Thin Pleadings Doom Another Not-So-Parallel Claim

Monday, September 19, 2011

Today is the birthday of Adam West, the great television Batman, so we are pleased to see a court deliver a Bam! Pow! and Socko! to another attempt to escape *Riegel* preemption via a bogus parallel claim. The case is called *DeSabio v. Howmedica Osteonics Corp.*, 2011 U.S. Dist. LEXIS 103288 (W.D.N.Y. September 13, 2011). It's not just another attempt to escape preemption; it's another attempt in a Trident artificial hip case.

We. Have. Seen. This. Before. Same Bat time, same Bat channel.

The plaintiff alleged that "the device squeaked and he 'suffered severe grinding and pain.'" 2011 U.S. Dist. LEXIS 103288 at *2. There were claims for negligence and *res ipsa loquitur*. There was also a claim for breach of express warranty. The plaintiff argued that the Trident components were negligently manufactured and carelessly designed. He also argued that because the component parts were solely in the control of the defendants, negligence could be presumed under the doctrine of *res ipsa loquitur*. But the court had little difficulty concluding that these claims were "based squarely" on a "purported breach of state tort duties of care." *Id*. at * 12. Moreover, the court had the benefit of five other cases involving the same Trident product, the same claims, and meeting the same fate of *Riegel* preemption. *Id*. at ** 12-13.

But like a persistent Batman villain (Joker? Mr. Freeze?) the plaintiff keeps coming back for more. The plaintiff sought permission to amend the complaint to allege a parallel claim. And here is what we get:

-- the components "were not in compliance with the [FDA's] [PMA] standards for Class III devices in general and this device in particular."

-- the components were "not in compliance with the requirements approved by the FDA and had an impurity, imperfection and/or other product defects allowed to be created, contained or placed within the product in the Defendant's manufacturing process."

-- this "impurity" was a "deviation from the Defendants' design and quality manufacturing standards for the [Trident System] approved by the FDA."

Id. at **14-15.

The court correctly saw these new and not-so-improved allegations as the sort of mere incantations disapproved by most courts that have encountered them. Note that we say "most." The *DeSabio* court caught on that these empty gestures toward federal violations were drawn directly from the hated *Hofts* case, which we have criticized before and at which we still shake a clenched fist. But Bam! - the *DeSabio* court "respectfully disagrees" with *Hofts*. *Id*. at * 16. The proposed amendments do not solve the plaintiff's preemption problem. There is no cliffhanger to keep us in suspense; further pleadings would be futile, and the case is dismissed.

Perhaps more interestingly, or even slyly, the *DeSabio* court distinguishes the plaintiff's allegations from those that passed "parallel" muster in a couple of other cases, including the one device preemption case that we revile even more than *Hofts*: the Seventh Circuit's abomination called *Bausch*. This case, too, has met the fury of our pen (or keyboard). The *DeSabio* court points out that at least in *Bausch*, the plaintiff alleged a recall for "dimensional anomalies" and that the FDA had informed the defendants of "numerous deficiencies" in manufacturing. Riddle me this: how does that threadbare stuff satisfy *Twombly*?

We get the sense that the *DeSabio* court wonders the same thing. In a sentence that we think is almost mischievous, the *DeSabio* court says this about *Bausch*: "The Court acknowledged that the complaint would have been stronger had the plaintiff specified the precise product defect or the specific federal requirements violated, but found she had pled with enough specificity to satisfy Rule 8 and *Twombly*." *Id*. at *19. That "would have been stronger" is a delicious understatement. *Bausch* is as wrong as *Hofts*, and the judge in *DeSabio* no doubt knew that the author of *Bausch* also authored *Hofts*. *Bausch* is an aberration that provokes excuse-making or denial. It's like trying to explain how the sublime Julie Newmar got replaced by Eartha Kitt to play Catwoman. Some things just don't make any sense.

A word about the *DeSabio* plaintiff's claim for breach of warranty. *Riegel* did not address such claims, but the reason behind preemption still applies. To prove breach of express warranty, "a plaintiff would need to show that the device was not fit for its intended use, and such a finding 'would directly conflict with the FDA's premarket approval of the device as reasonably safe and

effective,' such that preemption applies." *Id*. at * 20-21 (quoting *Leonard v. Medtronic, Inc*., 2011 U.S. Dist. LEXIS 93176, at *30 (N.D. Ga. Aug. 19, 2011). (We discussed *Leonard* here.) Finding that a defendant violated state law by not living up to FDA-approved promises "would necessarily conflict with the FDA's determination that the label was not false or misleading." *Id*. at * 21. Zonk!

The plaintiff simply could not execute a last-minute escape from the preemption pit. The problem is that the pleadings were way too thin. Somehow that's an appropriate point to end with, because today is also the birthday of Twiggy. She was the British model who convinced 1960's mods that thin was in.