



The New One-Two

Thursday, September 22, 2011

As you can tell from our old <u>drug preemption cheat sheet</u> (before we split off generic preemption after <u>Mensing</u>), the <u>Smith/Morris/Wilson</u> trilogy out of Kentucky has been hanging fire for quite awhile, since before <u>Levine</u>, actually. No longer. Today the Sixth Circuit ruled and delivered a one-two punch that's precisely the winning combination that we're looking for. <u>Smith</u>, et al. v. Wyeth, Inc., ___ F.3d ___, <u>slip op.</u> (6th Cir. Sept. 22, 2011).

It's a situation we've seen a lot in generic drug cases. These plaintiffs, having taken nothing but the generic product (actually one did not fit that scenario here), claim some sort of injury and sue not only the maker of the generic drug that actually injured them, but also sue the original brand name manufacturer (who never made a penny from selling the plaintiff anything) under some woolly, attenuated reliance theory.

Well, the Sixth Circuit had none of it in <u>Smith</u>. First, without any trouble at all, the court held that the warning claims against the generics were preempted:

"Just as in the present case, the plaintiffs in Mensing alleged that their long-term use of generic [drug] caused [injury], and they predicated the manufacturers' liability under state law on the failure to provide adequate warnings on the product's label. The Supreme Court held unequivocally, however, that federal law preempts state laws that impose on generic-drug manufacturers the duty to change a drug's label, thus barring the plaintiffs' state-law tort claims. The plain language of the Pliva decision compels the same result here."

Smith, slip op. at 4 (6th Cir. Sept. 22, 2011). That's the right hook to the jaw.

The Sixth Circuit also refused to have anything to do with allegations that branded manufacturers could be liable for defects in drugs they did not make or sell - but were in fact sold by their competitors. "Just because a company is in the same business as a tortfeasor, the company is not automatically liable for the harm caused by the tortfeasor's product." Slip op. at 5 (quoting district court). Kentucky law, the court held, did not allow that. "A threshold requirement of any products-liability claim is that the plaintiff assert that the defendant's product caused the plaintiff's injury." Smith, slip op. at 5 (citing Kentucky Supreme Court





case). The other, pure foreseeability, theories have been rejected almost anywhere, the court observed, and then agreed, deciding that Kentucky would not permit anything so adventurous under its product liability statute:

"The plaintiffs' argument – that the name-brand defendants' liability stems from the fact that the regulatory structure governing name-brand and generic drugs makes it foreseeable that patients and their physicians will rely on the name-brand labels to use and prescribe generic drugs – has been rejected by all but one of the courts that have considered it. [discussing and agreeing with Foster v. AHPC, 29 F.3d 165 (4th Cir. 1994) as "the leading case"; identifying Conte as exception] As have the majority of courts to address this question, we reject the argument that a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company. Moreover, and most significantly, the plaintiffs have not convinced us that the state courts of Kentucky would adopt their vicarious-liability argument under the Kentucky Products Liability Act."

<u>Smith</u>, <u>slip op.</u> at 6 (emphasis added). That's the left cross to the temple, and plaintiffs are down for the count.

As the first court of appeals ruling post-<u>Mensing</u> on both issues, <u>Smith</u> promises to be an important case.

We'll be adding Smith to the relevant scorecards in a moment.

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