Harris v. Medtronic Incorporated et al

2023 | Cited 0 times | D. Arizona | March 13, 2023

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

James Harris,

Plaintiff, v. Medtronic Incorporated, et al.,

Defendants.

No. CV-21-02210-PHX-DLR ORDER

Pending before the Court is Defendant

1 (Doc. 18, 20, 22). The Court grants the motion for the following reasons. 2 I. Background 3

manufactured by Medtronic and implanted into Plaintiff in 2007 to detect and correct cardiac arrhythmia. (Doc. 17 at 2-3.) The Device is a Class III device, subject to pre-market approv (Id. at 4.) Pre-market

1 The parties have also asked the Court to take judicial notice of other matters, but because the Court resolves the motion to dismiss for reasons entirely contained in the motion, the Court declines to take judicial notice.

2 Oral argument is denied because the motions are adequately briefed, and oral argument will not help the Court resolve the issues presented. See Fed. R. Civ. P. 78(b); LRCiv. 7.2(f).

3 well-pled factual allegations are taken as true and construed in the light most favorable to [him]. Cousins v. Lockyer, 568 F.3d 1063, 1067 (9th Cir. 2009).

approval imposes requirements on how the Device is manufactured. Riegel v. Medtronic, Inc., 552 U.S. 312, 552 (2008). The Device was removed from Plaintiff in 2019 after Id. at 3.) Plaintiff argues that he sustained injuries related to these shocks because Medtronic, after receiving pre-market approval

from the FDA, manufactured the Device using defective welding, metals, and insulation and failed to warn the FDA about these defects. (Id. at 7-11.) II. Standard

To survive motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a

Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). The task when alleged [plausibly] can be Adams v. Johnson, 355 F.3d 1179, 1183 (9th Cir. 2004); accord Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). When analyzing the sufficiency of a complaint, the well-pled factual allegations are taken as true and construed in the light most favorable to the plaintiff. Cousins v. Lockyer, 568 F.3d 1063, 1067 (9th Cir. 2009). However, legal conclusions couched as factual allegations are not entitled to the assumption of truth, Iqbal, 556 U.S. at 680, and therefore are insufficient to defeat a motion to dismiss for failure to state a claim, In re Cutera Sec. Litig., 610 F.3d 1103, 1108 (9th Cir. 2008). III. Analysis

A. Manufacturing Defect, Claims I and II The MDA creates an exclusive federal regulatory framework applicable to Class III medical devices, including the Device. Courts apply a two-prong test to determine whether claims are expressly preempted by the MDA. The first prong is whether the FDA has established requirements applicable to the device at issue. Riegel, 552 U.S. at 321. The parties agree that the first prong is met here.

The second prong is whether the claims in the case attempt to impose requirements relating to safety and effectiveness that are different from, or in addition to the federal

requirements. Id. at 322. -law causes of action for negligence and -empted by federal Riegel, 552 U.S. at 323-24 (2008) (quoting Medtronic, Inc. v. Lohr

An exception exists for so-called parallel claims, that is, state law claims predicated Weber v. Allergan, Inc., 940 F.3d 1106, 1111 (9th Cir. 2019). To qualify as a parallel claim, an allegation must specifically identify - to the device. See Id. (quoting In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.,

623 F.3d 1200, 1207 (8th Cir. 2010) (approving a parallel claim where a plaintiff had alleged that the FDA pre-market approval requires 400-degree welds, but the manufacturer had used 300-degree welds)). Bare allegations that Medtronic violated FDA regulations will not suffice. Pappas v. Medtronic Inc., No. CV-20-02016-PHX-DLR, 2021 WL 977165, at *2 (D. Ariz. Mar. 16, 2021).

Here, Plaintiff alleges that Medtronic the Device:

using a welding process that was never submitted to, or approved by the FDA with lower voltage amplitudes than had been submitted to the FDA and been approved by the FDA, using metals in the Subject Lead and wires of the Subject Lead that were never submitted to or approved by the FDA, and by using insulation material on the Subject Lead that was never submitted to or approved by the

FDA. (Doc. 17 at 6.) Plaintiff does not indicate what protocols or specifications concerning welding amplitudes, metals, or insulating materials were required by the FDA. Absent allegations specific to the relevant protocols or specifications, Plaintiff has not pled a parallel claim for manufacturing defect, and his claims are thus preempted. Weber, 940 F.3d at 1111. For this reason, the Court need not consider whether Plaintiff properly alleged that any differences in welding, metals, and insulating material caused his alleged injury. B. Failure to Warn Plaintiff alleges that Medtronic failed to warn the FDA of alleged deviations and defects. (Doc. 17 at 11.) But Arizona law does not recognize a duty to warn a third party

Conklin v. Medtronic, Inc., 431 P.3d 571, 579 (Ariz. 2018) (quoting Stengel v. Medtronic Inc., 704 F.3d 1224, 1233 (9th Cir. 2013)). Plaintiff urges the Court Stengle, which concluded that Arizona law recognizes a duty to warn third parties, such as the FDA. 704 F.3d at 1233. But the later Arizona Supreme Court Conklin opinion concluded Stengle had ed and applied it. 431 P.3d at 579. Because [t]he courts of a state alone can define the authoritative meaning of state law, the Court is bound to follow Conklin and not Stengle. Andrade v. City of Phoenix, 692 F.2d 557, 559 (9th Cir. 1982). Arizona law does not recognize a duty to warn a third party like the FDA, as Plaintiff alleges. He has therefore failed to state a failure to warn claim. IV. Conclusion Claims I and II are preempted by federal law. Claim III fails to state a claim. IT IS ORDERED 18) is GRANTED. The Clerk of the Court is directed to enter judgment accordingly and terminate this case. Dated this 13th day of March, 2023.

Douglas L. Rayes United States District Judge