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When To Push For A Determination Under Riegel

Law360, New York (February 7, 2011) -- In the products liability world, one would be hard-pressed to find a recent U.S. Supreme Court decision that has received as much attention as Riegel v. Medtronic Inc. Not surprising for a case that represents a near-unanimous decision by the court, thereby extending to medical device manufacturers a kill-shot against liability theories.

Still, with opportunities come decisions; and one somewhere near the top of the list is when to push for a determination on Riegel's application. At the first chance to file your responsive pleading? Or should you wait until the close of discovery? This article hopes to raise important considerations along this pathway and dispense insight as you weigh your various options with your own clients.

Plan A: Gather Intelligence and Move Early

As a general rule, the default approach among defense counsel is to raise and press legal defenses early, in a motion to dismiss. The reasons for this are apparent. If the case can't survive Riegel, there is no reason to spend time and money conducting discovery on claims that will never see the courtroom.

Also, most complaints represent the "kitchen sink" approach to theory pleading — as many claims as the printer will print — products, warning, warranty, consumer protection, among others, in an effort to find a parallel claim somewhere in the haystack. Inviting court guidance quickly seems sensible. The best illustration of this approach is the Medtronic Leads decision. 592 F. Supp. 2d 1147 (D. Minn. 2009), aff'd 623 F.3d 1200 (8th Cir. 2010).

We would embrace this approach, with some caveats, discussed below. At a minimum, to isolate those obvious claims that would not constitute parallel claims — failure to warn, for instance — at first blush has considerable appeal. Another reason is to raise early the court's consciousness to the favorable precedent. Some courts, particularly state court judges, may have limited familiarity with federal preemption. Those that do, however, may still be allergic to early dismissals.

Venue is obviously important to the determination. State courts pose unique challenges. On the one hand, raising their awareness early, even if the motion is ultimately unsuccessful, will likely serve you well down the road as you revisit the court on subsequent discovery matters. At worst, getting an early read will serve as the proverbial canary in the coal mine as to what to expect when a jury is in the box. There are risks in pushing too quickly, however. The court may commit to an interpretation that's wrong, and then retreating can be difficult.

On top of that, state judges tend to dislike motions to dismiss, especially ones that give plaintiffs no forum whatsoever. Take that as your cue to be realistic about your approach. If some of the claims are clearly sufficiently pleaded parallel claims, don't risk losing credibility with your judge by moving to dismiss them. Consider this your opportunity to frame the issue by moving to dismiss only the inadequate claims and to prime your judge for your upcoming summary judgment motion on the claims that survive the pleading stage.

Federal venues, on the other hand, afford an optimal environment with Twombly and Iqbal serving as the Bermuda Triangle for preempted claims — where factually thin cases disappear off the legal radar. If the U.S. Food and Drug Administration has not issued any warnings or advisories regarding the allegedly defective device, say so and make the plaintiff show his hand. Twombly would dictate that if there has been an FDA advisory regarding your client's device, the plaintiff's complaint should allege that the implanted device is the same model or lot as the affected devices.

In short, use Twombly to demand that plaintiffs' allegations are 1) specific to their devices and 2) allege injury caused by a deviation from the premarket approval (PMA) or FDA regulations.

All that said, federal venues are no lock for this either. Consider the recent appellate court decisions. Bausch v. Stryker Corp., No. 09-3434 (7th Cir. Dec. 23, 2010) is the first case to reverse a 12(b)(6) dismissal based on preemption. There, the court did not demand the specificity in pleading violations of federal regulations that the Eighth Circuit required — after invoking Twombly and Iqbal — in In re Medtronic Inc. Sprint Fidelis Leads Products Liability Litigation, 623 F.3d 1200, 1204 (8th Cir. 2010). Cf. Howard v. Sulzer Orthopedics Inc., 2010 WL 2545586 (C.A.6 (Ohio))(reversing summary judgment on negligence per se claims based on alleged violations of the FDA's good manufacturing practices).

A word of caution before waving the Medtronic victory flag: the court qualified its holding to the sparse record before it and discounted the plaintiffs' claim that every person with an allegedly defective lead was entitled to relief.

On the flip side, Bausch is not without its aid to defense counsel. In its analysis, the Seventh Circuit was concerned with the amount of information available to a plaintiff at the time a complaint is drafted and the confidentiality of PMA documents. Use this concern to do your due diligence. Find out what is publicly available about alleged device malfunctions and see whether the plaintiffs have used all that is at their disposal. Although citing to this kind of information in your motion could give plaintiffs a road map on how to plead, they will lose credibility with the court if they failed to find the low-hanging fruit before drafting the complaint.

Even in light of Bausch and the limitations of Medtronic, the majority of courts that have considered 12(b)(6) motions premised on Medical Device Amendments (MDA) preemption have sustained them.

Consider what the precedent tells us about when these are being filed. Since Riegel, 22 courts have granted 12(b)(6) motions; three of those were in state court. Preemption has also knocked out cases after motions for judgment on the pleadings in a few federal courts.

Plan B: Seek Bifurcated Discovery

If you lose your motion, or after reading this piece you think it may not be successful, all is not lost. Consider asking the court to bifurcate discovery so that preemption can be addressed first, and talk to your opponent about it. If a savvy products litigator, he or she may be concerned about an early Riegel attack and may join your motion to bifurcate or stipulate to other discovery limitations so that you both can get a handle on your prospects early.

And keep planning your motion for summary judgment — even outlining it before discovery begins to give yourself a road map of the documentary evidence you will need. Summary judgment on the basis of preemption under the MDA still outpaces 12(b)(6) dismissals by more than two to one — for now — so don't sell your defense short just because you're faced with a viable complaint.

Without question, the Supreme Court gave manufacturers a powerful weapon in Riegel. That authority continues to expand with additional lower court interpretations over the last 36 months. The decision about when to put preemption into play remains an important and increasingly difficult judgment call. Regardless of the shape Riegel takes in the coming months, we have, at least for now, a road map for an exit strategy from potentially long and expensive litigation. Let's use it.

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