

Mulhall v Hannafin

2006 NY Slip Op 30209(U)

April 26, 2006

Supreme Court, New York County

Docket Number: 0101900/2002

Judge: Stanley L. Sklar

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SUPREME COURT OF THE STATE OF NEW YORK — NEW YORK COUNTY

PRESENT: Stanley J. Sklar
Justice

PART 29

Mulhall et al

INDEX NO. 101900/02

- v -
Hannafin et al

MOTION DATE _____

MOTION SEQ. NO. 004

MOTION CAL. NO. _____

The following papers, numbered 1 to _____ were read on this motion to/for _____

Notice of Motion/ Order to Show Cause — Affidavits — Exhibits ...

Answering Affidavits — Exhibits _____

Replying Affidavits _____

PAPERS NUMBERED

Cross-Motion: Yes No

Upon the foregoing papers, it is ordered that this motion

**MOTION DECIDED IN ACCORDANCE WITH
THE ATTACHED MEMORANDUM DECISION.**

MOTION/CASE IS RESPECTFULLY REFERRED TO
JUSTICE

Dated: 4/26/06

[Signature]
J.S.C.

Check one: FINAL DISPOSITION

NON-FINAL DISPOSITION

SUPREME COURT OF THE STATE OF NEW YORK
 COUNTY OF NEW YORK: PART 29

-----X
 VICTORIA MULHALL and TIMOTHY MULHALL,

Plaintiffs,

Index No.: 101900/02

-against-

JO A. HANNAFIN, M.D., THE HOSPITAL FOR
 SPECIAL SURGERY, ACUFEX MICROSURGICAL,
 INC., SMITH & NEPHEW, INC. SMITH & NEPHEW,
 PLC, DIANE RYAN, M.S., P.T. and BRIDGEVIEW
 PHYSICAL THERAPY, P.C.,

Defendants.

-----X
Sklar, J.:

In this action in which it is claimed that a surgical device, Suretac, an absorbable fixator which was placed in plaintiff Victoria Mulhall's shoulder during a February 1999 surgery, caused, inter alia, inflammatory conditions known as synovitis and capsulitis and reflex sympathetic dystrophy ("RSD"), the defendant manufacturer Smith & Nephew* ("Smith") moves to dismiss the complaint which purports to assert four causes of action against it sounding in negligence (third cause of action), breaches of express and implied warranties (fourth and fifth causes of action), strict liability (sixth cause of action) and Mulhall's husband's loss of her services (seventh cause of action). Counsel asserts that the Suretac performed properly and that Smith issued appropriate warnings regarding possible adverse reactions "including the exact type of inflammatory response claimed by plaintiffs". See Kerner aff, ¶ 6 Smith's counsel in his

* It is undisputed that named defendants Smith & Nephew, Plc and Acufex Microsurgical, Inc., which was allegedly purchased by movant, are not proper parties to this action. See Kerner aff., Fns. 1, 4

moving affirmation maintains that plaintiffs have failed to offer evidence of a design or manufacturing defect, that the warnings were deficient, or that the product did not function as intended. Id ¶ 9 Smith's counsel's reply affidavit alleges that the Suretac's labeling warned of all "known side effects". Rosenberg reply aff ¶ 6 Thus it claims that under the informed intermediary doctrine it discharged its duty to plaintiff. Smith's counsel further urges that causation is lacking because notwithstanding any potential risks posed by the Suretac, Mulhall was determined to undergo surgical repair of her shoulder, as allegedly established by her deposition testimony.

The motion is not supported by the affidavit of an expert, much less one who is familiar with Suretac or its risks, or by the affidavit of anyone from the company. The motion is supported by a copy of the package insert which recites under the heading "ADVERSE REACTIONS":

As with and bioabsorbable implant, there is a chance of an inflammatory response **during the degradation period** of the device. A **transient** inflammatory reaction has been observed in some patients, during the second or third post-operative month. This reaction, which maybe associated with polymer breakdown, appears to be self-limiting or responds to non-steroidal anti-inflammatory medications in conjunction with physiotherapy. Additional complications are those seen with any method of internal fixation (Emphasis added).

In support of the motion Smith, which did not provide an affidavit from Dr. Hannafin in support of the motion, provided excerpts of her deposition transcript. At her deposition Dr. Hannafin testified, in response to whether the Suretac's package insert contained any adverse reactions, that the insert described "a reaction to the Suretac as it dissolves with the

recommendation that it be treated with non-steroidal anti-inflammatories with good resolution”. EBT, p 71 Dr. Hannafin did not warn Mulhall of the possibility of “transitory inflammation” since she warned her of stiffness which can come from a number of causes, including causes unrelated to Suretac. EBT, pp 71-72 Dr. Hanaffin further testified that her routine practice with respect to “shoulder arthroscopy of any type” was to advise patients of the risks of infection, bleeding, injury to the nerves and stiffness. Id p 38

Dr. Hannafin further testified that there were other companies which made bioabsorbable fixation devices of different materials but that she used Suretac since it had been used safely at her institution since 1991 or 1992 and that “we had published two series in the literature that documented it working well without side effects”. Id 70 It is unclear when those series were published or to whom “we” referred.

Following the surgery performed by Dr. Hanaffin, plaintiff was apparently “doing quite well” until about 3 months postoperatively when she began experiencing a loss of range of motion in her shoulder. See motion, exh N An MRI revealed that there was acute localized reactive synovitis in the area of the Suretac. Motion, exh O Dr. Hannafin performed another procedure on plaintiff on July 28, 1999 for a frozen shoulder and “Suretac Synovitis”. Motion, exh P According to plaintiff Dr. Hannafin told her that the fragmentation of the Suretac caused her to have a frozen shoulder. Mulhall EBT, p 585

Plaintiff, who claimed that the way Dr. Hannafin had explained the surgery to her caused her to believe that there were no risks (Id, p 253), commenced this action against Dr. Hannafin (asserting claims sounding in medical malpractice and lack of informed consent), Smith and others.

Smith did not serve a demand for a bill of particulars, but did serve interrogatories, the responses to which allege that the fragmented Suretac precipitated a mechanical irritation, foreign body reaction, reactive synovitis and possible adverse allergic reaction. Motion, exh Q As a result plaintiff allegedly suffers from a list of injuries including RSD, also known as Complex Regional Pain Syndrome, numbness and tingling and a swollen and discolored arm and hand. Id ¶ 6

Smith now seeks summary judgment dismissing the complaint as to it. At oral argument plaintiffs' counsel conceded that he had no valid cause of action or claim for design defect, manufacturing defect, breach of warranty and punitive damages, and urged that his claims against Smith were based on inadequate warnings which rendered the Suretac defective. Accordingly the fourth and fifth causes of action sounding in breach of express and implied warranty are dismissed as is the demand for punitive damages and any claim set forth in the third (negligence) and sixth (strict liability) causes of action which are premised on a manufacturing or design defect.

The balance of the motion is denied. As the movant Smith in the first instance has the burden of prima facie eliminating all material issues raised by the pleadings. The failure to do so mandates the denial of the motion irrespective of the adequacy of the opposing papers. Smith has wholly failed in its initial moving papers to establish that its warnings were adequate. No affidavit has been provided by any knowledgeable person from Smith or by an expert indicating that the warnings were adequate [See e.g. *McDonnell v Chelsea Manufacturing*, 259 AD2d 674, 676 (2nd Dept, 1999)], that the injuries allegedly suffered by plaintiff which are claimed to be attributable to Suretac were not caused by Suretac, or that even if they were such

injuries were, prior to plaintiff's surgery, unknown to have occurred as a result of Suretac, or with adequate testing could not have been known and that therefore the warnings were adequate. The only warnings referred to by Smith's counsel on this motion are those contained in the package insert which when discussing specific risks suggested that there could be an inflammatory response only "during the degradation period" and that this response would be "transient" and "self-limiting". Smith on this motion does not provide an expert's affidavit indicating that at the time of plaintiff's surgery it had no knowledge of any claimed injuries which were other than transient.

"A manufacturer has the duty to warn of all potential dangers... it either knows to exist or in the exercise of reasonable care should have known to exist". *McDonnell*, supra at 676; *Enright v Lilly & Co.*, 77 NY2d 377, 387 (1991), rearg. den. 77 NY2d 990; cert. den. 502 US 868 Smith has failed to prima facie establish via competent evidence that its warnings were adequate as a matter of law. See *Martin v Hacker*, 83 NY2d 1 (1993) In any event the affirmation of plaintiffs' expert** raises issues as to whether the package insert contained inadequate warnings.

In addition, that plaintiff was determined to have surgery does not as a matter of law result in a lack of causation. As noted by Dr. Hannafin (EBT, p 70), there were fixation devices of other materials available from other companies. A jury might conclude, assuming that the warnings were inadequate, that if proper warnings had been given to Dr. Hannafin of the risks of Suretac, she may have used another product. There is no indication on this record that Dr.

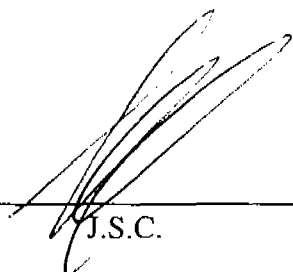
** The original unredacted version of the affirmation has been reviewed by me in camera, and the identity of that expert has been revealed by plaintiffs to movant's counsel pursuant to my interim order signed on April 12, 2006.

Hannafin, who has not served any papers on this motion, was aware that the risks associated with Suretac were other than fleeting (See Hannafin, EBT p 71)

In conclusion the motion is denied except to the extent indicated.

Settle order.

Dated: April 26, 2006
60 Centre Street
New York, NY



J.S.C.