The Ignominous End Of The Digitek Mass Tort

Friday, November 04, 2011

Bexis gave blood last weekend at the Red Cross – not just any old donation, either, but pheresis, a procedure that takes a couple of hours to complete. Because pheresis takes that long, the Red Cross supplies donors with movies to watch. This time it was the 2006 James Bond remake, "Casino Royale," the type of movie that Bexis waits for the Red Cross rather than actually spends money to see. In "Casino Royale" a delectable baddie poisons 007's martini with digitalis, nearly causing him to die from a v-fib.

Bexis being Bexis, James Bond's digitalis overdose got him wondering about whatever happened to the Digitek MDL, which involved an FDA-approved form of digitalis, called Digoxin. We hadn't posted anything about it in well over a year, since the court blew out some meritless economic loss class actions. Before that, we were impressed by the MDL court's Rule 11-based order requiring the plaintiffs' counsel to demonstrate that they'd done a bare minimum of investigation of their clients' supposed "cases" before filing suit.

Turns out, we didn't have long to wait. Yesterday, Madeleine McDonough over at Shook Hardy was good enough to tip us off to the ignominous end of that MDL. Yesterday, the MDL court filed three orders (documents 70, 149, and 608) that, frankly, all look pretty much the same to us. They all go under the general description of PTO (that's "pre-trial order" for you laypeople) 87, so we're only attaching the one that's actually called that.

Our first reaction: My God! Has there ever been a more meritless MDL? We thought Bone Screw was bad, since the plaintiffs never in ten years of litigation were able to find a practicing orthopedic surgeon who would opine on defect. But at least in (some of) those cases there were broken screws. In Digitek, the plaintiffs couldn't even prove exposure to the allegedly defective product! The alleged "defect" was that some Digitek tablets were manufactured bigger than they were supposed to be and thus contain too much of the active ingredient (see James Bond). But it turns out that, after years of litigation, no plaintiff ever proved that a **single one** of the supposedly defectively too large Digitek tablets was **ever sold to any consumer**.

Don't take our word for it; we'll let the Court describe it. Keep in mind that the product recall that prompted the massive attorney solicitation that gave rise to the Digitek litigation took place in April 2008 and involved pills made in January 2008. PTO 87 at 4-5:

"The plaintiffs' experts' opinions rely on the one and only verified instance of an extra thick Digitek® tablet making it to market in 2004. A pharmacist found and returned the tablet to [defendant]. A manufacturing investigation was conducted and the situation was reported to the FDA. After reviewing the investigation, the FDA said:

No additional complaints or reports ofthick tablets have been received for this high volume product. The event was considered an isolated incident and corrective actions were put in place to prevent its reoccurrence. Corrective actions (procedural enhancements and review of complaint files) were verified during the inspection.
(Def. Ex.71 at 6).

This is the only verified report of a thick tablet leaving [defendant's] facilities. The tablet was made in 2003. All recalled Digitek® was produced in 2006 or later. Since 2003, over one billion Digitek® tablets have been made and distributed to the marketplace. This single 2003-produced tablet is the only Digitek® tablet in the marketplace found and confirmed to be out of specification."

PTO 87, at 10-11.

Not one of the over 1000 Digitek MDL plaintiffs, id. at 11 – all claiming injury from taking supposedly too-large Digitek tablets – ever produced a **single** purportedly too big Digitek tablet at any time during the litigation. Id. at 2 ("Thousands of plaintiffs alleged that double-thick tablets hit the market and injured consumers. Not one of them produced a double-thick tablet."). Indeed, some Digitek plaintiffs affirmatively avoided having pills in their possession tested for conformity to specification. Id. at 19 ("Plaintiffs possess, but have refused to test (or reveal any testing of), an ample supply of unused Digitek® tablets").

The mind boggles. So our first reaction is "good riddance." What a collossal and utter waste of time, energy, and money on completely bogus cases. No wonder the court ordered a Rule 11-based inquiry. Digitek should be the "hot coffee" moment of drug and device litigation, a

poster child that demonstrates to everyone that litigation is entirely out of control and that legislation or a rules change - we'd suggest a more muscular Rule 11 applicable to any solicited case - is necessary to reign it in.

So what do plaintiffs do when they can't even prove that the supposedly defective product ever actually existed? They use a lot of scary words – like things that go "boo!" on Halloween. There are a lot of good things in PTO 87 (including Daubert rulings on some very questionable experts), but to us the best part of it is the court's blowing to smithereens the plaintiff's misuse of the term "adulterated."

"Adulterated" is an FDA regulatory term of art. It means only that some FDA regulation wasn't 100% complied with. "Adulterated" doesn't mean "unsafe" – not even close. The discussion of the plaintiffs' "adulteration" bogie man in PTO 87 is as good an exercise in refuting a plaintiffs' misuse of a "scary" regulatory term ("experimental," "investigational," and "misbranded" also come to mind) as anything we've ever read:

"When a manufacturing process falls short of a cGMP [that's FDA-speak for "current good manufacturing practice"] requirement, the product is referred to as "adulterated." This term has a specific meaning:

A drug or device shall be deemed to be adulterated ... if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter....

21 U.S.C. §351 (a)(2)(B). If a drug is "adulterated" it may still be safe for consumption and as represented on the label. The question is only whether the manufacturing process satisfied the FDA's regulations. A drug will be rendered "adulterated" if any aspect of the manufacturing process did not fully comply with any cGMP. That could be something as mundane as inadequate lighting or the lack of hot and cold running water in the building."

PTO 87 at 7-8. See Id. at 9 ("a pharmaceutically perfect drug could be manufactured, sealed, and packaged, and yet still be rendered 'adulterated' because the label on the drug is upside-down").

Thus, FDCA-based claims of "adulteration" have no bearing on whether a prescription medical product is "defective" for product liability purposes because the FDA's adulteration standard is based upon "a lesser showing of harm to the public than the preponderance-of-the-evidence or more-likely-than-not standards used to assess tort liability." PTO 87 at 21. The Court took judicial notice of the FDA's statement:

"If a company is not complying with cGMP regulations, any drug it makes is considered "adulterated" under the law. This kind of adulteration means that the drug was not manufactured under conditions that comply with cGMP. It **does not mean that there is necessarily something wrong with the drug**. . . . A drug manufactured in violation of cGMP may still meet its labeled specifications, and the **risk that the drug is unsafe or ineffective could be minimal**."

Id. (quoting FDA "Facts About Current Good Manufacturing Practices") (emphasis added).

So in the end, all the smoke and mirrors in the world couldn't help the Digitek plaintiffs in a litigation where there was ultimately no evidence that the purported defective product ever made it to the marketplace – period. In the future, whenever we encounter a plaintiff screaming "adulteration," Digitek PTO 87 is where we'll go first to try to restore calm.