

South Carolina Supreme Court Affirms Summary Judgment Based on Pre-Market Approval under the Medical Device Amendments of 1976

In a decision that could have implications for product manufacturers facing strict liability lawsuits in South Carolina, the South Carolina Supreme Court in Monica Weston v. Kim's Dollar Store and CIBA Vision, a Division of Novartis Company, Op. No. 27155 (Supreme Court filed August 8, 2012) confirmed that state causes of action that would impose requirements “different from, or in addition to” applicable FDA requirements, are preempted for devices that are approved through the pre-market approval (PMA) process.

In March 2004, Plaintiff purchased two pairs of FreshLook Colors contact lenses from Kim's Dollar Store. These lenses were non-corrective, or “plano” lenses. Along with changing the eye color, the contact lenses Plaintiff purchased had UV protection and were marked with a “prescription only” symbol. Kim's was not authorized to sell or distribute the contact lenses and had no affiliation with CIBA. Additionally, Plaintiff did not have a prescription for the contact lenses. Plaintiff was given no instructions concerning the care, cleaning, or usage of the lenses with her purchase, nor was she informed of the necessity of a medical prescription and oversight for usage of the contact lenses.

After wearing a pair of the contact lenses, Plaintiff developed an eye infection, which led to the temporary loss of vision in her left eye. She then brought this action against Kim's and CIBA alleging six causes of action: (1) negligence per se for selling misbranded contact lenses; (2) negligence in the manufacture, sale and/or distribution of contact lenses, and in failing to provide adequate warnings and instructions; (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 due to inadequate warnings; and (6) violation of the South Carolina Unfair Trade Practices Act by committing an unfair or deceptive act or practice, including inadequate labeling and warnings, in the conduct of trade or commerce. Essentially, Petitioner claimed CIBA knew its non-corrective 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 ultimately moved for summary judgment on the basis that the majority of Plaintiff's claims and legal theories were subject to federal preemption pursuant to the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. §§ 301-399a (West 1999 & Supp. 2008) (FDCA). The circuit court ultimately found CIBA was entitled to summary judgment on the basis of federal preemption on all of those causes of action that were “dependent on warning, labeling, design, marketing, misbranding, or other 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 non-corrective lenses underwent the pre-market approval process and were subject to device-specific FDA requirements.

Plaintiff argued to both the trial court and Court of Appeals that the contact lenses she purchased should be considered a cosmetic, rather than medical, device. However, when the case came before the Supreme Court the Plaintiff conceded that the lenses she purchased were Class III medical devices, but claimed they were never subject to pre-market approval. As a result, the only issue before the Supreme Court was whether the lenses were subject to FDA approval through the pre-market approval process.

The Supreme Court began by recognizing the case was controlled by the express preemption provisions in the Medical Device Amendments of 1976. The Court then pointed to the recent case of National Meat Ass'n v. Harris, 132 S.Ct. 965 (2012) to support its intention to interpret the express preemption provisions of a federal regulatory scheme in a very broad manner “with an eye towards a federal agency’s extensive authority and responsibility of ensuring the safety and effectiveness of consumer products.”

After expressing this intent, the Court undertook application of the test set forth in Riegel v. Medtronic, Inc., 552 U.S. 312, 322 (2008). It ultimately found that all of the evidence in the record clearly established that the FreshLook UV lenses were subject to preemption because the UV-absorbing component present in the lenses had undergone the pre-market approval process by the FDA. In doing so, the Supreme Court refused to allow the Plaintiff to argue that, in hindsight, the lenses should not have been subject to pre-market approval, focusing instead on whether they actually were.

After this determination, the Court affirmed the trial court’s dismissal of those causes of action that were “dependent on [claims of] warning, labeling, design, marketing, misbranding” because they sought to impose requirements different from or in addition to those set forth by the pre-market approval process. However, the Court also held any claim that “parallels applicable federal requirements” could proceed. As a result, a claim that the lenses were negligently manufactured was allowed to proceed. Unfortunately, because of a “lack of specificity” in the trial court’s order, the Court was unable to specify exactly what claims, beyond the one for negligent manufacture, survived the ruling. As a result, the case was remanded to the trial court for further proceedings to determine which claims paralleled applicable federal requirements.

Ultimately, this case reaffirms South Carolina’s intention to interpret and apply express preemption regulatory schemes in a very broad manner. It also makes clear that Plaintiffs will not be able to litigate *whether* a certain device should have been subject to pre-market approval. However, manufacturers will still need to rely on the trial courts to correctly determine which state law claims seek to impose requirements different from or in addition to those set forth by the pre-market approval process.