

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

RICHARD J. PINSONNEAULT,

Case No. 12-CV-1717 (PJS/JSM)

Plaintiff,

v.

ORDER

ST. JUDE MEDICAL, INC. and
PACESETTER, INC.,

Defendants.

JOSEPH D. HOULETTE,

Case No. 12-CV-1785 (PJS/JSM)

Plaintiff,

v.

ST. JUDE MEDICAL, INC. and
PACESETTER, INC.,

Defendants.

GARY ROUSE,

Case No. 12-CV-2396 (PJS/JSM)

Plaintiff,

v.

ST. JUDE MEDICAL, INC. and
PACESETTER, INC.,

Defendants.

Yvonne M. Flaherty, LOCKRIDGE GRINDAL NAUEN PLLP, for plaintiff Richard J. Pinsonneault.

Charles S. Zimmerman, Ronald S. Goldser, Genevieve M. Zimmerman, and Jason P. Johnston, ZIMMERMAN REED, PLLP, for plaintiff Joseph D. Houlette.

Daniel E. Gustafson, Karla M. Gluek, and Amanda M. Williams, GUSTAFSON GLUEK PLLC, for plaintiff Gary Rouse.

Blake Shepard, Jr. and Brian W. Thomson, STINSON LEONARD STREET LLP; Maja C. Eaton and Rebecca K. Wood, SIDLEY AUSTIN LLP; Daniel L. Ring and Andrew E. Tauber, MAYER BROWN LLP, for defendants.

Plaintiffs Richard Pinsonneault, Joseph Houlette, and Gary Rouse were all implanted with Riata defibrillation leads manufactured by defendants St. Jude Medical, Inc. and Pacesetter, Inc. (collectively “St. Jude”). In December 2011, the Food and Drug Administration (“FDA”) issued a recall for certain Riata models, including the models that had been implanted in plaintiffs. Plaintiffs’ leads were later explanted, and plaintiffs then filed these actions, alleging that their leads were defectively manufactured. The Court recently granted St. Jude’s motion for summary judgment in large part and dismissed most of plaintiffs’ claims as preempted under 21 U.S.C. § 360k(a).

This matter is before the Court on plaintiffs’ letter request to file a motion for reconsideration. In this District, motions to reconsider are prohibited absent the Court’s prior permission. D. Minn. L.R. 7.1(j). To obtain such permission, a party must show “compelling circumstances” *Id.*; see *Nelson v. Am. Home Assur. Co.*, 702 F.3d 1038, 1043 (8th Cir. 2012) (noting that motions to reconsider are treated as Fed. R. Civ. P. 60(b) motions when directed at non-final orders and require a showing of exceptional circumstances necessitating extraordinary relief).

Plaintiffs first contend that the Court misunderstood the basis of one of their claims. To understand their argument, a little background is necessary. A Riata lead consists of thin, insulated wires that connect an implantable cardioverter defibrillator (“ICD”) to one or more electrodes in, on, or near the patient’s heart. The wires are encased in a silicone tube of insulation that has four holes or “lumens” bored through it lengthwise to hold the wires. In their

complaints, plaintiffs alleged (among other things) that St. Jude violated a federal requirement — contained in the pre-market approval (“PMA”) documents submitted to the FDA — that the insulation be manufactured with a consistent diameter. Pinsonneault Am. Compl. ¶ 48; Houlette Am. Compl. ¶ 47; Rouse Am. Compl. ¶ 46. According to plaintiffs’ allegations, inconsistent insulation diameters lead to an increased risk that thinner insulation sites can fail, allowing the lead wires to protrude through the insulation. Pinsonneault Am. Compl. ¶¶ 48-49; Houlette Am. Compl. ¶¶ 47-48; Rouse Am. Compl. ¶¶ 46-47.

The fact that plaintiffs made allegations about the diameter of the *insulation* — rather than making allegations about the diameter of the *lead body* — made their complaints ambiguous. As noted, each lead body contains four separate lumens bored lengthwise through the insulation tube. Specifying the overall diameter of the lead body is not the same as specifying that each lumen must be surrounded by insulation of a certain thickness. Obviously, the amount of insulation between each lumen and the outer wall of the lead body will vary depending on the placement and size of the lumen. Given that plaintiffs were alleging that their leads failed because of insufficient insulation between the lumens and the outer wall of the lead body, it was unclear whether they were focusing on the thickness of the insulation surrounding each lumen or, instead, on the overall diameter of the lead body.

This ambiguity became apparent during discovery, when a St. Jude deponent noted that plaintiffs’ counsel seemed to treat thickness of insulation as equivalent to diameter and explained that “[i]nsulation diameters’ is itself nonsensical.” Anderson Dep. 118. Plaintiffs’ counsel could easily have put an end to the confusion by clarifying that he was referring to the diameter of the entire lead body rather than (or, at least, in addition to) the thickness of the insulation

surrounding each of the four lumens. This would have been an obvious clarification to make, as the parties' whole dispute over preemption turned on whether St. Jude violated any manufacturing specifications in the PMA. St. Jude has argued all along that there is no PMA specification concerning insulation thickness. There is, however, a specification for the lead-body diameter.¹ Any claim that plaintiffs' leads did not comply with the specification for the diameter of the lead body would therefore not be preempted (assuming that the specification was ultimately found to be part of the PMA). For that reason, it was very much in plaintiffs' interest to make sure that everyone understood that they were making such a claim — if, in fact, they were making such a claim. But plaintiffs never made such a clarification. Instead, plaintiffs' counsel seemed to adopt the witness's understanding of plaintiffs' claims during the remainder of the deposition, referring to “insulation thickness” and focusing on the dimensions of the insulation from the outer edge of the lumen to the outside edge of the insulation (that is, to the outer wall of the lead body). Anderson Dep. 119-26, 175.

Plaintiffs' summary-judgment briefing was as ambiguous as plaintiffs' complaints, citing the diameter specification but also arguing that “there is no meaningful distinction between ‘insulation diameters’ and ‘insulation thickness’ in this context.” Pls.' Mem. in Opp. at 10. Because the Court was having difficulty understanding plaintiffs' claims regarding insulation, the Court specifically asked plaintiffs to clarify those claims at oral argument:

So when your complaint cites to a lack of uniform insulation thickness I'll call it, how would you even — what kind of uniformity would we be talking about when there's various lumen

¹St. Jude contends that this specification is not part of the PMA. As the Court has noted, however, there is conflicting evidence on that point.

with various insulation? What insulation were you referring to in the complaint?

Hr’g Tr. 42, Jan. 6, 2014. Plaintiffs’ counsel replied that he “was referring to the *outer* insulation, *outside the lumens*.” *Id.* (emphasis added). Plaintiffs’ counsel was clear: Plaintiffs were not alleging that their leads failed to comply with the lead-body diameter specification, but instead were alleging that there was insufficient insulation between the lumens and the outer wall of the lead body. To further drive home the point, plaintiffs’ counsel later referred to the document containing the lead-body specification, stating, “PS 0069 has lots of evidence with respect to wall thickness. *I agree it doesn’t quite get me there*, but it suggests that there’s more there, and it’s strong evidence that there is a requirement with respect to that.” Hr’g Tr. 77 (emphasis added). Obviously, if plaintiffs were in fact claiming that their leads violated the lead-body diameter specification found in PS 0069, that specification alone *would* “get [them] there” Plaintiffs never contended that they were making such a claim, however.

Plaintiffs now argue that the Court misunderstood their claims, and that they were, in fact, *also* alleging that their leads violated the lead-body diameter specification. This contention is completely at odds with the representation that plaintiffs made at oral argument that their insulation claims involved “the outer insulation, outside the lumens” and the concession of plaintiffs’ counsel that the lead-body diameter specification “doesn’t quite get me there” Having made these unqualified clarifications, it is disingenuous for plaintiffs to now claim that the Court somehow overlooked the ambiguous allegations in their pleadings, particularly when the Court made a point of asking plaintiffs to clarify those allegations at oral argument. Plaintiffs had multiple opportunities and every incentive to clarify that they were attacking *both*

the thickness of the insulation *and* the diameter of the lead body. Having failed to do so, they cannot now credibly assert that they were somehow misunderstood.

Plaintiffs also contend that the Court made a factual error in finding that the lead-body diameter requirement sets a maximum diameter (rather than a precise diameter). It is true that the Court at one point referred to the diameter requirement as setting a maximum. June 24, 2014 Order at 20. St. Jude says that this was not an error, but, even if it was, it was an error about an irrelevant detail that did not affect the Court's analysis. Even if the lead body was required to be a precise diameter, that requirement does not solve plaintiffs' fundamental problem. Each plaintiff claims that he was harmed because there was insufficient insulation between the lumens and the outer wall of the lead body. It is the placement and size of the lumens within the lead body — not the overall diameter of the lead body — that ultimately determines the thickness of the insulation around each lumen.² Because there are no requirements as to the spacing or size of three of the four lumens, there is no requirement with respect to insulation thickness, and that is fatal to plaintiffs' insulation claims.

The Court finds no compelling circumstances that would warrant permitting plaintiffs to move for reconsideration. To the contrary, the Court finds that plaintiffs are seeking to use a motion to reconsider to try to assert a new claim — a claim that they specifically disavowed at oral argument. The Court denies plaintiffs' letter request to file such a motion.

²To cite a simple example: A narrow lumen at the center of an insulated one-inch tube will be separated from the outer wall by about a half inch of insulation. A narrow lumen at the periphery of an insulated six-inch tube might be separated from the outer wall by one-hundredth of an inch of insulation.

ORDER

Based on the foregoing, and on all of the files, records, and proceedings herein, IT IS
HEREBY ORDERED THAT plaintiffs' letter request to bring a motion for reconsideration
[ECF No. 118 in 12-CV-1717; ECF No. 116 in 12-CV-1785; and ECF No. 112 in 12-CV-2396]
is DENIED.

Dated: July 30, 2014

s/Patrick J. Schiltz
Patrick J. Schiltz
United States District Judge