10th Circuit Opinion Affirms Strength of Preemption Defenses for Medical Device Companies

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On January 26, 2021, the United States Court of Appeals for the Tenth Circuit issued a published opinion in *Brooks v. Mentor Worldwide, LLC* that affirms the continued strength and vitality of preemption defenses for makers of Class III medical devices[1]. The ruling is significant in that it rejects commonly seen efforts of plaintiffs' counsel to plead around both the express preemption bar set forth in 21 USC § 360k,[2] as discussed in *Riegel v. Medtronic, Inc.*, 552 US 312, 321-322 (2008), and the implied preemption bar found in 21 USC § 337,[3] as explained in *Buckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 341, 352 (2001). The court's opinion also makes clear that generalized allegations of manufacturing defects are insufficient to state a plausible claim that may withstand a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure.

In *Brooks*, plaintiffs Amber Brooks and Jamie Gale brought product liability claims against Mentor Worldwide for injuries they sustained when their "MemoryGel" silicone breast implants began deteriorating. Previously, Mentor had received premarket approval of the MemoryGel implants from the Food and Drug Administration (FDA) as Class III medical devices, subject to Mentor conducting a range of post-approval studies. Mentor moved to dismiss the complaint on federal preemption grounds. The district court granted the motion, finding that federal law preempted the claims and that the plaintiffs, in any event, failed to plead their claims for manufacturing defects with sufficient detail. On appeal, the Tenth Circuit affirmed this decision. In so doing, the court helpfully clarified three issues.

First, negligence per se claims predicated upon alleged violations of federal law cannot withstand implied preemption analysis. Under Section 337 and *Buckman*, a plaintiff may sue under a state-law cause of action for conduct that violates the Medical Device Amendments (MDA) to the Federal Food, Drug and Cosmetics Act (FDCA), as long as the conduct also violates a parallel state law requirement. For example, courts have permitted state-law manufacturing defect claims to proceed where the complaint alleges that the manufacturer deviated from a *particular* pre-market approval or other FDA requirement applicable to the device.[4] Simply alleging, however, that a manufacturer violated the MDA cannot support a viable cause of action, as only the federal government may enforce violations of the MDA under Section 337. Thus, negligence per se claims based solely on alleged violations of the MDA may not proceed.

Second, federal law also impliedly preempts claims alleging failure to properly conduct post-approval testing as attempts to enforce the MDA. As the court explained, in the absence of a state-law duty to comply with FDA-imposed post-approval requirements, such as testing and reporting, the implied preemption bar applies. In short, pursuant to Section 337, only the federal government may enforce the MDA.

Third, the court found that the *Brooks* plaintiffs failed to identify a federal *requirement* for a Class III device manufacturer to either provide a warning directly to patients, or to warn physicians directly by updating its warning labels. In the absence of such federal requirements, federal law expressly preempts both categories of claims because a hypothetical state-law requirement to provide such warnings would be "different from, or in addition to" the universe of applicable federal requirements.

Indeed, pursuant to Section 360k and *Riegel*, federal law expressly preempts claims against Class III device manufacturers that (a) rely upon any state-law "requirement" that would impose any obligation on a device manufacturer that is "different from, or in addition to" any federal requirement applicable to the device, and (b) relate to the safety or effectiveness of the device. Accordingly, a claim predicated upon an alleged state law requirement to warn a patient directly or to update the warning label may only survive express preemption analysis if there exists a *parallel federal requirement* to undertake these same activities.

As the Tenth Circuit found, however, the *Brooks* plaintiffs failed to make such showing. In fact, as it relates to the warning label, the court noted that Mentor could have changed its labeling without FDA approval by a permissive mechanism, but that federal law did not *require* such a change. Since federal law did not include a requirement to change the label, Section 360k expressly preempts any claim predicated on a state law duty to do so.

Conclusion

The Tenth Circuit's opinion in *Brooks v. Mentor Worldwide, LLC* shows that federal preemption law continues to provide a strong defense to medical device makers faced with product liability lawsuits. To survive preemption analysis, a plaintiff must allege conduct that violates the MDA in order to avoid express preemption, and must further demonstrate that such conduct violates a parallel state law requirement, as federal law impliedly preempts suits to enforce the MDA. As the Tenth Circuit and many other courts have recognized, this leaves only a narrow gap within which a plaintiff may successfully plead a tort claim arising from the failure of a medical device.

Brooks builds on the Tenth Circuit's own prior interpretations of federal preemption law [5], and adds to the weight of authority barring most product liability claims against Class III medical device manufacturers. A Ninth Circuit decision issued earlier this month, *Nunn v. Mentor Worldwide, LLC*, follows this same trend, as the Court affirmed the dismissal of a complaint against a Class III medical device manufacturer for failure to sufficiently allege parallel state law claims.[6]

Moving forward, the battleground for preemption arguments in medical device cases will continue to focus on whether plaintiffs have alleged claims for breach of state law requirements that truly *parallel* federal requirements under the MDA, and thus survive preemption analysis. As plaintiffs' lawyers stretch to artfully plead claims that thread the preemption needle, courts will be called on to address and decide what it means to allege a "parallel" claim, and whether state law recognizes any such claim. And even where plaintiffs assert claims that may survive the preemption bar, as may be the case with a claim for manufacturing defects, *Brooks* establishes that generalized allegations are insufficient to clear the plausibility threshold governing motions to dismiss in federal court.

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1 No. 19-3240, 2021 U.S. App. LEXIS 2085 (10th Cir. Jan. 26, 2021).

2 Section 360k states in relevant part:

(a) Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 USC § 360k.

3 Section 337 states in relevant part, "Except as provided in subsection (b), all such proceedings

for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. . . ." 21 USC § 337(a).

4 *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1112 (9th Cir. 2019).

5 *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335 (10th Cir. 2015) (affirming MDA preemption of state-law claims for failure to show parallel state-law requirements).

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