ARNOLD & PORTER LLP

Product Liability Litigation Update

Recent Developments in the Law

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Supreme Court to Hear Case Regarding Removal Requirements

The Supreme Court granted certiorari on April 7, 2014 in *Dart Cherokee Basin Operating Co., LLC v. Owens*, 730 F.3d 1234 (10th Cir. 2013), to consider whether a party removing a case to federal court needs to attach proof of jurisdictional facts to the notice of removal itself or can submit the evidence supporting removal later during briefing.

In *Dart Cherokee*, the plaintiff brought a suit on behalf of a class of royalty owners who were allegedly underpaid oil and gas royalties by defendants. Defendants removed the case to federal court under the "class action" provision of CAFA. 28 U.S.C. § 1332(d). Plaintiff moved to remand on the basis that defendants failed to satisfy CAFA's US$5,000,000 aggregate amount in controversy requirement. *Dart Cherokee*, 2013 WL 2237740, at *3 (D. Kan. May 21, 2013). In response, defendants submitted a declaration with detailed calculations as to the amount in controversy. *Id*. at *2.

Plaintiff did not dispute that defendants' declaration was sufficient to satisfy CAFA's amount in controversy requirement; instead, plaintiff argued that remand was proper because defendants failed to submit that evidence with their Notice of Removal. *Id*. at *2-3. Although the removal notice explained that defendants had calculated the amount in controversy to exceed US$5,000,000 based on the allegations in the complaint, plaintiff argued that this "bare allegation" was insufficient to satisfy a preponderance standard and could not be cured by the subsequent affidavit. Id. The district court granted plaintiff's remand motion holding that the amount in controversy requirement was not satisfied because defendants failed to incorporate any evidence, such as an economic analysis or settlement estimates, supporting their royalty calculations in the Notice of Removal. *Id*. at *4. Defendants' initial and en banc petitions to appeal were denied by divided panels of the United States Court of Appeals for the Tenth Circuit. *Dart Cherokee*, 730 F.3d at 1234.

The majority of federal Circuit Courts to consider the question have held that, just like a complaint, a removal notice need only include a "short and plain statement" of the jurisdictional facts supporting removal and the submission of evidence is not required until the adequacy of a notice is challenged. But the Supreme Court will decide whether the district court was correct to apply such a rigorous standard to defendants' factual allegations and require defendants to include evidence supporting federal jurisdiction with the notice of removal. The Supreme Court's decision in this action could provide valuable guidance regarding a removing defendant's burden to establish and set forth jurisdictional facts at the time of removal. In the meantime and in light of the uncertainty pending the Supreme Court's decision, removing parties should consider taking extra care to support removal petitions with appropriate evidence where possible.

District Court Refuses Invitation to Infer False Claims

In *United States ex rel. Palmieri v. Alpharma*, 2014 WL 1168953 (D. Md. Mar. 21, 2014), the U.S. District Court for the District of Maryland dismissed relator's False Claims Act (FCA) complaint for failure to plead fraud with particularity under Rule 9(b).

Relator, a pharmaceutical sales representative, alleged that the pharmaceutical manufacturer defendants violated the FCA by aggressively marketing their Flector Patch (a topical pain medication) to encourage doctors to prescribe it for off-label uses and at unapproved doses. According to the relator, some of the resulting off-label, excessive, or unlawfully-induced prescriptions of the Flector Patch were submitted for reimbursement to federal and state health care programs, such as Medicaid and Medicare. The district court, following the Fourth Circuit's decision in *U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451 (4th Cir. 2013), found the complaint failed to satisfy the requirements of Rule 9(b) because Relator was asking the Court to *infer* that false claims for reimbursement had been submitted, without providing any details of an actual false claim.

The district court reasoned that "when a defendant's actions . . . *could* have led, *but need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government." *Palmieri*, 2014 WL 1168953, at *10. The court found that relator's allegations that nine patients of two Pennsylvania doctors received off-label prescriptions were insufficient because they did not provide any details of these prescriptions being submitted for reimbursement to the government. *Id*. at *10-12. To illustrate why it is improper to infer that false claims were submitted, the court described the so-called "donut hole" in Medicare Part D coverage, which refers to an area between the initial drug coverage limit and the catastrophic drug coverage threshold where Medicare does not reimburse for prescription drugs. *Id*. at *11. Any Flector Patch prescription to a Medicare Part D patient falling in this coverage gap could not result in a false claim because that prescription would not be reimbursable by the government at all.

The *Palmieri* decision highlights the important function of Rule 9(b) in differentiating between allegations of *possible* fraud and *actual* fraud. Defendants should be vigilant in assessing allegations of FCA violations and can leverage this decision (and the Takeda decision on which it was based) to seek dismissal of suits that require courts to infer violations of the FCA.

Court Dismisses Evaporated Cane Juice Cases on Primary Jurisdiction Grounds

In nearly identical orders in *Figy v. Amy's Kitchen, Inc.*, --- F. Supp. 2d ---- 2014 WL 1379915 (N.D. Cal. Apr. 9, 2014), and *Swearingen v. Santa Cruz Natural Inc.*, 2014 WL 1339775 (N.D. Cal. Apr. 2, 2014), Judge Susan Illston of the U.S. District Court for the Northern District of California granted the defendants' motions to dismiss pursuant to the doctrine of primary jurisdiction, a judicial doctrine favoring deference to an administrative agency's authority to decide certain issues of first impression.

In each case, plaintiffs brought a putative consumer class action complaint against a manufacturer for its use of the term "organic evaporated cane juice" (ECJ) rather than the common term "sugar" on its products' labels in order to make its products appear healthier to consumers. Plaintiffs alleged that the use of the term ECJ violates Food and Drug Administration (FDA) regulations, which require food labels to reflect the common or usual name of an ingredient, and that defendants' failure to comply with these FDA regulations violates California's Sherman Law. Plaintiffs brought causes of action under various California consumer protection statutes, including its Unfair Competition Law, False Advertising Law, and Consumer Legal Remedies Act.

The court determined that all of plaintiffs' claims "hinge[d] on plaintiffs' contention that ECJ is not the common or usual name for the ingredient at issue" and "[t]herefore, the issues raised by plaintiffs' complaint 'fit [ ] squarely within' Congress' delegation of authority to the FDA." *Swearingen*, 2014 WL 1339775, at *2; *Figy*, 2014 WL 1379915, at *2. The court held that the determination of whether the term ECJ violates FDA regulations was best to left to the FDA, particularly in light of the agency's March 5, 2014 notice in the *Federal Register* announcing that it was actively reconsidering its own draft guidance concerning use of the term ECJ. The court noted that deferring to the FDA will allow the court to benefit from the agency's expertise on food labeling, promote judicial efficiency, ensure uniformity in the administration of the issue, and obviate the risk of a judicial decision in conflict with the FDA's expert decision on the issue. Further, the court determined that applying the doctrine of primary jurisdiction would not deny plaintiffs the opportunity to seek relief because they can participate in the FDA's rulemaking proceedings by submitting comments. Accordingly, the court granted the defendants' motions to dismiss without prejudice pursuant to the doctrine of primary jurisdiction.

Although these cases follow *Reese v. Odwalla, Inc.*, --- F. Supp. 2d ----, 2014 WL 1244940 (N.D. Cal. Mar. 25, 2014), which involved the use of the term ECJ and applied the doctrine of primary jurisdiction, they conflict with *Swearingen v. Amazon Preservation Partners, Inc.*, 2014 WL 1100944 (N.D. Cal. Mar. 18, 2014), in which the district court declined to apply the doctrine of primary jurisdiction in a case involving the use of the term ECJ.

Given these divergent opinions in the Northern District of California, the Ninth Circuit could potentially address this primary jurisdiction issue in the near future. In the interim, defendants should continue to be mindful of the doctrine of primary jurisdiction as a potential tool for challenging product liability suits involving a broad range of FDA regulated products.

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

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