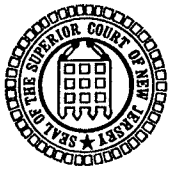
SUPERIOR COURT OF NEW JERSEY

CHAMBERS OF
VINCENT LeBLON
JUDGE



MIDDLESEX COUNTY COURT HOUSE
P.O. BOX 964
NEW BRUNSWICK, NEW JERSEY 08903 - 0964

June 18, 2012

Andrew Pepper, Esq.
Nagel, Rice
103 Eisenhower Parkway
Suite 103
Roseland, NJ 07065

Christopher Iannicelli, Esq.
Morgan, Lewis
502 Carnegie Center
Princeton, NJ 08540

David Cooner, Esq.
McCarter & English
Four Gateway Center
~~100 Mulberry Street~~
PO Box 652
Newark, NJ 07102

Adam Husik, Esq.
Hardin, Kundla
673 Morris Ave.
PO Box 730
Springfield, NJ 07081-0730

Mark A. Petraske, Esq.
Buckley & Theroux, LLC
932 State Road
Princeton, NJ 08540

RE: Reuter v. Medtronic, Inc., et al
Docket No. L-2592-10

Dear Counsel:

After hearing oral arguments and upon a review of the papers submitted to the Court by the parties, this Court finds that in accordance with the applicable statutes of New Jersey and in following the precedent of the case law provided that summary judgment is granted in favor of the Defendant. Plaintiff's Cross-Motion to Amend the Complaint is denied.

On June 1, 2007, Plaintiff, Nancy Reuter, was implanted with a pacemaker and atrial and ventricular leads at Robert Wood Johnson University Hospital. Three months later, on April 11, 2008, Plaintiff was admitted to St. Michael's Medical Center and was diagnosed with pacemaker atrial lead failures, premature pacemaker battery depletion, and sick sinus syndrome. Plaintiff's pacemaker generator was replaced; according to the operative report, the leads showed that a screw was within a lead, in a retracted position, and the tip was bent.

Plaintiffs filed this action alleging claims that involve both the failure of the cardiac devices (product liability) and medical negligence in the manner in which the cardiac devices were placed. Both the Medtronic IPG and the Ventricular Lead are Class III medical devices, which received premarket approval ("PMA") from the Food and Drug Administration ("FDA"). A PMA application was submitted on June 30, 2005, as a supplement to an earlier-filed PMA application for related Medtronic IPGs. Following thirteen (13) months of FDA review, the PMA Supplement for the Medtronic IPG was approved in July 2006. The PMA Supplement for the Ventricular Lead was approved by the FDA on June 9, 1998. The Medtronic Devices implanted in Mrs. Reuter were manufactured in accordance with FDA requirements and terms of the PMA Supplemental approvals as per Medtronic's records, kept in the normal course of business. The specific device implanted in Plaintiff was manufactured, assembled and packaged from March 19, 2007 through March 22, 2007. The Medtronic IPG was tested after it was manufactured but before it was packaged and no abnormalities were found.

In 1976, Congress enacted the Medical Device Amendments ("MDA"), and in doing so, vested the FDA with authority to regulate medical devices and establish a comprehensive system for federal oversight. In the case of Riegel v. Medtronic, the U.S. Supreme Court confirmed that Congress expressly preempted any state or common law claim challenging the design, manufacturing process, or labeling of a premarket-approved medical device, as these claims would involve the jury second-guessing the FDA's determination of the device's safety and effectiveness. 552 U.S. 312, 330 (2008).

Defendant argues that all of Plaintiffs' claims are preempted, and as such, summary judgment is appropriate. Further, that the Plaintiffs have failed to state a "parallel" claim, a narrow exception that evades preemption when state-law causes of actions parallel federal safety requirements.

Plaintiffs do not dispute the above arguments, but rather have made a Cross-Motion to Amend the Complaint to add a claim of negligence based upon the fact that a Medtronic representative was present when Plaintiff's device was tested on February 4, 2008, and was aware of the depletion of her pacemaker battery. Plaintiffs submit that the proposed amendment is not futile and discovery is ongoing.

In reply, Defendant asserts that Plaintiffs' Motion is untimely, because information that a Medtronic representative was present during interrogations as it was listed in medical records previously produced and Mrs. Reuter herself was present during these tests. Moreover, Defendant argues that this proposed amendment would be futile as it fails to state a claim. Here, there was no duty to recommend any treatment to Plaintiff's doctor; representatives were merely there for technical support. There is also no causation because Plaintiff's doctor was present at all tests and was in the position to make medical decisions. Finally, there was no damage as Plaintiffs do not allege that the IPG should have been replaced earlier than it was. Summary judgment may not be granted if "the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational fact finder to resolve the alleged disputed issue in favor of the non-moving party." Brill v. Guardian Life Ins. Co. of Amer., 142 N.J. 520, 540 (1995). However, "[b]y its plain language, Rule 4:46-2 dictates that a court should deny a summary judgment motion only where the party opposing the motion has come forward with evidence that creates a 'genuine issue as to any material fact challenged.'" Id. at 529.

Pursuant to federal case law, the MDA's preemption clause establishes a two-step procedure to determine if a state or common law claim is preempted. First, a court must determine whether "the Federal Government has established requirements applicable to" the particular medical device. Reigel, supra, 552 U.S. at 321. Claims involving a device that has received PMA satisfy the first step of the preemption test. Id. at 322. Second, the court must determine whether the state law claims raised would impose "requirements with respect to the device that are 'different from, or in addition to'" the federal requirements, and that relate to either (i) "safety or effectiveness," or (ii) "any other matter included in a requirement applicable to the device" under the MDA. Id. at 321-23.

Applying this two-step analysis to the case at bar, Plaintiff's claims are pre-empted and must be dismissed by way of summary judgment. Plaintiff has brought claims involving a devise that received PMA, and as such the first prong is automatically satisfied. Id. at 322. The second prong is also satisfied as Plaintiff's claims require a finding that the design, manufacture, and warnings should have been different from the federal requirements. Id. at 321-23. Plaintiff has also failed to plead a "parallel" claim, which is a narrow exception to this preemption rule. As such, Defendant's Motion for Summary Judgment is granted.

Turning to Plaintiff's Cross-Motion to Amend to add a negligence claim, the Court finds that the proposed amendment, while made in a timely fashion, would be futile. While a Motion to Amend the Complaint should be liberally granted, it may be properly denied where it is so meritless that a Motion to Dismiss under R. 4:6-2 would have to be granted. See Notte v. Merchants Mut. Ins. Co., 185 N.J. 490, 500-501 (2006). Here, Plaintiff has requested leave from the Court to add a negligence claim against the Defendant for failing to notify Plaintiff's doctor there was an issue with the medical device. However, the Court finds there was no duty on the part of the Defendant's representatives in such a situation. Defendant's representatives observed the device interrogation strictly as technical support. Any other role would have impermissibly injected the Defendant into the doctor-patient relationship. Furthermore, Defendant's representatives had only the ability to convey the technical information to Plaintiff's doctor, not recommend any course of treatment. Plaintiff's treating doctor has testified that he was aware of the information in the interrogation reports and there is no claim that he should have acted sooner in replacing the IPG. Accordingly, Plaintiff's Cross-Motion is denied.

Copies of the signed Orders are attached.

Vincent Le Blon J.S.C.

VINCENT Le BLON, J.S.C.

VLB/eac
ATTACHMENTS

NAGEL RICE, LLP
103 Eisenhower Parkway
Roseland, New Jersey 07068
(973) 618-0400
Attorneys for Plaintiffs

NANCY REUTER and JACK REUTER, her husband, Plaintiffs, v. MEDTRONIC, INC.; MEDTRONIC OF CANADA, LTD; GUIDANT CORPORATION; OSCOR, INC.; JASBIR S. SARKARIA, M.D.; ABC CORPORATIONS (being fictitious names); XYZ CORPORATIONS (being fictitious names); JOHN DOE (being fictitious names), Defendants.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION- MIDDLESEX COUNTY DOCKET NO.: MID-L-2592-10 **ORDER GRANTING LEAVE TO FILE AND SERVE A SECOND AMENDED COMPLAINT**

This matter having come before the Court upon application of Nagel Rice, LLP, (Barry M. Packin, Esq.) attorneys for Plaintiffs, for an Order granting leave to file and serve a Second Amended Complaint, and for good cause shown,

IT IS on this 18th June ~~May~~ **2012,**

ORDERED ~~that Plaintiffs are hereby granted leave to file and serve a Second Amended Complaint within _____ days of the date of this Order, and it is further;~~ Denied

ORDERED that Plaintiffs shall file their Second amended complaint within seven (7) days of entry and receipt of this order; and it is further Denied

ORDERED that Defendants shall file an answer to the Second amended complaint within fifteen (15) days after service of the filed Second amended complaint upon their counsel; and it is further Denied

ORDERED that a copy of this Order shall be served upon all counsel within 7 days of the date of entry of this Order.

Vincent LeBlon J.S.C.

HON. VINCENT LEBLON, J.S.C.

✓ Opposed

___ Unopposed

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MORGAN, LEWIS & BOCKIUS LLP
(A Pennsylvania Limited Liability Partnership)
502 Carnegie Center
Princeton, NJ 08540
(609) 919-6688
John P. Lavelle, Jr.
Christopher Iannicelli

Attorneys for Defendant Medtronic, Inc.

NANCY REUTER and JACK REUTER, her husband,

Plaintiffs,

v.

MEDTRONIC, INC.; MEDTRONIC OF CANADA, LTD; GUIDANT CORPORATION; OSCOR, INC.; JASBIR S. SARKARIA, M.D.; ABC CORPORATIONS (being fictitious names); XYZ CORPORATIONS (being fictitious names); JOHN DOES (being fictitious names),

Defendants.

SUPERIOR COURT OF NEW JERSEY
MIDDLESEX COUNTY
LAW DIVISION

CIVIL ACTION

DOCKET NO. MID-L-2592-10

ORDER GRANTING MOTION FOR SUMMARY JUDGMENT BY DEFENDANT MEDTRONIC, INC.

THIS MATTER having come before the Court on the motion of Defendant Medtronic, Inc. ("Medtronic"), by and through its attorneys Morgan, Lewis & Bockius LLP, and the Court having considered the moving and opposition papers, if any, and for good cause shown:

IT IS ON THIS 18th DAY OF June, 2012,

ORDERED that Medtronic's motion for summary judgment is hereby granted and the First Amended Complaint is hereby dismissed with prejudice as to Medtronic; and it is further

ORDERED that a copy of this Order shall be served on all counsel within seven (7) days of the date hereof.

Vincent LeBlon J.S.C.
Honorable Vincent LeBlon, J.S.C.

Opposed