Another PMA Preemption Win

Tuesday, September 13, 2011

For those of you who come here for wit, sarcasm, or pop-culture references, you may be disappointed today. This is a straight-forward post about a straight-forward PMA preemption summary judgment victory. So, we are going to let Haynes v. Cyberonics, Inc., 2011 U.S. Dist. LEXIS 99738 (N.D. Ga. Sep. 6, 2011) speak for itself.

At issue was a Class III PMA medical device, a vagal nerve stimulator, surgically implanted in plaintiff's neck to treat seizures associated with epilepsy. The device was removed after plaintiff experienced unexplained tingling and shocking sensations. Haynes, 2011 U.S. Dist. LEXIS at *1-3.

Before we get to the preemption discussion, we want to point out (with a smile) just a few blunders by plaintiff's counsel (so maybe we this post isn't completely without sarcasm): 1) Four days before the ten-month discovery period was set to end, plaintiff moved to dismiss the complaint without prejudice or for an extension of time for discovery. Id. at *4. Somebody didn't do their homework. Fortunately, whatever excuse plaintiff offered for his failure to conduct the necessary discovery – the court didn't buy it. 2) Not only did plaintiff's counsel forget his homework, he forgot to show up for the exam. After the device was removed it was tested by defendant's engineers and found to be operating normally – *plaintiff never had the device tested by its own expert*. Id. at *3, *17-18. Oops. So, plaintiff's manufacturing defect claim would have failed even if not preempted because plaintiff had no evidence of a defect. Id. 3) Finally, plaintiff failed to respond to defendant's Statement of Material Facts filed with its summary judgment motion. Which means, the court was required to deem defendant's facts admitted. Id. at *8. While not outcome determinative, it didn't hurt.

Now, as to preemption. We've been here before, and we know preemption will carry the day, but it is always nice to tally up another win. So, since under Riegel only a "parallel violation" claim survives, plaintiff's first move was to concede that his design defect claim was preempted. Id. at *13. Smart move, but plaintiff could have save the court some time by going a bit farther. Instead, he took a shot on his manufacturing, warning and warranty claims – and missed.

Strict Liability Manufacturing Defect: It is undisputed that the manufacturing process is regulated by the FDA. It is also undisputed that a manufacturer could comply with all the

federal manufacturing regulations and still unintentionally produce a flawed product. Id. at *16. "That being so, by holding a manufacturer liable under such circumstances, Georgia law would be in the position of imposing requirements in addition to federal law." Id. (quotation marks omitted). Claim preempted.

Negligent Manufacturing Defect: Here, without a clear pronouncement by the Supreme Court, the court was willing to "assume the possibility of a negligent manufacturing claim that tracks the requirements set out by the FDA and alleges a negligent deviation from those requirements." Id. at *24. In other words, if plaintiff alleged and proved that the device at issue was not manufactured in accordance with FDA regulations – a plaintiff verdict on that claim would parallel the federal regulations and not be preempted. But, as we mentioned above, plaintiff's manufacturing claims failed for lack of evidence of a defect. Id. at *24-25 (citing Georgia law rejecting the application of *res ipsa loquitur* to manufacturing defect claims). So, not necessarily preempted, but dismissed anyway.

Strict Liability Failure to Warn: Another easy one. FDA regulates medical device labeling. A finding that a manufacturer's label contained an inadequate warning under state law would impose a requirement different than the federal regulations. Id. at *21-22. Claim preempted.

Negligent Failure to Warn: Ditto. Id. at *22-23.

Breach of Express Warranty: We could just say "ditto" again – but since this is an area not specifically addressed by Riegel, we'll afford it a little more discussion. First, the court looked at plaintiff's claim on its face – an express warranty that the device was "safe, and generally fit for use as an implanted stimulator." Id. at *26.

"In order to prove that defendant breached this warranty, plaintiff would need to show that the stimulator was not safe: a finding that would directly conflict with the FDA's premarket approval of the device as reasonably safe and effective."

Id. Further – and here is the ditto part – if the express warranties were made in the FDA-approved labeling, packaging or marketing materials – the warranty claim fails for the same reason as the failure to warn claim. Id. at *27. Claim preempted.

Breach of Implied Warranty: First, the court ruled that this claim failed under Georgia law for lack of privity. Id. at *29. But, it also went on to find that it too would be preempted

since the "FDA has already set standards" for determining whether the device was "merchantable, safe and generally fit for its intended use, or, in other words, somehow defective." Id. at *31. Claim preempted.

All in all, a straight-forward, no nonsense good decision. Sometimes that's all we need.