ARNOLD & PORTER LLP

Product Liability Litigation Update

Recent Developments in the Law

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In This Issue

FDA Proposal to Permit Generic Drug Manufacturers to Initiate Labeling Changes

In a November 13, 2013 *Federal Register* notice—Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985 (proposed No. 13, 2013) (to be codified at 21 C.F.R. pts. 314 & 601)—the Food and Drug Administration (FDA) proposed to amend its "changes being effected" (CBE-0) regulations to create "parity" among brand and generic drug manufacturers with respect to certain safety-related labeling changes.

This proposal is largely a reaction to the recent Supreme Court decisions in *PLIVA Inc. v. Mensing*, 131 S. Ct. 2567 (2011), and *Mutual Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466 (2013), preempting most product liability claims against generic manufacturers because they cannot initiate CBE-0 labeling changes under current FDA regulations. Under the FDA's proposal, upon submission to FDA of a CBE-0 supplement, generic manufacturers would be permitted to distribute revised generic labeling that differs in certain respects, and on a temporary basis, from the labeling of the brand drug. The corresponding branded company would then have the opportunity to respond to the generic's proposal by submitting its own labeling supplement. If FDA ultimately approves the labeling change, it would be implemented in both the branded and generic labels.

If finalized, this proposal could have a major impact on the product liability landscape for both generic and branded drug manufacturers. If the Rule works as intended, it would likely do away with the broad preemption of claims against generic manufacturers. As to branded companies, it could undermine plaintiffs' attempts to establish "innovator liability"—the theory that branded companies should be held liable for alleged labeling deficiencies in corresponding generic labels. If generic companies have their own responsibility to implement labeling changes, that further refutes any argument that branded companies should be legally responsible for the labeling of generic products. Comments on the proposal are due by January 13, 2014. FDA has proposed that any final rule based on this proposal would become effective 30 days after the date of its publication in the *Federal Register*.

An in-depth advisory on FDA's proposed rule published by Arnold & Porter attorneys is available here.

Justices Hear Oral Argument on Whether State AG Suits Can Be CAFA Mass Actions

On November 6, 2013, the Supreme Court heard argument in *Mississippi ex rel. Hood v. AU Optronics Corp.*, involving the question of whether a state attorney general *parens patriae* action is removable as a "mass action" under the Class Action Fairness Act (CAFA).

In *AU Optronics*, the Mississippi attorney general sued LCD panel manufacturers and distributors under state statutes seeking, among other things, restitution for the injuries of individual consumers caused by defendants'

alleged price-fixing. Defendants removed the suit as a CAFA mass action on the theory that those individual consumers, who numbered over 100, were also "real parties in interest." The district court remanded the case, but the Fifth Circuit reversed the remand order. In light of conflicting authorities involving the very same company and issues in the Fifth and Fourth Circuit, certiorari was granted.

During oral argument, the questioning of Respondent AU Optronics focused on the plain language of CAFA's mass action provision. CAFA defines mass actions as cases "in which monetary relief claims of 100 or more persons are proposed to be tried jointly on the ground that the plaintiffs' claims involve common questions of law or fact . . . ." 28 U.S.C. § 1332(d)(11)(B)(i). The State urged that on its face, the mass action definition refers to "plaintiffs" in the plural and thus plainly contemplates a Rule 20/joinder-like "common questions of law and fact" analysis involving multiple named plaintiffs, each with their own claims. In a *parens patriae* action, the State argued, there was only ***one*** plaintiff with ***one*** set of claims. In contrast, AU Optronics argued that Congress' use of the term "persons" versus "plaintiffs" in the statutory language was meant to encompass representative actions where unnamed "persons" are real parties in interest even if not named as nominal plaintiffs. Justices Sotomayor and Kagan took the lead in challenging AU Optronics' interpretation in this regard. As to the State's argument, many of the Justices—most notably Chief Justice Roberts—appeared to be troubled by the prospect of double recoveries for harm to consumers because a consumer class action (which included Mississippi residents) involving the same claims as those brought by the Mississippi AG had already settled. The Chief Justice further raised the specter of copycat suits by state AGs around the country following on the heels of successful private consumer actions.

Overall, the justices were split in their questioning. Interestingly, the Court focused much more heavily on the statutory language and not on issues of State sovereignty and the "real parties in interest" question raised in earlier briefing. Depending on the breadth of its reasoning, the Court's ruling in the case could have significant implications for federal jurisdiction over state attorney general actions and interpretation of CAFA more generally.

Eighth Circuit Finds Consolidation Request Sufficient to Trigger CAFA Jurisdiction

In *Atwell v. Boston Scientific Corporation*, 2013 WL 6050762 (8th Cir. Nov. 18, 2013), the Eighth Circuit held that plaintiffs' request to assign three multi-plaintiff cases "to a single Judge for purposes of discovery and trial" constituted a proposal for the actions to be tried jointly as a mass action under CAFA.

CAFA defines a mass action as: "any civil action . . . in which monetary relief claims of 100 or more persons are *proposed to be tried jointly* on the ground that the plaintiffs' claims involve common questions of law or fact . . . ." 28 U.S.C. § 1332(d)(11)(B)(i) (emphasis added). In *Atwell*, plaintiffs filed three separate multi-plaintiff complaints (each containing under 100 plaintiffs) and subsequently moved to assign those actions "to a single Judge for purposes of discovery and trial." 2013 WL 6050762, at *1. The defendant removed the three actions to federal court arguing that plaintiffs' motions were a proposal to try the three cases jointly, collectively rending them a mass action under CAFA. *Id*.

The Eighth Circuit agreed, reversing remand orders issued by the lower courts. The Eighth Circuit found that the lower courts failed to follow or properly apply the Seventh Circuit decision in *In re Abbott Laboratories, Inc.*, 698 F.3d 568 (7th Cir. 2012). *Abbott* held that a request by plaintiffs for "consolidated pretrial, trial, or post-trial proceedings" in separate actions involving hundreds of claims constituted an implicit proposal to try those claims jointly. *Id*. at 571-73. Noting that the *Atwell* plaintiffs had requested a single judge who could "handle these cases for consistency of rulings, judicial economy, and administration of justice" and try the cases with a possible bellwether process, the Court found it was "'difficult to see how a trial court could consolidate the cases as requested by plaintiffs and not hold a joint trial or an exemplar trial with the legal issues applied to the remaining cases.'" 2013 WL 6050762, at *5 (quoting *In re Abbott Labs.*, 698 F.3d at 573). The Court concluded that "the motions for assignment to a single judge filed by the three plaintiff groups to the same state circuit court, combined with plaintiffs' candid explanation of their objectives, required denial of the motions to remand." *Id*.

Notably, the Eighth Circuit's ruling contrasts with a recent decision by the Ninth Circuit in *Romo v. Teva Pharmaceuticals USA, Inc.*, 2013 WL 5314334 (9th Cir. Sept. 24, 2013), highlighting the fact that whether a motion or request by plaintiffs constitutes a proposal for actions to be tried jointly under CAFA remains a fact-specific inquiry.

CPSC Takes on "Voluntary" Corrective Action Plans in Rulemaking

On November 13, 2013, the Commissioners of the U.S. Consumer Product Safety Commission (CPSC) voted three-to-one in favor of issuing a proposed interpretive rule concerning corrective action plans for "voluntary" recalls. Two of the most significant proposals—to make voluntary recall agreements that companies negotiate with CPSC legally binding and to permit the staff to include compliance programs in such agreements—are highlighted below.

Legally Binding Voluntary Recalls: Under the current regulation (16 C.F.R. § 1115.20(a)), such agreements—which identify the remedial actions a company intends to take to implement a product recall—have "no legally binding effect." That would no longer be true under the proposed rule.

Commissioner Anne Marie Buerkle, who voted against the proposal, characterized it as a "momentous shift." According to Commissioner Buerkle, the rule could cause companies to be more cautious in negotiating agreements with the staff, and could subject CPSC and companies to the pace of the judicial process in the event of an enforcement suit, thereby slowing down the recall process in a way that harms public safety.

By contrast, Commissioner Robert Adler—one of the three Commissioners voting in favor of the rule—described the rule as a "minor tweak" to existing policy. He and other Commissioners disagreed that the rule would slow the recall process. Commissioner Adler also explained that, "when only one firm fails to live up to its word, that may leave hundreds and hundreds and hundreds of thousands of consumers at risk of a defective product."

Compliance Programs: As another significant amendment, the proposed rule would allow voluntary recall agreements to include compliance programs. This proposal follows on the heels of recent CPSC civil penalty settlements through which settling companies agreed to "implement and maintain" compliance programs in addition to paying penalties. The proposed rule provides examples of circumstances that might warrant a compliance program, as well as examples of requirements that may be included in a compliance program. The proposed rule also sets forth enforcement measures CPSC may take to remedy violations, including seeking injunctive relief, specific performance, and sanctions.

Open issues include whether CPSC will include the above provisions in the final rule, and, if so, how CPSC staff will apply them in negotiating recalls, how CPSC will enforce them if companies decline to enter recall agreements that include CPSC's proposed terms, and whether the provisions can withstand any legal challenge.

The proposed rule is open for public comment until February 4, 2014.

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

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