SUPERIOR COURT OF CALIFORNIA

COUNTY OF SANTA CLARA

THOMAS S. ROBINSON,

Plaintiffs,

vs.

ENDOVASCULAR TECHNOLOGIES, INC.; GUIDANT CORPORATION; ADVANCED CARDIOVASCULAR SYSTEMS, INC.; and ORIGIN MEDSYSTEMS, INC.,

Defendants.

Case No.: 1-03-CV-009655

ORDER AFTER HEARING REGARDING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT, OR ALTERNATIVELY, FOR SUMMARY ADJUDICATION

Hearing Date: November 14, 2008
Time: 9:00 a.m.
Department: 17C/Complex Civil

Judge: Hon. Jack Komar

This is a products liability and personal injury action. Plaintiff Thomas S. Robinson alleges he suffered injuries after a defective medical device, the Ancure Endograft System ("ANCURE System"), was implanted in him. The device is used for abdominal aortic aneurysm repair. Defendant is alleged to have designed, manufactured, advertised, and sold the product.

Robinson's Complaint, filed on November 21, 2003, sets forth the following causes of action: [1] Strict Product Liability (Failure to Warn); [2] Strict Product Liability (Pursuant to

Restatement Second of Torts §402A (1965)); [3] Negligence; [4] Breach of Express Warranty; [5] Breach of Implied Warranty; [6] Fraudulent Concealment; and [7] Punitive Damages.

Defendants now move for summary judgment or, in the alternative, summary adjudication based on federal preemption.

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Defendants contend that the United States Food and Drug Administration's ("FDA") Investigational Device Exemption ("IDE") process imposes "requirements" that preempt additional or different state requirements. The PMA process is used for Class III devices, which receive the most federal oversight. The ANCURE System is a Class III device.

Under the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act ("MDA") [21 USCS §§ 301 *et seq*.],

> no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act
>
> (21 USCS §360k.)

The PMA process imposes "requirements" under the MDA which the manufacturer must follow precisely. State claims underlying negligence, strict-liability, and implied-warranty causes of action have been held to also constitute "requirements" and are therefore preempted under the MDA. (*Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008).)

Generally, Plaintiff Robinson alleges in his complaint under state law that the Ancure device was defective, that defendants failed to perform adequate testing, failed to provide adequate warning to users of the ANCURE System, falsely represented material facts to the FDA to induce approval of the IDE, and caused the FDA to violate its own regulations regarding the form of waiver.

The uncontradicted evidence is that the FDA approved the testing, and specified the warning requirements used by defendant. To the extent plaintiff contends defendants needed to perform further or different testing and provide additional or different warnings those would be "additional requirements" that are preempted by the MDA because of the FDA's earlier approval through the IDE process.

Plaintiff argues that the FDA approval of an IDE device does not determine that the device is safe and effective and therefore it should not be subject to the preemption provisions of the MDA. Plaintiff is partially correct. By its very nature, an investigational approval recognizes that the device may be neither safe nor effective, but the public interest may be served by using the device consensually to determine whether the benefits be achieved through its use outweigh safety or effectiveness issues. A purpose of the IDE process is to encourage experimentation. IDE approvals are within the express purview of the MDA, are a step on the way to potential Pre Marketing Approval, and the court is unable to differentiate the application of the preemption provisions of the MDA. The preemption provisions apply to IDE approvals.

Robinson argues that if the FDA has acted upon the fraudulent conduct of a defendant in approving an IDE, a plaintiff's state law claims should not be preempted, citing the concurring opinion of Justice Stevens in *Buckman Co. v. Plaintiffs' Legal Committee* (2001) 531 U.S. 341. *Buckman* involved injuries resulting from the use of orthopedic bone screws.

(*Buckman Co. v. Plaintiffs' Legal Committee, supra,* 531 U.S. at p. 343.) The majority opinion in Buckman held that:

> [T]he plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law. The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency, and that this authority is used by the Agency to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Agency can be skewed by allowing fraud-on-the-FDA claims under state tort law.
>
> (*Id*. at p. 348.)

Justice Stevens's concurrence in *Buckman* opined that ". . . [t]his would be a different case if, prior to the instant litigation, the FDA had determined that petitioner had committed fraud during the § 510(k) process and had then taken the necessary steps to remove the harm-causing product from the market. Under those circumstances, respondent's state-law fraud claim would not depend upon speculation as to the FDA's behavior in a counterfactual situation but would be grounded in the agency's explicit actions. In such a case, a plaintiff would be able to establish causation without second-guessing the FDA's decision making or overburdening its personnel, thereby alleviating the Government's central concerns regarding fraud-on-the-agency claims." (*Buckman Co. v. Plaintiffs' Legal Committee, supra,* 531 U.S. at p. 354.)

While plaintiff argues that he should be permitted to proceed on claims that are premised on fraud on the FDA, citing the Stevens concurrence in *Buckman* (*supra*), Robinson fails to plead or prove sufficient facts to bring the matter within the parameters of Justice Stevens concurring opinion or to plead or present evidence that the FDA withdrew its approval and ordered the device off the market. To the contrary, Defendants present evidence that the FDA never removed the ANCURE System from the market, but rather on August 17, 2001, it

re-approved the system with full knowledge of the history of the device. Plaintiff provides no evidence showing otherwise. Thus, even if Justice Stevens's concurring opinion is good law, there is no basis for its application here.

This is essentially a defective device and failure to warn case. Therefore, ROBINSON'S Complaint is preempted by the MDA because the ANCURE System as an Investigational Device, including its form of patient consent, was approved as exempt, and then reapproved by the FDA after going through the PMA process.

OBJECTIONS

The court sustains Defendant's objection to paragraph 3 of the Russell Declaration on the grounds that it is hearsay and not within the personal knowledge of the declarant. The court notes that it is in any event not probative of the issues the court must decide on this motion.

MOTIONS TO SEAL

The court grants the defendant's motion to seal Exhibits A, D, F, and H on the grounds that the exhibits contain proprietary and confidential trade secrets and the right of privacy outweighs the public's right to the documents, subject to further court order.

ORDER

Defendants' objection to paragraph 3 of the Russell Declaration is sustained.

Defendants' motion for summary judgment is GRANTED.

Exhibits A, D, F and H, lodged in support of Defendants' motion for summary judgment, are ordered sealed subject to further order of court.

SO ORDERED.

Dated: December 17, 2008

Judge of the Superior Court
JACK KOMAR

1-03-CV-009655: Robinson v. Endovascular Technologies, Inc.

Case document information:

View document:	Order - for Court's Use Only *(Click here to view document)*
Title:	Order After Hearing Regarding Defendants' Motion for Summary Judgment, or alternatively, for Summary Adjudication, signed by Judge Jack Komar
Author:	Komar, Jack
Filing date:	12/17/08
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Attached exhibits:

1. Proof of Electronic Serv
2. Electronic service mess