THE STATE OF SOUTH CAROLINA
In The Supreme Court

Monica Weston, Petitioner,

v.

Kim's Dollar Store and CIBA Vision, a Division of Novartis Company, Respondents.

ON WRIT OF CERTIORARI TO THE COURT OF APPEALS

Appeal from Richland County
G. Thomas Cooper, Jr., Circuit Court Judge

Opinion No. 27155
Heard January 26, 2012 – Filed August 8, 2012

AFFIRMED AND REMANDED

Robert L. Widener, Celeste T. Jones, A. Victor Rawl, Jr., and Andrew G. Melling, of McNair Law Firm, of Columbia; and Stevens Bultman Elliott, of Columbia, for Petitioner.

Daniel Thomas Sullivan, of Columbia, for Respondent Kim's Dollar Store.

Curtis L. Ott, of Gallivan White & Boyd, of Columbia; and Keith D. Munson and Sandi R. Wilson, of Womble Carlyle Sandridge & Rice, of

Greenville, for Respondent CIBA Vision, a Division of Novartis Company.

JUSTICE KITTREDGE: We granted a writ of certiorari to review the court of appeals' decision in this matter. *Weston v. Kim's Dollar Store*, 385 S.C. 520, 684 S.E.2d 769 (Ct. App. 2009). Petitioner Monica Weston purchased a pair of prescription decorative, colored contact lenses without a prescription from Respondent Kim's Dollar Store, an unauthorized seller. The lenses were manufactured by Respondent CIBA Vision (CIBA). Petitioner developed an eye infection which led to the loss of vision in her left eye. Thereafter, Petitioner brought an action against Kim's Dollar Store and CIBA alleging six causes of action. The trial court granted partial summary judgment in favor of CIBA as to three of the six causes of action based on federal preemption, and the court of appeals affirmed.

On certiorari, Petitioner concedes the lenses she purchased are Class III medical devices but argues her claims are not preempted because CIBA failed to show the lenses were approved by the Food and Drug Administration (FDA) through the pre-market approval (PMA) process. Having carefully canvassed the voluminous record, we find these lenses were FDA approved through the PMA process. Accordingly, we affirm the court of appeals to the extent partial summary judgment was granted on claims that would impose common-law requirements "different from, or in addition to" applicable FDA requirements. As to the remaining causes of action, we remand for further proceedings consistent with this opinion.

I.

PROCEDURAL HISTORY

The underlying facts are set forth in the court of appeals' well-reasoned opinion. For ease of reference, we reiterate only that the contact lenses Petitioner purchased were FreshLook Colors brand lenses with ultraviolet (UV) protection, to be sold by prescription only, and approved for extended wear. The lenses were non-corrective, or "plano" lenses.

Petitioner filed suit against Kim's Dollar Store and CIBA alleging six causes of action and seeking damages for her injuries.[1] Essentially, Petitioner claimed CIBA knew its plano lenses were frequently sold without a prescription and by unauthorized sellers, yet CIBA failed to take steps to ensure customers received lenses by prescription only and with appropriate warnings and instructions. CIBA moved for summary judgment on the basis that Petitioner's claims were preempted by federal law. Following a hearing, the trial court granted partial summary judgment in favor of CIBA as to Petitioner's claims based on "warning, labeling, design, marketing, misbranding, or similar claims."

The court of appeals affirmed the partial grant of summary judgment, finding CIBA demonstrated that no genuine issue of material fact existed as to whether FreshLook Colors plano lenses underwent the PMA process and were subject to device-specific FDA requirements. As to Petitioner's state common-law claims, the court of appeals found "[a]ny state requirements imposed by a jury verdict in favor of the causes of action at issue would be in addition to or in contradiction of federal requirements, and therefore . . . were properly dismissed by the circuit court." *Weston*, 385 S.C. at 537, 684 S.E.2d at 778.

Before now, Petitioner has vigorously claimed that the contact lenses she purchased should be considered a cosmetic, not a medical device, and substantial portions of the trial court's order and the court of appeals' opinion were devoted to that issue. However, Petitioner now concedes the plano lenses she purchased are Class III medical devices. Thus, the sole issue before this Court is Petitioner's claim that a genuine issue of material fact exists as to whether FreshLook Colors UV plano lenses were subject to FDA approval through the PMA process.

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[1] The six causes of action in Petitioner's amended complaint are as follows: (1) negligence per se for violating state and federal statutory requirements regarding the manufacture, promotion, and sale of FreshLook Colors lenses; (2) negligence in the manufacture, sale, promotion, and distribution of FreshLook Colors lenses; (3) breach of implied warranty of merchantability and fitness because the lenses were not safely labeled; (4) strict liability for placing defectively labeled products into the stream of commerce; (5) sale of a defective product for inadequate warnings; and (6) a claim under the South Carolina Unfair Trade Practices Act, based on CIBA's willful and knowing failure to comply with state and federal statutes regarding the sale and distribution of FreshLook Colors lenses.

II.

STANDARD OF REVIEW

A trial court may grant summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Rule 56(c), SCRCP. "Summary judgment should be granted only where it is perfectly clear that no genuine issue of material fact exists and inquiry into facts is not desirable to clarify application of the law." *Wortman v. Spartanburg*, 310 S.C. 1, 4, 425 S.E.2d 18, 20 (1992). "An appellate court applies the same standard used by the trial court under Rule 56(c) when reviewing the grant of a motion for summary judgment." *Epstein v. Coastal Timber Co.*, 393 S.C. 276, 281, 711 S.E.2d 912, 915 (2011). "In determining whether summary judgment is proper, the court must construe all ambiguities, conclusions, and inferences arising from the evidence against the moving party." *Byers v. Westinghouse Elec. Corp.*, 310 S.C. 5, 7, 425 S.E.2d 23, 24 (1992).

III.

ANALYSIS

The applicable law regarding federal regulation of contact lenses is set forth in the court of appeal's well-researched and reasoned opinion. Here, we reiterate only that Congress included an **express preemption** provision in the Medical Device Amendments of 1976 (MDA),[2] which provides:

> [N]o State or political subdivision of a State may establish or continue with respect to a device intended for human use any requirement—
> (1) **which is different from, or in addition to, any requirement applicable under this chapter to the device**, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

[2] *See generally* Federal Food, Drug, & Cosmetic Act, 21 U.S.C. §§ 301-399d.

21 U.S.C. § 360k(a) (emphasis added). The United States Supreme Court made clear in its recent decision in *National Meat Ass'n v. Harris*, that express preemption provisions should be construed broadly, with an eye towards a federal agency's extensive authority and responsibility of ensuring the safety and effectiveness of consumer products.[3] 132 S.Ct. 965 (2012). Although *Harris* examined a different federal regulatory scheme, we believe that opinion is instructive as to the broad manner in which express preemption provisions should be construed, particularly where, as here, the federal regulatory scheme at issue does not contain a saving clause.

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[3] *Harris* involved the Federal Meat Inspection Act (FMIA), which imposes requirements upon slaughterhouses' handling of certain animals. At issue was the efficacy of a California statute governing the treatment of certain animals in slaughterhouses, including those regulated under FMIA. The FMIA includes an express preemption provision stating:

> Requirements within the scope of [FMIA] with respect to premises, facilities and operations of any establishment at which inspection is provided under [FMIA] which are *in addition to, or different than* those made under [FMIA] may not be imposed by any State.

21 U.S.C. § 678 (emphasis added).

The FMIA also includes a saving clause, which states that the Act "shall not preclude any State . . . from making requirement[s] or taking other action, consistent with this [Act], with respect to any other matters regulated under this [Act]." *Harris*, 132 S.Ct. at 969, n.3 (quoting 21 U.S.C. § 678).

Notwithstanding the saving clause, the United States Supreme Court construed the FMIA's express preemption provision to find that it "sweeps widely—and in so doing, blocks the applications of [the California statute] challenged here. The clause prevents a State from imposing any additional or different—even if non-conflicting—requirements that fall within the scope of the [FMIA] and concern a slaughterhouse's facilities or operations." *Id.* at 970. The Supreme Court stated, "California's [statute] endeavors to regulate the same thing, at the same time, in the same place—except by imposing different requirements [than the FMIA]." *Id*. at 975. Accordingly, the Supreme Court concluded the California statute was preempted. *Id*.

As to federal requirements, pre-market approval imposes device-specific requirements as contemplated by the MDA. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008). "Absent other indication, reference to a State's 'requirements' includes its common-law duties." *Id*. at 324. However, "State requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." *Id.* at 330. "Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.*

Thus, the first step in the preemption inquiry is to determine whether the federal government has established requirements applicable to the device through the PMA process. *Id*. at 321. If so, the next step is to determine whether the state common-law claims parallel the federal requirements (then, the state claim is not preempted) or whether the state common-law claims are "different from, or in addition to" the federal requirements (then, state claim is preempted). Petitioner now argues the contact lenses at issue here—plano lenses with UV protection—were never subject to PMA or supplemental PMA.

The key question in the present case is whether the lenses Petitioner purchased were subject to device-specific federal requirements imposed by virtue of the PMA process.[4] Like the court of appeals, we find there is no genuine issue or dispute that the lenses Petitioner purchased are subject to device-specific federal requirements by virtue of the PMA process.

There is no dispute that the lenses Petitioner purchased were UV lenses. In 1996, CIBA received a letter from the FDA approving PMA supplement number 39, which "requested approval for incorporating an ultra-violet absorber" into

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[4] CIBA asserts there exists a mechanism whereby the FDA's position on whether a device is covered by a PMA may be sought. At the trial court level and on appeal, CIBA has requested that each court seek the FDA's position on whether it granted PMA with respect to the lenses in question. However, Petitioner has consistently objected to such an inquiry being made. We have not researched the availability of this option because we find further steps to ascertain the FDA's position are unnecessary. We find the record is manifestly clear that the lenses Petitioner purchased received PMA.

FreshLook Colors UV lenses. Additionally, the FDA approved a supplemental PMA in 1999 that provided in part that FreshLook lenses "with UV-absorbing monomer help protect against the transmission of harmful UV radiation to the cornea and into the eye." Thus, because of the presence of the UV-absorbing component, we find that these lenses were subject to device-specific FDA requirements. The record establishes as a matter of law that these lenses are covered by PMAs. The first prong of the *Riegel* standard has been met and, therefore, express preemption is triggered.

This leads to the section 360k inquiry—whether Petitioner's state claims are different from or in addition to the device's specific federal requirements. As noted above, only state requirements that are "different from, or in addition to" the requirements imposed by the PMA process are preempted. State common law claims premised on a violation of FDA requirements that "parallel," rather than add to, federal requirements are not preempted. *Riegel*, 552 U.S. at 330. Here, Petitioner claims CIBA knew or should have known that its lenses were being marketed and sold unlawfully.[5]

The trial court granted summary judgment as to Petitioner's "claims that are dependent on warning, labeling, design, marketing, misbranding, or similar claims. Specifically, Count II, Count V, and Count VI of the Complaint are hereby dismissed." At oral argument, CIBA's counsel conceded that Petitioner's claim regarding negligence in the manufacture of FreshLook Colors lenses survives summary judgment. Accordingly, to the extent partial summary judgment was granted in that regard, we vacate the trial court's order.

Further, we hold that, to the extent Petitioner seeks to challenge the sufficiency of the FDA-approved requirements imposed in the PMA process, the partial grant of summary judgment was entirely proper. Any claim that imposes requirements different from or additional to those set forth in the PMA is expressly preempted. However, any claim that parallels applicable federal requirements may proceed.

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[5] Essentially, Petitioner claims CIBA knew its plano lenses were frequently sold without a prescription and by unauthorized sellers, yet CIBA failed to take steps to ensure customers received the lenses through prescriptions only and with appropriate warnings and instructions.

IV.

CONCLUSION

Due to the lack of specificity in Petitioner's complaint and the trial court's order granting summary judgment, we regret we cannot be more specific in delineating which claims survive the partial grant of summary judgment. Therefore, for the foregoing reasons and in accordance with section 360k, we affirm the partial grant of summary judgment to the extent it was granted on claims that would impose common-law requirements "different from, or in addition to" applicable FDA requirements. As to the remaining causes of action, we remand for further proceedings consistent with this opinion.

AFFIRMED AND REMANDED.

TOAL, C.J., PLEICONES, BEATTY and HEARN, JJ., concur.