Generic Reasoning

Monday, October 31, 2011

Have you ever noticed how if you're thinking about something, you start noticing it everywhere? For example, if you are contemplating the purchase of a soul-crushing Scandinavian station wagon, you start seeing them every other block, right?

Lately, we've been thinking about generic pharmaceuticals and preemption. Naturally, we're confronting the issue all over the place. Maybe it's because courts are eagerly embracing *Mensing* and ridding their dockets of bogus cases. Or maybe plaintiff attorneys are getting creative (and desperate) in devising ways to escape the clutches of *Mensing*.

We remember seeing generics everywhere in the early 1980s. Most supermarkets had entire aisles filled with those plain white and blue-labeled generics: string beans, chili, corn flakes, orange juice, rutabagas, etc. The 1984 movie **Repo Man** had a running gag about the proliferation of generics. The characters read a newspaper called "Paper". Guys pick up a six-pack of "Drinks" from a convenience store. Emilio Estevez goes home to find his drug-addled parents planted in front of the television, too stoned to make dinner, but telling him there's food in the refrigerator. Sure enough, sitting on a shelf is a can of "Food".

In the pharmaceutical market, generics are big, big business. They are also now big, big litigation.

You might think that last week's decision in *Hughes v Mylan, Inc.*, 2011 U.S. Dist. LEXIS 123544 (E.D. Pa. Oct. 25, 2011), is no big deal. It merely remands a case that had been removed on *Mensing* grounds. And the more we think about *Hughes*, the more we think it should be no big deal. It's the plaintiff lawyers who are trying to tease undue significance out of it.

The problem is that the *Hughes* opinion is - how do we say this? - far from pellucid.
There are multiple plaintiffs, whose cases were consolidated for the remand motion. Those plaintiffs sued Mylan in Pennsylvania state court, alleging injuries from fentanyl patches. We have the usual collection of claims, including negligence, strict liability, warranty, etc. The theories involve failure to warn and (significantly, as we shall see) design defect.

We said that the plaintiffs sued Mylan. In fact, they sued several Mylan entities, which were citizens of different states. One of those states was Pennsylvania. The presence of Pennsylvania Mylan would seem to block removal ... unless Pennsylvania Mylan was fraudulently joined.

While the plaintiffs' cases were pending, the U.S Supreme Court issued the *Mensing* decision, which held that failure to warn claims against generic manufacturers were preempted. Once the original deadline for removal has passed, a notice of removal can be filed within 30 days of receipt of "an amended pleading, motion, order or other paper" making the case removable. 28 USC section 1446(b). The *Hughes* court held that the *Mensing* decision does not constitute the type of "other paper" permitting removal. But the plaintiffs had amended their complaint to try to escape *Mensing*, and that amended complaint probably triggers 1446(b), so on to the removal analysis.

As alluded to above, the analysis in *Hughes* is a bit vague, but we know right away it isn't headed anyplace good. The first line in the opinion is: "A number of people died using Defendants' pain relief product and as a result Plaintiffs sued in the Philadelphia Court of Common Pleas". 2011 U.S. Dist. LEXIS 123544 at 9. Really? Nothing like assuming causation, right? Forgive us if we think that this sentence - which has nothing to do with any removal analysis - sounds like the opening line from a plaintiff's brief. Then we read about a million times in the opinion that there is a presumption in favor of remand. It's amazing how many times a presumption is invoked to supply a fig leaf for an ugly or unclear ruling.

The *Hughes* opinion also contains a number of snappy lines, though we're seldom sure what they mean:

"The flaw in the Mylan defendants' arguments is their assumption that somehow a 'landmark' Supreme Court ruling lessens the standard to prove fraudulent joinder." 2011 U.S. Dist LEXIS 123544 at 24. . Huh?

Or

"[B]eing able to point to an 'amended pleading' which may serve as a basis for removal does not unlock the doors to the federal courthouse". *Id*. at 23. Well, it is Halloween, after all, so we

guess we ought to be happy to see a straw man.

Or:

"The Mylan Defendants may ultimately win the war, but they are stuck fighting on the turf Plaintiffs selected." *Id*. at 24. As usual, war imagery offers more heat than light.

Or:

"*Mensing* merely provides a framework for the state court to adjudicate Plaintiffs' claim; it is not a hook that lands these cases in federal court." *Id*. at 27.

You get the idea. ... Or do you?

It seems clear that *Mensing* precludes the plaintiffs' failure to warn claims against Mylan. The *Hughes* court doesn't ever rule on that issue. It basically says, Tell it to the state court. All we get is, "Plaintiffs have stated a reasonable basis for their claims against Mylan. Thus, this court need not address the ultimate outcome of Plaintiffs' claims following Mensing because a state court is the proper forum for that issue." *Id*. at 27. We dare you to read the opinion and tell us what the "reasonable basis" is for the failure to warn claims, given that *Mensing* is the law of the land.

In any event, according to the *Hughes* court, it doesn't matter, because the plaintiffs also alleged design defect claims against Mylan Pennsylvania. The *Hughes* court points out that "Negligent design defect claims remain actionable under Pennsylvania law." *Id*. at 27, citing *Lance v. Wyeth*, 4 A.3d 160, 165 (Pa Super Ct 2010). True enough - the Superior Court did persist in the curious Pennsylvania sport of always always always treating strict liability claims differently from negligent claims, and bizarrely held that even though there cannot be strict liability design defect claims against FDA-approved pharmaceuticals, there can be negligent design defect claims. We expect the Pennsylvania Supreme Court to overturn that result, and we would have liked to see a federal judge make the prediction that that's exactly what would happen. Moreover, Lance came out before *Mensing*, and it would be perfectly reasonable to follow the reasoning of *Mensing* to mean that a bioequivalent generic cannot constitute a design defect. But the *Hughes* court doesn't go anywhere near that issue. The presumption

against remand ends up being a presumption against further thought. The shame of it is that now plaintiffs are running around saying that a federal court has ruled that design defect claims are a way to circumvent *Mensing*. No, the district court was really straining not to rule on anything.

Why?

It occurred to us that maybe the district court was bothered by the odd procedural posture of the removal and the fraudulent joinder theory. The fact is that if *Mensing* precludes the claims against Mylan-Pennsylvania, it precludes the claims against all the Mylans. In truth, the removal is really just an argument that the whole case lacks merit, and the district court seems to believe that such arguments can be made just as well to the state court. That is the "common defense" notion used by the Southern District of Illinois to remand cases. We criticized that notion as being weird, because it essentially says that there's removal if the claims against only the nondiverse defendant are specious, but no removal if the claims against all defendants are bogus. The Seventh Circuit in the *Walton* case eventually spanked the "common defense" theory and put it to bed.

Anyway, the *Hughes* court didn't go off on that now-retired theory. Rather, it's as if the court didn't want to look at any theory at all, besides the "heavy burden" facing any removing defendant. We get some tough-sounding rhetoric but no real substance. It's even more disappointing than those generic string beans.