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Recent Developments in the Law

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In this Issue:

- Innovator Liability: Tenth Circuit Joins Other Federal Courts In Rejecting Innovator Liability for Users of Generic Drugs
- <u>Class Actions: Ninth Circuit Limits Plaintiffs' Strategy to Avoid Class Action Fairness Act Removal</u>
 After Standard Fire Insurance Co. v. Knowles
- Preemption: S.D.N.Y. Finds Failure to Update Claims Not Preempted
- Upcoming Events: "Consumer Product In Crisis: Decision Making and Risk Reduction Throughout a Product's Lifecycle"

Innovator Liability: Tenth Circuit Joins Other Federal Courts In Rejecting Innovator Liability for Users of Generic Drugs

In Schrock v. Wyeth, Inc., --- F.3d ---, 2013 WL 4529359 (10th Cir. Aug. 28, 2013), the U.S. Court of Appeals for the Tenth Circuit joined the growing list of federal circuit courts to have rejected plaintiffs' arguments that brand-name drug manufacturers can be liable for injuries allegedly caused by the generic version of their drug.

The Schrocks brought tort claims under Oklahoma law against both generic and brand-name manufacturers after Mrs. Schrock allegedly developed tardive dyskinesia from taking generic metoclopramide. Affirming the District Court's grant of summary judgment dismissing the claims against the branded company, the Tenth Circuit predicted that the Oklahoma Supreme Court, "consistent with the trend among courts nationally and Oklahoma law in general[,]" would not find brand-name manufacturers to owe a duty to consumers of generic drugs. *Id.* at *7. For strict liability, negligence, and breach of warranty claims, Oklahoma courts generally require a defendant to have some connection with the product, through manufacture, sale, or distribution. *Id.*

Plaintiffs also argued that the branded companies improperly concealed defects in the product and had a general duty to speak up about the defects. But the court rejected that argument, reasoning that liability still requires some relationship between the plaintiff and the defendant which creates a duty between the parties. *Id.* at *8. The court thus found no liability for misrepresentation, fraud, and failure-to-warn claims because a manufacturer cannot be liable for concealing a defect in a product the plaintiff did not purchase. And the court commented, in looking to "the general weight and trend of authority in the relevant area of the law," that "the courts of other states have overwhelmingly rejected the very theory advanced by the Schrocks." *Id.* at *10.

Despite plaintiffs' continuing efforts to expand this area of tort law, the Tenth Circuit thus joined the Fourth, Fifth, Sixth, Eighth, and Eleventh Circuits in rejecting so-called "innovator liability."

Class Actions: Ninth Circuit Limits Plaintiffs' Strategy to Avoid Class Action Fairness Act Removal After Standard Fire Insurance Co. v. Knowles

In Rodriguez v. AT&T Mobility Services LLC, --- F.3d ----, 2013 WL 4516757 (9th Cir. Aug. 27, 2013), the U.S. Court of Appeals for the Ninth Circuit overruled prior precedent and lowered the standard for satisfying the aggregate amount in controversy requirement under the Class Action Fairness Act of 2005 (CAFA). The Ninth Circuit took this action in light of the Supreme Court's intervening decision in Standard Fire Insurance Company v. Knowles, --- U.S. ---, 133 S. Ct. 1345 (2013), which unanimously rejected a state class action plaintiff's attempt to avoid federal court by using a precertification stipulation to limit damages below the amount in controversy requirement of the statute.

In Rodriguez, the plaintiff filed a putative class action in state court, alleging that the amount in controversy did not exceed US\$5 million and purporting to waive any claim by the class in excess of that amount. 2013 WL

4516757, at *1. After the defendant removed, the district court granted the plaintiff's motion to remand based on his purported waiver. *Id.* On appeal, both parties agreed that the district court's order should be vacated in light of *Standard Fire*. But the parties disputed the proper legal standard for the district court to assess amount in controversy on remand. A prior Ninth Circuit case, *Lowdermilk v. US Bank National Association*, 479 F.3d 994 (9th Cir. 2007), had required defendants to prove "to a legal certainty" that the amount in controversy exceeded the statute's US\$5 million threshold. The *Rodriguez* court determined, however, that the reasoning in *Standard Fire* was "clearly irreconcilable" with *Lowdermilk*. *Rodriguez*, 2013 WL 4516757, at *6. While *Lowdermilk* was based on the principle that a plaintiff is the master of her complaint and can plead to avoid federal jurisdiction, *Standard Fire* held that courts may determine their jurisdiction by aggregating all potential class members' individual claims without regard to what is pleaded. Recognizing *Lowdermilk* as overruled by *Standard Fire*, the Ninth Circuit held that a defendant seeking removal of a putative class action must demonstrate by a preponderance of evidence — not a legal certainty — that the aggregate amount in controversy exceeds the jurisdictional minimum. *Id.*

The *Rodriguez* case illustrates that courts must look past pleading formalities to the substance of the plaintiffs' claims in assessing CAFA jurisdiction — a key principle that should govern a wide variety of clever pleading tactics that plaintiffs employ to try to avoid federal jurisdiction.

Preemption: S.D.N.Y. Finds Failure to Update Claims Not Preempted

In *In re Fosamax Products Liability Litigation*, 2013 WL 4306434 (S.D.N.Y. Aug. 15, 2013), the Southern District of New York decided an issue of first impression in the Second Circuit, holding that failure to update claims against generic drug manufacturers are not preempted by federal law.

Plaintiffs brought suit against the branded and generic manufacturers of Fosamax, alleging the drug caused them to suffer from a condition known as osteonecrosis of the jaw. Plaintiffs asserted claims for failure to warn, negligence, design defect, breach of warranty, and fraud. The generic defendants moved for judgment on the pleadings, arguing that the state law claims were preempted under *PLIVA*, *Inc. v. Mensing*, 131 S. Ct. 2567 (2011) and *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013). Plaintiffs conceded that some of their failure to warn claims were preempted, but argued that generic manufacturers may still be held liable under state law for failure to timely update drug warning labels. *In re Fosamax*, 2013 WL 4306434 at *3. The court agreed, holding the failure to update claims were not preempted because "it was possible for the [g]eneric [d]efendants to comply with their federal duty to match their labels to the Fosamax label, while also satisfying their state tort law duty to adequately warn the consumers of [the generic drug]." *Id.* at *4. The court also rejected defendants' argument that failure to update claims are impliedly preempted, finding they "are not premised on federal law, but rather on an independent state duty." *Id.*

This holding contrasts with certain other jurisdictions that have found that failure to update claims against generic manufacturers preempted because they "sound[] exclusively in federal (not state) law" and essentially amount to failure to warn claims preempted by *Mensing. See Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013); *Gross v. Pfizer*, 825 F. Supp. 2d 654, 660 (D. Md. 2011).

The *Fosamax* court also held that, pursuant to Mensing, any claims stemming from the generic defendants' alleged failure to communicate additional warnings through some method other than their package inserts — such as "dear doctor letters" — are preempted. 2013 WL 4306434, at * 5. The court also rejected plaintiffs' argument that their design defect claims are not preempted because *Bartlett* applies only to design defect claims predicted on label inadequacies. *Id.* at *6.

The Fosamax decision demonstrates that although many claims against generic drug manufacturers may be preempted in light of Mensing and Bartlett, the contours of preemption continue to be hotly litigated.

Upcoming Events: "Consumer Product In Crisis: Decision Making and Risk Reduction Throughout a Product's Lifecycle"

Consumer Product In Crisis: Decision Making and Risk Reduction Throughout a Product's Lifecycle

Date: Tuesday, November 5, 2013

Time: 8:00am PT

Location: Arnold & Porter's San Francisco Office, 3 Embarcadero Center, 10th Floor, San Francisco, CA 94111

This workshop will involve the evaluation of a hypothetical "product in crisis," tracing a product through the various stages of a company's risk management process. Attendees will participate in real time decision-making throughout the product's life cycle and will assess the consequences of those decisions as the hypothetical unfolds.

Click here for more details.

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

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