

SUPREME COURT OF SOUTH CAROLINA

Weston v. Kim's Dollar Store

399 S.C. 303 (2012) · Decided August 8, 2012

SUMMARY

The South Carolina Supreme Court reviewed a partial summary judgment ruling in a product-liability action involving prescription decorative contact lenses. The court held that the lenses were subject to device-specific FDA requirements through the premarket approval process, and that state-law claims imposing requirements different from or additional to those federal requirements were expressly preempted. The court affirmed in part and remanded claims that could parallel federal requirements, including a manufacturing-negligence claim.

CASE DETAILS

COURT	Supreme Court of South Carolina
WRITING FOR THE COURT	Justice Kittredge; Chief Justice Toal; Justice Pleicones; Justice Beatty; Justice Hearn
JURISDICTION	South Carolina
DECIDED	August 8, 2012
DISPOSITION	remanded
PROCEDURAL POSTURE	The South Carolina Supreme Court granted certiorari to review the Court of Appeals' affirmance of partial summary judgment for CIBA based on federal preemption.
STANDARD OF REVIEW	The Supreme Court applied the same Rule 56(c), SCRCp, standard as the trial court. Summary judgment is proper only when no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law; ambiguities, conclusions, and inferences are construed against the moving party.
PRECEDENTIAL VALUE	Published opinion; precedential decision of the Supreme Court of South Carolina.
PARTIES	Monica Weston v. Kim's Dollar Store, CIBA Vision, a Division of Novartis Company

TOPICS

- products liability
- fda regulation
- summary judgment
- federalism
- civil procedure

PRACTICE AREAS

products liability

federal preemption

summary judgment

medical-device regulation

QUESTIONS PRESENTED

1. Whether the FreshLook Colors UV piano contact lenses were subject to device-specific federal requirements through the FDA's pre-market approval process.
2. Whether Weston's state common-law and statutory claims were expressly preempted under the Medical Device Amendments because they would impose requirements different from or additional to FDA requirements.
3. Whether claims that parallel applicable FDA requirements, including the conceded negligent-manufacture claim, could proceed.

HOLDINGS

1. The FreshLook Colors UV piano lenses were subject to device-specific federal requirements because the FDA approved PMA supplements authorizing incorporation of an ultraviolet absorber and describing the UV-absorbing component.
2. Claims that would impose common-law requirements different from or additional to the requirements imposed through the PMA process are expressly preempted under 21 U.S.C. § 360k(a).
3. State claims premised on violations of FDA requirements that parallel, rather than add to, those requirements are not preempted and may proceed.
4. The partial summary judgment order could not stand insofar as it dismissed the negligent-manufacture claim, because CIBA conceded that claim survived summary judgment.

KEY QUOTATIONS

“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.” (at 310)

“The record establishes as a matter of law that these lenses are covered by PMAs.” (at 311)

“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.” (at 311-312)

“AFFIRMED AND REMANDED.” (at 312)

FACTUAL BACKGROUND

Monica Weston purchased FreshLook Colors UV decorative, noncorrective contact lenses from Kim's Dollar Store without a prescription, even though the lenses were intended to be sold by prescription only. The lenses were manufactured by CIBA Vision and had FDA-approved ultraviolet-absorbing components and extended-wear approval. Weston developed an eye infection that resulted in loss of vision in her left eye and alleged that CIBA failed to prevent unlawful sales and failed to provide appropriate warnings and instructions.

PROCEDURAL HISTORY

Weston sued Kim's Dollar Store and CIBA Vision after developing an eye infection and losing vision in her left eye following her purchase of prescription decorative contact lenses without a prescription. The trial court granted CIBA partial summary judgment on claims based on warning, labeling, design, marketing, misbranding, or similar theories. The Court of Appeals affirmed, and the Supreme Court granted certiorari. The Supreme Court affirmed the preemption ruling as to claims imposing requirements different from or additional to FDA requirements, vacated the ruling insofar as it encompassed the conceded surviving negligent-manufacture claim, and remanded for further proceedings.

DISPOSITION

remanded

REMAND INSTRUCTIONS

Proceed consistently with the opinion, distinguishing preempted claims that impose requirements different from or additional to FDA requirements from claims that parallel applicable federal requirements. The negligent-manufacture claim is to remain viable to the extent recognized in the opinion.

CASES CITED

- Weston v. Kim's Dollar Store, 385 S.C. 520, 684 S.E.2d 769 (Ct. App. 2009)
- Wortman v. Spartanburg, 310 S.C. 1, 425 S.E.2d 18 (1992)
- Epstein v. Coastal Timber Co., 393 S.C. 276, 711 S.E.2d 912 (2011)
- Byers v. Westinghouse Elec. Corp., 310 S.C. 5, 425 S.E.2d 23 (1992)
- National Meat Ass'n v. Harris, 565 U.S. 452, 132 S. Ct. 965, 181 L. Ed. 2d 950 (2012)
- Riegel v. Medtronic, Inc., 552 U.S. 312, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008)