

IN THE CIRCUIT COURT OF GREENE COUNTY, MISSOURI
CIRCUIT DIVISION

FILED

JAN 02 2014

**GREENE COUNTY
CIRCUIT COURT**

WILLIAM H. MCDONALD and)
JANICE MCDONALD,)

Plaintiffs,)

vs.)

Case No. 1231-CV02646

LESTER E. COX MEDICAL CENTERS,)

OZARK ANESTHESIA)

ASSOCIATES, INC.,)

BARON CARDIOLOGY GROUP, P.C.,)

And BOSTON SCIENTIFIC)

CORPORATION,)

Defendants.)

SUMMARY JUDGMENT

Before this court is Defendant Boston Scientific Corporation's ("BSC") Motion for Summary Judgment to dismiss all claims asserted by Plaintiffs William H. McDonald and Janice McDonald ("Plaintiffs") pursuant to Mo. R. Civ. P. 74.04(c)(1). Plaintiffs did not timely admit or deny BSC's factual statements. Having carefully considered BSC's motion and affidavit and in light of Plaintiffs' failure to timely and specifically respond to the motion, the court hereby grants BSC's Motion for Summary Judgment and, for the reasons set forth herein, all claims and other pending motions asserted by Plaintiffs against BSC are hereby dismissed with prejudice.

Judgment is hereby entered in favor of BSC and against Plaintiffs. Plaintiffs' various Motions for Default Judgment and Motion to Strike are denied, and all of Plaintiffs' claims against BSC asserted in both the original and amended petitions are hereby dismissed with prejudice. Each side shall bear its own costs.

Plaintiffs brought this case against BSC on February 21, 2012, to recover for injuries they allegedly incurred when Plaintiff William H. McDonald (“Mr. McDonald”) was implanted with a “pacemaker/defibrillator” on February 22, 2010. Plaintiffs’ last amended petition asserts several causes of action in their latest pleadings against BSC for negligence, breach of express warranty contract, and loss of consortium. In their pleadings, Plaintiffs do not specifically identify which of Mr. McDonald’s devices are at issue in this case. Instead, Plaintiffs generally link their state-law claims to the “pacemaker/defibrillator,” and also refer to “three leads” in an amended petition.

Summary judgment is appropriate where there is no genuine issue as to any material fact. Mo. R. Civ. Pro. 74.04(c). A “genuine” issue or dispute is one that is real and substantial, not one consisting “merely of conjecture, theory and possibilities.” *ITT Commercial Finance v. Mid-Am. Marine*, 854 S.W.2d 371, 378 (Mo.banc 1993); *see also Martin v. City of Washington*, 848 S.W.2d 487, 492 (Mo.banc 1993) (“[m]ere doubt and speculation do not create a genuine issue of material fact”). Summary judgment permits “resolution of claims as early as they are properly raised in order to avoid the expense and delay of meritless claims or defenses and to permit the efficient use of scarce judicial resources.” *ITT Commercial*, 854 S.W.2d at 376. A defendant is entitled to summary judgment by demonstrating: (1) facts that negate one of the elements necessary for judgment in Plaintiff’s favor; (2) that Plaintiff cannot establish one of the elements necessary for her claims; or (3) facts supporting all the elements of one of Defendant’s affirmative defenses. *Id.* at 381; *Webb v. Reisel*, 858 S.W.2d 767, 768 (Mo.App. E.D. 1993). The facts set forth by affidavit or otherwise in support of the party’s motion are taken as true unless they are contradicted by the non-moving party’s response to the summary judgment motion. *Butler v. The Burlington Northern*, 119 S.W.3d 620, 621

(Mo.App. W.D. 2003). “A denial may not rest upon the mere allegations . . . of the party’s pleading. Rather, the response shall support each denial with specific references to the discovery, exhibits or affidavits that demonstrate specific facts showing there is a genuine issue for trial.” Mo. S. Ct. R. 74.04(c)(2).

“If a party bearing the burden of proof is unable to make a showing that facts exist to support submission of the issue to the jury, full or partial summary judgment is appropriate.” *Martin*, 848 S.W.2d at 492. “A summary judgment movant who is a ‘defending party’ need not controvert each element of the non-movant’s claim in order to establish a right to summary judgment.” *Held & Assoc., Inc. v. Wolff*, 39 S.W.3d 59, 62 (Mo.App. E.D. 2001). Rather, a “defending party” becomes entitled to summary judgment by showing “facts that negate *any one* of the claimant’s elements facts.” *Id.* at 62.

Although Plaintiffs in this case are proceeding *pro se*, Plaintiff William McDonald is an inactive attorney. Missouri courts have consistently held that litigants “acting *pro se* are bound by the same rules and procedures as lawyers, and they are entitled to no indulgence they would not have received if represented by counsel.” *Auto. Leasing Corp. v. Westerhold*, 945 S.W.2d 600, 602 (Mo.App. E.D. 1997) (quoting *Lamastus v. Lamastus*, 886 S.W.2d 721, 726 (Mo.App. E.D. 1994). “While this court recognizes the problems faced by pro se litigants, we cannot relax our standards for non lawyers. It is not for lack of sympathy but rather it is necessitated by the requirement of judicial impartiality, judicial economy and fairness to all parties.” *Sutton v. Goldenberg*, 862 S.W.2d 515, 517 (Mo.App. E.D. 1993); *see also In re Estate of Miller*, 9 S.W.3d 760, 767 (Mo.App. S.D. 2000), and *Crowe v. Clairday*, 935 S.W.2d 343, 347 (Mo.App. S.D. 1996).

In support of its Motion for Summary Judgment, BSC filed a Statement of Uncontroverted Facts ("SOF") citing 18 facts and attaching supporting documentation.

Supreme Court Rule 74.04(c)(2) provides:

Within 30 days after a motion for summary judgment is served, the adverse party shall serve a response on all parties. The response shall set forth each statement of fact in its original paragraph number and immediately thereunder admit or deny each of movant's factual statements. . . . A response that does not comply with this Rule 74.04(c)(2) with respect to any numbered paragraph in movant's statement **is an admission of the truth of that numbered paragraph.** (Emphasis added.)

Because Plaintiffs have not filed a response to BSC's Motion for Summary Judgment, the below facts are deemed admitted by Plaintiffs.

1. The products that are or may be at issue in this proceeding are:
 - (a) INSIGNIA Ultra I Implantable Pacemaker System, Model 1291 ("INSIGNIA 1291");
 - (b) COGNIS Cardiac Resynchronization Therapy Defibrillator ("CRT-D"), Model N118 ("COGNIS N118");
 - (c) RELIANCE SG lead, Model 0180 ("RELIANCE 0180");
 - (d) EASYTRACK 2 lead, Model 4518 ("EASYTRACK 4518"); and
 - (e) FINELINE II lead, Model 4469 ("FINELINE 4469").

Affidavit from Richard M. Dujmovic, Vice President of Regulatory Affairs at BSC.

2. The Class III medical devices in Paragraph 6 of this Affidavit are prescription medical devices which are restricted to sale, distribution and use only by or on the order of a physician.

3. The FDA approved the devices implanted in Mr. McDonald as Class III devices through the supplemental Pre-Market Approval (PMA) process or the Product Development Protocol ("PDP") process.

4. Supplemental PMA or PDP applications are subject to the same rigorous standards of review as initial PMA or PDP applications.
5. The original and supplemental PMA and PDP approvals remain in effect and have never been withdrawn.
6. Mr. McDonald's devices that are or may be at issue were manufactured, packaged and labeled in compliance with all FDA-approved specifications and processes.
7. The devices at issue were each packaged with a limited warranty that specifically disclaimed any express or implied warranties other than those contained on the package inserts.
8. BSC is not a licensed health care provider, and thus never makes any "personal service contracts" regarding the surgical or medical aspects of implantation procedures.
9. A BSC representative's role during an implantation procedure is to provide purely technical support and assist the physicians in determining whether the ICD is correctly calibrated – as ordered by the physician – and whether the lead is sensing and pacing the heart's rhythms appropriately.
10. BSC and its representatives, including Mr. Holaday, are not licensed as physicians, and, accordingly, never prescribe for, implant in, or remove from a patient any heart device or leads, nor are they qualified to perform such procedures or to oversee, supervise, or direct a physician in performing such procedures.
11. Licensed physicians, as highly-skilled professionals, are responsible for determining whether, in their best medical judgment, a particular patient would benefit from device therapy.

12. During implant procedures such as Mr. McDonald's February 2010 surgery, sales representatives do not act as physicians or nurses, but rather remotely assist the implanting surgeon and other physicians present in determining whether the devices are operating as the physicians desire.

13. BSC representatives do not scrub in for implant procedures, and thus they remain outside the sterile field for the entirety of the procedure, which is several feet away from the implant site on the patient's body.

14. All technical assistance provided to physicians by BSC representatives is done so at the direction and supervision of the physicians present in the operating room.

15. Because both BSC and its sales representatives are not licensed health care providers, they do not make warranties concerning surgical or medical aspects of implantation procedures of devices, including, but not limited to, a patient's medical need for device therapy or implant procedures, or medical details concerning the implantation procedure, including risks and dangers, nor do they make statements about the qualifications of health care providers or a patient's medical condition necessitating surgery.

16. Mr. Holaday denies ever making the eleven statements concerning surgical or medical aspects of Mr. McDonald's February 22, 2010 implantation procedure.

17. Further, in his twenty-eight years of experience in selling medical devices, Mr. Holaday has never made such statements about the medical or surgical aspects of an implantation procedure, a patient's medical condition, or the health care providers performing the procedure, nor is he aware of any other sales representatives making such statements.

18. Mr. Holaday denies ever making the three statements Plaintiffs allege concerning the devices at issue, nor in his twenty-eight (28) years of experience as a sales representative has he ever made any such statements.

Under *Riegel v. Medtronic, Inc.*, 552 U.S.312 (2008) and 21 USC §360(k)(a), federal law preempts each of Plaintiffs' claims. See Defendant's suggestions and proposed judgment for a well-written discussion of federal preemption as it applies to the facts of this case. Under the facts as admitted in this summary judgment proceeding, Plaintiffs cannot establish the necessary elements for each of their claims.

Because Plaintiffs' loss of consortium claim is derivative, it fails for all the same reasons as Plaintiffs' other claims set forth in this Judgment. See *Bosch v. St. Louis Healthcare Network*, 41 S.W.3d 462, 465 (Mo. 2001) (en banc) ("Loss of consortium is a derivative claim that arises out of the original injury to the spouse."); *Hooe v. Saint Francis Med. Ctr.*, 284 S.W.3d 783 n.1 (Mo.App. S.D. 2009) (noting that plaintiff's spouse's loss of consortium claim is "derivative and depends on the validity of the primary claim") (citing *Kamerick v. Dorman*, 907 S.W.2d 264, 267 (Mo.App. W.D. 1995)).

These matters having been brought before the court by way of Defendant Boston Scientific Corporation's Motion for Summary Judgment, which was unopposed by Plaintiffs, and Plaintiffs' various combined motions for default, motions to strike, and other requested relief; and the court having considered the papers submitted; and for good cause shown:

IT IS ORDERED that Plaintiffs' various combined motions for default, motions to strike, and other requested relief are denied; and,

As no genuine issues remain for trial, summary judgment is hereby entered in favor of Defendant Boston Scientific Corporation, and all Plaintiffs' claims are hereby dismissed with prejudice with each side to bear their own costs.

So ordered this 26th day of December 2013:

A handwritten signature in black ink, consisting of several overlapping loops and a horizontal line, positioned above the printed name.

DAVID P. EVANS
Presiding Judge, 37th Judicial Circuit