Bush v Merola
2008 NY Slip Op 32725(U)
September 19, 2008
Supreme Court, Queens County
Docket Number: 27494/2005
Judge: Patricia P. Satterfield
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MEMORANDUM

SUPREME COURT : QUEENS COUNTY
IA PART 19

SUSAN BUSH, etc.,

Plaintiff,

- against -

STEPHEN MEROLA, M.D., et al.,

Defendants.

INDEX NO. 27494/2005

SEQ. NO. 2

MOTION DATE: JUNE 25, 2008

MOTION CAL. NO. 6

BY: SATTERFIELD, J.

DATED: September 19, 2008

This is a products liability action commenced by plaintiff Susan Bush, as the executrix of the estate of her husband, Michael Bush, deceased, who allegedly died from complications following gastric bypass surgery for morbid obesity as a result of the alleged malfunctioning of a surgical stapling device manufactured by defendants Ethicon Endo-Surgery, Inc., Ethicon, Inc., and Johnson & Johnson (collectively the "Ethicon" defendants).

Relevant Facts

Michael Bush suffered from morbid obesity which caused diabetes, hypertension, degenerative joint disease and other problems. After dieting failed to control his weight which reached 423 pounds, he consulted with Dr. Stephen Merola, a bariatric surgeon, about bypass surgery which would reduce the stomach area used to hold and digest food, causing weight loss. In

January 2004, Michael Bush and Susan Bush, his wife, attended a ninety-minute group program during which Dr. Merola discussed the risks of gastric bypass surgery, and in February 2004, Michael and Susan Bush had a one hour private consulting session with Dr. Merola who discussed Michael's individual health problems which increased the risks of surgery. In March 2004, Michael and Susan Bush received another private consultation from Dr. Merola. They learned that the patient assumes a risk that an abdominal leak will occur from areas cut by the surgeon and will cause an infection. However, plaintiff Susan Bush ("plaintiff") denies that she and her husband were told of the use of a stapling device that could malfunction.

On May 10, 2004, Dr. Merola performed open gastric bypass surgery on Michael Bush, known as a Roux-en-Y gastric bypass, in which the stomach was cut into two sections, leaving one section connected to the esophagus and one section unused. Dr. Merola used a device manufactured by Ethicon known as the ETS Long 45 (the Long 45), an instrument that cuts and staples the stomach. Prior to closure, Dr. Merola visually inspected the stomach and saw that there was an intact "full staple line," and he also tested the stomach for leaks using air, a saline solution, and a blue dye. He concluded that there was "no leakage, no hole." However, Michael Bush underwent a second surgery on the following day after his physical signs indicated the possibility of a gastric leak, and the

surgeons found a leak in his suture line that was approximately one to two-centimeters long. Thereafter, Michael Bush developed pneumonia, which plaintiff attributes to complications arising from the bypass surgery, and he passed away on May 31, 2004. Dr. Laurie Horowitz conducted an autopsy and allegedly found an intact suture line. Dr. Merola, who attended the autopsy, also allegedly observed an intact suture line. It is upon the foregoing that the Ethicon defendants move for summary judgment dismissing the complaint against them.[1]

Discussion

On a motion for summary judgment, the initial burden is on the movant to establish a prima facie entitlement to judgment as a matter of law by tendering sufficient evidence to demonstrate the absence of any material issues of fact. (Alvarez v Prospect Hosp., 68 NY2d 320 [1986].) As such, the function of the court on the

[1] By order of this Court dated September 16, 2008, the motion by the Ethicon defendants for an order, inter alia, excluding from evidence on this instant summary judgment motion and at the trial of this action, documents known as "adverse event reports," "medical device reports," and "MedWatch reports" and the cross motion by those defendants seeking to strike the affirmation of Suzanne Parisian, MD dated May 16, 2008, was denied. In so finding, this Court stated, in pertinent part, the following: "The defendants failed to establish on this motion that the AER reports concern incidents which are not similar to that in the case at bar. Moreover, the affidavit of Susan Parisian, MD., one of the plaintiff's experts, refutes the defendants' contention that the AER reports are 'irrelevant,' 'misleading,' 'untrustworthy,' and 'not worthy of consideration.'

instant motion is issue finding and not issue determination. (D.B.D. Nominee, Inc., v. 814 10th Ave. Corp., 109 AD2d 668, 669 [2nd Dept. 1985]; Zuckerman v. City of New York, 49 NY2d 557, 562 [1980].) If there is any doubt whether an issue of fact exists, summary judgment should be denied as it is a drastic remedy. (Rotuba Extruders v Ceppos, 46 NY2d 389 [1978]; Andre v. Pomeroy, 35 NY2d 361, 364 [1974]; Taft v. New York City Tr. Auth., 193 AD2d 503, 505 [1st Dept. 1993].) In this instance, the Ethicon defendants established, prima facie, their entitlement to summary judgment and dismissal of the action.

In opposition to the instant motion, plaintiff alleges that the Ethicon stapler had misfired during the first surgery producing mal-formed or U-shaped staples, and the surgeons had to place sutures into the stomach to stop the leakage. Plaintiff submitted the affirmation of Michael Leitman, M.D., the Chief of General Surgery at Beth Israel Medical Center, who has experience with obesity surgery and the Long 45 stapler. He concludes that the Long 45 stapler used on Michael Bush malfunctioned and caused leakage of gastric contents and subsequent death. According to Dr. Leitman, "What happens in a situation such as this where the device malfunctions is that although the stapler fires, some staples 'crimp' the tissue but do not form the perfect 'B' shape along the length of the entire staple line ... As such, if staples have closed in something less than a perfect 'B' formation, then a leak,

which may not be evident immediately upon proper testing, is likely to occur." According to plaintiff, the Ethicon defendants had knowledge of problems associated with the use of the Long 45, such as incomplete staple formation, as early as 1999.

Plaintiff also submitted the affidavit of Dr. Yadin David, a registered professional engineer and certified clinical engineer, who concludes that "the Long 45 malfunctioned during the surgery at issue due to an inherent flaw or defect in the manufactured device which prevented it from functioning as it should, i.e., firing fully formed 'B' shaped staples ..." Dr. David alleges that the Long 45 is defectively designed because: "(a) it does not permit the physician ... to appreciate the degree and extent of tissue thickness ...; (b) the device lacks a gauge or other mechanism employed in other similar instruments on the market that would assist the physician in determining whether the tissue that he/she has grasped in the jaws of the instrument prior to deploying the firing trigger is within the recommended indications for use of a particular staple size cartridge ...; (c) that the 'force to fire' applied with a single hand ... is not sufficient in many instances to form perfectly closed 'B' shaped staples over compressed tissue ...; and (d) that the product labeling is insufficient in terms of its warnings ... that the physician will be required to use two hands ..."

A product may be defective when it contains a manufacturing flaw, is improperly designed, or is not accompanied by adequate warnings for the use of the product. (See, Liriano v Hobart Corp., 92 NY2d 232 [1998].) A plaintiff injured by a defective product may seek to recover damages from the manufacturer pursuant to as many as four theories of liability: express contract, implied contract, negligence, or strict products liability. (See, Voss v Black & Decker Mfg. Co., 59 NY2d 102 [1983].) In a strict products liability action, a plaintiff may assert that a product is defective because of a mistake in the manufacturing process, because of an improper design, or because the manufacturer failed to provide adequate warnings regarding the use of the product. (See, Sukljian v Charles Ross & Son Co., Inc., 69 NY2d 89 [1986]; Voss v Black & Decker Mfg. Co., supra.)

In regard to defective manufacture, harm must have arisen from a product's failure to perform in an intended manner because of some defect in the fabrication process. (See, Denny v Ford Motor Co., 87 NY2d 248, 257 [1995].) The manufacturer must have produced a product which did not conform to specifications. (See, McArdle v Navistar Intern. Corp., 293 AD2d 931 [3rd Dept. 2002]; Searle v Suburban Propane Div. of Quantum Chem. Corp., 263 AD2d 335 [3rd Dept. 2000.)

"[A] defectively designed product is one which, at the time it leaves the seller's hands, is in a condition not reasonably

contemplated by the ultimate consumer and is unreasonably dangerous for its intended use; that is one whose utility does not outweigh the danger inherent in its introduction into the stream of commerce ..." (Robinson v Reed-Prentice Division of Package Machinery Co., 49 NY2d 471, 479 [1980]; see, Scarangella v Thomas Built Buses, Inc., 93 NY2d 655 [1999]; Voss v Black & Decker Mfg. Co., supra.) "In order to establish a prima facie case in strict products liability for design defects, the plaintiff must show that the manufacturer breached its duty to market safe products when it marketed a product designed so that it was not reasonably safe and that the defective design was a substantial factor in causing plaintiff's injury." (Voss v Black & Decker Mfg. Co., 59 NY2d 102, 107 [1983]; see, McArdle v Navistar Intern. Corp., 293 AD2d 931 [3rd Dept. 2002].) The plaintiff is also "under an obligation to present evidence that the product, as designed, was not reasonably safe because there was a substantial likelihood of harm and it was feasible to design the product in a safer manner." (Voss v Black & Decker Mfg. Co., supra, 108; see, Cleary v Reliance Fuel Oil Associates, Inc., 17 AD3d 503 [2nd Dept. 2005]; Wesp v Carl Zeiss, Inc., 11 AD3d 965 [4th Dept. 2004]; Gonzalez v Delta Intern. Machinery Corp., 307 AD2d 1020 [2nd Dept. 2003]; Felix v Akzo Nobel Coatings Inc., 262 AD2d 447 [2nd Dept. 1999].)

The opponent of a motion for summary judgment must produce evidence showing that there is a genuine issue of fact

which must be tried. (See, Alvarez v Prospect Hospital, 68 NY2d 320 [1986].) Plaintiff successfully carried this burden. There are issues of fact pertaining to, inter alia, whether the Long 45 was defectively manufactured or defectively designed, and, if so, whether the defect proximately caused the death of Michael Bush. (See, Wesp v Carl Zeiss, Inc., supra; Vigio v New York Hosp., 228 AD2d 278 [1st Dept. 1996]; Lehoczky v New York State Electric & Gas Corp., 117 AD2d 870 [3rd Dept. 1986]; Craft v Mid Island Dept. Stores, Inc., 112 AD2d 969 [2nd Dept. 1985]; Miceli v Purex Corp., 84 AD2d 562 [2nd Dept. 1981].) In regard to defective manufacture, some staples examined by plaintiff's expert that came from the Long 45 used on Michael Bush allegedly did not form properly, and Dr. David allegedly experienced "resistance" when testing the Long 45 used on Michael Bush that he did not experience on an exemplar Long 45. In regard to defective design, there are issues of fact concerning whether under all of the facts and circumstances of this case, the Ethicon defendants manufactured and marketed a defectively designed product. (See, Voss v Black & Decker Mfg. Co., 59 NY2d 102 [1983].) Dr. David has opined that the Long 45 was not reasonably safe for its intended purpose, and he identified design changes which could have made the stapler safer. There are, for example, competitor products on the market that use electronic sensors to measure tissue thickness.

Conclusion

The conflicting affidavits of the experts in this products liability case have created genuine issues of fact which preclude summary judgment dismissing the complaint. (See, Steuhl v Home Therapy Equipment, Inc., 51 AD3d 1101 [3rd Dept. 2008]; McDermott v Coffee Beanery, Ltd., 9 AD3d 195 [1st Dept. 2004].) Accordingly, the motion by defendants Ethicon Endo-Surgery, Inc., Ethicon, Inc., and Johnson & Johnson for summary judgment and dismissal of the complaint is denied. Short form order signed herewith.

J.S.C.