of involvement was insufficient to create a triable issue with respect to strict liability under O.C.G.A. § 51-1-11.²²

B. Causation

Proximate cause is an essential element of any product liability claim.²³ This requirement applies regardless of the type of defect the plaintiff alleges (such as design defect or manufacturing defect) or the theory of recovery (such as strict liability or negligence). Any break in the chain of causation precludes plaintiff's recovery.²⁴

In *Roper v. Kawasaki Heavy Industries, Ltd.*,²⁵ the District Court for the Northern District of Georgia also discussed the causation element.²⁶ In *Roper*, the plaintiff filed suit against certain defendants, including Kawasaki, seeking to recover for injuries resulting from a motorcycle accident. A year after the accident, Kawasaki issued a "Warning and Recall Notice" because of a defect with the voltage regulator (VR) in certain motorcycle models, including the one plaintiff owned and was riding when he crashed. The VR helps maintain the battery's charge while the engine is running. Kawasaki filed a motion to exclude plaintiff's expert testimony and a motion for summary judgment for lack of causation evidence.²⁷

The court excluded the plaintiff's experts' testimony under the *Daubert*²⁸ standard.²⁹ Georgia law requires expert testimony "to prove causation if the causal connection between the defective product and the plaintiff's injuries is not 'a natural inference that a juror could make through human experience.'"³⁰ The question, therefore, was "whether a juror could infer through natural human experience that the VR in Plaintiff's motorcycle caused his engine to stall."³¹ The court could not say that a juror could infer causation through human experience where the case involved alleged failure of a complex electrical system.³² With

22. *Id.*

23. *Powell v. Harsco Corp.*, 209 Ga. App. 348, 350, 433 S.E.2d 608, 610 (1993).

24. *Id.* at 350, 433 S.E.2d at 610.

25. No. 1:13-CV-03661-ELR, 2015 U.S. Dist. LEXIS 187419 (N.D. Ga. June 29, 2015).

26. *Id.* at *3-4.

27. *Id.* at *2-6.

28. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

29. *Roper*, 2015 U.S. Dist. LEXIS 187419, at *62-63.

30. *Id.* at *60-61 (quoting *Brown v. Roche Labs., Inc.*, No. 1:06-cv-3074-JEC, 2013 U.S. Dist. LEXIS 79250, at *8 (N.D. Ga. June 6, 2013) *aff'd*, 567 F. App'x 860 (11th Cir. 2014)).

31. *Id.* at 61.

32. *Id.*

his expert having been excluded, the plaintiff could not establish a causal relationship between the motorcycle VR and the underlying accident, entitling Kawasaki to summary judgment.³³

In *Dennis v. D&F Equipment Sales, Inc.*,³⁴ the District Court for the Middle District of Georgia considered whether certain facts took the question of proximate cause away from a jury.³⁵ Dennis filed suit, alleging that D&F was strictly liable for injuries she sustained as a proximate result of a defective vertical conveyor at the factory at which she worked because it lacked an emergency stop button (e-stop) in the immediate vicinity of the conveyor's intended workstation. D&F moved for summary judgment as to all claims. D&F argued that Dennis could not establish a causal connection between any defect in the vertical conveyor and Dennis's injury because there was no evidence that an e-stop would have prevented her injury. The defendant pointed out that:

(1) an individual other than Ms. Dennis would have needed to trigger the e-stop, and it is not clear whether any employees were close enough to do so; and (2) it is impossible to say without speculation or conjecture whether Ms. Dennis's injury would have been minimized by the addition of an e-stop.³⁶

The court held that it was not "the role of the Court to speculate as to whether other employees would have been able to turn off the [conveyor] if there had been an e-stop, or as to whether the triggering of an e-stop would have minimized Ms. Dennis's injury"; these were jury questions.³⁷

D&F also argued that, "even if an e-stop would have minimized Ms. Dennis's injury, the fact that she was instructed to stand in an area that was not a designated workstation was an unforeseeable negligent act that negate[d] D&F's liability as the manufacturer."³⁸ The court concluded that the relevant question "to this argument [was] whether D&F could have foreseen that an employee might be working in the area where Ms. Dennis was standing."³⁹ The court found that this question was far from "plain and undisputed" and was a question for a jury.⁴⁰

33. *Id.*

34. No. 7:14-CV-132 (HL), 2016 U.S. Dist. LEXIS 42847 (M.D. Ga. Mar. 31, 2016).

35. *Id.* at *14.

36. *Id.* at *15.

37. *Id.* at *15–16.

38. *Id.* at *16.

39. *Id.*

40. *Id.*

II. CLAIMS

A. Manufacturing Defect

Georgia law defines a manufacturing defect as “a deviation from some objective standard or a departure from the manufacturer’s specifications established for the creation of the product.”⁴¹ However, a plaintiff cannot put forth a mere allegation that a product malfunctioned to create an issue of disputed material fact as to whether a manufacturing defect existed when a product left the manufacturer’s control.⁴²

The plaintiff in *McClendon v. Manitou Americas, Inc.*⁴³ sustained injuries to his head and neck while operating a forklift manufactured by defendant. The plaintiff alleged that the brakes failed while he was operating a forklift aboard a cargo ship, causing the forklift to collide with the inside wall of the ship. He then sued alleging a manufacturing defect in the brake system of the forklift. The defendant moved for summary judgment.⁴⁴

In examining the plaintiff’s claim, the United States District Court for the Southern District of Georgia recognized that a plaintiff must prove the following: “(1) the manufacturer’s product was not merchantable and reasonably suited to the use intended when sold; and (2) the product’s condition when sold was the proximate cause of the injury sustained.”⁴⁵ The district court determined that, to prove the first element, a plaintiff must establish that the product contained a manufacturing defect.⁴⁶

The plaintiff argued that its assertion that the brakes failed should be sufficient to survive summary judgment and that its claim did not require expert testimony.⁴⁷ The district court rejected this argument, finding there was simply no evidence to support a conclusion that the forklift brakes were defective when the forklift left the defendant’s control.⁴⁸ Without further evidence that the brakes were faulty and only a bare allegation that faulty brakes caused the injury, the district court granted summary judgment on the strict product liability claim.⁴⁹

41. *Jones v. Amazing Prods., Inc.*, 231 F. Supp. 2d 1228, 1236 (N.D. Ga. 2002).

42. *See id.*

43. No. CV 415-250, 2016 U.S. Dist. LEXIS 134827 (S.D. Ga. Sept. 29, 2016).

44. *Id.* at *1–3.

45. *Id.* at *6.

46. *Id.*

47. *Id.* at *9.

48. *Id.* at *8–9.

49. *Id.* at *9.

B. Breach of Warranty

Georgia's Uniform Commercial Code⁵⁰ codified an implied warranty of merchantability that goods will be fit for the ordinary purposes for which the goods are used.⁵¹ An express warranty is made when a seller makes an affirmation of fact or promise related to the goods, and the affirmation or promise becomes a part of the basis of the bargain.⁵² Georgia applies a four-year statute of limitations to warranty claims, regardless of whether they are based on express warranties or implied warranties.⁵³

The plaintiff in *Paws Holdings v. Daikin Industries*⁵⁴ incurred out-of-pocket repair and service costs and diminished property values due to the alleged corrosion and leaking of an HVAC system purchased from and manufactured by the defendant. The plaintiff filed suit asserting the following claims: "(1) [violation of a federal warranty act] (2) breach of express warranties; (3) breach of the implied warranty of merchantability; [and] (4) breach of the implied warranty of fitness for a particular purpose."⁵⁵ The defendant filed a motion to dismiss for failure to state a claim, arguing that the warranty-based claims must be dismissed because they are time-barred and fail for lack of notice. In support of its implied warranty claims, the plaintiff asserted that the statute of limitations should be tolled under O.C.G.A. § 9-3-96⁵⁶ for the defendant's "fraudulent concealment of the defect and the applicable warranty."⁵⁷ The court found that, because the plaintiff did not plead the existence of a confidential relationship between itself and the defendant or a duty to disclose, the plaintiff had to demonstrate actual fraud involving moral turpitude to conceal the defect. Because the plaintiff failed to plead any affirmative act of fraud to conceal the plaintiff's warranty-based causes of action, the District Court for the Southern District granted the defendant's motion to dismiss the implied warranty claims.⁵⁸

The court then examined the plaintiff's express warranty claim.⁵⁹ As an initial matter, the court found that as a matter of law the alleged

50. O.C.G.A. tit. 11 (2017).

51. O.C.G.A. § 11-2-314 (2017).

52. *Grieco v. Tecumseh Prods. Co.*, No. 4:12-cv-195, 2013 WL 5755436, at *17 (S.D. Ga. Oct. 23, 2013).

53. O.C.G.A. § 11-2-725 (2017).

54. No. CV116-058, 2017 U.S. Dist. LEXIS 24684 (S.D. Ga. Feb. 22, 2017).

55. *Id.* at *6.

56. O.C.G.A. § 9-3-96 (2017).

57. *Paws Holdings*, 2013 WL 5757436, at *39–42.

58. *Id.* at *42–43.

59. *Id.* at *43–48.

representations regarding the HVAC units' performance "were vague and indefinite statements of the seller's opinion" and insufficient as a matter of law to create an express warranty.⁶⁰ Further, the court found that plaintiff's express warranty claims were time-barred.⁶¹ The plaintiff argued that his cause of action accrued at the time of his knowledge of the breach.⁶² The court, however, found that the express warranties did not explicitly extend to the future performance of the goods, so any breach of warranty would have occurred at the time of delivery of the HVAC units.⁶³ Therefore, the plaintiff's claims would have accrued at the time of delivery.⁶⁴ Because the plaintiff failed to initiate its lawsuit within four years of this delivery, the court held the plaintiff's claims to be time-barred and granted the defendant's motion to dismiss the express warranty claims.⁶⁵

III. DEFENSES

A. Contributory Negligence/Comparative Fault

In *Bullock v. Volkswagen Group of America, Inc.*,⁶⁶ the District Court for the Middle District of Georgia considered whether the Georgia apportionment statute applied in strict liability product defect actions as defined by two discrete issues:

(1) whether the Georgia Supreme Court is likely to hold that the Georgia comparative fault statute requires a reduction of the jury's award of damages to a partially at-fault plaintiff who asserts a strict liability product defect claim; and (2) whether the Georgia Supreme Court [would be] likely to hold that the statute or any other applicable law requires a reduction of the jury's award of damages to the non-at-fault spouse who asserts a loss of consortium claim.⁶⁷

In *Bullock*, the jury found in favor of the plaintiffs on both a strict product liability claim arising from an automobile crash and a companion loss of consortium claim.⁶⁸

60. *Id.* at *44–45.

61. *Id.* at *47.

62. *Id.* at *42–43.

63. *Id.* at *47.

64. *See id.*

65. *Id.*

66. No. 4:13-CV-37, 2015 U.S. Dist. LEXIS 121443 (M.D. Ga. Sept. 11, 2015).

67. *Id.* at *2–3.

68. *Id.* at *1–2.

The district court relied on the Georgia Supreme Court's analysis in *Couch v. Red Roof Inns, Inc.*⁶⁹ to decide the case.⁷⁰ In *Couch*, the Georgia Supreme Court "construed the plain language of the [apportionment] statute to mean that the plaintiff's claim did not have to be couched in terms of negligence for the statute to apply."⁷¹ The apportionment statute plainly states that it applies to an action "brought against one or more persons for injury to person or property."⁷² The statute does not state that it "only applies to actions for injury to person or property based on a theory of negligence."⁷³

The court in *Bullock* applied the rationale of *Couch* and held that the apportionment statute "does not distinguish between causes of action based on the nature of the tortious conduct upon which the claim is based."⁷⁴ Thus, it provides no exception for actions based on a theory of strict liability and, as a result, the jury was permitted to apportion fault to the plaintiff.⁷⁵

B. Assumption of Risk

To prevail on an assumption of risk defense, a defendant must establish that the plaintiff: "(1) had actual knowledge of the danger; (2) understood and appreciated the risks associated with such danger; and (3) voluntarily exposed himself to the risks."⁷⁶

In *Roberts v. Tractor Supply*,⁷⁷ the plaintiff's friend purchased a floor model of a hunter's tree stand from the defendant supply company and assembled it with the plaintiff. Because the tree stand was a floor model, it was not accompanied by any instructions or safety procedures. When the plaintiff attempted to ascend the stand, it buckled and fell. The plaintiff jumped off, shattering his right leg below the knee. The plaintiff filed suit against the product manufacturer and seller, alleging negligence, strict product liability for design defect, and strict product liability for a warning defect.⁷⁸ The defendants filed motions for summary judgment and argued that the plaintiff assumed the risks associated with using the tree stand. One defendant argued that the plaintiff's admission

69. 291 Ga. 359, 729 S.E.2d 378 (2012).

70. *Bullock*, 2015 U.S. Dist. LEXIS 121443, at *4.

71. *Id.*

72. *Id.* (quoting O.C.G.A. § 51-12-33(a) (2017)).

73. *Id.* at *5.

74. *Id.*

75. *Id.* at *6.

76. *Muldovan v. McEachern*, 271 Ga. 805, 807-08, 523 S.E.2d 566, 569 (1999).

77. No. 1:14-CV-02332-RWS, 2015 U.S. Dist. LEXIS 180366 (N.D. Ga. Dec. 15, 2015).

78. *Id.* at *1-3.

that he did not read or follow the instructions precluded any dispute over the plaintiff's actual knowledge of the risk. The other defendant contended that the plaintiff assumed the risk because he was an experienced hunter.⁷⁹

The District Court for the Northern District of Georgia found that a genuine issue of material fact existed as to the plaintiff's knowledge of specific risks.⁸⁰ The court found that while the plaintiff admitted to not following the instructions, he asserted that he did not know the tree stand would collapse and send him falling.⁸¹ The court acknowledged that "Georgia case law has repeatedly recognized a distinction between knowledge of the general risk of falling versus knowledge of the specific risk of harm created by a defendant's conduct."⁸² The court further found that the plaintiff had testified that he had never before constructed a hunter's stand and, therefore, it was unclear if he was experienced enough to assume the risk associated with improperly assembling the stand.⁸³ Finding that a genuine issue of material fact existed as to the plaintiff's actual knowledge of specific risks, the court denied defendants' motions for summary judgment.⁸⁴

C. Economic Loss

In Georgia, the injury required to state a negligence or strict liability claim based on an allegedly defective product must be distinct from a loss of value or use of the product. This economic-loss rule bars recovery in tort when a plaintiff can only show purely economic losses.⁸⁵

The plaintiff in *Paws Holdings v. Daikin Industries*⁸⁶ incurred out-of-pocket repair and service costs and diminished property values due to the alleged corrosion and leaking of an HVAC system purchased from and manufactured by the defendants. The plaintiff filed suit asserting breach of warranty claims. The plaintiff's complaint alleged that it sustained out-of-pocket repair and service costs, loss of appliance value, and loss of property value.⁸⁷ The defendants filed a motion to dismiss, arguing that

79. *Id.* at *6, *9–10.

80. *Id.* at *7.

81. *Id.*

82. *Id.* at *8–9.

83. *Id.* at *10.

84. *Id.* at *10–11.

85. See *Chrysler Corp. v. Taylor*, 141 Ga. App. 671, 672, 234 S.E.2d 123, 124 (1977).

86. No. CV116-058, 2017 U.S. Dist. LEXIS 24684 (S.D. Ga. Feb. 22, 2017). This case is also discussed in section II of this Article. See *supra* text accompanying notes 54–65.

87. *Id.* at *4–5.

the claims are barred by the economic-loss rule.⁸⁸ The plaintiff asserted that it suffered non-economic loss from the substantial health and safety risk of the leaking HVAC units. The plaintiff also argued that even if the economic-loss rule applied, its claims would survive because the defendants misrepresented the HVAC units to be free from defects, thus triggering the negligent misrepresentation exception.⁸⁹ “Under the ‘negligent misrepresentation’ exception to the economic-loss rule, ‘one who supplies information during the course of . . . any transaction in which he has a pecuniary interest has a duty of reasonable care . . . to parties who rely upon the information.’”⁹⁰

The District Court for the Southern District of Georgia held that, because the plaintiff only alleged purely economic losses, Georgia’s economic-loss rule bars its tort-based claims and the court dismissed them.⁹¹ The court found that the plaintiff had not alleged actual exposure to health and safety risks and that increased risks of injury are insufficient to state an injury recoverable in tort.⁹² Further, the court held that, because the plaintiff failed to assert a cause of action for fraud or negligent misrepresentation or assert any negligent supply of false information, it was not entitled to invoke the negligent misrepresentation exception to the economic loss doctrine.⁹³

D. Preemption

In *Brazil v. Janssen Research & Development, LLC*,⁹⁴ the District Court for the Northern District of Georgia considered defendant’s motion to dismiss for failure to state a claim.⁹⁵ There, the plaintiff used the drug Invokana® to control her type-2 diabetes. After using Invokana®, the plaintiff began losing weight, suffered nausea and vomiting, and was diagnosed with diabetic ketoacidosis. The plaintiff claimed she would not have used the drug had defendants properly disclosed the associated risks because safer alternatives were available.⁹⁶ The defendants filed a motion to dismiss claiming, among other things, that the plaintiff’s “design defect claims [were] preempted because federal law precludes

88. *Id.* at *31.

89. *Id.* at *34–36.

90. *Id.* at *37 (quoting *Squish La Fish, Inc. v. Thomco Specialty Prods.*, 149 F.3d 1288, 1291 (11th Cir. 1998)).

91. *Id.* at *38–39.

92. *Id.* at *35.

93. *Id.* at *38–39.

94. No. 4:15-CV-0204-HLM, 2016 U.S. Dist. LEXIS 137695 (N.D. Ga. Mar. 24, 2016).

95. *Id.* at *8–9.

96. *Id.* at *7–8.

Defendant manufacturers from redesigning a prescription drug without [Food and Drug Administration (FDA)] approval.”⁹⁷

In ruling on defendants’ preemption defense, the district court considered two recent Supreme Court of the United States holdings—*Wyeth v. Levine*⁹⁸ and *PLIVA, Inc. v. Mensing*⁹⁹—discussing conflict preemption.¹⁰⁰ In addition, the district court also found guidance in *Mutual Pharmacy Co. v. Bartlett*,¹⁰¹ where “the Supreme Court addressed [federal] preemption of FDA regulations with respect to a design defect claim against a drug manufacturer.”¹⁰² The district court reasoned that “[a]s *Levine*, *Mensing*, and *Bartlett* make clear, the conflict preemption analysis turns on the duties imposed by state law,” and the court noted that “Georgia’s risk-utility analysis for design defect claims closely resemble[d] the analysis used by New Hampshire that the Supreme Court analyzed in *Bartlett*.”¹⁰³ The district court concluded that “[a] design defect claim under Georgia law therefore allows a drug manufacturer to ameliorate the risks of danger of the drug and thus to fulfill its legal duty by improving the warnings attached to the product.”¹⁰⁴ The district court noted that in *Bartlett*, “the Supreme Court decided that the drug manufacturer could neither redesign its product nor alter its warning labels without FDA approval, and it was thus impossible for the manufacturer to comply with both state and federal law.”¹⁰⁵ However, the district court distinguished the case before it because the case involved a brand name drug manufacturer and held that “a brand name drug manufacturer may use the FDA’s [Changes Being Effected] regulation to unilaterally change its labeling without prior FDA approval.”¹⁰⁶ The district court concluded that “[i]n doing so, a brand name drug manufacturer may comply with both state and federal law.”¹⁰⁷ “State law claims, including a design defect claim, requiring a brand name drug manufacturer to provide a more robust warning are therefore

97. *Id.* at *38.

98. 555 U.S. 555 (2009).

99. 564 U.S. 604 (2011).

100. *Brazil*, 2016 U.S. Dist. LEXIS 137695, at *39–42.

101. 133 S. Ct. 2466 (2013).

102. *Brazil*, 2016 U.S. Dist. LEXIS 137695, at *44.

103. *Id.* at *49–50.

104. *Id.* at *51.

105. *Id.*

106. *Id.* at *51–52.

107. *Id.* at *52.

not preempted.”¹⁰⁸ In construing *Bartlett* narrowly, the district court concluded that the plaintiff’s design defect claims were not preempted.¹⁰⁹

*Kaku v. Alphatec Spine, Inc.*¹¹⁰ was a product liability action involving Alphatec Zodiac® polyaxial pedicle screws. The screws were implanted into the plaintiff’s vertebrae during a surgical fusion.¹¹¹ When the screws allegedly failed, the plaintiff brought strict liability claims against the defendant for the defective design and manufacture of the screws.¹¹² The defendant moved to dismiss the plaintiff’s strict liability claim, arguing, in part, that they were preempted by the Medical Device Amendments of 1976.¹¹³ The defendant claimed that, as in *PLIVA, Inc. v. Mensing*, it could not independently do under federal law what Georgia law required of it resulting in implied preemption of the plaintiffs’ strict product liability claims.¹¹⁴ In support of this argument, the defendant referred to the premarket notification submission process, which requires a manufacturer to notify the FDA of any product change that could “significantly affect the safety or effectiveness of the device.”¹¹⁵

Thus, the defendant argued that this process forced it to obtain advance approval from the FDA for any product modification that was made to comply with state law, that it could not therefore act independently, and that *Mensing* precluded the plaintiffs’ claim.¹¹⁶

The court disagreed and held that the issue of whether design changes could have been made that would comply with Georgia law was a factual issue for the jury and not a legal determination for the court.¹¹⁷ The court determined there was no language in the plaintiffs’ First Amended Complaint alleging that the alternative design changes for the screw related in any way to the premarket submission requirements outlined in title 21, section 807.81(a)(3) of the Code of Federal Regulations.¹¹⁸ As a result, the district court held that because the defendant may be able to design a pedicle screw that complied with Georgia and federal law, the plaintiffs’ claim was not impliedly preempted by impossibility.¹¹⁹

108. *Id.*

109. *Id.* at *57.

110. No. 7:16-CV-9 (HL), 2017 U.S. Dist. LEXIS 45118 (M.D. Ga. Mar. 28, 2017).

111. *Id.* at *1.

112. *Id.* at *4.

113. *Id.* at *4–5.

114. *Id.* at *21.

115. *Id.* at *20.

116. *Id.* at *21.

117. *Id.*

118. *Id.*; 21 C.F.R. § 807.81(a)(3) (2017).

119. *Kaku*, 2017 U.S. Dist. LEXIS 45118, at *21.

Accordingly, the court denied the motion to dismiss on the preemption defense.¹²⁰

In *PLIVA, Inc. v. Dement*,¹²¹ the Georgia Court of Appeals considered whether the trial court properly granted the defendant's motion to dismiss based on preemption in a matter arising from the plaintiffs use of the generic versions of metoclopramide. The plaintiffs sued multiple defendants, including the manufacturers of the generic medication they consumed. Using the federal preemption defense outlined in *PLIVA, Inc. v. Mensing*, the generic drug manufacturers filed motions to dismiss, and the trial court dismissed the various failure to warn claims asserted by the plaintiffs. *Dement* appealed the ruling, "contending that *Mensing* was distinguishable and did not require dismissal."¹²²

The court in *Mensing* previously held that the state-law claims in that case "were barred because it was impossible for generic drug manufacturers to comply with both state-law duties to adequately warn consumers and safely label their products and federal requirements that generic drug labels be the same as federally-approved labels for the name-brand drug (the federal "sameness" requirement)."¹²³ The court of appeals held that "under *Mensing*, the impossibility preemption applies to those claims involving a generic drug manufacturer's failure to unilaterally alter its labeling to comply with state-law warning duties; *Mensing* does not provide generic drug manufacturers with blanket immunity against all state-law warning claims."¹²⁴ The court held that plaintiffs "asserted claims other than those regarding the generic drug manufacturers' federal 'sameness' duties" and "the impossibility principle was not implicated as to *Dement's* claims."¹²⁵ Thus, preemption, as set out in *Mensing*, did not apply to those claims.¹²⁶

The court of appeals also held that *Mensing* did not "require dismissal of *Dement's* claims based on the generic drug manufacturers' failure to suspend or withdraw sales of a misbranded drug" because it was "not impossible for the generic drug manufacturers to simultaneously comply with both state and federal law."¹²⁷ Accordingly, the state-law claims asserted by *Dement* did not run afoul of *Mensing*.¹²⁸ "However, the trial

120. *Id.*

121. 335 Ga. App. 398, 780 S.E.2d 735 (2015).

122. *Id.* at 398–99, 780 S.E.2d at 737–38.

123. *Id.* at 401, 780 S.E.2d at 739.

124. *Id.*

125. *Id.* at 401–02, 780 S.E.2d at 739–40.

126. *Id.*

127. *Id.* at 402–03, 780 S.E.2d at 740.

128. *Id.* at 403, 780 S.E.2d at 740.

court properly dismissed Dement's claims based on 'failure to communicate' warning label change information to the healthcare community, as those claims are preempted by federal law."¹²⁹

IV. EXPERT TESTIMONY

"*Daubert* motions," based on the United States Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,¹³⁰ refer to motions to exclude the testimony of expert witnesses. In *Daubert*, the Supreme Court tasked trial courts with acting as "gatekeepers" to ensure that a proposed expert's testimony is relevant and reliable.¹³¹ As a gatekeeper, the trial court must make a "rigorous three-part inquiry" to determine whether

(1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable . . . and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or determine a fact in issue.¹³²

In 2005, the Georgia General Assembly adopted this evidentiary standard for use in Georgia courts, allowing Georgia courts to rely on federal court opinions interpreting and applying the *Daubert* standard.¹³³

In *Roper v. Kawasaki Heavy Industries, Ltd.*,¹³⁴ the plaintiff was operating a motorcycle "along a curvy stretch of road when the engine suddenly stalled causing him to lose control and collide with an oncoming vehicle."¹³⁵ The plaintiff sustained severe injuries in the collision.¹³⁶ A year after the accident, the manufacturer of the motorcycle issued a recall because of a defect in the battery. The plaintiff subsequently filed suit, asserting claims of strict liability, failure to warn, and negligence. The defendant moved to exclude the testimony of two of the plaintiff's

129. *Id.* at 403, 780 S.E.2d at 740–41.

130. 509 U.S. 597 (1993).

131. *Id.* at 597.

132. *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004).

133. Ga. S. Bill 7, Reg. Sess., 2005 Ga. Laws 1, § 7 (codified at O.C.G.A. § 24-7-702 (2017)).

134. 2015 U.S. Dist. LEXIS 187419 (N.D. Ga. June 29, 2015). This case is also discussed in section I of the Article. *See supra* text accompanying notes 25–33.

135. *Id.* at *2.

136. *Id.*

experts: one a mechanical engineer and the other an expert motorcycle driver.¹³⁷

The defendant argued that the plaintiff's mechanical engineering expert testimony should be excluded because the expert was not qualified, his work not reliable, and his opinions would not assist the trier of fact. The defendant further argued that the expert was not a licensed electrical engineer and had limited experience working on VRs in motorcycles.¹³⁸ The District Court for the Northern District of Georgia noted that a degree or license in a professed specialty only goes to the weight of an expert's testimony, not the admissibility, but was skeptical of the expert's full understanding of motorcycle VRs.¹³⁹

While skeptical of the expert's qualifications, the court's ruling focused on the lack of reliability of the expert testimony.¹⁴⁰ The defendant was highly critical of the methodology employed by the plaintiff's expert and criticized the use and results of his differential diagnosis analysis.¹⁴¹ Differential diagnosis analysis is primarily used in the medical field to compile a comprehensive list of potential causes and explain why each alternative is ruled out. The court determined that even though differential diagnosis is a valid and reliable methodology, it could not find an Eleventh Circuit case in which an expert was allowed to testify to the use of differential diagnosis in a motor vehicle accident.¹⁴² Further, the court found the expert could not show, through reliable evidence, that the VR was capable of causing the condition at issue.¹⁴³ The plaintiff's expert did not rule out a comprehensive list of alternative causes or provide reliable evidence to prove his differential analysis theory.¹⁴⁴ The court concluded that the mechanical engineer's causation testimony was unreliable but assumed that the expert's opinion regarding the existence of a product defect was reliable.¹⁴⁵ Therefore, the court granted the defendant's motion to exclude in part.¹⁴⁶

The defendant also sought to exclude the testimony of the plaintiff's expert motorcycle driver for being unreliable.¹⁴⁷ The court reviewed the

137. *Id.* at *4-6.

138. *Id.* at *12.

139. *Id.* at *12-15.

140. *Id.* at *15.

141. *Id.* at *27.

142. *Id.* at *37.

143. *Id.* at *43.

144. *Id.* at *38.

145. *Id.* at *43-44.

146. *Id.* at *44.

147. *Id.* at *44.

expert driver's analysis of the incident based on riding through the accident site five times on an exemplar motorcycle.¹⁴⁸ The court determined that his testimony was not based on concrete data or testing and that the expert had no basis to testify that engine power loss was the probable cause of the plaintiff's accident.¹⁴⁹ Because he did not conduct independent tests on the motorcycle or rely on his past testing experience, the court determined that his opinion testimony was inadmissible.¹⁵⁰ The court assumed the expert rider's testimony was reliable to the limited extent that if the plaintiff's motorcycle suddenly stalled, it is possible that the plaintiff could lose control, but excluded the causation testimony.¹⁵¹ Therefore, the court granted defendant's motion to exclude in part.¹⁵²

In *Seamon v. Remington Arms Co.*,¹⁵³ the plaintiff sued a gun manufacturer, alleging her husband died as a result of a defect in his rifle when he was deer hunting. Law enforcement officers concluded that the rifle was at least five to ten feet away from the decedent when it fired, leaving the question of what caused the rifle to fire. The plaintiff's liability expert concluded that a defect in the gun's trigger system caused it to misfire, and the defendant filed a *Daubert* motion seeking the exclusion of this expert's opinions.¹⁵⁴ The district court granted defendant's motion on the basis that the opinion was speculative and, thus, unreliable.¹⁵⁵ The Eleventh Circuit Court of Appeals considered the lower court's decision to exclude the expert's testimony.¹⁵⁶

The lower court determined that the plaintiff's expert's opinion was unreliable because the expert had not adequately accounted for possible alternative causes and because the expert had formed his opinions based on facts not in the record.¹⁵⁷ The Eleventh Circuit held it was evident from the record that the expert adequately ruled out alternative causes.¹⁵⁸ The expert testified that he had no evidence pointing to the alternative cause of a trigger pull, and the record supported this opinion.¹⁵⁹

148. *Id.* at *46.

149. *Id.* at *49–50.

150. *Id.*

151. *Id.* at *50.

152. *Id.* at *50–51.

153. 813 F.3d 983 (11th Cir. 2016).

154. *Id.* at 986.

155. *Id.* at 985–87.

156. *Id.* at 987.

157. *Id.* at 989.

158. *Id.*

159. *Id.*

The court then concluded that the district court had mischaracterized the evidentiary support for the expert's opinion in several ways.¹⁶⁰ "First, the district court conflated reasonable inference with improper speculation."¹⁶¹ It was not speculative for the expert to infer a theory occurred when the defendant's alternative theory was inconsistent with the evidence.¹⁶² Regardless, the Eleventh Circuit concluded that, when an expert opinion has satisfied *Daubert*, a court may not exclude that opinion because it is not particularly strong.¹⁶³ The weight given to admissible expert testimony is a matter for the jury.¹⁶⁴

Second, it was clearly erroneous for the district court to draw an adverse inference from a failed expert test when the expert purposely did not conduct that test in the first place.¹⁶⁵ Lastly, the district court incorrectly excluded the expert's inference that debris in the gun housing created the possibility of jar-off¹⁶⁶ where evidence demonstrated that the expert found debris and had previously observed debris interference in similar rifles.¹⁶⁷ The court held that the district court manifestly erred by mischaracterizing the plaintiff's expert's opinion, and it was an abuse of discretion for the district court to exclude the expert's testimony.¹⁶⁸

In *Moore v. Cottrell*,¹⁶⁹ the plaintiff sustained serious injuries while operating a car hauler for a trucking company. After driving two cars onto a car hauler, the plaintiff exited a vehicle parked on the top level of a two-level trailer. He did not attempt to use a portable ladder equipped with the hauler, as he alleged it could only be safely used on dirt and the hauler was parked on asphalt. While attempting to reach the ground, he lost his footing and fell. The plaintiff sued the manufacturer, alleging strict liability, negligence, and breach of warranty claims. The defendant moved to exclude the testimony of the plaintiff's car-hauler expert. The trial court granted this motion, finding that although the expert was qualified to testify, he failed to apply reliable principles or methods to the case.¹⁷⁰

160. *Id.*

161. *Id.*

162. *Id.* at 990.

163. *Id.*

164. *Id.*

165. *Id.*

166. Jar-off is a condition in which "the rifle contacted an external force like the tree, rope, or ground, and the connector was further jarred out of position, allowing the rifle to fire." *Id.* at 987.

167. *Id.* at 991.

168. *Id.*

169. 334 Ga. App. 791, 780 S.E.2d 442 (2015).

170. *Id.* at 791-92, 780 S.E.2d at 444-45.

The Georgia Court of Appeals reviewed the trial court decision for abuse of discretion.¹⁷¹ The plaintiff argued that the trial court erred by striking the expert's testimony.¹⁷² The court of appeals reviewed the expert's report and found several issues.¹⁷³ The expert never inspected or saw the car hauler, had never inspected any fall protection systems for similar car haulers, had never been subject to peer review, had never completed any scientific testing to support his theories, and did not opine regarding the actual cause of plaintiff's fall.¹⁷⁴ For these reasons, the court of appeals determined that his testimony did not meet the requirements of O.C.G.A. § 24-7-702(b).¹⁷⁵ The court of appeals held that the trial court did not abuse its discretion by excluding the expert's testimony.¹⁷⁶

171. *Id.* at 793, 780 S.E.2d at 445.

172. *Id.* at 792, 780 S.E.2d at 445.

173. *Id.* at 794, 780 S.E.2d at 446.

174. *Id.* at 794, 780 S.E.2d at 445–46.

175. *Id.* at 794, 780 S.E.2d at 446; O.C.G.A. § 24-7-702(b) (2017).

176. *Moore*, 334 Ga. App. at 794, 780 S.E.2d at 446.

