To Linsanity and Beyond (to the Tierney case)

Wednesday, February 15, 2012

Some of us on this blog have rooting interests that lie far from where The Schuylkill and The Delaware meet. They're up past the New Jersey Turnpike, all the way to New York City. For us, ever since the echoes of the Giants' raucous ride through the Canyon of Heroes faded, it's been all about the Knicks and Linsanity! And after watching the Linsane 3-pointer to win the game last night, we must admit that we expected it to be difficult to sit down calmly, think, and then write a post about medical device decisions. But that's what we're here for, and it gave us another thing to occupy our time while we wait for Linsanity to tip off once again tonight.

Fortunately, the case we'd like to discuss, Tierney v. AGA Medical Corp., No. 4:11CV3098 (D. Neb), has two recent opinions that contain so many things that we like that discussing it isn't difficult at all. It has preemption. It has Twiqbal-like pleadings standards. It has enforcement of the rules. And it displays the type of judicial distaste for the use of discovery as a fishing expedition that heartens us.

The background of the case is rather ordinary. The plaintiff filed negligence and strict liability claims against the manufacturer of a heart-related medical device, claiming that the device contained nickel elements that caused an allergic reaction. Slip Op. at 1-2. But the device was approved under the FDA's pre-market approval process. That means that the claims are preempted. In fact, the plaintiff himself responded to the manufacturer's motion to dismiss by outright conceding that his claims are preempted. Slip Op. at 5.

But what's heartening about this case is how the court handled the procedural machinations from the plaintiff. For instance, after conceding, the plaintiff requested the court to grant him 180 days to conduct discovery and amend his complaint to bring a parallel violation claim – i.e., that the manufacturer didn't follow FDA specifications. Slip Op. at 6-7. In other words, the plaintiff wanted the court to authorize him to go on a search for a claim that he didn't have. The court didn't do it and gave numerous reasons why. A request to amend must be made by motion, not in opposition papers like plaintiff tried. *Id.* That motion should attach a proposed amended complaint, which the plaintiff didn't do. *Id.* The proposed amendment should be backed by "sufficient factual allegations," not the bare legal conclusion about not following FDA specifications that the plaintiff provided. Accordingly, the court dismissed the complaint with prejudice, noting along the way that a plaintiff must "show that he or she is not merely engaged in a fishing expedition." *Id.*

It didn't end there, though. A few weeks later, the plaintiff tried again. He filed what seems to have been styled as a motion under Rule 59 to alter or amend the previous judgment, under Rule 60 for relief from the previous judgment, and/or under Rule 15 for leave to amend his complaint, and this time the plaintiff attached an amended complaint. This filing also had a litany of procedural and pleading problems, and the court addressed them all. Tierney v. AGA Medical Corp., 2012 U.S. Dist. LEXIS 14212 (D. Neb. Feb. 7, 2012).

First, plaintiff wanted to proceed on the failure to warn claim that he stated in his first complaint but now under the theory that the manufacturer failed to file required adverse event reports, an allegation contained in his amended complaint. *Id.* at *9-10. But this particular allegation was nowhere to be found in the original complaint, so dismissing it with the court's previous order could not have been "manifest error" under Rule 59. *Id.* at *10-11. Plaintiff also failed to show that his new parallel violation claim rested upon evidence that could not have been discovered earlier. So there also was no basis under Rule 60(b)(2) to alter the judgment. *Id.* at *11-12. Second, the plaintiff tried to rely on a patient guide that he had downloaded from the manufacturer's web site, arguing that the guide showed a failure to warn about allergic reactions to nickel. But, again, the plaintiff made no showing that this evidence could not have been discovered earlier. Moreover, he provided no factual allegation to indicate that this alleged omission was material to any FDA specification, or even something that the plaintiff himself relied on. *Id.* at *12-13. Finally, the plaintiff asked the court to simply accept his allegation that the manufacturer did not follow the FDA's standards. Explaining once again that "bare legal conclusions" with "no supporting factual allegations whatsoever" are not enough, the court rejected this argument, and with that upheld its previous judgment. *Id.* at *13-15.

It's not often that we see such strong products liability decisions rendered at the motion to dismiss stage. While the Tierney court's decisions are loaded with procedural discussion, they're important. Proper application of the rules allowed the court to dismiss a claim that was clearly preempted and stop the plaintiff from getting around that dismissal. But, even more important, reading and reporting on the Tierney decisions has taken up some time. We've moved closer to tonight. Linsanity tips-off at 7:30 EST.

Labels: Medical Device, Parallel Violation Claims, Pleading, Preemption