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Medical Devices

Petition Expected in Parallel Claims Case; Pleading, Preemption Issues Divide Circuits

A medical device manufacturer's expected petition for review of a Seventh Circuit decision allowing a plaintiff's manufacturing defect ''parallel claim'' could give the U.S. Supreme Court a chance to tackle a preemption question that has divided some federal appeals courts.

Observers differ on whether the evolving circuit split in the medical device cases would entice the court to take on the questions raised in *Bausch v. Stryker Corp.*, or whether the still-developing law might hedge against review. Stryker Corp. has received additional time to file a petition for certiorari; the filing is due by June 24.

Over the past 10 months, four federal appeals courts have issued published opinions analyzing parallel claims, which remain valid under the Supreme Court's decision in *Riegel v. Medtronic Inc.* 552 U.S. 312 (2008) (36 PSLR 182, 2/25/08), because the state-law requirement a plaintiff seeks to impose is not ''different from or in addition to'' the federal requirements.

Collectively, the post-*Riegel* appeals court rulings span a range of approaches to the intertwined issues of whether a plaintiff has alleged a violation of federal law that can establish a parallel claim, and whether that claim was properly pleaded under the heightened standards set by the U.S. Supreme Court in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009).

Twombly and *Iqbal* make a medical device plaintiff's job ''more difficult than it would be in a typical product liability case,'' a federal district court in Kentucky recently observed (39 PSLR 379, 4/11/11).

The *Riegel* court did not specify what type of federal violation must be alleged to constitute a parallel claim. Points of disagreement among the appeals courts include whether a plaintiff must assert that the defendant violated the requirements of its premarket approval (PMA)—which applies only to that device—or whether a plaintiff may state a parallel claim by asserting the defendant violated general Good Manufacturing Practices (GMPs), broad quality control requirements applicable to all devices. And some discussion by courts that have allowed an alleged GMP violation to serve as the basis for a parallel claim hints that the answer to the GMP question may hinge on the nature of the particular GMP. The decisions also show a split on the appropriate role of discovery in allowing a plaintiff to ascertain facts to support the allegations.

''We are in a state of flux right now,'' observed David J. Walz of Carlton Fields in Tampa, Fla., who represented one of the defendants in a case decided by the Eleventh Circuit that took a relatively strict stance, saying plaintiffs must allege facts that support a specific federal violation.

Supreme Court and Preemption Cases. The Supreme Court has lately shown a keen interest in preemption. This term, it decided *Williamson v. Mazda Motor of America Inc.*, an auto preemption case (39 PSLR 210, 2/28/11); ordered a state court to revisit a pro-preemption ruling in *Priester v. Ford Motor Co.* (39 PSLR 238, 3/7/11), involving auto glazing; decided the *Bruesewitz v. Wyeth* vaccine case (39 PSLR 212, 2/28/11); denied a petition for review in *McNeil PPC Inc. v. Valdes*, a case involving cold medication (39 PSLR 78, 1/24/11); is expected to issue a decision in *Pliva Inc. v. Mensing*, a generic drug preemption case; and recently asked the U.S. Solicitor General to weigh in on whether review should be granted in *Farina v. Nokia Inc.*, a cell phone radiation preemption case. The court also granted review in *Kurns v. Railroad Friction Prods. Corp.*, involving preemption under the Locomotive Inspection Act (*see related story*).

Origin of 'Parallel Claims.' The parallel claims issue flowed from the *Riegel* court's ruling that Section 360k(a) of the Medical Device Amendments to the federal Food, Drug, and Cosmetic Act preempts most claims against makers of medical devices that undergo the Food and Drug Administration's premarket approval process.

Quoting the statute, the *Riegel* court said, ''State requirements are preempted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law. Thus, § 360k(a) does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements.''

Enter Supreme Court? In a submission seeking an extension of time to file a certiorari petition, attorneys representing Stryker said the Seventh Circuit decision ''misapplied, and therefore raises significant questions about the scope of'' *Riegel* and *Iqbal*.

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In *Bausch v. Stryker Corp.*, 630 F. 3d 546 (2010) (39 PSLR 24, 1/10/11), Margaret J. Bausch alleged she suffered harm caused by a hip replacement system. According to her original complaint, the device she received included a component known as a Trident Hemispherical Acetabular Shell bearing the catalog number 502-01-54E, which was recalled by the defendants Jan. 21, 2008. Bausch also alleged that six days before her surgery, the Food and Drug Administration had issued a warning letter to defendants, telling them that the Trident Acetabular Hip Systems were adulterated due to manufacturing methods that were not in conformity with industry and regulatory standards.

A district court dismissed the complaint. Bausch moved to set aside the judgment and sought leave to file an amended complaint. The proposed amended complaint said the device was not compliant with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation, 21 C.F.R. Part 820, concerning nonconforming products. The district court denied both motions, prompting the plaintiff's appeal to the Seventh Circuit.

The Seventh Circuit found the original complaint was sufficient even though it identified no particular federal regulation, not even a GMP. It said key facts referenced in the complaint, such as a recall and a warning letter to the defendants from the Food and Drug Administration, saying their manufacturing methods did not conform to federal standards, made the claim ''plausible on its face'' as required under *Twombly* and *Iqbal*.

Stryker asserted that the GMPs are too vague to be capable of enforcement through a jury verdict. But the Seventh Circuit, agreeing with an unpublished decision by the Sixth Circuit, said it did ''not see a sound legal basis'' for distinguishing ''between general requirements and 'concrete, device-specific' requirements.'' Section 360k(a), it noted, prohibits states from adopting ''any requirement'' different from or in addition to federal requirements.

The Seventh Circuit also said the lower court wrongly dismissed the plaintiff's complaint before allowing her to take discovery. For Bausch to have pleaded her claims with more detail, she would need access to the confidential materials in the premarket approval application setting forth the device's specifications. ''This is simply not possible without discovery,'' the Seventh Circuit reasoned. And if Bausch were to access the implant outside the scope of discovery, she would risk charges of spoliation of evidence.

Agreeing with the reasoning of Judge Michael J. Melloy, who dissented from an Eighth Circuit decision that said a plaintiff failed to plead a parallel claim, the Seventh Circuit said a plaintiff's pleading burden should depend on the amount of information available, and concluded that Bausch pleaded sufficiently, given the amount of information to which she had access.

The court also found no implied preemption under *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), saying that the *Buckman* court distinguished ''fraud on the agency'' claims from claims based on state law tort principles. Bausch's claims are based on the duty of a manufacturer to use due care in producing a device, not fraud on a federal agency, the Seventh Circuit said.

Stryker unsuccessfully sought rehearing, arguing that the panel's ruling effectively overrules *Twombly* and *Iqbal* in the Seventh Circuit, that the opinion creates a circuit split as to whether a plaintiff can avoid express preemption by alleging a manufacturer violated Current Good Manufacturing Practices, and that it conflicts with the U.S. Supreme Court's decision in *Buckman*.

Petition Expected by Late June. The Seventh Circuit's decision falls on one side of a split with decisions by the Eighth, Fifth, and Eleventh Circuits on both the preemption and pleading questions. Especially significant, some observers said, is the Seventh Circuit's allowance of discovery despite *Twombly*'s admonition that the factual allegations must be presented ''in advance of discovery.''

Stryker has retained Paul D. Clement, of Bancroft PLLC in Washington, D.C., as appellate counsel. Justice Elena Kagan granted Stryker an extension of time to file a petition for certiorari: The petition is now due June 24.

The *Bausch* decision ''raises important issues of federal preemption and sufficient pleading,'' Clement said in a May 4 submission to Justice Kagan. The decision implicates splits of authority among the lower courts. In particular, the filing noted the Seventh Circuit's agreement with the dissenting opinion in the Eighth Circuit case, *In re Medtronic Inc. Sprint Fidelis Leads Product Liability Litigation*, 623 F. 3d 1200 (8th Cir. 2010).

Pleading Exception? Robert M. Connolly of Stites & Harbison in Louisville, Ky., one of Stryker's attorneys, told BNA, ''I think the Seventh Circuit attempts to carve out a new exception that I don't think is warranted under *Iqbal* and *Twombly*.''

The court has also ''made an assumption that there is an imbalance of information'' between a plaintiff and a medical device defendant. But Connolly said he ''doesn't necessarily agree that there is a disparity of information.'' A plaintiff with a device that needs to be removed or replaced has access to the device, and to the surgeons who can provide information related to a possible defect or cause of failure, he said.

But Joshua L. Weisberg of the Rapoport Law Offices PC in Chicago, who represented plaintiff Bausch, told BNA the Seventh Circuit appropriately made a plaintiff's pleading burden commensurate with the amount of information available. Plaintiffs can look through public records and ''make a good faith effort to find out what they can.'' But if the only way a plaintiff can get confidential materials is through discovery, they should be entitled to discovery, he said.

''For purposes of pleading rules, what the Seventh Circuit said makes sense. If, on its face, it looks like a plaintiff may have a valid claim, courts should let them investigate,'' Weisberg said. He also said a patient can't depend on access to a device or on a treating doctor, who is under no obligation to talk to a plaintiff's attorney before a suit is filed. ''Sometimes the manufacturer takes the device back after surgery. In some cases, a hospital pathology department may take possession. This is not something a court can require of a plaintiff,'' he told BNA.

Weisberg said he would not make any predictions concerning the *Bausch* case, but said, ''In my view, the Seventh Circuit correctly decided this; there is no reason for the Supreme Court to take the case.''

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Wrong Posture? Scott Nelson of the Public Citizen Litigation Group in Washington, D.C., suggested the court might not take a parallel claim case in this posture. ''Now, given the shakeout of the Supreme Court's *Iqbal* and *Twombly* opinions and a couple of recent signals from the Supreme Court that they weren't intended to be as far-reaching as was thought, I'm not sure the court wants to dive into pleading issues again,'' Nelson told BNA.

In *Matrixx Initiatives Inc. v. Siracusano*, 79 U.S.L.W. 4187 (2011), the court cited *Iqbal* but upheld the validity of complaints pleaded in fairly bare-bones fashion, he said. *Skinner v. Switzer*, 79 U.S.L.W. 4157 (2011), does not cite *Iqbal* or *Twombly*, ''but has a description of the pleading standard that seems to indicate that the court is not treating those cases as altering the basic requirement that a claim just be pleaded in a short and plain fashion,'' Nelson said.

Nelson said that to determine whether a plaintiff has stated a valid parallel claim, it is hard to analyze simultaneously what is the standard and how to plead. ''Trying to address that through the lens of how a claim is pleaded is hardly the way a court would want to consider it,'' he said, adding that the Supreme Court may be more likely to review a substantive parallel claims question on a summary judgment record where the facts are established.

Nelson, who represented the plaintiff in *Hughes v. Boston Scientific Corp.* (39 PSLR 104, 1/31/11), where the Fifth Circuit found a plaintiff pleaded a failure-to-warn parallel claim, told BNA he is surprised that by now there isn't a larger body of decisions regarding parallel claims, but said that at this point, it would be ''quite premature'' to take up *Bausch* to address the sufficiency of parallel claims.

Walz took a guarded stance. ''Arguably, you have a split between the 7th Circuit, and the 8th and 11th Circuits.'' But, he observed, ''It's only three years since *Riegel*, and cases are still percolating through the system. That could hedge against the Supreme Court taking this case. The court may let other circuits weigh in. It may let the split between the circuits sharpen or lessen over time.''

The Other Decisions. The Eighth Circuit, deciding *In re Medtronic Inc. Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200 (38 PSLR 1090, 10/25/10), was the first federal appeals court to address whether a complaint sufficiently stated a parallel claim. The majority opinion, written by Judge James B. Loken, was released the day after defendant Medtronic Inc. announced that it would pay $268 million to settle claims related to the Sprint Fidelis defibrillator leads, which were the subject of a 2007 recall. The Eighth Circuit said claims asserting violations of general federal requirements applicable to all devices—including general GMPs—are not sufficient to avoid express preemption.

The Eighth Circuit also cited *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009), in observing that there is a ''narrow gap'' through which a plaintiff's state claim must fit to escape express preemption or implied preemption under *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). The plaintiff must be suing for conduct that violates the federal law—but must not be suing because the conduct violates federal law, meaning there must be an actionable state wrong.

Walz observed, ''The Eighth Circuit said you can't plead a manufacturing defect claim in the abstract by pointing to an objective that applies to all manufacturers or all devices.''

The Eighth Circuit plaintiffs argued that requiring them to cite specific violations of the PMA would hold them to an impossible pleading standard because the FDA's specific manufacturing requirements are set forth in the agency's PMA approval files that are accessible, without discovery, only to Medtronic and to the FDA.

''This argument—which focuses on the timing of the preemption ruling—would have considerable force in a case where a specific defective Class III device injured a consumer, and the plaintiff did not have access to the specific federal requirements in the PMA prior to commencing the lawsuit,'' the Eighth Circuit said.

''But this is not the case the plaintiffs presented to the district court,'' the Eighth Circuit said. The plaintiffs conceded the PMA authorized the use of spot welding and they disclaimed the need for discovery in opposing Medtronic's motion to dismiss.

Thus, it said, the manufacturing defect claims challenging spot welding were not parallel, but rather were ''a frontal assault on the FDA's decision to approve a PMA Supplement after weighing the product's benefits against its inherent risks.'' The court concluded that the manufacturing defect claim was preempted.

Discovery in the Eighth Circuit? Weisberg said the Eighth Circuit decision ''in dicta provides support for allowing discovery to proceed before deciding the preemption issue.''

According to Weisberg, ''The Eighth Circuit acknowledged that plaintiffs' argument that they were being held to an impossible pleading standard without the opportunity to conduct discovery would have 'considerable force' in many cases involving premarket approved medical devices, but in that particular case the plaintiffs had been offered discovery by the district court and waived it, unlike in *Bausch* where the district court refused to allow discovery to proceed before deciding the motion to dismiss over the Plaintiff's objection. Thus, while it is not binding law in the Eighth Circuit, I do not believe there is a conflict between the circuits on that point.''

Nelson said he is ''not sure that whatever tension exists between the Seventh and Eighth Circuits is a ripe enough conflict to attract the court's attention.''

Fifth Circuit Dismisses Claim. In *Funk v. Stryker Corp.*, 631 F. 3d 777 (2011) (39 PSLR 106, 1/31/11), another case involving the Trident system, the Fifth Circuit affirmed dismissal of a manufacturing defect claim.

The appeals court found that plaintiff Ronald Funk did not state a non-preempted parallel claim because his complaint did not specify the manufacturing defect, how the manufacturing process failed, or how the manufacturing process deviated from the FDA-approved manufacturing process.

The court noted that Funk's second amended complaint cured these particular defects, but said that complaint was not before it. The district court had denied Funk leave to file the second amended complaint, and he did not appeal that order.

Eleventh Circuit Weighs In. The most recent case, *Wolicki-Gables v. Arrow International Inc.* (39 PSLR 290, 3/21/11), set forth the standard requiring the highest level of pleading specificity.

''Plaintiffs cannot simply incant the magic words '[Appellees] violated FDA regulations' in order to avoid preemption,'' the court said, quoting the Eighth Circuit's *Medtronic* decision. ''To properly allege parallel claims, the complaint must set forth facts'' pointing to specific PMA requirements that have been violated, the court said, quoting *Parker v. Stryker Corp.*, 584 F.Supp. 2d 1298, 1301 (D. Colo. 2008).

The plaintiffs' allegations do not ''set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged,'' the Eleventh Circuit said. Because the Gableses have failed to allege facts in their complaint demonstrating the presence of the elements of a parallel claim, the district court properly deemed the claim preempted.

Walz pointed out that the Eleventh Circuit's opinion in *Wolicki-Gables*, although it reads like a dismissal analysis, arose on appeal from summary judgment. It is a ruling on summary judgment that concludes the complaint wasn't sufficient to get to summary judgment, he said.

''*Wolicki-Gables* is an example of what the Supreme Court was afraid of in *Twombly*.'' The case went through discovery, and ''after two years, the plaintiff still had nothing to flesh out the allegations,'' he said.

The opinion arose from ''very bare assertions'' in the complaint, Walz noted: The plaintiff alleged the defendants ''(a) fail[ed] to reasonably design the implantable drug delivery system in a manner which would have prevented injury to those like Linda Wolicki-Gables; (b) fail[ed] to reasonably manufacture the implantable drug delivery systems in a reasonable manner; [and] (c) fail[ed] to reasonably provide adequate warnings regarding the defective and unreasonably dangerous implantable drug delivery system, having actual or constructive knowledge of the hazards associated with the product.''

Sixth Circuit Issues Unpublished Opinion. The Sixth Circuit issued an unpublished opinion in June 2010, *Howard v. Sulzer Orthopedics Inc.*, 382 Fed. Appx. 346 (2010) (38 PSLR 624, 6/21/10). The Sixth Circuit said the plaintiff adequately stated a parallel claim by alleging the defendant violated a GMP that required manufacturers to establish disposal procedures for potentially hazardous manufacturing material.

That GMP, the court said, ''is not so vague as to be incapable of enforcement.'' It provides, ''Manufacturing Material. Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.'' 21 C.F.R. § 820.70(h).

BY JULIE A. STEINBERG

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