

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
TERRE HAUTE DIVISION

MILES THOMPSON,)
)
 Plaintiff,)
)
 vs.) No. 2:16-cv-00041-LJM-MJD
)
 ST. JUDE MEDICAL, INC.,)
)
 Defendant.)

ORDER ON DEFENDANT’S MOTION TO DISMISS

Defendant St. Jude Medical, Inc. (“St. Jude”) has moved to dismiss Plaintiff Miles Thompson’s (“Thompson’s”) Complaint pursuant to Rules 8 and 12(b)(6) of the Federal Rules of Civil Procedure (“Rules 8 and 12(b)(6)”) because the claims are preempted by the Medical Device Amendments of 1976, 21 U.S.C. § 312 (2008) (“MDA”), and/or because it fails to articulate a plausible claim for relief. Dkt. No. 12. Thompson opposes the Motion relying upon several cases that stand for proposition that medical device claims that allege that a specific federal requirements was violated and resulted in an injury are not preempted. Dkt. No. 19-1, at 1-4. Alternatively, Thompson asserts that he was not required to make any specific showing under the Federal Rules of Civil Procedure because he filed the case in state court; therefore, only pleadings filed after removal are required to comply with the Rules. *Id.* at 4-7.

For the reasons stated herein, the Court **GRANTS in part and DENIES in part** St. Jude’s Motion to Dismiss.

I. FACTUAL ALLEGATIONS

The bare-bones allegations in the Complaint are set forth here verbatim:

1. That at some point prior to June 12, 2015, the Plaintiff had undergone insertion of a Riata Implantable Cardioverter Defibrillator (ICD).
2. That the Riata Implantable Cardioverter Defibrillator (ICD) was manufactured by Defendant, St. Jude Medical, Inc.
3. That on June 12, 2015, the Plaintiff underwent removal of the ICD due to severe and significant medical complications related to the ICD.
4. That the ICD manufactured by Defendant, St. Jude Medical, Inc., was a faulty defibrillator, with faulty leads as well.
5. That Plaintiff suffered, and continues to suffer, significant personal injuries and damages, including but not limited to injuries to his person, pain and suffering, future pain and suffering, medical expenses, future medical expenses, lost wages, future lost wages, and inability to live his normal life.
6. That the proximate cause of the aforementioned injuries and damages is negligence on the part of the Defendant, St. Jude Medical, Inc.

Dkt. No. 1-1, at 4.

II. DISCUSSION

Under the Supreme Court's directive in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), to survive St. Jude's motion for failure to state a claim upon which relief may be granted, Thompson must provide the grounds for its entitlement to relief with more than labels, conclusions or a formulaic recitation of the elements of a cause of action. *Id.* at 555 (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). The Court assumes that all the allegations in the Complaint are true, but the "allegations must be enough to raise a right to relief above the speculative level." *Id.* The touchstone is whether the Complaint gives St. Jude "fair notice of what the ... claim is and the grounds upon which it rests." *Id.* (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). Legal conclusions or conclusory

allegations are insufficient to state a claim for relief. *McCauley v. City of Chicago*, 671 F.3d 611, 617 (7th Cir. 2011). The Court may also consider publicly available documents to decide the motion. See *Williamson v. Curran*, 714 F.3d 432, 436 (7th Cir. 2013). Notwithstanding Thompson's argument to the contrary, it is clear that these standards apply to all complaints, even those removed from state court. See *Windy City Metal Fabricators & Supply, Inc. v. CIT Tech. Fin. Servs., Inc.*, 536 F.3d 663, 670 (7th Cir. 2008) (concluding that there is no reason not to apply federal pleading requirements to complaints filed in state court, even if state law is at issue).

With respect to preemption, the seminal case in this area is *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). "State requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." *Riegel*, 552 U.S. at 330. Therefore a state may provide "a damages remedy for claims premised on a violation of FDA regulations; [where] the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)). In other words, to avoid preemption, Thompson must allege that St. Jude's medical device violated a specific federal standard for manufacture of the device in question. See *id.*

Applying these standards to Thompson's Complaint, although he alludes to a product recall in his Memorandum in Opposition and discusses cases that conclude that the plaintiffs therein had adequately stated a claim, in his Complaint Thompson did not specifically identify an MDA or premarket approval requirement that has been violated. Clearly after *Riegel*, such an allegation is necessary to survive a motion to dismiss on preemption grounds.

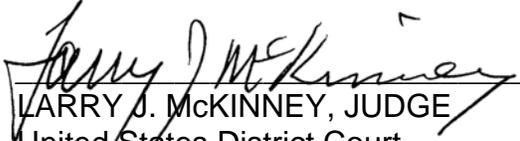
Even if the claims as plead were not preempted, under *Twombly*, Thompson has failed to plead a causal nexus between any violation of a federal standard and his injuries. Thompson has also failed to allege how his particular device malfunctioned or that the leads were defective. Conclusory allegations like those in Thompson's Complaint are simply not enough. See *McCauley v. City of Chi.*, 671 F.3d 611, 616 (7th Cir. 2011).

St. Jude requests a dismissal with prejudice because Thompson failed to argue in his brief that he could re-plead the proper foundation for a claim. Dkt. No. 24 at 5-6. The Court declines the invitation to dismiss the Complaint with prejudice and instead will allow Thompson time to re-plead; if after that period of time, he fails to make a plausible claim for relief, the Court will dismiss this action with prejudice.

III. CONCLUSION

For the reasons stated herein, the Court **GRANTS in part and DENIES in part** Defendant St. Jude Medical, Inc.'s Motion to Dismiss. Plaintiff Miles Thompson's Complaint is hereby **DISMISSED WITHOUT PREJUDICE**. Plaintiff Miles Thompson shall have to an including April 11, 2016, to file an Amended Complaint or the Court will dismiss his Complaint with prejudice.

IT IS SO ORDERED this 21st day of March, 2016.


LARRY J. MCKINNEY, JUDGE
United States District Court
Southern District of Indiana

Distribution attached.

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