Portfolio Media. Inc. | 111 West 19th Street, 5th Floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

3rd Circ. Gets It Partly Right On Component Preemption

By **Michelle Yeary** (March 9, 2018, 10:55 AM EST)

Michelle Hart Yeary

We closely followed the Shuker v. Smith & Nephew PLC case, as the Eastern District of Pennsylvania systematically dismantled the case on the grounds of preemption and pleading deficiencies. Unfortunately, the recent Third Circuit opinion deciding the plaintiff's appeal isn't the full affirmance we had been hoping for.

But before you get the wrong idea, the Third Circuit got the most important issue right — when you have a multicomponent medical device, PMA preemption is to be addressed on a component-by-component basis. After that, however, the appellate decision does some unraveling of the district's dismissal of the claims that survived preemption, and so the case is going back to the Eastern District.

Briefly, the facts are that the plaintiff underwent a hip replacement surgery in which his surgeon opted to use a Smith & Nephew device that consisted of several component parts, one of which was the R3 metal liner.[1] Unlike the other components of the device, the liner had undergone U.S. Food and Drug Administration premarket approval.[2] And the parties are in agreement that the surgeon's decision to use the R3 metal liner with this particular device was an off-label use.[3] The plaintiff suffered complications that required additional revision surgeries.

In its first decision, the district court tossed out almost all claims as preempted and any non-preempted claims for being inadequately pleaded. When the plaintiff filed an amended complaint attempting to correct the pleading deficiencies for the non-preempted claims, he again missed the mark, and his remaining claims were dismissed with prejudice. The district court also entered a decision finding that it lacked personal jurisdiction over Smith & Nephew PLC — a foreign parent company. Those three rulings are what the Third Circuit addressed in last week's decision.

The question of how to apply PMA preemption to a multicomponent device was one of first impression in the courts of appeal.[4] And it is an important question, because surgeons engaging in off-label use do mix and match parts with different regulatory backgrounds. The Third Circuit did a precise analysis that landed at the proper conclusion. However, the analysis does start up with a bit of a hiccup.

Since we are talking about PMA preemption, we are dealing with express preemption. Yet, in a footnote, the court refused to follow the U.S. Supreme Court's recent abolition of the presumption against preemption in the express preemption context set forth in Puerto Rico v. Franklin Cal. Tax-Free Tr.,[5] because that decision wasn't a products liability case and therefore did not directly concern the "historic

police powers of the States."[6] We respectfully disagree with this conclusion, and simply point out that other courts have reached the opposite conclusion.[7]

Fortunately, that did not derail the Third Circuit from ultimately concluding that the plaintiff's negligence, strict liability and breach of implied warranty claims were all preempted under Riegel. To do that, the court had to determine to what device it was applying the preemption analysis. The plaintiff argued that you have to look at the device that was implanted as a whole. Whereas the defendant, bolstered by an amicus brief filed by the FDA at the court's request, maintained that the proper focus is on the component of the device with which the plaintiff takes issue.[8] Agreeing with the defense position, the court anchored its decision on three findings.

First, the FDCA defines "device" to include "components, parts and accessories."[9] Second, the FDCA's off-label provisions specifically acknowledge that a physician can and will use components separately from the system for which the FDA approved use.[10] And despite the use to which the component is put, the FDA's PMA-regulations for the component follow with it. In other words, "premarket approval requirements apply equally to the components, as manufacturers generally may not deviate from the requirements imposed through premarket approval regardless of how [a component] is used."[11]

Third, the FDA's position is that the device is not limited to the device as a whole but includes components. Further, the FDA is charged with assuring the safety and effectiveness of components as well as finished devices.[12]

Therefore,

[t]aken together, the statutory definition of "device," the treatment of off-label uses and the guidance of the FDA all counsel in favor of scrutinizing hybrid systems at the component-level. ... And the Riegel test is properly framed at Step One as "whether the Federal Government has established requirements applicable" to a component of the hybrid system.[13]

Because the part of the device that the plaintiff attacked was the R3 metal liner which was premarket-approved, any state tort claim that seeks to impose requirements that are different from or in addition to the FDA's requirements for that component are preempted. That includes the plaintiff's negligence, strict liability and implied warranty claims.

The appellate court next reviewed the dismissal of the plaintiff's claims that survived preemption — negligence and fraud claims based on alleged off-label promotion in violation of federal law — and found that the negligence claim was adequately pleaded but that the plaintiff failed again to satisfy Rule 9's heightened standard for pleading fraud. As to negligence, the court found TwIqbal satisfied as to duty, breach and causation where the plaintiff alleged:

- The R3 metal liner was approved only for use with a different system and therefore under federal law the defendant had a duty to refrain from false or misleading advertising;
- In a press release, the defendant misleadingly marketed the R3 metal liner as an option for the system used by the plaintiff's surgeon (one other than the one it was approved for); and
- The plaintiff's surgeon "either read" or "was aware" of the press release.[14]

Like the district court, the Third Circuit considered and relied upon the press release cited in the

plaintiff's complaint. Unlike the district court, the Third Circuit appears to only focus on the portions of the press release upon which the plaintiff relied, and concludes that's enough to get the plaintiff to the discovery stage.[15] But we wonder if the court's calling the plaintiff's allegations enough to "nudge" the claim over the threshold is a veiled acknowledgement of just how narrowly the complaint squeaked by.[16]

Meanwhile, the plaintiff's fraud claim needed more than a nudge, and it didn't get even that. The court focused on the plaintiff's failure to plead justifiable reliance on the alleged misrepresentation. The "read" or "was aware" of allegation that sufficed for negligence lacked the requisite details regarding how the press release "induced or influenced" the plaintiff's surgeon for a fraud claim.[17]

The plaintiff has to allege the "circumstances of the alleged [influence on Mr. Shuker's surgeon] with sufficient particularity to place [the defendant] on notice of the precise misconduct with which it is charged."[18] Despite this having been the plaintiff's second failed attempt at meeting the pleading standard on fraud, the Third Circuit decided to give the plaintiff another chance and found that the claim should only be dismissed without prejudice.

Finally, there was a separate finding by the district court that it did not have personal jurisdiction over Smith & Nephew PLC, a foreign parent company. The Third Circuit agreed with the district court that specific personal jurisdiction was not conferred on a stream-of-commerce theory.[19] We've examined this before — recently, in light of BMS v. Superior Court — and like the Third Circuit "we have no cause to revisit" the precedent on the issue.

But the court did think the plaintiff alleged enough in his complaint to allow some limited jurisdictional discovery on possible alter ego based personal jurisdiction.[20] Emphasis on the limited part.[21]

So, on the third pass the plaintiff got a little life breathed back into this case, which is unfortunate — but as the first appellate decision on component preemption, we'll put it in the win column.

Michelle Hart Yeary is counsel at Dechert LLP, with experience in product liability litigation, including the defense of mass torts in federal multidistrict litigation and coordinated state court proceedings. She is a regular contributor to the Drug & Device Law blog.

[1] Shuker v. Smith & Nephew PLC, 2018 U.S. App. LEXIS 5160, *11 (3d Cir. Mar. 1, 2018).

[2] Id.

[3] Id. at *12.

[4] Id. at *2.

[5] 136 S.Ct. 1938 (2016).

[6] Shuker, at *16n.9.

[7] Accord Watson v. Air Methods Corp., 870 F.3d 812, 817 (8th Cir. 2017) (following Franklin and rejecting presumption against preemption in express preemption case); EagleMed LLC v. Cox, 868 F.3d 893, 903, (10th Cir. 2017) (same); Atay v. Cty. of Maui, 842 F.3d 688, 699 (9th Cir. 2016) (same); Conklin v. Medtronic Inc., ___ P.3d ___, 2017 WL 4682107, at *2 (Ariz. App. Oct. 19, 2017) (under Franklin courts may not invoke a presumption against preemption in PMA preemption cases); Olmstead v. Bayer Corp., 2017 WL 3498696, at *3 n.2 (N.D.N.Y. Aug. 15, 2017) (the plaintiff's assertion of presumption against preemption in PMA preemption case held "frivolous" after Franklin).

[8] Shuker, at *18.

[9] Id. at *19.

[10] Id. at *20.

[11] Id. (citation and quotation marks omitted).

[12] Id. at *21-22.

[13] Id. at *22-23.

[14] Id. at *28-29.

[15] Id. at *29n.18.

[16] See id. at *30.

[17] Id. at *33-34.

[18] Id. at *34.

[19] Id. at *36-37.

[20] Id. at *38-40.

[21] See id. at *40n.20 ("District Court should take care to circumscribe the scope of discovery ... to only the factual questions necessary to determine its jurisdiction;" further referencing proportionality amendment to Rule 26(b)(1)).