Generic Drug Product Liability: An Emerging SCOCA Issue?

Even as the Supreme Court of California prepares to hear oral argument in *In re Cipro Cases I & II* (S198616) on March 3, 2015, another issue involving pharmaceutical science and regulatory law may be headed for consideration at 350 McAllister Street.

The decision in *Teva Pharms. USA, Inc. v. Superior Ct.* ("*Pikerie*") — which arguably broadened the scope of California product liability claims that may lie against generic drug manufacturers — dodged high court review when the U.S. Supreme Court denied certiorari on January 20, 2015. SCOCA had previously denied Teva's petition for review on September 25, 2013. Superior Courts are thus bound to follow *Pikerie* and entertain liability theories based on allegations that the product label for a generic drug did not match the label of its brand-name equivalent.

Background

As any consumer of American television understands, generic drugs are marketed as suitable equivalents to the (sometimes more expensive) brand-name drugs that first reached our neighborhood pharmacies. One reason that generic drug makers can sell their drugs at lower cost is the streamlined approval process laid out in the Federal Food, Drug, and Cosmetic Act. Under that framework, generic makers need only submit an abbreviated new drug application to the Food and Drug Administration ("FDA") showing that a generic drug is "bioequivalent" to the brand-name counterpart in terms of its active ingredient(s), safety, and efficacy. The product labeling for the generic drug must also be the same as that used for the branded counterpart in its material respects.

FDA may waive the longer and more expensive approval process the agency typically requires of innovator drug companies. However, while innovators can make moderate changes to approved product labels without FDA permission, current FDA rules do not permit generic makers the same opportunity. This practice makes it difficult for generic drug makers to update their product packaging with safety

information that does not necessarily apply to the branded counterpart.

Pikerie Decision

In *Pikerie*, the plaintiff and real party in interest alleged injuries caused by her ingestion of a brand name drug and its generic equivalents. She claimed that the labeling on these products inadequately warned of known safety risks and that the drug manufacturers failed to take steps within their control to guard against her injuries.

The generic drug manufacturers demurred. Relying on *PLIVA v. Mensing*, the generic manufacturers argued that federal law preempted any state law claim that a generic drug should carry stronger warning labels than those approved for use on the equivalent brand name product. The U.S. Supreme Court had indeed explained in *Mensing* that federal food and drug law requires that a generic drug label match its branded counterpart. Compliance with any state law duty to the contrary is thus impossible, and so the state mandate is preempted.

The *Pikerie* plaintiff, however, alleged that the generic makers failed to update their product labels following updates to the brand-name label, so the two labels did not match. By that reasoning, the generics had not complied with federal labeling requirements and thereby placed their actions beyond the reach of federal law. The Court of Appeal agreed and held that "a state law tort claim can survive demurrer when it is based on an allegation that a generic drug's label did not match the [brand-name] label approved by the FDA."

With the decision escaping U.S. Supreme Court review, *Pikerie* extends a "failure to warn" cause of action to California plaintiffs seeking damages for alleged injuries from ingesting generic drugs. No Court of Appeal has yet to consider the viability of *Pikerie* as a statement of California law. However, two appellate courts outside of California (the U.S. 5th Circuit and the Iowa Supreme Court) have declined to follow its rationale. *Pikerie* thus looks to represent a minority view that puts drug companies at a disadvantage at the pleading stage relative to other jurisdictions around the country.

California Stands Out on Drug Liability

California is already home to *Conte v. Wyeth, Inc.*, which held:

> that the common law duty to use due care owed by a name-brand prescription drug manufacturer when providing product warnings extends not only to consumers of its own product, but also to those whose doctors foreseeably rely on the name-brand manufacturer's product information when prescribing a medication, even if the prescription is filled with the generic version of the prescribed drug.

This so-called "innovator liability" arose even though Wyeth had no role in manufacturing the injurious product, a circumstance which puts *Conte* in the minority among California appellate decisions considering the issue. To date, no Court of Appeal decision has applied *Conte's* liability rule in the pharmaceutical drug context, with one unpublished opinion avoiding the issue as improperly raised for the first time on appeal.

SCOCA declined to review *Conte* in 2009, with Justice Baxter voting in favor of taking the case. And when SCOCA took a pass on *Pikerie* in 2013, Justices Werdegar, Chin, and Corrigan did not participate in the decision. How the present SCOCA might view these extensions in pharmaceutical products liability is a topic for another day. But the way is set for branded and generic drug manufacturers to pursue a split in state appellate authority that may convince SCOCA to take on either of these issues. California is too important a market, and personal jurisdiction or venue fights can only get the industry so far. At least in the opinion of this observer, our state high court will be asked to consider one or both of these pharmaceutical products liability issues in an upcoming case.

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