



COMMONWEALTH OF KENTUCKY

JEFFERSON CIRCUIT COURT

NO. 07CI12014

DIVISION SEVEN

JUDGE AUDRA J. ECKERLE

THOMAS E. MATTINGLY, JR.

PLAINTIFF

vs.

OPINION AND ORDER

JOHN G. HUBBARD, M.D.

and

THE HUBBARD CLINIC AND
CENTER FOR BLADDER CONTROL, P.L.L.C.

and

GREATER LOUISVILLE ANESTHESIA SERVICES, P.L.L.C.

and

UROLOGIX, INC.

and

UNKNOWN DEFENDANT

DEFENDANTS

This action stands submitted on the motion of Defendant, Urologix, Inc. (hereinafter, "Urologix") for summary judgment. Having thoroughly reviewed and carefully considered the pleadings, the arguments of the parties and the applicable law, the Court will grant Urologix's motion.

OPINION

On December 4, 2006, Plaintiff, Thomas E. Mattingly, Jr. (hereinafter, "Plaintiff"), underwent a transurethral microwave therapy procedure performed by Defendant, John G. Hubbard, M.D. (hereinafter, "Dr. Hubbard"). In performing the procedure, Dr. Hubbard used

the Targis System, a Class III medical device that had received premarket approval from the Food and Drug Administration (hereinafter, "the FDA"). The Targis System was manufactured by Urologix. Following the procedure, Plaintiff developed a fistula. On December 3, 2007, he filed a Complaint in this Court. Specifically, with regard to Urologix, Plaintiff seeks recovery for his alleged injuries under theories of strict liability (Count I), breach of implied warranty (Count III), negligence (Count VII) and gross negligence (Count VIII).

Urologix now seeks summary judgment arguing that because all of the Targis System components used by Dr. Hubbard had received FDA approval, Plaintiff's claims are preempted by federal statute and must be dismissed. See Riegel v. Medtronic, Inc., 128 S.Ct. 999 (2008). According to Urologix, Plaintiff does not have any factual knowledge to support his claims.

Plaintiff stipulates as to the premarket approval of the Targis System, but opposes Urologix's motion arguing that under Riegel, Plaintiff's claims would not be subject to preemption if he could establish that Urologix changed the device without permission of the FDA or failed to maintain post-approval requirements. Plaintiff further argues that his negligence claims are unaffected by Riegel since they relate to Urologix's training of physicians rather than its FDA approval for or manufacturing of the Targis System.

As set forth in Civil Rule 56, summary judgment is granted when there is "no genuine issue as to any material fact" and "the moving party is entitled to a judgment as a matter of law." In determining whether to grant a motion for summary judgment, this Court is to view the record "in a light most favorable to the party opposing the motion ... and all doubts are to be resolved in his favor." Steelvest, Inc. v. Scansteel Service Center, Inc., 807 S.W.2d 476, 480 (Ky., 1991). "A party opposing a properly supported summary judgment motion cannot defeat

it without presenting at least some affirmative evidence showing that there is a genuine issue of material fact for trial." Id. at 482.

The Riegel case holds that the common law tort claims of the 50 states shall not be applied to medical devices because such damage claims are expressly preempted by federal law. That Court detailed the "rigorous" process that is undertaken to scrutinize medical devices, especially those that fall within Class III, such as the device at issue here. Riegel, supra, 128 S.Ct. at 1003. Class III devices receive "the most federal oversight." Id. Accordingly, the Court refused to allow state law "claims of strict liability, breach of implied warranty and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale" to proceed. Id. at 1005-1006. It also prohibited the "derivative" state law claim of loss of consortium. Id. at 1006. Because the state law claims attempted to impose different or additional conditions than the federal requirements relating to the safety and effectiveness of the device, they were pre-empted.

Here, because Urologix's Targis System was a Class III medical device that had received premarket approval from the FDA, the federal law proscribes state law tort claims of product liability and any derivative claims of negligence from proceeding. While Plaintiff argues that "[i]t is premature to extinguish Plaintiff's strict liability claims as a matter of law because there has been no evidence presented to Plaintiff that the device was not changed," he admits that he is "unaware as to whether Urologix has made any changes to said device . . ." (See Plaintiff's Response to Defendant's Motion for Summary Judgment at pp. 2-3.) In a products liability action, the burden is on the Plaintiff, not a Defendant, to prove any such defect claimed. See Leslie v. Cincinnati Sub-Zero Products, Inc., 961 S.W.2d 799, 803 (Ky. App., 1998). Further, while Plaintiff argues that his claims of negligent failure to train

physicians properly is separate from the FDA approval process, the Court finds that such a claim would nonetheless impose an additional substantive requirement for a specific device. "General tort duties of care . . . 'directly regulate' the device itself" *Id.* at 1010. Thus, such requirements are preempted. *Id.* at 1011. Therefore, given that Plaintiff has not presented any affirmative evidence demonstrating a genuine issue of material fact for trial, summary judgment will be granted as a matter of law with regard to Plaintiff's allegations of strict liability, breach of implied warranty, negligence and gross negligence against Urologix.

ORDER

Wherefore, IT IS HEREBY ORDERED that the motion of Defendant, Urologix, Inc., for summary judgment is granted with regard to the claims of Plaintiff, Thomas E. Mattingly, Jr., for strict liability (Count I), breach of implied warranty (Count III), negligence (Count VII) and gross negligence (Count VIII). Those portions of Plaintiff's Complaint are hereby dismissed with prejudice. There being no just cause for delay, this is a final and appealable Order as to Defendant, Urologix, Inc.

ENTERED IN COURT
DAVID L. NICHOLSON, CLERK
AUG 30, 2008
BY *[Signature]*
DEPUTY CLERK

[Signature]
AUDRA J. ECKERLE, JUDGE
Jefferson Circuit Court

cc: Mr. Ethan T. Manning
Mr. Chris Meinhart
Meinhart & Smith, P.L.L.C.
Co-Counsel for Plaintiff
462 South Fourth Street, Suite 1750
Louisville, KY 40202

Mr. Brett Oppenheimer
Co-Counsel for Plaintiff
950 Breckenridge Lane, Suite 40
Louisville, KY 40207

Mr. W. Kennedy Simpson
Thompson, Miller & Simpson, P.L.C.
Counsel for Defendant, Urologix, Inc.
600 West Main Street, Suite 500
Louisville, KY 40202

Mr. Donald W. Darby
Mr. Robert J. Shilts
Darby & Gazak, P.S.C.
Counsel for Defendant, Greater Louisville Anesthesia Services, P.L.L.C.
3220 Office Pointe Place, Suite 200
Louisville, KY 40220

Mr. Craig L. Johnson
Whonsetler & Johnson, P.L.L.C.
Counsel for Defendants, John G. Hubbard, M.D. and The Hubbard Clinic
and Center for Bladder Control, P.L.L.C.
6011 Brownsboro Park Boulevard, Suite E
Louisville, KY 40207