IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MICHAEL MURPHY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 20-983-CJB
	)	
ST. JUDE MEDICAL, LLC, formerly known as St. Jude Medical, Inc., and ABBOTT LABORATORIES, INC.,	)	
	)	
Defendants.	)	

David G. Culley, TYBOUT, REDFEARN & PELL, Wilmington, DE, Attorney for Plaintiff.

Brian M. Rostocki, REED SMITH LLP, Wilmington, DE, Attorney for Defendants.

MEMORANDUM OPINION

December 3, 2021
Wilmington, Delaware

Christopher J. Burke
BURKE, United States Magistrate Judge

Plaintiff Michael Murphy ("Plaintiff" or "Mr. Murphy") brings this products liability action against Defendants St. Jude Medical, LLC and Abbott Laboratories, Inc. (collectively, "St. Jude" or "Defendants"). Presently before the Court is St. Jude's motion to dismiss Plaintiff's Amended Complaint, filed pursuant to Federal Rule of Civil Procedure 12(b)(6) (the "Motion"). (D.I. 24) For the reasons that follow, the Court GRANTS-IN-PART and DENIES-IN-PART St. Jude's Motion.

I. BACKGROUND

A. Factual Background

Mr. Murphy, a New Jersey resident, has experienced low back pain since the early 1990s. (D.I. 17 at ¶¶ 4, 78) Following a lumbar spine surgery in 1996, his symptoms ultimately worsened, and he experienced radiation of pain and weakness in both legs. (*Id.* at ¶ 78) In March 2014, Mr. Murphy underwent a posterior lumbar interbody fusion procedure performed in New York, New York by Dr. George DiGiacinto; the procedure was meant to address diagnoses of L4-5 spondylosis and L5-S1 instability. (*Id.* at ¶ 79) Mr. Murphy's pain management specialist, Dr. Ajay Varma, subsequently recommended a spinal cord stimulator trial after conservative medical treatment failed to improve Mr. Murphy's functional capacity or help with his reliance on opioid medications. (*Id.* at ¶ 80)

On October 11, 2017, Mr. Murphy proceeded with surgery to facilitate a spinal cord stimulator trial (via the implantation of two St. Jude Octrode leads connecting to an external implantable pulse generator, or "IPG"); the surgery was performed by Dr. Varma in Middletown, New Jersey. (*Id.* at ¶ 81) The trial went well, as the device reduced Mr. Murphy's pain, allowed him to be more functionally active and helped him to use less pain medication. (*Id.* at ¶ 82) Mr.

Murphy decided to proceed with a permanent implant of a St. Jude spinal cord stimulator device (i.e., the Proclaim™ 7 Elite Model 3662—hereinafter referred to as the "Proclaim 1"—and Octrode leads). (*Id.* at ¶¶ 10, 82-83)

The surgery took place on December 6, 2017 in Holmdel, New Jersey. (*Id.* at ¶ 83) Dr. Varma surgically implanted the IPG into a surgically-created pocket in Mr. Murphy's right buttock, and the IPG was connected to two St. Jude Model 3186 Octrode leads. (*Id.*) A St. Jude representative was present during the procedure. (*Id.*)

In the months following the surgery, Mr. Murphy experienced little to no relief from his pain, despite repeated efforts to re-program the Proclaim 1 for better pain coverage. (*Id.* at ¶¶ 84, 85) On December 14, 2018, Mr. Murphy underwent x-rays of the lumbar spine, which revealed that the tips of the leads had slipped. (*Id.* at ¶ 85) Dr. Varma recommended that a third percutaneous lead be implanted to take the place of the least effective lead. (*Id.*)

Mr. Murphy consulted with Dr. DiGiacinto for a second opinion. (*Id.* at ¶ 86) Dr. DiGiacinto recommended that the two implanted leads be replaced by a paddle-type lead, and he subsequently performed this procedure on February 22, 2019 in New York, New York. (*Id.*) The placement of the paddle lead in Mr. Murphy's thoracic spine required Dr. DiGiacinto to perform a partial laminectomy of the T9 disc space. (*Id.*) The new lead was then passed through a tunnel from the thoracic incision to the right upper buttock and connected to a replacement Proclaim Elite spinal cord stimulator device (hereinafter referred to as the "Proclaim 2"). (*Id.* at ¶¶ 10, 86) A St. Jude representative was present during this procedure and took possession of the Proclaim 1. (*Id.* at ¶ 86) Dr. DiGiacinto's operative report described the Proclaim 1 as a "[m]alfunctioned spinal cord stimulator." (*Id.* (internal quotation marks omitted))

The Proclaim 2 did not work any better than the Proclaim 1, even with repeated attempts to re-program the device. (*Id.* at ¶ 87) Beginning in or around May 2019, Mr. Murphy began to experience burning pain and electrical shocks at the site of the IPG and across his lower back. (*Id.*) These episodes also caused an increase in Mr. Murphy's right leg pain, which he described as feeling like "boiling water." (*Id.* (internal quotation marks omitted))

On August 12, 2019, Mr. Murphy saw Dr. DiGiacinto's partner Dr. Chan Roonprapunt. (*Id.* at ¶ 88) Mr. Murphy reported specific pain over the IPG site and requested that the Proclaim 2 be surgically explanted. (*Id.*) On October 4, 2019, Dr. Roonprapunt surgically removed the Proclaim 2 and the leads from Mr. Murphy's body in New York, New York. (*Id.*)

B. Procedural History

Mr. Murphy filed this action on July 24, 2020. (D.I. 2) On January 28, 2021, Mr. Murphy filed the currently operative Amended Complaint ("FAC"). (D.I. 17) In the FAC, Mr. Murphy has asserted claims under New Jersey law for strict product liability for manufacturing defect (Counts I and II) and strict product liability for failure to warn (Count III).[1] (*Id.* at ¶¶ 90-136; D.I. 31 at 1 n.2) In lieu of filing an answer, on February 18, 2021, St. Jude filed the instant Motion. (D.I. 24) The Motion was fully briefed on March 18, 2021. (D.I. 36)[2]

II. STANDARD OF REVIEW

The Court incorporates by reference the legal principles regarding motions to dismiss filed pursuant to Federal Rule of Civil Procedure 12(b)(6), and those regarding the legal doctrine of preemption, all of which were set out in its Memorandum Opinion in the related case *Mellott*

[1] Mr. Murphy's failure to warn claim in the FAC is based on a "failure to supplement product's labeling" theory; he is no longer pressing a failure to warn claim based on a "failure to report adverse events" theory. (D.I. 31 at 1)

[2] The parties have consented to the Court's jurisdiction to conduct all proceedings in the case, including trial, the entry of final judgment and all post-trial proceedings. (D.I. 13)

v. St. Jude Med., LLC, Civil Action No. 19-1779-CJB (D. Del. Nov. 16, 2020) (D.I. 45 at 7-8, 9-14).

III. DISCUSSION

The Court here writes primarily for the parties, who are well familiar with the issues in this case. In doing so, the Court assumes familiarity with the following opinions that are relevant to the Court's decision here: (1) the December 23, 2020 and October 27, 2021 Memorandum Opinions in the related case *Guinn v. St. Jude Med., LLC* (hereinafter, "*Guinn*"), Civil Action No. 20-71-CJB (D.I. 50 (hereinafter, "*Guinn I*"); D.I. 77 (hereinafter, "*Guinn II*")) (D. Del.); and (2) the November 29, 2021 Memorandum Opinion in the related case *Ross v. St. Jude Med., LLC*, Civil Action No. 20-971-CJB (D.I. 42 (hereinafter, "*Ross*")) (D. Del.). The plaintiffs' claims in *Guinn* and *Ross* also involve the Proclaim device (i.e., the same device at issue here). (*Ross* at 6)

Here, St. Jude moves to dismiss all of Mr. Murphy's claims. (D.I. 25 at 1) Most of St. Jude's arguments for dismissal here are similar or identical to arguments that the Court has already considered and rejected in *Guinn II* and in *Ross*. (*See id*. at 2 ("Plaintiff here filed an Amended Complaint with substantively the same new factual allegations as in the *Guinn* Amended Complaint, but these only serve to confirm that the Proclaim device is different from the earlier SCS devices, and that there are no allegations sufficient to state a parallel claim."); *id.* at 10 ("Plaintiff's [Proclaim-specific allegations in the FAC] here do[] not cure the [] problems" described in *Guinn I*.); *see also Ross* at 6-9) For the same reasons as discussed in *Guinn II* (which the Court will not repeat here), the FAC's allegations are sufficient to establish plausible claims that the Proclaim devices implanted in Mr. Murphy were defective and that St. Jude failed to supplement the labeling of the Proclaim to warn of such defects. (*See Guinn II* at 5-13) And

for the same reasons discussed in *Guinn II*, these plausibly-pled claims survive preemption. (*Id.* at 13 & n.8; *see also* D.I. 31 at 13-15)

St. Jude makes one unique argument for dismissal, relating to Count II, which was not at play in *Guinn* and *Ross*. (D.I. 25 at 16; D.I. 36 at 9-10) The Court will take up that argument here.

Count II is labeled in the FAC as "Strict Product Liability Based on [New Jersey's] Indeterminate Product Test[.]" (D.I. 17 at 32; D.I. 31 at 1 n.2) The FAC purports to allege a claim based on the "indeterminate product test" as set forth by the Restatement (Third) of Torts, which has been adopted in New Jersey. (D.I. 17 at ¶ 112) This test provides that:

> It may be inferred that the harm sustained by the plaintiff was caused by a product defect existing at the time of sale or distribution, without proof of a specific defect, when the incident that harmed the plaintiff:
>
> (a) was of a kind that ordinarily occurs as a result of product defect; and
>
> (b) was not, in the particular case, solely the result of causes other than product defect existing at the time of sale or distribution.

Restatement (Third) of Torts § 3 (1998); *see also Myrlak v. Port Auth. of N.Y. & N.J.*, 723 A.2d 45, 55 (N.J. 1999). In its opening brief, St. Jude argues with respect to Count II that, *inter alia*, no such standalone claim based on the indeterminate product test exists; instead, St. Jude asserts that this test "allows the factfinder to draw an *inference* that a product is defective under certain limited circumstances." (D.I. 25 at 16 (internal quotation marks and citation omitted)) The Court agrees.

As even Mr. Murphy acknowledges, "New Jersey courts have addressed the indeterminate product test as a separate *method for proving* a manufacturing defect[.]" (D.I. 31 at 15 (emphasis added)); *see also Great N. Ins. Co. v. Schwartz*, Docket No. L-5819-06, 2011

WL 2304135, at *5 (N.J. Super. Ct. App. Div. June 1, 2011) (referring to the indeterminate product test as a "mode of proof"); *Snell v. Bostrom Prods. Co.*, [D]ocket No. L-5865-00, 2005 WL 2654303, at *3 (N.J. Super. Ct. App. Div. Oct. 19, 2005) (referring to the indeterminate product test as a "method of proof"). In other words, under New Jersey law, a plaintiff can prove the existence of a manufacturing defect by: (1) relying on direct evidence; (2) relying on circumstantial evidence; (3) negating other causes of the failure of the product for which the defendant would not be responsible, in order to create an inference that the defect was attributable to the manufacturer; or (4) relying on the indeterminate product test. *See, e.g.*, *McManus v. Barnegat Operating Co., L.P.*, 828 F. App'x 846, 848-49 (3d. Cir. 2020); *Smith v. Covidien LP*, 1:19-cv-11981-NLH-AMD, 2019 WL 7374793, at *5 & n.3 (D.N.J. Dec. 31, 2019).

But as St. Jude notes, while the indeterminate product test is undisputedly one *evidentiary method of proving* a manufacturing defect claim under New Jersey law, the test does not itself amount to a legal claim. The legal claim that Mr. Murphy presses is for strict liability manufacturing defect under the PLA, and Mr. Murphy has already set out that claim in Count I. Going forward, Mr. Murphy may wish to rely on the indeterminate product test as a method of proving up his claim in Count I. But because the Court is not persuaded that Mr. Murphy's claim in Count II really is an independent, separate legal claim from that pleaded in Count I, the Court GRANTS the portion of St. Jude's Motion requesting that Count II be dismissed with prejudice.

IV. CONCLUSION

The Court GRANTS-IN-PART and DENIES-IN-PART the Motion, in that it GRANTS the Motion as to Count II and will dismiss Count II with prejudice, but it DENIES the Motion as to Counts I and III.

An appropriate Order follows.

Because this Memorandum Opinion may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Memorandum Opinion. Any such redacted version shall be submitted no later than **December 8, 2021** for review by the Court. It should be accompanied by a motion for redaction that shows that the presumption of public access to judicial records has been rebutted with respect to the proposed redacted material, by including a factually-detailed explanation as to how that material is the "kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure." *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Memorandum Opinion.