No. 09-2290

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

IN RE MEDTRONIC, INC. SPRINT FIDELIS LEADS PRODUCTS LIABILITY LITIGATION

ANNA BRYANT, et al.,

Plaintiffs–Appellants

v.

MEDTRONIC, INC., et al.,

Defendants–Appellees

On Appeal From The United States District Court
For The District Of Minnesota, MDL No. 08-1905 (RHK/JSM)

DEFENDANTS-APPELLEES' OPPOSITION TO APPELLANTS' PETITION FOR REHEARING OR REHEARING *EN BANC*

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Pursuant to the Clerk's letter of November 3, 2010, Medtronic submits this opposition to Appellants' Petition for Rehearing or Rehearing *En Banc* (PFR). Panel rehearing is not warranted because the petition largely repeats arguments that were made to and rejected by the panel or misrepresents what was argued below. And rehearing *en banc* is not warranted because this case turns merely on the application of settled legal principles to this case. The panel's decision does not conflict with any decision of the Supreme Court or the Eighth Circuit.

INTRODUCTION AND SUMMARY OF ARGUMENT

This appeal follows the dismissal of all 21 claims pleaded by certain plaintiffs who chose to adopt the Master Consolidated Complaint (MCC) in the MDL for Medtronic's Sprint Fidelis defibrillator leads. The leads are Class III medical devices approved by the FDA through its rigorous Premarket Approval (PMA) process. The district court found that each of the claims in the MCC is expressly preempted under 21 U.S.C. § 360k and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). This Court (Loken, Shepherd, and Melloy, JJ.) affirmed, with Judge Melloy dissenting only with respect to the dismissal of the manufacturing-defect claim. Plaintiffs' petition raises four issues. None has merit.

First, in affirming dismissal of the manufacturing-defect claim, the panel did *not* hold that federal pleading standards are inflexible. Indeed, the panel was sympathetic to the principle that, in certain contexts, a plaintiff may have a good basis

to request discovery before the district court acts on a motion to dismiss, and it favorably cited the very Eighth Circuit decision with which plaintiffs now suggest the panel's opinion conflicts. Instead, the panel held only that—given the context of *this* litigation, including the proposed amended complaint—the flexible nature of federal pleading standards does not save the claims plaintiffs actually pleaded or attempted to plead. Plaintiffs' disagreement with the panel's application of this legal principle is not a proper basis for rehearing and, in any event, has no merit.

Second, the plaintiffs in this appeal each chose to adopt the MCC as their individual complaint, and thus the panel did not err in holding them to it.

Third, the panel did not address the dismissal of plaintiffs' fraud, misrepresentation, and statutory fraud claims because plaintiffs did not appeal from that dismissal. Similarly, the panel did not address plaintiffs' alleged "second category" of express-warranty claims because plaintiffs never argued any such claims until this petition, and thus have waived them—and in any event, those claims would also appropriately have been dismissed.

Finally, plaintiffs' contention that the underlying controversy is moot, making the panel's issuance of its opinion an abuse of discretion, is incorrect. The Master Settlement Agreement (MSA) contains a number of conditions that have yet to be satisfied and provides Medtronic and plaintiffs (both appellants and those whose cases are still in the district court) with opt-out rights that remain available.

ARGUMENT

I. Plaintiffs' Manufacturing-Defect Claim Was Properly Dismissed.

Plaintiffs' primary argument for rehearing is that the panel allegedly failed to apply the federal pleading standards under *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), in a "flexible, context-specific manner." PFR 2. They contend that this places the panel's opinion in conflict with *Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585 (8th Cir. 2009), and other cases endorsing a flexible standard.

But the panel cited *Braden* favorably (*In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.* (*In re Fidelis*), 2010 WL 4026802, at *4 (8th Cir. Oct. 15, 2010)), and said nothing to indicate that federal pleading standards are inflexible or indifferent to context. Indeed, the panel stated that plaintiffs' present argument "would have considerable force" in a different context, but that it does not apply to "the case Plaintiffs presented to the district court." *Id.* Thus, plaintiffs' petition boils down to a dispute over the panel's application of settled law to the unique facts of their case. A petition for rehearing that merely seeks a second bite at the apple should be denied. Regardless, the panel's decision was correct.

The panel correctly found that, as pleaded and argued, plaintiffs' manufacturing-defect claim is preempted. As the panel stated, "the crucial question on appeal is whether [plaintiffs'] claims are parallel claims that avoid preemption be-

cause they would not impose state requirements 'different from or in addition to' the federal requirements established by PMA approval of the Sprint Fidelis Lead." *In re Fidelis*, at *2 (quoting 21 U.S.C. § 360k). Although plaintiffs previously disputed the criteria for preemption under § 360k and *Riegel* and the contours of the "parallel claim" exception to that preemption, they do not challenge the panel's determinations on those issues. Their attempt to cast doubt on the panel's and the district court's application of those legal doctrines to plaintiffs' manufacturing-defect claim is baseless.

As an initial matter, the relevant question is *not* whether plaintiffs have "plausibly allege[d] that Medtronic defectively manufactured a product that injured Appellants" (PFR 5), but whether they have plausibly alleged a manufacturing-defect claim that would not impose any requirements that *differ from or add to* existing federal requirements for the manufacture of the leads (*In re Fidelis*, at *2, *4-*5). As both the panel and the district court found, plaintiffs did not.

Furthermore, all of the allegations that plaintiffs cite in the petition (at 5-6) come from their proposed amended complaint. That complaint, however, is not before the Court: The panel unanimously affirmed the district court's denial of plaintiffs' motion for leave to amend the MCC as both untimely and futile. *In re Fidelis*, at *6; JA378-83. The petition does not challenge that holding. Plaintiffs' misleading citation to the wrong pleading is sufficient ground for rejecting the petition.

Regardless, as both the panel and the district court found, analysis of the pleadings and the regulations cited by plaintiffs confirms that none of plaintiffs' allegations suffices to remove their claims from the preemptive scope of § 360k:

- The EIR referenced by plaintiffs (at 5), by its terms, is not a final FDA action. Furthermore, the "manufacturing violations" supposedly identified in the EIR relate to sterilization procedures, but plaintiffs have made no allegations related to those procedures. Nothing in the EIR reflects or suggests a deviation from the PMA or any federal requirements. *See* Brief for Appellees (BA) 45-46.

- The FDA approved the manufacturing process for the leads, so even if that process is "one possible cause of the fracture failures" (PFR 5), that would not help plaintiffs to avoid preemption. *See* BA 46 n.17.

- Contrary to plaintiffs' suggestion (at 6), FDA regulations allow manufacturers to make certain manufacturing changes without first seeking FDA approval and give them the discretion, in the first instance, to decide whether approval is required. These allegations of non-compliance with FDA filing requirements also are impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). *See* BA 52-54.

- The other allegations that plaintiffs reference (at 5-6) all deal with the FDA's Current Good Manufacturing Practices (CGMP). As the district court held, the CGMP cannot save plaintiffs' claims from preemption because those regulations are "inherently flexible" and "require manufacturers to develop *their own* quality-system controls." JA175. The panel unanimously affirmed that holding (*In re Fidelis*, at *4), consistent with numerous other courts (*see, e.g.*, *Anthony v. Stryker Corp.*, 2010 WL 1387790, at *2-*3 (N.D. Ohio Mar. 31, 2010); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 586-89 (E.D.N.Y. 2009); *Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270, 1288 (M.D. Fla. 2009); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 284 (E.D.N.Y. 2009).

Thus, plaintiffs have failed to provide any reason to reexamine the panel's conclusion that, as pleaded and argued, the manufacturing-defect claim is

preempted. The only remaining question is whether the district court abused its discretion by ruling on Medtronic's motion to dismiss without allowing discovery.

There is no basis for rehearing the panel's conclusion that the district court acted within its discretion when it denied plaintiffs' belated request for discovery. First, as the panel found, plaintiffs waived any preemption–related discovery. *In re Fidelis*, at *4. Plaintiffs protest that finding, claiming that the panel took their statements to the district court out of context. PFR 4 n.1. The district court was intimately familiar with the situation, however, and also found—based not only on plaintiffs' express waiver but also on their course of conduct throughout the briefing and argument of the motion to dismiss—that plaintiffs waived discovery. JA255-58. Indeed, the "condition" that plaintiffs claim they placed on their waiver (PFR 4 n.1) is irrelevant because Medtronic's motion to dismiss did not "pull[] in information outside the pleadings." *See* JA257-58 & n.2.

In any event, the district court and the panel plainly were correct that, in this context, plaintiffs are "put[ting] the proverbial cart before the horse" by asking for discovery in order to help them try to identify a viable claim rather than pleading a viable claim and then asking for discovery to confirm the basis of that claim. JA254. Plaintiffs are simply mistaken when they assert that discovery is required to plead a potentially viable claim in the PMA context. The request plaintiffs are

making—to be allowed to conduct unspecified and perhaps massive discovery[1] despite having filed a complaint that fails to state a claim, in the hope that they can thereafter identify a requirement that they can allege was violated—is a paradigmatic fishing expedition properly rejected by the panel and district court. *See* BA 69-75.

The panel's pleading standard does not create an "impossible hurdle." Plaintiffs repeatedly describe the panel as creating a standard that no plaintiff can meet. That is simply not true because, as noted, the panel's opinion is consistent with allowing preemption-related discovery for a plaintiff who has properly pleaded a claim that justifies such discovery. Moreover, as both the panel and the district court noted, plaintiffs in a number of other cases have pleaded non-preempted claims in the PMA context under this standard without discovery. *See, e.g.*, *Rollins v. St. Jude Med.*, 583 F. Supp. 2d 790 (W.D. La. 2008); *Purcel v. Advanced Bionics Corp.*, 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008).

The* Hofts *opinion is not a basis for rehearing. Throughout this litigation, plaintiffs have repeatedly invoked *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830 (S.D. Ind. 2009), to buttress their assertion that they have alleged a viable claim and should be allowed discovery. They do so once again (PFR 6), but

[1] Although Judge Melloy suggested discovery limited to the terms of the PMA (*see In re Fidelis*, at *7), plaintiffs never so limited their discovery arguments, and indeed do not endorse that limitation in the petition.

Hofts, in addition to being merely a district court decision (*cf.* Fed. R. App. P. 35(b)(1)(B)), has properly been rejected as fundamentally inconsistent with *Riegel* not only by the district court in this case (JA382) but also by at least five other courts. *See Anthony*, 2010 WL 1387790, at *5; *Ilarraza*, 677 F. Supp. 2d at 589; *Covert v. Stryker Corp.*, 2009 WL 2424559, at *5, *12-*13 (M.D.N.C. Aug. 5, 2009); *Horowitz*, 613 F. Supp. 2d at 284-85; *see also Lemelle v. Stryker Orthopaedics*, 698 F. Supp. 2d 668, 674-76 (W.D. La. 2010); *Funk v. Stryker Corp.*, 673 F. Supp. 2d 522, 528-29 (S.D. Tex. 2009).

II. The Master Consolidated Complaint Binds Plaintiffs.

Plaintiffs criticize the panel for holding them to the allegations in the MCC, which they assert was merely an "administrative" device and not "a formal pleading." PFR 8-9. Not so. Unlike some plaintiffs in the MDL (*see* PFR 9 n.2), each of the plaintiffs in this appeal voluntarily chose to "adopt[] the MCC without any additional claims" as their individual complaint (JA383-84). Nor were plaintiffs forced to undertake "a frontal assault on the FDA's decision to approve [the leads]" in order to create a master pleading. Rather, the plaintiffs have consistently chosen to base this litigation on the theory that there was a systemic defect in *all* Fidelis leads. Indeed, the same strategy is reflected in the Minnesota-state-court Fidelis litigation, where each of the nine individual complaints plaintiffs selected as "representative" (most of which were drafted by attorneys involved here) also

"allege[s] a systemic flaw in the FDA-approved design of the Leads and the manufacturing process used to create them." *In re Medtronic Sprint Fidelis Lead Prods. Liab. State Ct. Litig.*, 2009 WL 3417867, at *13 (Minn. D. Ct. Oct. 20, 2009).

III. Plaintiffs Never Appealed From The Dismissal Of Their Misrepresentation And Consumer Protection Claims, And Have Never Before Asserted A "Second Category" Of Express-Warranty Claims.

Plaintiffs complain that the panel did not address an alleged "second category" of express-warranty, misrepresentation, and fraud claims that allegedly are unrelated to safety or effectiveness. But no such claims were presented to the panel.

First, plaintiffs did not appeal from the dismissal of their misrepresentation, fraud, and statutory-fraud claims. Of the nine claims referenced in the petition for rehearing (at 9), plaintiffs addressed *only* the express-warranty claim in their opening brief (at 55-57) or reply brief (at 24-27). *See* BA 58. The dismissal of the remaining, unpreserved, claims thus cannot form an appropriate basis for rehearing.

Second, the panel unanimously concluded that plaintiffs' express-warranty claim was preempted because it challenged the safety or effectiveness of the leads. Plaintiffs do not dispute that result—and thus their citations (at 10-11) to *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), and *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), are inapposite. Instead, they now say that the panel ignored another type of express-warranty claim that allegedly did not relate to safety or effectiveness. But such a claim was never pleaded (JA54-68), raised before the dis-

trict court (JA188), or briefed in this Court (Pls.' Br. 55-57; Reply Br. 24-27). The only express-warranty claim that plaintiffs have pursued involves an alleged warranty that the leads "were safe, effective, fit and proper for their intended use." JA54; Pls.' Br. 57. Whatever "second category" of non-safety-related claims plaintiffs now have in mind, they did not plead or preserve them.[2]

IV. The Panel's Decision To Issue Its Opinion Was Within Its Discretion.

Contrary to plaintiffs' representations (PFR 12-14), this case is not moot either technically or "prudentially." As plaintiffs acknowledge (at 13), the MSA is "subject to certain conditions" that have yet to be satisfied and provides both plaintiffs (including all appellants here) and Medtronic with opt-out rights that remain available. Indeed, *none* of the plaintiffs in this appeal, or those still before the district court, has yet moved to dismiss his or her claims. Under these circumstances, the panel's opinion controls the pending litigation. Accordingly, the panel did not abuse its discretion by denying a stay request and releasing its opinion.

CONCLUSION

The petition for rehearing or rehearing *en banc* should be denied.

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[2] Claims based on plaintiffs' "second category" of alleged misrepresentations would in any event fail as a matter of law. This Court recently held that the 2007 "Dear Doctor" letter on which plaintiffs focus (at 9-10) cannot provide the basis for a fraud claim because it purports to contain only "preliminary and partial" information about an ongoing investigation. *Detroit Gen. Retirement Sys. v. Medtronic, Inc.*, 2010 WL 3583388, at *3-*4 (8th Cir. Sept. 16, 2010). The other statements plaintiffs identify—that the leads were "state of the art" or "based on" prior leads—are too vague to support a claim (and are indisputably true).

Respectfully submitted.

s/Kenneth S. Geller

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November 15, 2010

CERTIFICATE OF SERVICE

I hereby certify that on November 15, 2010, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the CM/ECF system.

I further certify that some of the participants in the case are not CM/ECF users. I have mailed the foregoing document by First-Class Mail, postage prepaid, to the following non-CM/ECF participants:

> C. Brooks Cutter, Camilo K. Salas III, Eric M. Quetglas-Jordan, Fred Thompson III, Hugh F. Young Jr., Hunter J. Shkolnik, James L. Doyle II, Mark P. Robinson, Nicholas J. Drakulich.

s/ David M. Gossett