ARNOLD & PORTER LLP

Product Liability Litigation Update

Recent Developments in the Law

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CAFA Removal: Fifth Circuit Continues to Split With Other Circuits, Holds State Attorney General's Suit Removable under CAFA's Mass Action Provision

In *Mississippi ex rel. Hood v. AU Optronics Corp.*, 701 F.3d 796 (5th Cir. 2012), the Fifth Circuit Court of Appeals held that a state attorney general suit brought on behalf of individual consumers against liquid crystal display (LCD) panel makers was a removable "mass action" under the Class Action Fairness Act (CAFA). On December 5, 2012, the State Attorney General moved for a rehearing *en banc*.

The opinion illustrates judicial concern with state attorney general consumer protection suits which seek to circumvent class action requirements and procedural protections available under CAFA. Citing a need to prevent "jurisdictional gamesmanship," the Fifth Circuit likened the State's role to that of a class representative and held that the individual LCD consumers on whose behalf the State was suing—numbering well over 100—must be counted among the "real parties in interest" for the purposes of the numerosity requirement under CAFA. *AU Optronics*, 701 F.3d at 799-800. In determining the real parties in interest, the Fifth Circuit adhered to the "claim-by-claim approach" established in its 2008 decision in *Louisiana ex rel. Caldwell v. Allstate Insurance Co.*, 536 F.3d 418 (5th Cir. 2008), under which the court "pierces" the complaint to look at each claim; any party that stands to benefit from a particular claim (such as restitution) is deemed to be a real party in interest. *Id*. This approach differs from the "whole case approach" endorsed by the Fourth, Seventh, and Ninth Circuits, under which "a claim for restitution, when tacked onto other claims being properly pursued by the State, alters neither the State's quasi-sovereign interest in enforcing its own laws, nor the nature and effect of the proceedings," rendering the State the sole real party in interest (and the case non-removable as a mass action). *AU Optronics Corp. & LG Display Co. v. South Carolina*, 699 F.3d 385, 394 (4th Cir. 2012).

First Amendment: Second Circuit Strikes Down Criminal Prohibition on Truthful and Non-Misleading Off-Label Communications by Pharmaceutical Companies

In *United States v. Caronia*, No. 09-5006-cr, --- F.3d ---, 2012 WL 5992141 (2d Cir. Dec. 3, 2012), the Second Circuit Court of Appeals issued a 2-1 decision holding that construing the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations to prohibit pharmaceutical companies from engaging in truthful and non-misleading speech regarding unapproved or "off-label" uses of Food and Drug Administration (FDA) approved drugs violates the First Amendment. The *Caronia* court ruled that this restriction on the free flow of

information not only fails to advance directly the government's substantial interests in drug safety and public health, but also is far more restrictive of protected speech than necessary to achieve the government's stated ends. Because the First Amendment bars the government from prohibiting pharmaceutical companies from engaging in truthful and non-misleading speech about off-label uses, the Second Circuit interpreted the FDCA not to prohibit this speech.

While the *Caronia* decision's impact on off-label prosecutions and False Claims Act litigation remains to be seen, this landmark ruling calls into question the core prosecutorial theory used by the government to bring criminal enforcement actions for off-label promotion under FDA's "intended use" regulations. It may also limit the ability of the government and private plaintiffs to argue that off-label promotion leads to the submission of false claims, impacting the viability of federal *qui tam* actions based on allegations of off-label promotion. An in-depth Advisory on the *Caronia* decision published by Arnold & Porter attorneys is available here.

Consumer Products: Federal Court Provides Guidance to Companies Challenging Consumer Product Safety Commission's Product Reporting

In *Company Doe v. Tenenbaum*, No. 8:11-cv-02958-AW, 2012 WL 5245523 (D. Md. Oct. 22, 2012), the U.S. District Court for the District of Maryland issued an opinion that for the first time prohibited the Consumer Product Safety Commission (CPSC) from publishing a report "implicating" a consumer product on its SaferProducts.gov website, a database mandated by Congress under the Consumer Product Safety Improvement Act of 2008 (CPSIA). Pursuant to the CPSIA, the website shall include reports of harm "relating to" the use of consumer products and other products or substances regulated by CPSC. In *Company Doe*, the plaintiff-manufacturer argued that the report CPSC was seeking to publish was "materially inaccurate" because it did not "relate to" the use of the manufacturer's consumer product. CPSC rejected this argument and the plaintiff-manufacturer brought suit in federal court under the Administrative Procedure Act (APA), challenging CPSC's decision as arbitrary and capricious and an abuse of discretion. On cross motions for summary judgment, the district court held that the phrase "relating to" requires a meaningful nexus between the consumer product and the harm addressed in the report. *Company Doe*, 2012 WL 5245523, at *21. Without this nexus, CPSC's decision to publish the report "bears no rational relationship to the public safety purposes the CPSIA purports to promote." *Id*. The district court further explained that to be "related," the report of harm must be "connected with" or "associated with" the consumer product. *Id*. at *12.

Company Doe demonstrates that, when called upon, courts are willing to review CPSC decisions to publish reports mandated by the CPSIA. The case also provides meaningful guidance to consumer product companies regarding the statutory terms contained in the CPSIA.

Federal Question Removal: Federal Court Finds State Law Failure to Warn Claims Removable Based On Federal Question Jurisdiction

In *Bowdrie v. Sun Pharmaceutical Industries, Ltd*., No. 12-cv-853-WFK-MDG, 2012 WL 5465994 (Nov. 9, 2012 E.D.N.Y.), the U.S. District Court for the Eastern District of New York held that a case alleging state law claims against a generic drug manufacturer was properly removed to federal court on the basis of federal question jurisdiction.

The plaintiffs alleged, among other things, that the defendants failed to utilize the "changes being effected" (CBE) process to update their generic products' FDA-approved labeling to mirror its brand-name equivalent. The court held, first, that the federal issue was not merely an affirmative defense of preemption, but was an essential element of plaintiffs' state law claim in light of plaintiffs' allegation that defendants did not adhere to FDA regulations. Rejecting the argument that the federal issue was not substantial enough to confer jurisdiction, the court then held that "the federal issue involved goes far beyond simply incorporating a federal standard into a state law cause of action" and that "Plaintiffs' causes of action implicate the labeling requirements for generic drug manufacturers nationwide." *Bowdrie*, 2012 WL 5465994, at *4. The court explained that "[t]he federal question present in this case involves a responsibility that is in the first instance, and primarily, federal." *Id*. Having found the case properly removed, the court went on to dismiss the plaintiffs' failure to warn claims preempted under *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). *Bowdrie* thus provides an important avenue for drug manufacturers to remove cases alleging state law failure to warn claims where the allegations involve a responsibility to satisfy a federal obligation.

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