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# Takeaways From McPhee V. DePuy's Preemption Pronouncement

*Law360, New York (October 29, 2013, 2:02 PM ET)* -- We think most litigators would agree that doing legal research is sometimes like following Hansel and Gretel's trail of bread crumbs. You sort of wander around in the darkness for a little while reading cases that Westlaw or Lexis thought you might be looking for — but they turn out to be dead ends.

Then you pick up a faint scent of warm bread and you start to follow it. And in that first crumb of a case you find a cite to another case that sounds even more like what you were looking for. Then from there you pick up a headnote that looks promising. And so on, and so on.

If you aren't keen on the fairy tale analogy, there's always that 1980s hit by the The Fixx — "One Thing Leads to Another." Not sure they were talking about the same thing, but the title sums up the concept nicely.

And that's just what happened when we picked up the case of McPhee v. DePuy Orthopedics Inc., (W.D. Pa. Sep. 30, 2013) (McPhee II) and it led us to an early decision in the same case — McPhee I, No. 3:11-cv-287, slip op. (W.D. Pa. Sep. 28, 2012).

The two decisions, rendered almost exactly one year apart, dismiss plaintiff's original and amended complaints. More often than not, when we are reporting on a motion to dismiss where leave is granted to amend the complaint — we never hear about the case again. So, we found it interesting to look at these two rulings together to see what plaintiff was told to fix and how she apparently didn't do so.

The case involves a premarket approved (PMA) hip implant that was implanted in plaintiff in 1999 and broke in 2008. McPhee II at *2-3. In her original complaint, plaintiff alleged causes of action for strict liability, negligence and breach of express and implied warranties. McPhee I, slip op. at 3.

Let's get rid of the strict liability claim right from the beginning. This is Pennsylvania law. No strict liability for prescription medical devices. Id. at 11-13.

Plaintiff's breach of implied warranty claims suffered the same fate — not viable under Pennsylvania law. Id. at 18-19. (The court also agreed with defendant that the implied warranty claims were time-barred. Id. at 15-17).

That brings us to preemption and failure to state a claim. The court walks through PMA preemption under Riegel v. Medtronic Inc., 552 U.S. 312 (2008) and, no surprise here — finds that state law claims are preempted if they impose requirements on manufacturers that are different from or in addition to the Federal Food, Drug, and Cosmetic Act regulations. McPhee I, at 6-7.

Equally unsurprising is plaintiff's argument that her claims aren't preempted because they are parallel violation claims. However, examining the original complaint, the court couldn't find the parallel claim:

Plaintiffs' ... negligence claim[ is] premised on the assertion that defendant placed the device in the stream of commerce in a defective and dangerous condition, without adequate warnings and instructions. Generalized common law theories of liability, such as these, differ from or add to federal requirements ... and are precisely the type of claims the [Medical Device Amendments] sought to preempt.

Id. at 9 (citations and quotation marks omitted).

The court had already dismissed plaintiff's breach of implied warranty claims, but also found that even if viable — they would be preempted too: "Plaintiffs' claims merely assert that the device was unsafe or ineffective despite the PMA process, which premises liability on a requirement different from or in addition to the U.S. Food and Drug Administration requirements applicable to the device." Id. at 17-18.

Express warranty claims in the Third Circuit, however, are governed by Michael v. Shiley, 46 F.3d 1316 (3d. Cir. 1995) — a pre-Riegel decision holding that the MDA does not preempt such claims. McPhee I, slip op. at 21. But just because they weren't preempted didn't mean they passed TwIqbal muster.

While plaintiffs' complaint repeatedly alleges that defendant made [express] warranties, plaintiffs fail to identify any affirmation of fact or promise giving rise to these alleged warranties. Moreover, plaintiffs have not pled any details regarding the content of the express warranties.

Id. at 23.

If you are keeping score, at the end of McPhee I — strict liability and implied warranty are not viable under Pennsylvania law, negligence and breach of implied warranty are preempted, and breach of express warranty was not sufficiently pled.

But, the court found that there was enough in the margins to give plaintiff one more try on negligence and express warranty.

As for negligence, the court said it found three "clauses" in the original complaint that could "possibly" be parallel violation claims: defendant misrepresented material facts concerning the character or quality of the product, defendant suppressed information about the "harmful effects" of the product (court assumed for these first two that plaintiff was talking about misrepresentations to the FDA), and defendant violated regulations applicable to the device. Id. at 10.

We don't really agree that these even come close to viable parallel violation claims (think Buckman preemption) — but since we know what happens next, we won't dwell on it.

Fast forward one year. Plaintiff amended her complaint and apparently abandoned her express warranty claim. Her only cause of action now is negligence.

On the second motion to dismiss, the court once again walks through Riegel and parallel violation claims. McPhee II at *10-14. And despite telling plaintiff what she needed to do, the amended complaint still didn't allege a parallel violation:

Plaintiffs have again failed to set forth any facts showing action or inaction in defendant's efforts to take part in the PMA process. While plaintiffs have amended their complaint to include citation to several provisions of the Code of Federal Regulations (CFR) to support their claim that defendant violated applicable laws, codes and regulations, plaintiffs have nevertheless failed to specify how the defendant

has violated those provisions. Instead, plaintiffs merely list the CFR provisions and assert that defendant was negligent in violating the listed provisions ... Accordingly, as before, plaintiffs' averment merely amounts to an incantation that "defendant violated FDA regulations," which is insufficient to avoid preemption.

Id. at *15-16 (citations omitted).

Plaintiff alleged that she was relying on defendant's noncompliance with Current Good Manufacturing Practices (CGMP) and Quality System Regulations (QSR) and cited In re Medtronic Inc. Sprint Fidelis Leads Products Liab. Litig., 592 F. Supp. 2d 1147 (D. Minn. 2009) in support of her position. McPhee I, at *17. That reliance was misplaced. Plaintiff McPhee's complaint suffered from the same defect as plaintiffs in In re Medtronic:

Plaintiffs' reliance on the CGMPs and QSR ... does not save [plaintiffs'] claims from preemption ... [because] they are simply too generic, standing alone, to serve as the basis for plaintiffs' manufacturing-defect claims .... The FDA recognizes that the CGMPs and QSR simply cannot cover, in detail, all of the design, production and marketing elements for every medical device in existence .... Rather, they are intended to serve only as 'an umbrella quality system,' providing 'general objectives' medical-device manufacturers must seek to achieve.

McPhee II, at *18 (quoting In re Medtronic, 592 F. Supp. 2d at 1158).

"Vague references to general FDA manufacturing requirements without alleging facts concerning any specific requirements that [d]efendant ... purportedly violated" is simply not enough.

Because this was plaintiff's second attempt and second failure to state a claim, the court concluded permitting any further amendment would be futile. While not a groundbreaking development, it is another one for the arsenal.

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