IP 01-0752-C Y/K Theofanis v Boston Scientific [2]
Judge Richard L. Young Signed on 3/16/05

NOT INTENDED FOR PUBLICATION IN PRINT

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

THEOFANIS, KATHERINE PERSONAL RESPRESENTATIVE OF THE ESTATE OF CHRIS C THEOFANIS DECEASED,	)	
Plaintiff,	)	
vs.	)	
BOSTON SCIENTIFIC CORPORATION, BOSTON SCIENTIFIC SCIMED INC,	)	CAUSE NO. IP01-0752-C-Y/K
Defendants.	)	

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

KATHERINE THEOFANIS, Personal Representative of the Estate of CHRIS C. THEOFANIS, Plaintiff,	)	
vs.	)	IP-01-752-C-Y/K
BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., Defendants.	)	

ENTRY ON DEFENDANTS' SECOND MOTION FOR SUMMARY JUDGMENT

On July 1, 1999, Dr. Edward T. Fry ("Dr. Fry") performed a rotational atherectomy and balloon angioplasty on Chris Theofanis' ("Mr. Theofanis") left coronary artery. During the procedure, Dr. Fry used the Rotablator System sold and marketed by Defendants, Boston Scientific Corporation ("Boston Scientific") and Boston Scientific Scimed, Inc. (collectively "Defendants"), in an effort to remove arterial plaque blocking normal blood flow. A perforation of a coronary artery occurred toward the end of the procedure. After the procedure, Dr. Fry discovered a break in the .009" diameter stainless steel wire used to guide the Rotablator's diamond-coated burr. The procedure was stopped, and Mr. Theofanis later died.

Katherine Theofanis, as personal representative of the estate of Mr. Theophanis ("Plaintiff"), brought suit against the Defendants under theories of strict product liability (i.e., the product was defective and unreasonably dangerous when placed into the stream of commerce) and negligence (i.e., Defendants failed to exercise reasonable and ordinary care in the manufacture and design of their product). On July 1, 2002, Defendants filed a motion for

summary judgment on grounds that Plaintiff's claims were preempted by the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 301 *et seq*. In the court's Entry on Defendants' Motion for Summary Judgment, dated June 24, 2003, the court granted Defendants' motion with respect to the Plaintiff's strict liability claim and denied Defendants' motion with respect to Plaintiff's negligence claim.

Plaintiff's one remaining claim is that Defendants allegedly failed to comply with the reporting requirements imposed by the FDA as part of the agency's PMA process for Defendants' Rotablator System. Defendants contend that because the reporting requirements are administrative – and not substantive – Plaintiff cannot form the basis for a negligence claim. In support of their position, Defendants cite the court to *Talley v. Danek Medical, Inc.*, 179 F.3d 154 (4th Cir. 1999).

In *Talley*, the plaintiff alleged that Danek, the manufacturer of an internal fixation device called the Dyna-Lok Device, negligently failed to comply with the FDA regulations by not obtaining FDA approval. *Id*. at 160. At the time relevant to the *Talley* case, internal fixation devices intended for use in the pedicles of the spine were considered Class III medical devices and, pursuant to the MDA, required Food and Drug Administration ("FDA") approval. However, internal fixation devices could lawfully be sold without FDA approval for use in other parts of the body. Plaintiff contended that Danek marketed and sold the Dyna-Lok Device for use in the spine even though it did not have FDA approval for that use as required by the MDA. *Id*.

The *Talley* court held that the requirements for FDA approval is purely an administrative requirement, rather than a legislative judgment of the standard of care, and that the alleged violation of the approval cannot support a claim for negligence per se. *Id*. at 161. The Fourth

Circuit reasoned that a statute or regulation can at times provide the standard of care for a negligence action, as is typically the case in a negligence per se action. *Id*. at 158. However, "not all statutory provisions dictate a standard of care, and therefore not all statutory violations provide a basis for establishing negligence per se." *Id*. at 159.

The court distinguished between statutory provisions that impose a standard of care and those that do not. Statutory provisions that impose an administrative requirement, such as the requirement to obtain regulatory approval or to file a report to support a regulatory scheme, do not establish a standard of care. *See id.* This is true even if the regulatory scheme as a whole is designed to protect or promote public safety. *Id*.

If this case were in the Fourth Circuit, the court would agree that the *Talley* court's reasoning would most likely control the disposition of this case. The premarket approval process is an administrative requirement, and does not, in and of itself, impose a standard of care. However, the court respectfully declines to follow the reasoning in that Fourth Circuit case for several reasons. First, the Seventh Circuit has not had the occasion to address this issue presented in Defendants' second summary judgment motion. Thus, the court's initial decision denying summary judgment based upon Seventh Circuit case law – *Mitchell v. Collagen Corp*., 126 F.3d 901, 914 (7th Cir. 1997) and *Chambers v. Osteonics Corp*., 109 F.3d 1243, 1248-50 (7th Cir. 1997) – is still based upon good law. Second, to rule in favor of the Defendants would be an injustice to the Plaintiff. Defendants materially altered the brake system design after receiving the FDA's premarket approval, and did not inform[1] the FDA of this design change as

[1] In August of 1999, one month after Mr. Theofanis died, Defendants pulled the product from the market and reinstituted the one-piece collet brake design. Thus, the product with the two-piece collet design was never before the FDA.

required by 21 C.F.R. § 814.39(6).[2] Thus, Defendants completely bypassed the FDA process and put into the stream of commerce a Class III medical device materially different from the one which the FDA had previously rendered safe and effective for use in heart patients. Finally, the court does not believe that by allowing this case to go to a jury, it is substituting its judgment for that of the FDA, or in any way frustrating the FDA's regulatory process. This case is not a case in which the Plaintiff is bringing a common law claim which works to frustrate or second-guess the judgment of the FDA. Rather, this is a case in which the FDA was never notified of the design change and thus, never given the opportunity to adjudge the product's safety or effectiveness.

There are two final arguments raised by the Defendants. First, they contend the that even if the FDA regulations and conditions of approval permit a negligence claim, there is no evidence that the changes affected the "safety and effectiveness of the device" for purposes of violating the regulations. As pointed out by Plaintiff, Defendants' Regulatory Affairs Vice President, Michael Kallok, admitted that the failure of the brake to adequately secure the guide wire affects the safety and effectiveness of the device. Deposition of Michael Kallok at 56-57. That evidence, in combination with the other evidence produced by Plaintiff in the first summary

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[2] That section reads, in relevant part:

> After the FDA's approval of a PMA, an applicant shall submit a PMA supplement for review and approval by the FDA before making a change affecting the safety and effectiveness of the device for which the applicant has an approved PMA. . . [C]hanges for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety and effectiveness of the device: . . . (6) Changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device.

judgment submission, is sufficient to establish that the changes to the brake design did affect the safety and effectiveness of the device.

Second, Defendants contend there is no evidence that the failure to comply with the premarket approval process caused Mr. Theofanis' death. 21 C.F.R. § 814.80 reads:

> A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device.

By manufacturing and distributing the product without the prior approval necessary from the FDA, Defendants breached this federal regulation. Accordingly, Plaintiff is not required to prove that the FDA would not have approved the brake design; it is sufficient for Plaintiff to demonstrate that the unapproved and illegally distributed component of the device failed and caused Mr. Theofanis' death. Further, Plaintiff has designated evidence from biomedical engineer, Dr. Barkalow, as well as Mr. Theofanis' physician, Dr. Fry. Dr. Barkalow testifies that the defective break design caused the wire to loop or kink and fracture. Dr. Fry testified that the complications caused by the wire fracture led to Mr. Theofanis' death. The court therefore finds that Plaintiff has come forward with evidence to show that the Defendants' defective product caused Mr. Theofanis' death. Defendants' (Second) Motion for Summary Judgment must therefore be **DENIED**.

SO ORDERED this 16th day of March 2005.

RICHARD L. YOUNG, JUDGE
United States District Court
Southern District of Indiana

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