ARNOLD & PORTER LLP

Product Liability Litigation Update

Recent Developments in the Law

April 2013 A publication of the Product Liability Practice Group

In this Issue:

Damages: Fifth Circuit Upholds Constitutionality of $1 Million State Statutory Damages Cap

In *Learmonth v. Sears, Roebuck & Co*., No. 09-60651, 2013 WL 708170 (5th Cir. Feb. 27, 2013), the U.S. Court of Appeals for the Fifth Circuit affirmed the constitutionality of Mississippi's $1 million statutory cap on non-economic damages, holding that the cap does not violate Mississippi's jury trial guarantee or separation of powers clause.

Learmonth challenged the statutory cap after the trial judge reduced the non-economic damages component of her $4 million jury award to the statutory limit of $1 million. The Court held that the statutory limit does not invade the jury's fact-finding role because the judge applies the cap only after the jury's verdict and because the jury is not informed of the cap beforehand. The Court also held that the right to a jury does not include the right to a judgment equal to the jury's damages finding. Rejecting the separation of powers challenge, the Court held that the damages cap defines only substantive legal rights and did not intrude into the mode of proceedings by which a legal right is enforced. Finally, the Court noted that although Mississippi's Due Process Clause might constrain the legislature's authority to cap compensatory damages in some circumstances, Learmonth had waived any such challenge.

Although this federal decision is not binding on Mississippi state courts, it is influential. The reasoning of the decision also has general applicability for constitutional challenges to similar state statutory damages caps around the country, an issue that has divided state high courts.

Preemption: Fifth and Sixth Circuits Split on Viability of "Failure to Update" Claims Against Generic Drug Manufacturers

Two federal appeals courts recently reached different conclusions on whether "failure to update" labeling claims against a generic drug manufacturer are preempted by federal law. These cases illustrate continuing disagreement among the lower courts concerning proper implementation of the Supreme Court's generic preemption decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

In *Fulgenzi v. PLIVA, Inc*., No. 12-3504, 2013 WL 949096 (6th Cir. Mar. 13, 2013), the Sixth Circuit held that plaintiff's claim was not preempted under *Mensing* because it was not impossible for PLIVA to update its label to match the branded counterpart, as both federal and state law required PLIVA to do so. 2013 WL 949096, at *5. The Court also found that permitting state law actions against "sameness-violating" defendants would not frustrate federal objectives. Finally, the Court held that plaintiff's claim was not impliedly preempted under

Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001), because the allegations sounded in "an independent state duty" relating to the adequacy of the warnings. *Id*. at *7.

One month earlier, the Fifth Circuit reached the opposite conclusion in *Morris v. PLIVA, Inc*., No. 12-30319, 2013 WL 563506 (5th Cir. Feb. 14, 2013), a case involving the same generic manufacturer and branded drug as *Fulgenzi*. In a non-precedential opinion, the Fifth Circuit rejected the argument that a generic manufacturer could be held liable for failing to update the generic drug label to match a revised brand-name label. Plaintiff had sought leave to add a claim that the generic defendant had failed to update its label to match the branded company's 2004 version. But the Court held that such a claim for a breach of a federal labeling obligation is preempted under *Buckman* because it "sounds exclusively in federal (not state) law." 2013 WL 563506, at *2. The Court also noted that the proposed amendment was futile since plaintiff alleged elsewhere in its complaint that no pre-2009 label was adequate.

Preemption: Off-Label Claims Are Subject to Preemption Analysis in Medical Device Context

In *Caplinger v. Medtronic*, Inc., No. 12-cv-630, 2013 WL 453133 (W.D. Ok. Feb. 6, 2013), the district court rejected plaintiff's argument that medical device claims premised on off-label promotion automatically escape express preemption under § 360k of the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act.

In rejecting this argument, the Court held that the federal requirements imposed by the pre-market approval (PMA) process for Class III medical devices applied to the device, rather than to a particular use: "nothing in § 360k(a) suggests that the preemption analysis somehow depends on how the device is being promoted to be used." 2013 WL 453133, at *10. The Court thus held that off-label promotion allegations are subject to preemption under the MDA. The Court then held that plaintiff's off-label claims were impliedly preempted under *Buckman* because they did not validly "parallel" a state law claim and were "not genuinely equivalent" to the state law duty to provide adequate warnings. 2013 WL 453133, at *10 n.4. Rather, the Court stressed, "the concept of 'off-label use' is a creature of the FDCA, is defined by the FDCA, and is not a part of Oklahoma substantive law." *Id*. at *11.

Courts are divided on this issue but *Caplinger* will be helpful precedent for medical device manufacturer defendants arguing preemption of off-label claims.

California Proposition 65: Plaintiffs Target Flame Retardants in Industry-Wide Claims

In the past several months, private plaintiffs have issued more than 100 California Proposition 65 notice letters to companies concerning the compound "Tris" in furniture products and in children's nap mats and mattresses. Tris (also known as TDCPP) was listed as a carcinogen under Proposition 65 in October 2011. Plaintiffs' lawyers have already filed litigation against some companies relating to Tris, claiming that defendants violated Proposition 65 by failing to warn consumers of exposures to Tris.

Tris is widely used as a flame retardant and to meet flammability standards set by the U.S. Consumer Products Safety Commission for certain products, as well as flammability standards under California's longstanding regulations. In response to concerns raised by environmental groups and others about the safety of flame retardants, California's lead agency responsible for state flammability standards is proposing regulatory amendments to make those standards less stringent. The agency believes the amendments will encourage manufacturers to remove chemical flame retardants such as Tris from their products. No California public enforcer has elected to sue on Tris claims, however.

Proposition 65 does not ban the sale of products containing Tris (or any other listed chemical). Instead, Proposition 65 requires warnings if a product causes exposures to Tris above a certain level. It is a Proposition 65 plaintiff's burden to prove an exposure to Tris. Because Tris may not necessarily be found in areas of furniture exposed to the user, whether the plaintiffs can meet their burden of proof is likely to be a key issue in the litigation.

Upcoming Events

April 9, 2013

What Your Company Needs to Know About The Current State of SEC Conflict Minerals Regulations
In person in New York or via Webinar
Participants: Mara V.J. Senn and Samuel M. Witten

April 23, 2013

Mass Tort Litigation: All's Well That Ends Well
Via Webinar
Participants: Matthew T. Heartney, Steven G. Reade and William H. Voth

---

For questions or comments on this newsletter, please contact the Product Liability group at product@aporter.com.

arnoldporter.com