Why Does the Parallel Violation Exception Remind us of Nietzsche and Frampton?

Monday, November 07, 2011

Last week saw the birth of the seven billionth current human on the planet. This week sees us comment on the parallel claim exception to *Riegel* preemption for what feels like the seven billionth time. It puts us in mind of Nietzsche's theory of the eternal return, where everything we've done we'll do again an infinite number of times. Really? We've got to go through that junior prom again, with all the plaid bell-bottoms and the awful Peter Frampton "tribute" band playing "Show Me the Way" as we fought off the effects of smuggled-in Southern Comfort?

We wish courts would do a better job of showing us the way on the parallel claim exception. Is it possible that the parallel claim exception is poorly conceived and poorly described, thereby prompting plaintiffs to parade various attempts to plead around it, leading to courts issuing rulings on the issue that are inconsistent and opaque? Yes, it is. Some parallel claims decisions have been reasonably coherent; others have blessed complaints resembling mackerels in the moonlight -- they shine, they stink. *Bausch* is an example of the latter, and yet the Seventh Circuit waved it by. We'll not regale you again with our Why We Hate *Bausch* litany, though the U.S. Supreme Court's recent refusal to review it led to a marathon teeth-grinding session here on the West Bank of the Schuykill.

Can our BFF *Twlqbal* save us from the craziness? Sometimes yes and sometimes no. Here is how we think the analysis ought to play out:

(1) What exactly is the alleged violation of federal law? Cite the specific regulation and the specific problem with the product.

(2) How exactly does state law make such violation actionable? (And here we will confess our esurient desire to appropriate Judge Posner's identicalness test from the *Turek* case we blogged about a couple of weeks ago. Yeah, yeah, it's a different statute. That being said…. Oh, heck, maybe it's asking too much for drug-and-device law to make sense.)

(3) How exactly did the alleged infraction cause the plaintiff's alleged injury?

We do not get that elegant tripartite analysis in *Rhynes v. Stryker Corp*., 2011 WL 5117168 (N.D. Cal. Oct. 27, 2011), but what we do get is pretty good. It sure ain't *Bausch*. (More on that later.) The plaintiff's first complaint alleged injuries arising from a defective artificial hip, asserting claims for negligence, strict liability, violation of California's Unfair Competition Law, and wanton and reckless misconduct. That last bit sounds bad. The court dismissed with leave to amend.

In the first amended complaint, the plaintiff reasserted claims for negligence, strict liability, and wanton and reckless miscounduct. The defendants again moved to dismiss, based on the statute of limitations and *Riegel* preemption. The court held that the discovery rule saved the plaintiff from the statute of limitations, but that the complaint was preempted.

As you've all heard before again and again, the preemption clause of the Medical Device Amendments to the Food, Drug and Cosmetics Act (21 U.S.C. section 360(a)) provides that states cannot impose requirements that are "different from, or in addition to, any requirement applicable under [the FDCA]." The defendants pointed out "that at least fourteen district courts have dismissed actions brought against Defendants' hip replacement system based on the Supreme Court's holding in *Riegel*." *Rhynes*, 2011 WL 5117168 at *4 (citing a nice collection of cases). Naturally, the plaintiff argued that its "claims impose 'requirements that are parallel with, not in addition to, federal requirements.'" *Id*. Cue up the Frampton. Pin on the corsage (this time don't stick the poor girl). Dance more. But: Do. Not. Do. "the Worm." It's happening again. Plus, the plaintiff cites *Bausch*, which is like making us reenact the climactic scene in **Carrie**.

What, pray tell, are the parallel claims in *Rynes*? The plaintiffs alleged that "the FDA warned Defendants about 'bad manufacturing and quality control practices.'" *Id*. at *5. That's a bit vague, isn't it? Luckily, that's how the *Rynes* court saw it: "Plaintiffs do not allege what FDA requirements were violated, much less how Defendants' manufacturing process deviated from those particular requirements." *Id*. That is a refreshingly sane take on the issue. *TwIqbal* to the rescue. We admire the court's clarity.

We also sort of admire the way the court dances around *Bausch*. First, the *Rynes* court says that the claims in that case were vaguer than in *Bausch*. Maybe. But, as you know, we think the claims in *Bausch* were plenty vague. Second, the defendants in *Rynes* had the temerity

(and good sense) to argue that *Bausch* (and another crummy case, *Warren*), contravened Rule 8 and *TwIqbal*. The *Rynes* court concluded that it "need not presently address this issue as it finds that, even under *Bausch* and *Warren*, Plaintiff's allegations are inadequate." *Id*. at 5 n. 7. So the *Rynes* court finesses the *Bausch* issue. We cannot blame the court for doing so, and we have a sneaking suspicion that the defendants' double-pronged approach -- both distinguishing and attacking *Bausch* -- is exactly the right way to go.

We're not going to say our junior prom ended badly, but let's just say it ended ambiguously. Call it unfinished business, half-measures, or the typical kind of clumsiness attending that time and place. We sort of get that from *Rynes*. Sadly, and almost inevitably, the court gave the plaintiff leave to amend. Talk about eternal return.