United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 09-2290

In re: Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation,	*	
Anna Bryant, et al.,	*	
Plaintiff - Appellant,	*	
v.	*	Appeal from the United States District Court for the District of Minnesota.
Medtronic, Inc., et al.,	*	
Defendant - Appellee.	*	
Product Liability Advisory Council,	*	
Amicus on Behalf of Appellee.	*	

Submitted: April 12, 2010
Filed: October 15, 2010

Before LOKEN, MELLOY, and SHEPHERD, Circuit Judges.

LOKEN, Circuit Judge.

Defendant Medtronic, Inc., designed, manufactured, and sold the Sprint Fidelis Lead, a wire that delivers signals that allow an implantable cardiac defibrillator to detect an abnormal heart rhythm and deliver a shock to help the heart return to an appropriate rhythm. After Medtronic recalled the product in October 2007, Anna

Bryant and other patients with implanted Sprint Fidelis Leads filed suits across the country against Medtronic and its affiliates (collectively, Medtronic) asserting tort and breach of warranty claims for injuries allegedly caused by the defective leads. The cases were transferred to the District of Minnesota for pretrial proceedings by the Judicial Panel on Multidistrict Litigation.

Plaintiffs filed a Master Consolidated Complaint seeking damages and equitable relief on behalf of "all Plaintiffs who had Sprint Fidelis Leads implanted," asserting some twenty distinct state law causes of action including failure to warn, defective design and manufacturing, breach of express warranty, and fraud. Applying the preemption principles of Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), and the pleading principles of Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), the district court[1] granted Medtronic's motion to dismiss and denied Plaintiffs' post-judgment motions for recusal and for leave to file an amended complaint. Plaintiffs appeal these rulings. We affirm.

I. Background

In the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act ("MDA"), Congress authorized the Food and Drug Administration ("FDA") to regulate the safety and effectiveness of medical devices. The Sprint Fidelis Lead was a Class III device, one that presents a potentially unreasonable risk of injuring patients or that is used to sustain life. See 21 U.S.C. § 360c(a)(1)(C); Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996). Before a new Class III device may be marketed, the manufacturer must assure the FDA through a rigorous Pre-Market Approval ("PMA") process that the device is safe and effective. Once the product is approved, the manufacturer may not change its design, manufacturing process, labeling, or other

[1] The HONORABLE RICHARD H. KYLE, United States District Judge for the District of Minnesota.

attributes that would affect safety or effectiveness without filing a PMA Supplement. 21 C.F.R. § 814.39(a). The PMA Supplement is reviewed using the same standard as the original PMA. See generally Riegel, 552 U.S. at 315-19.

In December 1993, the FDA granted Medtronic premarket approval for the Transvene Lead System. Progressively smaller leads, such as the Sprint Quattro, were later approved in a series of PMA Supplements. In June 2004, the FDA approved a PMA Supplement for the Sprint Fidelis Lead. Patients with implanted Sprint Fidelis Leads began suffering unnecessary shocks. Dr. Robert G. Hauser of the Minneapolis Heart Institute and his colleagues investigated patient complaints, published a report finding that the Sprint Fidelis Lead was more likely to fracture than other types of leads, met with Medtronic to voice their concerns, and advised the FDA of those concerns. Despite knowing the leads were unsafe, Plaintiffs allege,[2] Medtronic undertook a vigorous defense of its product that included sending a "Dear Doctor" letter to practitioners asserting that failures may be the result of improper surgical technique and assuring doctors that the Sprint Fidelis Leads performed as well as other Medtronic leads.

In May 2007, Medtronic applied for a PMA Supplement approving design and manufacturing changes to the Sprint Fidelis Leads without, Plaintiffs allege, advising FDA of the high rate of failures. A PMA Supplement was approved in July. Medtronic continued to sell previously manufactured Sprint Fidelis Leads, "finally" filed 120 adverse event reports in September, and suspended sales in early October, but doctors continued to implant Sprint Fidelis Leads. Not until October 15, 2007, did Medtronic announce a world-wide recall of the Sprint Fidelis Lead. Soon after, the FDA announced a Class I recall, the most serious type of medical device recall. These product liability lawsuits followed.

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[2]For purposes of reviewing Medtronic's motion to dismiss, we assume that facts pleaded in Plaintiffs' Master Consolidated Complaint are true. Zutz v. Nelson, 601 F.3d 842, 846 (8th Cir. 2010).

The MDA contains an express preemption provision: no State "may establish or continue in effect with respect to a device . . . 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." 21 U.S.C. § 360k(a).[3] In Riegel, the Court held that, for § 360k(a) preemption purposes, (i) FDA pre-market approval is "federal safety review" that results in federal "requirements" specific to the approved device, and (ii) common law product liability claims result in "state requirements" that are preempted to the extent they relate to the safety and effectiveness of the device and are "different from, or in addition to," the federal requirements established by PMA approval. 552 U.S. at 322-24. However, the Court noted, § 360k "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." Id. at 330.

The MDA also provides that all actions to enforce FDA requirements "shall be by and in the name of the United States," 21 U.S.C. § 337(a). In Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n.4 (2001), the Court construed § 337(a) as barring suits by private litigants "for noncompliance with the medical device provisions." Read together -

> Riegel and Buckman create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman).

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[3]The term "relates to" reflects Congress's "intent to pre-empt a large area of state law." Altria Group, Inc. v. Good, 129 S. Ct. 538, 548 (2008).

Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009). The contours of the parallel claim exception were not addressed in Riegel and are as-yet ill-defined.

Medtronic moved to dismiss the Master Consolidated Complaint, arguing that the claims were preempted by § 360k(a). The district court granted the motion, holding all claims preempted. In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., 592 F. Supp. 2d 1147 (D. Minn. 2009) ("Medtronic Leads"). Plaintiffs' product liability claims (design defect, manufacturing defect, failure to warn, breach of warranty, and fraud, among others) unquestionably relate to the safety or effectiveness of the Sprint Fidelis Lead. Thus, the crucial question on appeal is whether these claims are parallel claims that avoid preemption because they would not impose state requirements "different from or in addition to" the federal requirements established by PMA approval of the Sprint Fidelis Lead.[4]

II. Parallel Claim Issues

A. Failure to Warn and Related Claims. In the Master Consolidated Complaint, Plaintiffs alleged that Medtronic failed to adequately warn consumers of "known defects" and that the Sprint Fidelis Leads presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect. These claims are preempted by § 360k. The FDA's PMA approval includes specific language for Class III device labels and warnings. Plaintiffs did not allege that Medtronic modified or failed to include FDA-approved warnings. Rather, they alleged that, by reason of state law, Medtronic was required to give additional

[4]In opposing Medtronic's motion to dismiss in the district court, Plaintiffs' lead argument was that Medtronic lost its federal preemption defense when the Sprint Fidelis Leads were recalled. Plaintiffs briefed this issue on appeal but did not press it at oral argument. We reject the contention for the reasons stated by the district court. Medtronic Leads, 592 F. Supp. 2d at 1155-56.

warnings, precisely the type of state requirement that is "different from or in addition to" the federal requirement and therefore preempted. See Riegel, 552 U.S. at 330.

Even if federal law *allowed* Medtronic to provide additional warnings, as Plaintiffs alleged, any state law *imposing* an additional requirement is preempted by § 360k. "Where a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted." McMullen v. Medtronic, Inc., 421 F.3d 482, 489 (7th Cir. 2005), cert. denied, 547 U.S. 1003 (2006). Plaintiffs' reliance on Wyeth v. Levine, 129 S. Ct. 1187 (2009), for a contrary rule is unavailing. Wyeth turned on implied conflict preemption, not express preemption, because Congress did not extend the express preemption for medical devices in § 360k to prescription drugs. Id. at 1200.

Plaintiffs further alleged that Medtronic was negligent in continuing to sell the original version of the Sprint Fidelis Lead after it had received FDA approval to sell a modified version. However, as the FDA did not prohibit Medtronic from continuing to sell the unmodified lead, a state requirement to that effect would be "different from or in addition to" the federal requirement and preempted under § 360k. Finally, Plaintiffs alleged that Medtronic failed to provide the FDA with sufficient information and did not timely file adverse event reports, as required by federal regulations. As the district court concluded, 592 F. Supp. 2d at 1161, these claims are simply an attempt by private parties to enforce the MDA, claims foreclosed by § 337(a) as construed in Buckman, 531 U.S. at 349, 353. See Hughes v. Boston Scientific Corp., 669 F. Supp. 2d 701, 710-12 (S.D. Miss. 2009).

B. Design Defect Claims. The Master Consolidated Complaint alleged that Medtronic designed the Sprint Fidelis Leads "in a dangerous and defective condition" and "in a manner violative of the [MDA]." Absent concrete allegations that the product sold by Medtronic was not the product design approved in the PMA Supplement, these are not parallel claims. Rather, they are attacks on the risk/benefit

analysis that led the FDA to approve an inherently dangerous Class III device. Such claims are expressly preempted by § 360k. See Mitchell v. Collagen Corp., 126 F.3d 902, 913-14 (7th Cir. 1997), cert. denied, 523 U.S. 1020 (1998). "State tort law that requires a manufacturer's [Class III device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme." Riegel, 552 U.S. at 325.

C. Manufacturing Defect Claims. Plaintiffs assert that the Sprint Fidelis Leads were defectively manufactured because Medtronic used unreliable direct resistence spot welding to affix the device's cables to electrodes. Count II of the Master Consolidated Complaint further alleged that "facilities or controls used by [Medtronic] in the manufacture, packing, storage, or installation of the Sprint Fidelis Leads were not in conformity with applicable requirements" of the MDA. In opposing Medtronic's motion to dismiss, Plaintiffs explained to the district court that the referenced "applicable requirements" were FDA Current Good Manufacturing Practices ("CGMPs") found in the Quality System Regulations applicable to all medical devices. See 21 C.F.R. Part 820.

The district court concluded that Plaintiffs' general allegations of failure to comply with CGMPs -- practices that FDA has described as "an umbrella quality system" providing "general objectives" for all device manufacturers -- do not save these claims from preemption under § 360k because Plaintiffs failed to identify any specific federal requirement in the PMA approval for the Sprint Fidelis Leads that forms the basis for an unpreempted parallel claim. By contrast, the court noted, the plaintiff in Rollins v. St. Jude Medical, 583 F. Supp. 2d 790, 799-800 (W.D. La. 2008), alleged that the Class III device manufacturer failed to comply with the device's specific PMA requirements. As a result, the court concluded, 592 F. Supp. 2d at 1157-59, Plaintiffs failed to allege a parallel manufacturing defect claim with the detail required by Twombly, 550 U.S. at 555 ("[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions,

and a formulaic recitation of the elements of a cause of action will not do."). Accord Ashcroft v. Iqbal, 129 S. Ct. 1937, 1951 (2009).

On appeal, Plaintiffs primarily argue that the district court's application of Twombly in this case held them to an impossible pleading standard because the FDA's specific federal 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. Compare Braden v. Wal-Mart Stores, Inc., 588 F.3d 585, 598 (8th Cir. 2009) (while plaintiffs "must offer sufficient factual allegations to show that he or she is not merely engaged in a fishing expedition or strike suit, we must also take account of their limited access to crucial information.").[5]

But that is not the case Plaintiffs presented to the district court. Plaintiffs alleged that state law entitles *every* person who has an implanted Sprint Fidelis Lead to damages (for emotional distress) and to equitable relief (monitoring or implanting of a replacement device) because all Sprint Fidelis Leads have an unreasonably high risk of fracture failure. In the district court, Plaintiffs conceded that the PMA Supplement doubtless authorized the use of spot welding, and they specifically disclaimed the need for discovery in opposing Medtronic's motion to dismiss. Thus,

[5]At oral argument, Medtronic argued Plaintiffs' claims fail because the FDA did not find any violation of federal requirements. Without question, a prior FDA enforcement action is relevant to whether a plaintiff has adequately pleaded a parallel claim against a Class III device manufacturer. See Purcel v. Advanced Bionics Corp., 2008 WL 3874713 at *2 (N.D. Tex. Aug. 13, 2008). But the absence of FDA enforcement does not preclude the assertion of parallel claims and therefore is relevant only at the summary judgment stage or at trial.

as pleaded and argued, the manufacturing defect claims are not parallel, they are a frontal assault on the FDA's decision to approve a PMA Supplement after weighing the product's benefits against its inherent risks. On this record, the district court properly concluded these claims are preempted.

At oral argument, Plaintiffs posited a hypothetical case in which the plaintiffs could not know without discovery that every Class III device was defectively manufactured because the PMA approval required 400 degree welds but the manufacturer used a 300 degree welding process. This hypothetical well illustrates the care that courts must exercise in applying Riegel's parallel claim principle at the pleading stage, particularly to manufacturing defect claims. But here, Plaintiffs simply failed to adequately plead that Medtronic violated a federal requirement specific to the FDA's PMA approval of this Class III device. The district court did not abuse its discretion in denying Plaintiffs' motion to reconsider the dismissal order and grant their belated request for discovery to see if they could find such a requirement. Medtronic Leads, 2009 WL 294353 at *3 (D. Minn. Feb. 5, 2009).

III. Breach of Express Warranty Claims

In the Master Consolidated Complaint, Plaintiffs alleged the breach of express warranties that Sprint Fidelis Leads "were safe, effective, fit and proper for their intended use." The district court concluded that these claims are preempted because "the safety and effectiveness of the leads are matters solely for the FDA, and because the FDA determined that the leads were safe and effective." Medtronic Leads, 592 F. Supp. 2d at 1164. On appeal, Plaintiffs argue that express warranties are not state "requirements" preempted by § 360k because "the 'requirement[s]' imposed by an express warranty claim are not 'imposed under State law,' but *by the warrantor*." Cipollone v. Liggett Group, Inc., 505 U.S. 504, 525 (1992) (plurality opinion) (emphasis in original).

Though Cipollone construed a different, narrower express preemption provision, the opinion suggests that breach of express warranty claims are not expressly preempted by § 360k. See In re Medtronic, Inc. Implantable Defibrillators Litig., 465 F. Supp. 2d 886, 898 (D. Minn. 2006); contra Parker v. Stryker Corp., 584 F. Supp. 2d 1298, 1303 (D. Colo. 2008). However, we need not decide that issue. To succeed on the express warranty claim asserted in this case, Plaintiffs must persuade a jury that Sprint Fidelis Leads were not safe and effective, a finding that would be contrary to the FDA's approval of the PMA Supplement. A state common law claim is preempted if it "actually conflicts with the federal requirement -- either because compliance with both is impossible, or because the state requirement stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Lohr, 518 U.S. at 507 (Breyer, J., concurring) (quotations and citations omitted). The MDA in § 360k expressly prohibits States from imposing requirements "in addition to" federal requirements. The district court correctly concluded that this express warranty claim interferes with the FDA's regulation of Class III medical devices and is therefore conflict preempted. See Gomez v. St. Jude Medical Daig Div., Inc., 442 F.3d 919, 932 (5th Cir. 2006); cf. Pet Quarters, Inc. v. Depository Trust & Clearing Corp., 559 F.3d 772, 780-81 (8th Cir. 2009).

IV. Denial of Leave to Amend

Following the district court's dismissal of their claims and denial of their motion to reconsider, Plaintiffs moved for leave to file an 85-page Revised Amended Master Consolidated Complaint. The district court denied the motion because (i) Plaintiffs did not seek leave to amend before the adverse dismissal ruling, (ii) many of the allegedly newly-discovered facts were available before they filed the Master Consolidated Complaint, and (iii) "even if not untimely the Court would deny Plaintiffs' Motion because the proposed amendments would be futile." Medtronic Leads, 2009 WL 1361313 at *1-2 (D. Minn. May 12, 2009). Plaintiffs appeal that ruling. We review denial of leave to amend for an abuse of discretion, but the legal

conclusions underlying a determination of futility are reviewed *de novo*. In re NVE Corp. Sec. Litig., 527 F.3d 749, 752 (8th Cir. 2008).

Post-dismissal motions to amend are disfavored. United States ex rel Roop v. Hypoguard USA, Inc., 559 F.3d 818, 824 (8th Cir. 2009). The untimeliness factor is particularly acute in this case because Plaintiffs did not seek leave to amend until after they failed to persuade the district court to reconsider its dismissal order. On the merits of their motion, though the proposed amended complaint added more factual details, it again alleged no violation of a specific federal requirement. The amended complaint continued to allege that every person with an implanted Sprint Fidelis Lead is entitled to damages and equitable relief, the frontal assault on the FDA's PMA approval that resulted in the district court's dismissal. After careful review of the proposed amended complaint, we agree with the district court's futility ruling; the court did not abuse its discretion in denying the post-judgment motion to amend. See Briehl v. General Motors Corp., 172 F.3d 623, 629-30 (8th Cir. 1999).

V. The Recusal issue

More than one year after the Judicial Panel on Multidistrict Litigation consolidated and transferred what became hundreds of cases to Judge Kyle for pretrial purposes, two months after Judge Kyle dismissed the Master Consolidated Complaint, and one month after he denied the motion to reconsider, Plaintiffs filed a Motion for Recusal based upon the fact that Judge Kyle's son, Richard Kyle, Jr., is a shareholder at Fredrikson & Byron, a Minneapolis law firm that represents Medtronic in other matters. Fredrikson & Byron did not represent Medtronic in any matter relating to the Sprint Fidelis Leads. Mr. Kyle Jr. has a criminal defense practice and has never worked on a case on behalf of Medtronic. Judge Kyle denied the motion after thoroughly reviewing the governing law, the facts relevant to the recusal issue, and the "prudential considerations" militating against recusal. Medtronic Leads, 601 F. Supp. 2d 1120 (D. Minn. 2009). Plaintiffs appeal that ruling.

Plaintiffs knew, or with due diligence could have known, that Medtronic is a significant client of Fredrikson & Byron, and that Judge Kyle's son is a shareholder of the firm, before the Judicial Panel transferred this litigation to Judge Kyle. Thus, the recusal motion was untimely. It was also a device "interposed for suspect tactical and strategic reasons" following the district court's adverse rulings. In re Kansas Public Employees Retirement System, 85 F.3d 1353, 1360 (8th Cir. 1996). As the grant of such a belated motion would have serious adverse effects on the efficient use of judicial resources and the administration of justice, "on this basis alone, the district court's . . . denial of the recusal motion is affirmed." Tri-State Fin., LLC v. Lovald, 525 F.3d 649, 654 (8th Cir.), cert. denied, 129 S. Ct. 630 (2008). We reject, summarily, Plaintiffs' additional contention that Judge Kyle's response to press inquiries concerning the recusal motion would cause a reasonable person to question his impartiality in these proceedings. See 28 U.S.C. § 455(a). Cf. White v. Nat'l Football League, 585 F.3d 1129, 1138-41 (8th Cir. 2009); United States v. Fortier, 242 F.3d 1224, 1229-30 (10th Cir.), cert. denied, 534 U.S. 979 (2001).

The judgment of the district court is affirmed. Medtronic's motion to file an oversized 28(j) letter is granted.

MELLOY, Circuit Judge, Concurring in Part and Dissenting in Part.

I.

I concur with the majority except as to the dismissal of the manufacturing-defect claim and the related issues of the denial of the plaintiff's discovery request and motion to amend. On these issues, I would reverse and remand for limited discovery and the opportunity to amend the master consolidated complaint.

I would hold the specificity requirements of Twombly must be applied in a practical manner that recognizes the parties' relative access to information necessary

to articulate claims with specificity. Here, as described by the majority and determined by the district court, the parallel state claim that may escape preclusion under § 360k requires the plaintiffs to prove Medtronic failed to manufacture the Sprint Fidelis Leads in compliance with the requirements set forth in the confidential PMA and supplemental PMAs. To apply Twombly rigidly without permitting discovery as to these documents effectively creates an impossible-to-achieve specificity requirement. I do not believe the Court intended Twombly to create this type of insurmountable hurdle. Rather, I believe the application of Twombly must be pragmatic. Here, that means requiring only a degree of specificity that may be achieved without use of the confidential documents. After discovery—an interrelated issue discussed below—a court reasonably and consistently with Twombly may demand more from plaintiffs in the articulation of their claims.

Regarding the discovery request and the motion to amend, I would hold, in the context of the present case, that it was an abuse of discretion to deny the request and motion. I emphasize that the requested discovery would be quite limited and impose virtually no burden on the defendants. What the plaintiffs seek, in fact, they already possess in redacted form: the PMA and supplemental PMAs. What they require is an unredacted copy of these clearly identified documents that undisputedly rest in the possession of the FDA and Medtronic. This case does not raise the specter of burdensome and speculative discovery proceedings as referenced in Twombly and bears no resemblance to the discovery-related parade of horribles described with rhetorical flare in the defendant's brief. The plaintiffs here do not seek a fishing expedition in order to discover possible claims, and they have not asked for anything resembling a protracted and expensive discovery process.

The defendants argue the plaintiffs did not ask for discovery until after the district court's initial grant of the motion to dismiss. The majority states the plaintiffs disclaimed the need for discovery and concludes with no discussion that the district court did not abuse its discretion "in denying . . . [the plaintiff's] belated request for

discovery." I disagree. Early in this matter, at least one attorney had strongly urged the court to allow discovery. Later, the plaintiffs represented in a status conference that discovery would not be needed *unless the motion rested on information outside the pleadings*. By applying Twombly in a manner that requires the plaintiffs to first obtain PMAs and specifically articulate claims through reference to deviations from manufacturing requirements as set forth in the PMAs, the district court necessarily brought the PMAs into the case. Doing so advanced the motion to dismiss beyond the mere pleadings. Accordingly, I view the record as showing that the plaintiffs had indicated discovery would be needed in this exact situation.

Unfortunately, the plaintiffs did not know until after the district court dismissed their complaint that the viability of their manufacturing-defect claims at the pleading stage would rest wholly upon the contents of the PMAs. When this disputed legal issue was clarified through the district court's application of Twombly in its preemption decision, plaintiffs sought the opportunity to review the documents that were made outcome determinative by the district court's dismissal order. Only review of these documents could empower the plaintiffs to amend their pleadings in a manner consistent with the district court's interpretation of the preemption/parallel claim doctrine.

The combination of the rigid application of Twombly and the now-articulated parallel claim exception to § 360k preemption have, in these cases, led to the dismissal of over two hundred potentially meritorious lawsuits on a technicality. I view this as unjust in this evolving and complex area of the law. It is particularly inappropriate where all that is required to avoid this result is the grant of a request for focused discovery that will involve truly de minimis costs. In some case, concerns for efficient case administration may dictate a result like that reached today. Efficiency cannot rule the day, however, when plaintiffs seek only the disclosure of clearly identified documents undisputedly held by the defendants.

II.

Supplemental PMAs impose requirements specific to individual devices based on manufacturers' submissions to the FDA. Riegel, 552 U.S. at 323. "And while the FDA does not require that a device allowed to enter the market as a substantial equivalent take any particular form for any particular reason, the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." Id. (internal quotations and citation omitted); see also 21 C.F.R. § 814.80 ("A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device."); id. § 820.70(a) ("Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications.").

The plaintiffs allege (mostly in their amended master complaint) that they were injured because the Sprint Fidelis Leads failed to conform to the device's specifications. At a general level, this is a classic example of a "parallel" state-law claim because the plaintiffs' claim does not seek relief based on some duty or requirement specific to the Sprint Fidelis Leads beyond what is imposed by federal law. The district court recognized this type of claim as a "back door for plaintiffs" that was left open by Riegel. See generally Miller v. DuPuy Spine, Inc., 638 F. Supp. 2d 1226, 1230 (D. Nev. 2009) ("Only a departure from such FDA-approved specifications could conceivably escape preemption. . . ."). In general, plaintiffs attempting to the fit into this narrow category nearly always rely on the manufacturer's submissions to the FDA.[6]

[6]The Sixth Circuit, pre-Twombly, explained that a manufacturer's submissions to the FDA are critical to discerning what requirements are applicable to a medical device:

The present plaintiffs do not allege how the Sprint Fidelis Leads failed to conform to FDA-approved specifications. Instead, they assert that they "cannot specify the requirements because filings with the FDA are confidential."[7] Thus, the discovery issue on appeal is intertwined with the question of the sufficiency of the pleadings. The question with regard to the motion to dismiss, therefore, is whether the plaintiffs must allege that the Sprint Fidelis Leads violated a particular and confidential FDA-approved specification.

The district court held that the plaintiffs' "conclusory allegation" about FDA-approved specifications "fails to pass muster." I view this holding as failing to take into account the practical difficulties inherent in situations, like this, where the "crucial information . . . tend[s] systematically to be in the sole possession of the

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> It is true that in granting approval for a Class III device, the FDA does not set forth the reasons justifying its decision. Impliedly, however, the FDA has relied upon both the PMA submission approved for the original Class III device and the PMA Supplement providing specific information on the proposed modification in question. These specific submissions form the basis of the FDA's approval of the PMA Supplement. Thus, we conclude the specific requirements applicable to the Model 4004M include the entire relevant PMA and accompanying PMA Supplement, rather than certain portions thereof. In the case of the Model 4004M, then, the information submitted to and approved by the FDA in both the Model 4003 PMA and as modified by the Model 4004M PMA Supplement comprise the specific federal requirements applicable to Medtronic's Model 4004M pacemaker lead.

Kemp v. Medtronic, Inc., 231 F.3d 216, 228 (6th Cir. 2000).

[7]Federal regulations provide that the information about a PMA applicant's "[m]anufacturing methods or processes, including quality control procedures" generally are not available for public disclosure unless that information has been previously disclosed to the public. 21 C.F.R. § 814.9(h)(1).

defendants . . . ." Braden v. Wal-Mart Stores, Inc., 588 F.3d 585, 598 (8th Cir. 2009) (describing a similar information imbalance in certain ERISA actions). In Braden, our court reversed a dismissal on the pleadings and called for "careful and holistic evaluation of . . . factual allegations" where defendants were in sole possession of facts necessary to state claims with particularity. In my view, this "careful and holistic evaluation" should accommodate the possibility of limited discovery when the subject matter at hand makes clear that the discovery burden will be slight.

In Hofts v. Howmedica Osteonics Corp., 597 F. Supp. 2d 830, 838 (S.D. Ind. 2009), for example, the court refused to use Twombly to cut off manufacturing-defect claims articulated in a manner almost identical to those in the present case. There, in fact, the court commented on the district court's order from the present case, suggesting that it is "an unusually stringent application of Twombly and Rule 8 of the Federal Rules of Civil Procedure at the motion to dismiss stage." Id. The court explained:

> Manufacturing defect claims are not subject, for example, to the "particularity" pleading requirements of Rule 9. By way of comparison, in Lohr, the Supreme Court reversed dismissal of similar claims, even though "the precise contours of their theory of recovery have not yet been defined," because it was clear that the plaintiffs allegations "may include claims that Medtronic has, to the extent that they exist, violated FDA regulations." 518 U.S. at 495.

Id. In Hofts, the plaintiff "brought claims premised on Howmedica's alleged failure to manufacture the [device] in accordance with the PMA issued by the FDA." Id. Ultimately, that court held the allegations—virtually identical to the present allegations—sufficient to state a claim.

I agree with the court in Hofts because its pragmatic approach does not turn Twombly into an insurmountable hurdle for plaintiffs. Importantly, submissions to

the FDA for PMAs and supplemental PMAs are confidential, and, as in the present case, redacted copies obtained through Freedom of Information Act requests are not always adequate to supply plaintiffs with the manufacturing requirements critical to articulate a non-preempted claim. If plaintiffs must allege that the defendant violated a particular FDA-approved specification before discovery, then it is difficult to appreciate how any plaintiff will ever be able to defeat a Rule 12(b)(6) motion. In essence, application of Twombly in this manner eliminates the remaining exception to § 360k preemption.

The basic principle I would apply recognizes, simply and fairly, that a plaintiff's pleading burden should be commensurate with the amount of information available to them. This is not an unorthodox approach. See Michaels Bldg. Co. v. Ameritrust Co., N.A., 848 F.2d 674, 680 (6th Cir. 1988) ("Courts have held that the [Rule 9(b) particularity requirement] may be relaxed where information is only within the opposing party's knowledge. Especially in a case in which there has been no discovery, courts have been reluctant to dismiss the action where the facts underlying the claims are within the defendant's control.") (internal citations omitted). Most of the arguments that would militate against this approach rely upon the risk that discovery will create unnecessary burdens for defendants and permit unworthy plaintiffs to file frivolous suits merely to fish for possible claims. See, e.g., United States ex rel. Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 559 (8th Cir. 2006) (rejecting a request for discovery in the context of a qui tam action and rejecting a request to relax Rule 9(b)'s heightened particularity requirements for pleading fraud claims, noting, "The reluctance of courts to permit qui tam relators to use discovery to meet the requirements of Rule 9(b) reflects, in part, a concern that a qui tam plaintiff, who has suffered no injury in fact, *may be particularly likely to file suit as a pretext to uncover unknown wrongs*." (quoting United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 231 (1st Cir. 2004)) (emphasis added)). I fail to appreciate how these concerns relate in any manner to the present case, where all that is needed through discovery is an unredacted copy of the PMAs, where at least

some of the plaintiffs have suffered actual and serious injuries, and where other plaintiffs are at heightened risk for future medical intervention.

Regarding the district court's discovery ruling in particular, some additional facts are helpful to provide the full context for this matter. The defendants argue that the plaintiffs shifted positions following the district court's initial dismissal of their claims and now seek discovery after having expressly disavowed any need for discovery. I view this as an inaccurate description of the case. The plaintiffs had sought the PMA documents through FOIA requests, but according to them, "the documents the FDA produced were too heavily redacted to provide the specifications that the district court required." The plaintiffs moved to compel production of unredacted documents or to amend the protective order to allow the FDA to produce the documents without redaction. A magistrate judge denied the plaintiffs' motion. One day later, the district court issued its order dismissing all claims with prejudice and staying all proceedings pending appeal. The plaintiffs filed a letter asking the district court "to clarify that their time to object to [the magistrate judge's] Order is stayed along with the rest of this case." The district court ordered that the stay of proceedings includes the time for the plaintiffs to object to the magistrate judge's order on compelling unredaction of the FDA documents. Thus, the magistrate judge's discovery order is not ripe for appeal.

During a status conference on January 28, 2009, plaintiffs' counsel indicated that they intended to seek leave to file a motion to amend the master consolidated complaint. According to the district court, "Plaintiffs argued strenuously that they are entitled to discovery before moving to amend . . . ." The district court denied discovery. The district court, in denying leave to amend and pursue discovery, suggested that the plaintiffs were unclear about the scope of discovery and how they believed the material will help them. However, the order itself demonstrates that the court was aware that the plaintiffs specifically sought to discover the specifications contained in the Sprint Fidelis Leads' PMAs. Indeed, the plaintiffs have sufficiently

alleged that the Leads were defective, they have discovered violations of other FDA requirements, but they cannot allege a violation of an FDA-approved specification without access to Medtronic's submissions. This is far from"play[ing] Court-sanctioned roulette, hoping that they will hit the discovery 'jackpot' and uncover facts to support their claims," as suggested by the district court and as echoed by the defendants.

The defendants note that the district court stated "Plaintiffs' lead counsel made clear from the outset of this case that no discovery was necessary in order to resolve the preemption issue." The majority also makes this point. In fact, the district court rejected the plaintiffs' attempt to explain the statement in an earlier status conference stating "counsel is attempting to engage in revisionist history by suggesting that he left open the door for discovery at the initial status conference."

Discussing the motion to dismiss, however, counsel did not disavow the need for discovery if the motion was "going to be some sort of broader motion that pulls in information outside of the pleadings." The attorney who made this statement was subsequently appointed lead attorney, but he was not lead attorney at the time he made the statement. Another attorney at the same conference suggested, presciently, that discovery was necessary on the manufacturing-defect issues in order to establish an exception to Riegel—and he even said that he could be sued for legal malpractice for failing to request such discovery. All of these circumstances lead me to believe that Plaintiffs' account of the scheduling conference was not so "revisionist," and also that it was improper for the district court to rely on this exchange to deprive Plaintiffs of discovery that is seemingly necessary for them to state a claim that will avoid federal preemption.

Finally, regarding the motion for leave to amend, I do not present an exhaustive analysis. I note only that I can find no suggestion of bad faith by the plaintiffs or prejudice to the defendants associated with granting leave to amend. Accordingly, for

the reasons set forth above, I would hold denial of the motion for leave to amend and the request for discovery was an abuse of discretion.
