Rel: October 25, 2019

SUPREME COURT OF ALABAMA

OCTOBER TERM, 2019-2020

1180387

Forest Laboratories, LLC

v.

Kevin J. Feheley, Sr., as administrator and personal representative of the Estate of Sheila Clay Joubran, deceased, and as guardian and conservator of Kevin J. Feheley, Jr., an incapacitated person

Appeal from Calhoun Circuit Court
(CV-17-900399.80)

WISE, Justice.

Forest Laboratories, LLC ("Forest"), filed a permissive appeal pursuant to Rule 5, Ala. R. App. P., from the Calhoun

Circuit Court's order denying Forest's motion for a summary judgment. We reverse and remand.

Facts and Procedural History

Lexapro is the brand name of a prescription drug used to treat depression. It appears that Forest manufactured and marketed Lexapro and that Forest Pharmaceuticals, Inc. ("FPI") sold and distributed Lexapro. Escitalopram is the generic form of Lexapro.

On December 29, 2015, Elias Joubran's physician prescribed Lexapro for Elias's depression. Elias's prescription was filled with generic escitalopram that was manufactured and sold by a company other than Forest. On December 30, 2015, Elias entered the house belonging to him and his wife, Sheila Clay Joubran; he shot and killed Sheila and then shot and killed himself.[1]

On July 13, 2017, Kevin J. Feheley, Sr., as administrator and personal representative of Sheila's estate and as guardian and conservator of Kevin J. Feheley, Jr., an incapacitated

[1]Evidence was presented indicating that, although Elias and Sheila were married at the time, Sheila was in the process of separating from Elias.

person,[2] filed suit in the Calhoun Circuit Court against Mary Joubran, in her capacity as the personal representative of Elias's estate, Forest, FPI, and fictitiously named defendants. The complaint alleged that, at the time of the murder/suicide, Elias "was under prescription for, and was ingesting, under certain physicians' prescription, certain pharmaceuticals, including those pharmaceuticals manufactured by the defendants as described more particularly herein." The complaint went on to allege that "Forest's Lexapro[] enhanced, enabled and aggravated [Elias's] depression and violent behaviors." The complaint alleged, in part:

> "Defendants [FPI] and [Forest] (collectively hereinafter, 'Forest') were severally, the marketer, promoter, seller, manufacturer, distributor, and entity which did manufacture, create, design, test, label, package, distribute, market, sell, advertise, fail to warn, and otherwise handle and distribute in commerce, the products, Lexapro 10 mg tablets."

After including extensive allegations regarding Forest's marketing activities, Feheley alleged:

> "32. The foregoing and similar activity has continued in an effort to induce physicians to

[2]In an affidavit, Feheley asserted that he is Sheila's ex-husband; that he is the father of Kevin J. Feheley, Jr.; that Kevin J. Feheley, Jr., is Sheila's son and sole surviving heir; and that Kevin J. Feheley, Jr., is incapacitated.

prescribe Lexapro and to increase sales to persons such as [Elias Joubran] as a matter of specific intent by the Defendants. Defendants suppressed the true facts as to the dangers of Lexapro, while at the same time, communicating to physicians and to the body of physicians generally that Lexapro was safe and effective with the specific intent to enlarge and enhance the market for Lexapro and with the proximate result that the prescriptions of Lexapro were in fact greatly increased and enhanced, the drug much more generally accepted by the prescribing physician public, and that customers such as Elias Joubran would be prescribed Lexapro by physicians who were not aware of all of the true dangers of the drug including:

"a. That the drug was particularly dangerous for patients who were already experiencing unusual agitation and upset,

"b. That the drug was particularly dangerous during the time period shortly after its use was commenced by a patient, and shortly after the dose was increased, in either case, a greater risk for suicide and violence was and is enhanced by the drug,

"c. That the drug heightened the risk of increased agitation, suicidal behaviors, violent behaviors, and patients acting on thoughts that would otherwise be mediated or restrained by the patient, but in the presence of this drug would, instead, be acted upon. Defendants misrepresented that the increased risk of suicide was essentially, solely, a product of younger age when in fact [D]efendants knew or should have known that the risk was related to factors that occurred more commonly, but not at all uniquely, with younger age, and these factors existed in Elias Joubran and other vulnerable populations who were targeted consumers of the drugs, and,

> "d. On information and belief, Plaintiff avers that neither Elias Joubran, nor his prescribing physician were aware of the extent and true nature of the facts which were misrepresented and or suppressed by Defendants and neither discovered the true facts at any time before the prescription and the acts described elsewhere in this Complaint, all with the proximate result and consequence that the killing of [Sheila Joubran] and the suicide of Elias Joubran took place as elsewhere described herein."

The complaint alleged that Forest

> "was aware that when new doses are given or increased, there is an enhanced risk period for suicide or violence, but failed to warn adequately of this risk, and actively suppressed, concealed and misrepresented the extent of this enhanced danger."

It further alleged:

> "42. The pharmaceutical product manufactured by [D]efendants and sold by them, being placed in the stream of commerce by them, were dangerous and defective in that each was unreasonably unsafe when put to the ordinary use and purpose for which it was sold and designed.
>
> "43. The said drug was dangerous and defective in that it did not meet the reasonable expectations of the ordinary consumer as to safety, and that further it was not accompanied by the proper and necessary warnings that should have been provided with the said drugs to prevent harm and injury by consumers of the said drugs to persons like [Elias Joubran], all of which was reasonably foreseeable to the [D]efendants. Plaintiffs further allege and aver that [D]efendants were negligent and wanton in their design, manufacture, sale, advertising, failure to warn, and other dealing with, and handling of, the subject products, all of which combined and concurred to be a substantial proximate

> cause of the harm and injury suffered by [P]laintiffs as complained of herein.
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> "44. The [D]efendants, including named and fictitious defendants, were negligent, careless, wanton, and violated the Alabama Manufacturers Extended Liability Doctrine, and their conduct combined and concurred, with the conduct of Defendant's decedent, Elias Joubran, to proximately cause the injuries and damages and losses and the death suffered by the [P]laintiff's decedent, Sheila Clay Joubran, deceased, on December 30, 2015, as described herein.
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> "45. The conduct of the [D]efendants was gross, oppressive, burdensome, willful, intentional, wanton, and otherwise such as to justify the imposition of punitive damages under applicable law."

The complaint asserted various claims against Forest, including various products-liability claims, negligence and wantonness claims, breach-of-express- and implied-warranty claims, and a civil-conspiracy claim. Count II alleged a claim of "Product Liability (Failure to Warn)":

> "57. Defendants are designers, developers, manufacturers, testers, marketers, distributors, promoters, and sellers of the pharmaceutical product Lexapro.
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> "58. The pharmaceutical product Lexapro, designed, developed, manufactured, tested, marketed, distributed, promoted, and sold by Defendants was and is unaccompanied by proper warnings regarding all possible adverse side effects associated with the use of pharmaceutical product Lexapro, and the comparative severity and duration of such adverse

effects; the warnings given did not accurately reflect the symptoms, scope or severity of the side effects.

"59. Defendants failed to perform adequate research, investigation and testing, in that adequate testing, research and investigation would have shown that, used individually and/or in any combination thereof, [Lexapro] possessed serious potential hazards with respect to which full and proper warnings accurately and fully reflecting hazards, symptoms, scope and severity should have been made, both with respect to the use of the pharmaceutical product Lexapro, individually and with respect to any combination use with any other pharmaceutical products.

"60. Defendants also failed to effectively warn users and physicians that numerous other suitable pharmaceutical products made by other manufacturers, did not have such severe side effects.

"61. The pharmaceutical product Lexapro, designed, developed, manufactured, tested, marketed, distributed, promoted, and sold by Defendants was defective due to inadequate post-marketing research and warning or instruction because, after the manufacturer, developer, designer, and marketer knew or should have known of the risk of injury from the pharmaceutical product Lexapro, it and they failed to provide adequate warnings to users or consumers of the product and continued to aggressively promote the product, and no accurate or appropriate warning was given to [Elias Joubran] or his physicians by Defendants Forest Pharmaceuticals, Inc., and Forest Laboratories, Inc., or the other defendants at the point and time of sale or by anyone else."

Count VII alleged claims of misrepresentation, fraud, suppression, and deceit:

"87. Forest[3] and fictitious Defendants were aware that when new doses are given or increased, there is an enhanced risk period for suicide or violence, but fraudulently suppressed information about this risk. Defendants have made, and some of them continue to make, false and fraudulent misrepresentations to physicians and general public including, but not limited to, that the pharmaceutical product Lexapro, is safe, fit and effective for its uses and is not hazardous to the health of users.

"88. At all pertinent times, Defendants conducted, and/or conspired jointly to conduct, a sales and marketing campaign to promote the sale of the pharmaceutical product Lexapro, through advertisements and other promotional literature and fraudulently deceived the Plaintiff, [Elias Joubran], physicians and the general public as to the health risks and consequences of the pharmaceutical product Lexapro. Defendants also failed to disclose other effective methods for treating depression. Defendants suppressed material facts that, if disclosed to [Elias Joubran] or his Physician would have resulted in refusal of use of the pharmaceutical product Lexapro. Forest was aware that when new doses are given or increased, there is an enhanced risk period for suicide or violence, but failed to warn adequately of this risk, and actively suppressed, concealed and misrepresented the extent of this enhanced danger.

"89. Defendants Forest Pharmaceuticals, Inc., and Forest Laboratories, Inc., and fictitiously designated defendants' misrepresentation and suppressions of material facts were done intentionally, willfully, wantonly and/or negligently. Plaintiff alleges in the alternative or in addition that even if the misrepresentations

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[3]"Forest" is used collectively in the complaint for the defendants referred to as "Forest" and "FPI" in this opinion.

> and suppressions made by Defendants Forest Pharmaceuticals, Inc., and Forest Laboratories, Inc., and fictitious defendants, were merely negligent or even innocent misrepresentations they are nonetheless actionable under Alabama and other applicable law. [Elias Joubran] and his physician reasonably relied upon the representations based on the skill and judgment of said Defendants as to whether the pharmaceutical product Lexapro, was of merchantable quality, safe and fit for its intended uses.
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> "90. In reliance of the foregoing misrepresentation whether innocent, negligent, wanton, or not by Defendants, [Elias Joubran] was induced to and did subject himself to the use of pharmaceutical product Lexapro, and committed homicide and suicide. If [Elias Joubran] and physician had known the true facts, he would not have taken such action and subjected himself to the aforesaid risks."

On August 8, 2017, Forest filed a notice of removal in the United States District Court for the Northern District of Alabama. On August 25, 2017, Forest filed its answer to the complaint in the federal district court. In its affirmative defenses, Forest asserted:

> "Forest did not manufacture the product allegedly ingested by Mr. Joubran. Accordingly, Forest may not be held liable to plaintiff for any of the alleged injuries or damages in this lawsuit."

On October 20, 2017, the United States District Court for the Northern District of Alabama, Eastern Division, remanded the case to the Calhoun Circuit Court.

On December 1, 2017, Feheley filed an amendment to the complaint. The amended complaint substituted Camber Pharmaceutical for one of the fictitiously named defendants. In the amended complaint, Feheley alleged that Camber was

> "the marketer, manufacturer, promoter, seller, distributor, and entity which did manufacture, create, design, test, label, package, distribute, market, sell, advertise, fail to warn, and otherwise handle and distribute in commerce, the products escitalopram tablets."

Forest subsequently filed its response and answer to the amended complaint, incorporating the answer it had previously filed in the federal district court.

On February 26, 2018, Feheley and Forest entered into the following stipulation:

> "1. Elias Joubran's prescription for Lexapro/escitalopram was filled with generic escitalopram manufactured and sold by a company other than Forest.
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> "2. In the interest of conserving the resources of the Court and the parties, the issue of whether Forest is entitled to judgment solely based on the fact that Forest did not manufacture or sell the escitalopram that Elias Joubran received will be pled and briefed in the near future without prejudice to Forest's ability to file a subsequent dispositive motion in the event Forest's motion on the product use issue is denied."

On the same day, Forest filed a "Motion for Summary Judgment Based on Lack of Product Use."[4] In that motion, Forest alleged that the injury claimed by Feheley was not caused by a product that was sold or manufactured by Forest. In its memorandum in support of that motion, Forest stated that it markets the brand-name prescription pharmaceutical Lexapro, which is generically known as escitalopram; that escitalopram has been available in generic form for many years; that Feheley and Forest agreed that Forest did not manufacture or sell the escitalopram at issue in this case; and that the prescription at issue in this case was filled with a generic escitalopram that was manufactured and sold by a competitor of Forest's. Forest also asserted that it could not be liable for the alleged injuries caused by another manufacturer's product. It went on to argue:

> "For decades, a well-established principle of Alabama tort law has been that for a manufacturer to owe a duty (or have any liability) to a consumer, the manufacturer must have manufactured or sold the product that allegedly caused the consumer harm. As the Alabama Supreme Court explained decades ago:

[4]Forest asserted that, although FPI had also been named as a defendant, FPI had not been served.

> "'The breach of duty charges against defendants is the failure to give notice to or warn plaintiffs of the dangerous nature of the vine killer. Do the facts alleged in the complaint show that the defendant, Bertolla, owed a duty to warn plaintiffs? As plaintiffs candidly admit in brief, it is not alleged that plaintiffs purchased the vine killer from Bertolla. It is not alleged that Bertolla ever had possession of or any connection whatsoever with the particular substance which plaintiffs sprayed and which allegedly caused the death of plaintiffs' cattle. The rule, upon which plaintiffs' right to recover is based, imposes the duty on one who, with knowledge of its dangerous quality, manufactures or sells an imminently dangerous article and fails to warn. It is not alleged that Bertolla manufactured the dangerous article. It is not alleged that Bertolla sold it. How, then, did Bertolla owe a duty to warn?'

"See Thompson-Hayward Chemical Co. v. Childress, 169 So. 2d 305, 312 (1964)(emphasis added).

"Federal courts in Alabama understood that to be Alabama law in cases involving prescription medications. See Mosley v. Wyeth, Inc., 719 F. Supp. 2d 1340 (S.D. Ala. 2010) (holding where consumer ingested generic prescription drug product, manufacturer of brand-name drug had no relationship to consumer and owed no duty to consumer). But in August 2014, the Alabama Supreme Court carved out a narrow exception to that well-established principle in the context of prescription medications. See Wyeth, Inc. v. Weeks, 159 So. 3d 649 (2014).

"In Weeks, based on the federal regulatory scheme for prescription medicines and the United States Supreme Court's decision in PLIVA, Inc. v.

> Mensing, 564 U.S. 604, 131 S. Ct. 2567 (2011), the Alabama Supreme Court held that a brand-name-drug company may be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company.
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> "The Court[5] in Weeks stressed the limited scope of its holding:
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> > "'Our answer to this certified question ... is extraordinarily narrow in scope. The posture in which the certified question is asked (assuming a fraud cause of action), the facts of this case, and the impact of strict federal regulation on the prescription-drug industry drastically confine our holding and wholly remove the facts of this case from situations where parties are allegedly being held liable under general products-liability theories for products they did not make. I cannot see our answer to the certified question as in any way speaking to the applicability of Alabama law outside the narrow context created by federal law in this case.'
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> "Id. at 680.
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> "The court further noted:
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> > "'Nothing in this opinion suggests that a plaintiff can sue Black & Decker for injuries caused by a power tool manufactured by Skil based on labeling or otherwise. The unique relationship between

[5]The quotation that follows is actually taken from Justice Shaw's special concurrence, not the opinion of the Court.

> brand-name and generic drugs as a result of federal law and [Food and Drug Administration] regulations, combined with the learned-intermediary doctrine and the fact that representations regarding prescription drugs are made not to the plaintiff but to a third party, create the sui generis context in which we find prescription medication.'

"Id. at 677.

"Justice Murdock's dissent in Weeks noted that the majority's decision ran contrary to a 'mountain of authority' and 'overwhelming national consensus.' Id. at 702-706. The Alabama legislature agreed with Justice Murdock and acted swiftly to abrogate Weeks.

"It quickly passed Alabama Code 1975[,] § 6-5-530, which became effective November 1, 2015. The statute provides, in pertinent part:

> "'(a) In any civil action for personal injury, death, or property damage caused by a product, regardless of the type of claims alleged or the theory of liability asserted, the plaintiff must prove, among other elements, that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based, and not a similar or equivalent product. Designers, manufacturers, sellers, or lessors of products not identified as having been used, ingested, or encountered by an allegedly injured party may not be held liable for any alleged injury.' (Emphasis added.)

"[Section 6-5-530] is dispositive in this case. It is undisputed that Forest did not manufacture or

> sell the product plaintiff alleges caused the harm. Forest therefore is entitled to judgment as a matter of law."

(Footnotes omitted.)

Feheley filed a response in opposition to Forest's motion for a summary judgment. In his response, Feheley argued that § 6-5-530, Ala. Code 1975, did not abrogate this Court's decision in Wyeth, Inc. v. Weeks, 159 So. 3d 649 (2014), and that, if it did, § 6-5-530 "would be unconstitutional as to the claims made in the case now before the Court."

On June 6, 2018, Forest filed a reply to Feheley's response. On June 29, 2018, Forest filed a reply memorandum in support of its motion for a summary judgment. Forest attached affidavits from two Alabama legislators to support its assertion that Senate Bill 80 ("S.B. 80"), which was introduced during the 2015 Regular Session of the Alabama Legislature and was subsequently enacted and then codified as § 6-5-530, was a direct result of this Court's decision in Weeks. Feheley filed a motion to strike those affidavits, which the trial court granted.

On August 13, 2018, Feheley filed his response to Forest's June 29, 2018, memorandum. In that response, Feheley

asserted that discovery should be allowed for a factual development of the statutory and, if necessary, constitutional issues.

On February 8, 2019, the trial court entered the following order denying Forest's motion for a summary judgment:

> "[A motion for s]ummary judgment was filed by Defendant Forest Pharmaceuticals in the above-styled matter on the limited issue of whether under current Alabama law a pharmaceutical manufacturer can be liable for a product it did not manufacture. After considering the testimony and the filings and giving deference to the non-moving party, this Court denies summary judgment on this issue. ...
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> "Based on the conflict between Alabama Code 1975, § 6-5-530, and Wyeth, Inc. v. Weeks, 159 So. 3d 649 (Ala 2014), this interlocutory order involves a controlling question of law as to which there is a substantial ground for difference of opinion that an immediate appeal from the order would materially advance the ultimate termination of the litigation, and the appeal would avoid protracted and expensive litigation. The controlling question is whether Alabama Code 1975, § 6-5-530, abrogated the Weeks decision and whether under current Alabama law a pharmaceutical manufacturer can have liability for a product it did not manufacture."

Subsequently, Forest filed a petition for permission to appeal in this Court, which this Court granted.

Discussion

With regard to permissive appeals, this Court has stated:

> "In the petition for a permissive appeal, the party seeking to appeal must include a certification by the trial court that the interlocutory order involves a controlling question of law, and the trial court must include in the certification a statement of the controlling question of law. Rule 5(a), Ala. R. App. P. In conducting our de novo review of the question presented on a permissive appeal, 'this Court will not expand its review ... beyond the question of law stated by the trial court. Any such expansion would usurp the responsibility entrusted to the trial court by Rule 5(a).' BE&K, Inc. v. Baker, 875 So. 2d 1185, 1189 (Ala. 2003). ..."

Alabama Powersport Auction, LLC v. Wiese, 143 So. 3d 713, 716 (Ala. 2013).

In this case, the trial court certified the following question for permissive appeal:

> "The controlling question is whether Alabama Code 1975, § 6-5-530, abrogated the Weeks decision and whether under current Alabama law a pharmaceutical manufacturer can have liability for a product it did not manufacture."

On appeal, Forest argues that § 6-5-530 abrogated this Court's decision in Weeks and that, under current Alabama law, a pharmaceutical manufacturer cannot be held liable for a product it did not manufacture. Thus, it argues that it is entitled to a judgment as to all the claims against it. This case presents a pure question of law. This Court has held that, "'"[o]n appeal, the ruling on a question of law carries

no presumption of correctness, and this Court's review is de novo."' Rogers Found. Repair, Inc. v. Powell, 748 So. 2d 869, 871 (Ala. 1999) (quoting Ex parte Graham, 702 So. 2d 1215, 1221 (Ala. 1997))." City of Prattville v. Corley, 892 So. 2d 845, 847 (Ala. 2003).

In answering the trial court's question, we are guided by the following principles of statutory construction:

> "'In determining the meaning of a statute, this Court looks to the plain meaning of the words as written by the legislature.' DeKalb County LP Gas Co. v. Suburban Gas, Inc., 729 So. 2d 270, 275 (Ala. 1998).
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> > "'"Words used in a statute must be given their natural, plain, ordinary, and commonly understood meaning, and where plain language is used a court is bound to interpret that language to mean exactly what it says. If the language of the statute is unambiguous, then there is no room for judicial construction and the clearly expressed intent of the legislature must be given effect."'
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> "Blue Cross & Blue Shield of Alabama, Inc. v. Nielsen, 714 So. 2d 293, 296 (Ala. 1998) (quoting IMED Corp. v. Systems Eng'g Assocs. Corp., 602 So. 2d 344, 346 (Ala. 1992))."

City of Prattville v. Corley, 892 So. 2d at 848.

> "In Archer v. Estate of Archer, 45 So. 3d 1259, 1263 (Ala. 2010), this Court described its responsibilities when construing a statute:

> "'"'[I]t is this Court's responsibility in a case involving statutory construction to give effect to the legislature's intent in enacting a statute when that intent is manifested in the wording of the statute. ... "'"'[I]f the language of the statute is unambiguous, then there is no room for judicial construction and the clearly expressed intent of the legislature must be given effect.'"'" ... In determining the intent of the legislature, we must examine the statute as a whole and, if possible, give effect to each section.'

"'"Ex parte Exxon Mobil Corp., 926 So. 2d 303, 309 (Ala. 2005). Further,

> "'"'when determining legislative intent from the language used in a statute, a court may explain the language, but it may not detract from or add to the statute. ... When the language is clear, there is no room for judicial construction. ...'

> > "'"Water Works & Sewer Bd. of Selma v. Randolph, 833 So. 2d 604, 607 (Ala. 2002)."'
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> "(Quoting Ex parte Birmingham Bd. of Educ., 45 So. 3d 764, 767 (Ala. 2009).) Similarly, in Lambert v. Wilcox County Commission, 623 So. 2d 727, 729 (Ala. 1993), the Court stated:
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> > "'"The fundamental rule of statutory construction is that this Court is to ascertain and effectuate the legislative intent as expressed in the statute. ... In this ascertainment, we must look to the entire Act instead of isolated phrases or clauses ... and words are given their plain and usual meaning. ... Moreover, just as statutes dealing with the same subject are in pari materia and should be construed together, ... parts of the same statute are in pari materia and each part is entitled to equal weight."'
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> "(Quoting Darks Dairy, Inc. v. Alabama Dairy Comm'n, 367 So. 2d 1378, 1380-81 (Ala. 1979).)"

First Union Nat'l Bank of Florida v. Lee Cty. Comm'n, 75 So. 3d 105, 111-12 (Ala. 2011).

This Court released its original decision in Weeks on January 11, 2013. On August 15, 2014, on application for rehearing, this Court withdrew that opinion and substituted another opinion. In Weeks, Danny and Vicki Weeks sued five current and former drug manufacturers in the United States

District Court for the Middle District of Alabama, Southern Division ("the federal court"), for injuries Danny allegedly suffered as a result of his long-term use of metoclopramide, the generic from of the brand-name drug Reglan. The Weekses conceded that Danny did not ingest any Reglan that had been manufactured by the three brand-name defendants -- Wyeth, Inc., Pfizer, Inc., and Schwarz Pharma, Inc. However,

> "'[t]he Weekses nonetheless assert[ed] that the brand-name defendants [were] liable for Mr. Weeks's harm on fraud, misrepresentation, and/or suppression theories because they at different times manufactured or sold brand-name Reglan® and purportedly either misrepresented or failed adequately to warn Mr. Weeks or his physician about the risks of using Reglan® long-term.'"

159 So. 3d at 653 (quoting federal district court's certification). The brand-name defendants moved to dismiss the claims against them, arguing that the Weekses' claims were, in fact, product-liability claims that were barred "'for failure of "product identification"'" and that they did not have any duty to warn about the risks associated with the ingestion of their competitors' generic products. The federal court granted the brand-name defendants' motion in part and denied it in part. The federal court held that the Weekses might be able to state a claim under Alabama law if they could

prove that the brand-name defendants had a duty to warn Danny's physician about the risks associated with the long-term use of Reglan and that the Weekses, as third parties, had a right to enforce an alleged breach of that duty. The federal court certified the following question to this Court:

> "'Under Alabama law, may a drug company be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture or distribution of a brand-name drug, by a plaintiff claiming physical injury from a generic drug manufactured and distributed by a different company?'"

159 So. 3d at 653. In answering that certified question, this Court stated:

> "We answer the certified question as follows: Under Alabama law, a brand-name-drug company may be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company. Prescription drugs, unlike other consumer products, are highly regulated by the FDA [Food and Drug Administration]. Before a prescription drug may be sold to a consumer, a physician or other qualified health-care provider must write a prescription. The United States Supreme Court in Wyeth v. Levine[, 555 U.S. 555 (2009),] recognized that Congress did not preempt common-law tort suits, and it appears that the FDA traditionally regarded state law as a complementary form of drug regulation: The FDA has limited resources to monitor the approximately

11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge; state-law tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly and serve a distinct compensatory function that may motivate injured persons to come forward with information. Wyeth v. Levine, 555 U.S. at 578–79.

"FDA regulations require that a generic manufacturer's labeling for a prescription drug be exactly the same as the brand-name manufacturer's labeling. The Supreme Court in PLIVA[, Inc. v. Mensing, 564 U.S. 604 (2011),] held that it would have been impossible for the generic manufacturers to change their warning labels without violating the federal requirement that the warning on a generic drug must match the warning on the brand-name version, preempting failure-to-warn claims against generic manufacturers.

"In the context of inadequate warnings by the brand-name manufacturer placed on a prescription drug manufactured by a generic manufacturer, it is not fundamentally unfair to hold the brand-name manufacturer liable for warnings on a product it did not produce because the manufacturing process is irrelevant to misrepresentation theories based, not on manufacturing defects in the product itself, but on information and warning deficiencies, when those alleged misrepresentations were drafted by the brand-name manufacturer and merely repeated, as allowed by the FDA, by the generic manufacturer.

"In answering the question of law presented to us by the federal court, we emphasize the following: We are not turning products-liability law (or tort law for that matter) on its head, nor are we creating a new tort of 'innovator liability' as has been suggested. Instead, we are answering a question of law involving a product that, unlike any other product on the market, has unprecedented

> federal regulation. Nothing in this opinion suggests that a plaintiff can sue Black & Decker for injuries caused by a power tool manufactured by Skil based on labeling or otherwise. The unique relationship between brand-name and generic drugs as a result of federal law and FDA regulations, combined with the learned-intermediary doctrine and the fact that representations regarding prescription drugs are made not to the plaintiff but to a third party, create the sui generis context in which we find prescription medication. Again, the fraud or misrepresentation claim that may be brought under Alabama law against a drug manufacturer based on statements it made in connection with the manufacture of a brand-name prescription drug by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company is premised upon liability not as a result of a defect in the product itself but as a result of statements made by the brand-name manufacturer that Congress, through the FDA, has mandated be the same on the generic version of the brand-name drug."

Weeks, 159 So. 3d at 676-77.

S.B. 80 was introduced in March 2015. After passing the Senate and the House, it was assigned Act No. 2015-106. Act No. 2015-106 was approved by the Governor on May 1, 2015. Section 4 of Act No. 2015-106 provides:

> "This act shall become effective six months following its passage and approval by the Governor, or its otherwise becoming law, and shall apply to civil actions filed thereafter."

Act No. 2015-106 was codified as § 6-5-530, Ala. Code 1975, and became effective on November 1, 2015. Section 6-5-530(a) provides:

> "In any civil action for personal injury, death, or property damage caused by a product, regardless of the type of claims alleged or the theory of liability asserted, the plaintiff must prove, among other elements, that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based, and not a similar or equivalent product. Designers, manufacturers, sellers, or lessors of products not identified as having been used, ingested, or encountered by an allegedly injured party may not be held liable for any alleged injury. A person, firm, corporation, association, partnership, or other legal or business entity whose design is copied or otherwise used by a manufacturer without the designer's express authorization is not subject to liability for personal injury, death, or property damage caused by the manufacturer's product, even if use of the design is foreseeable."
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> This Court has stated:
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> "'[T]he Legislature is presumed to be aware of existing law and judicial interpretation when it adopts a statute,' Carson v. City of Prichard, 709 So. 2d 1199, 1206 (Ala. 1998), and 'we presume "that the legislature does not intend to make any alteration in the law beyond what it explicitly declares."' Ware v. Timmons, 954 So. 2d 545, 556 (Ala. 2006)(quoting Duncan v. Rudulph, 245 Ala. 175, 176, 16 So. 2d 313, 314 (1944))."

Grimes v. Alfa Mut. Ins. Co., 227 So. 3d 475, 489 (Ala. 2017).

In Arthur v. Bolen, 41 So. 3d 745 (Ala. 2010), the plaintiffs, Samuel and Julie Bolen, had purchased a house that had been built by Tom Arthur. As Samuel was climbing into the attic, the pull-down ladder, which had been installed by Arthur, separated and fell from the attic opening to which it was attached. The Bolens sued Arthur. Before trial, Arthur filed a motion in limine to prevent the Bolens' expert, Michael Van Bree, from testifying as to the cause of the failure of the attic stairway. Arthur argued that § 34-11-1(7), Ala. Code 1975, prohibited Van Bree from providing expert testimony because Van Bree was not a licensed professional engineer in Alabama or any other state. Arthur renewed his objection to Van Bree's proposed testimony at trial. Counsel for the Bolens asserted that Arthur's motion was based on this Court's decision in Board of Water & Sewer Commissioners v. Hunter, 956 So. 2d 403 (Ala. 2006), and that that case was no longer good law because § 34-11-1, Ala. Code 1975, in Chapter 11, "Engineers and Land Surveyors," had been amended since that decision had been released. The trial court allowed Van Bree to testify. The jury returned a verdict in favor of the Bolens.

On appeal, Arthur argued that the trial court should not have allowed Van Bree to testify as to the cause of the failure of the attic stairway. In addressing that issue, this Court stated:

> "As the colloquy in the trial court revealed, § 34-11-1(7)[, Ala. Code 1975,] was amended in 2007 in response to Board of Water & Sewer Commissioners of Mobile v. Hunter, 956 So. 2d 403 (Ala. 2006), which applied, as written, the former version of the statute defining the rendering of expert testimony as the 'practice of engineering,' for which an Alabama engineering license was essential. By Act No. 2007-365, Ala. Acts 2007, the legislature deleted the reference to 'testimony' from the definition of 'practice of engineering' in the introductory portion of subsection (7) and added the paragraph quoted by the Bolens' counsel in the trial court. It also added subpart d. to subsection (7), which states: 'The practice of engineering shall include the offering of expert opinion in any legal proceeding in Alabama regarding work legally required to be performed under an Alabama engineer's license number or seal, which opinion may be given by an engineer licensed in any jurisdiction.' (Emphasis added.) Thus, § 34-11-1, as amended and as applicable to this case, differs considerably from its predecessor.
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> "Arthur contends that 'Van Bree's testimony, that the subject attic [ladder] was not installed in accord with the manufacturer's specifications ..., constitutes "the review of construction or other design products for the purpose of monitoring compliance with drawings and specifications."' Reply brief, at 9 (quoting § 34-11-1(7)). According to Arthur, such testimony triggered the provision in § 34-11-1(7)d., which, he contends, required Van Bree to be licensed in at least one state. The

> Bolens disagree with this construction of the statute. Because the resolution of this issue is a matter of mere statutory construction, the standard of review is de novo. Ex parte Birmingham Bd. of Educ., 45 So.3d 764, 767 (Ala. 2009) (when issues on appeal '"concern only questions of law involving statutory construction, the standard of review is de novo"').
>
> "'The intent of the Legislature is the polestar of statutory construction.' Sigelman v. Alabama Ass'n of School Bds., 819 So. 2d 568, 579 (Ala. 2001). In construing this statute, we are hardly writing on a clean slate. The substantial amendment to § 34-11-1, coming, as it did, on the heels of this Court's decision in Hunter, reveals much regarding legislative intent."

41 So. 3d at 748-49 (final emphasis added).

Similarly, the enactment of § 6-5-530, coming on the heels of this Court's decision in Weeks, clearly demonstrates the legislature's intent in enacting that statute. Weeks held that the manufacturer of a brand-name drug could be held liable for fraud or misrepresentation based on statements made in connection with the manufacture of the brand-name prescription drug, even though the plaintiff's claim was based on a physical injury that had been caused by a generic drug manufactured by a different company. In reaching that decision, this Court rejected Wyeth's argument that the Weekses' claims were, in essence, product-liability claims,

noting that a fraudulent-suppression claim is separate from an Alabama Extended Manufacturer's Liability Doctrine ("AEMLD") claim. This Court noted that that case did not involve a claim that the drug ingested by one of the plaintiffs was defective. Rather, it was a claim that Wyeth had fraudulently misrepresented or suppressed information about the manner in which the drug was to be taken. This Court went on to state:

> "Because a warning label is not a part of the manufacturing process, we do not agree that the fact that a brand-name manufacturer did not produce the version of the drug ingested by the plaintiff bars the plaintiff's tort action when the plaintiff is arguing that he or she was injured by a failure to warn."

159 So. 3d at 670. However, § 6-5-530 specifically provides that a plaintiff who is suing based on personal injury, death, or property damage caused by a product "must prove ... that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based" regardless of the type of claims or theory of liability the plaintiff asserts. It goes on to provide that "that ... manufacturers ... of products not identified as having been ... ingested ... by an

allegedly injured party may not be held liable for any alleged injury." (Emphasis added.)

Further, in reaching its decision in Weeks, this Court also stated:

> "A brand-name manufacturer is well aware of the expiration of its patent and well aware that a generic version of the drug will be made when that patent expires. It is recognized that the generic substitutions are allowed in all 50 states. A brand-name manufacturer could reasonably foresee that a physician prescribing a brand-name drug (or a generic drug) to a patient would rely on the warning drafted by the brand-name manufacturer even if the patient ultimately consumed the generic version of the drug."

159 So. 3d at 670. However, § 6-5-530(a) provides, in pertinent part:

> "A person, firm, corporation, association, partnership, or other legal or business entity whose design is copied or otherwise used by a manufacturer without the designer's express authorization is not subject to liability for personal injury, death, or property damage caused by the manufacturer's product, even if use of the design is foreseeable."

(Emphasis added.) Thus, it appears that, in enacting § 6-5-530, the legislature also incorporated provisions that rejected some of the reasoning this Court relied upon in reaching its decision in Weeks. Based on the foregoing, it is clear that, in enacting § 6-5-530, the legislature intended

to abrogate this Court's decision in Weeks. Further, under the plain language of § 6-5-530, a pharmaceutical manufacturer cannot be held liable for injury caused by a product it did not manufacture.

Because this is a permissive appeal, the questions before us are limited to whether § 6-5-530 effectively overruled this Court's decision in Weeks and whether a manufacturer can be held liable for an injury caused by a product it did not manufacture. Any questions as to whether Forest was excluded from the protections of § 6-5-530 because it was the designer of the generic escitalopram and of the labeling, warnings, and package inserts for the generic escitalopram, or whether drug labeling, warnings, and package inserts actually constitute a "product" as that term is used in § 6-5-530, or regarding the constitutionality of § 6-5-530 are not properly before this Court. See Alabama Powersport Auction, supra; BE&K, Inc. v. Baker, 875 So. 2d 1185, 1189 (Ala. 2003) (noting that "this Court will not expand its review on permissive appeal beyond the question of law stated by the trial court").[6]

[6]In his brief to this Court, Feheley argues that "[d]iscovery should be allowed for a factual development of the statutory and if necessary, constitutional, issues in this case with regard to the issues presented by Forest and by the

Conclusion

Section 6-5-530 abrogates this Court's prior decision in Weeks. Further, under the plain language of § 6-5-530, a pharmaceutical manufacturer cannot be held liable for injury caused by a product it did not manufacture. Based on our answer to the trial court's certified question in the permissive appeal, we reverse the trial court's order denying Forest's motion for a summary judgment and remand this case for proceedings consistent with this opinion.

REVERSED AND REMANDED.

Parker, C.J., and Bolin, Bryan, Sellers, and Mitchell, JJ., concur.

Mendheim and Stewart, JJ., concur in the result.

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plaintiff." (Feheley's brief at p. 12.) Feheley also argues that Forest would be excluded from the protections of § 6-5-530 because it was the designer of both the warning labels used and the generic escitalopram ingested by Elias. Feheley further argues that "an issue not presently before this Court is the statute's unconstitutionality if Forest's interpretation is accurate and 6-5-530 has any application here." (Feheley's brief at p. 34.) However, those issues are not part of the questions of law certified by the trial court. As we noted previously, "this Court will not expand its review on permissive appeal beyond the question of law stated by the trial court." BE&K, Inc. v. Baker, 875 So. 2d at 1189. Therefore, we will not address those issues.