Venza v Benatar
2014 NY Slip Op 32201(U)
August 6, 2014
Sup Ct, Suffolk County
Docket Number: 07-23646
Judge: Joseph A. Santorelli

[* 1]

SHORT FORM ORDER

INDEX No. 07-23646
CAL. No. 13-01819MM

SUPREME COURT - STATE OF NEW YORK
I.A.S. PART 10 - SUFFOLK COUNTY

PRESENT:

Hon. JOSEPH A. SANTORELLI
Justice of the Supreme Court

MOTION DATE 3-26-14
ADJ. DATE 7-8-14
Mot. Seq. # 001 - MD

LOUISA VENZA and JOHN VENZA,

Plaintiffs,

- against -

BENZION BENATAR, M.D., SOUTH NASSAU COMMUNITIES HOSPITAL and BIOMET ORTHOPEDICS, INC.,

Defendants.

DUFFY & DUFFY, PLLC
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BARTLETT, MCDONOUGH, & MONAGHAN
Attorney for Defendant South Nassau Communities Hospital
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Attorney for Defendant Biomet Orthopedics
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Upon the following papers numbered 1 to 37 read on this motion for summary judgment; Notice of Motion/ Order to Show Cause and supporting papers (001)1 - 28; Notice of Cross Motion and supporting papers _; Answering Affidavits and supporting papers 29-31; 32-35; Replying Affidavits and supporting papers 36-37; Other _; (~~and after hearing counsel in support and opposed to the motion~~) it is,

ORDERED that motion (001) by defendant South Nassau Communities Hospital for summary judgment dismissing the complaint as asserted against it is denied.

In this negligence/medical malpractice action, the plaintiff, Louisa Venza, alleges she sustained serious personal injuries as a result of the negligent departures from the standard of care by the

defendants during her admission to South Nassau Communities Hospital. She had been admitted to defendant hospital for a total right hip replacement surgery on September 26, 2005. During the surgery, she sustained injury to her sciatic nerve, resulting in drop foot. It is asserted by defendant Dr. Benzion Benatar that, at some point during the surgical procedure, the acetabular trial liner, manufactured by defendant Biomet Orthopedics, Inc., fractured into multiple pieces impacting the sciatic nerve and acetabulum, and in turn, resulted in permanent injury and damage to plaintiff's right sciatic nerve, right acetabulum, and right lower extremity. It is further alleged that defendant hospital failed to advise the plaintiff or her family of the surgical injury, failed to comply with the mandates of the Public Health Law section 2805, and failed to properly and safely sterilize the liner and/or implant, compromising the integrity of the liner. Causes of action for negligence as to each defendant, medical malpractice, lack of informed consent, strict product liability, breach of express warranties, breach of implied warranties, failure to warn, and derivative and loss of services claims, have been asserted.

The proponent of a summary judgment motion must make a prima facie showing of entitlement to judgment as a matter of law, tendering sufficient evidence to eliminate any material issues of fact from the case (***Sillman v Twentieth Century-Fox Film Corporation***, 3 NY2d 395, 165 NYS2d 498 [1957]). The movant has the initial burden of proving entitlement to summary judgment (***Winegrad v N.Y.U. Medical Center***, 64 NY2d 851, 487 NYS2d 316 [1985]). Failure to make such a showing requires denial of the motion, regardless of the sufficiency of the opposing papers (***Winegrad v N.Y.U. Medical Center***, *supra*). Once such proof has been offered, the burden then shifts to the opposing party, who, in order to defeat the motion for summary judgment, must proffer evidence in admissible form...and must "show facts sufficient to require a trial of any issue of fact" (CPLR 3212[b]; ***Zuckerman v City of New York***, 49 NY2d 557, 427 NYS2d 595 [1980]). The opposing party must assemble, lay bare and reveal his proof in order to establish that the matters set forth in his pleadings are real and capable of being established (***Castro v Liberty Bus Co.,*** 79 AD2d 1014, 435 NYS2d 340 [2d Dept 1981]).

In support of this motion, defendant hospital has submitted, inter alia, an attorney's affirmation; the affidavit of James Pugh, P.E., PhD.; copies of the summons and compliant, defendant's answer and demands, plaintiff's verified bill of particulars, plaintiff's amended verified bill of particulars; unsigned but certified transcripts of plaintiff Louisa Venza's examination before trial and continuing examinations before trial without proof of service pursuant to CPLR 3116 (except that the transcript of June 19, 2009 is signed by plaintiff Louisa Venza); unsigned but certified transcripts of plaintiff John Venza's examination before trial; the unsigned but certified transcript of the examinations and continuing examinations before trial of non-party witness Richard Del Plato which is not in admissible form (*see* ***Martinez v 123-16 Liberty Ave. Realty Corp***, 47 AD3d 901, 850 NYS2d 201 [2d Dept 2008]; ***McDonald v Maus***, 38 AD3d 727, 832 NYS2d 291 [2d Dept 2007]; ***Pina v Flik Intl. Corp.***, 25 AD3d 772, 808 NYS2d 752 [2d Dept 2006]); the unsigned but certified transcript of the examination before trial of defendant Ben Benatar, M.D., and as continued, Elizabeth Perepezko on behalf of Biomet Orthopedics, which are not objected to by any party (*see* ***Zalot v Zieba***, 81 AD3d 935, 917 NYS2d 285 [2d Dept 2011]; the signed and certified transcript of the examination before trial of non-party witness Peter Kenny; certified copy of the hospital record; and uncertified/unauthenticated copy of the recommendations for care and handling of Biomet Surgical Instruments and Instrument Cases, dated June 2004, which is not in admissible form pursuant to CPLR 3212; and an unauthenticated and undated

Flash Sterilization Policy, without the referenced "Flash Records," which is not in admissible form pursuant to CPLR 3212.

Elizabeth Perepezko testified that she began working for Biomet Incorporated in September 2005, as a research scientist in materials and process development, developing new materials for various instrument and implant applications in the orthopedic field, including hip replacements. She has not designed or developed new materials for hip replacements, however, she had engaged in testing various instrument plastics. She has tested various provisional instruments used to mimic the device geometry, but intended to be used, reused instrumentation. She has tested material, alternate plastics, for use in trial liner cups used in hip replacement procedures. She did not know what the trial liner cups manufactured by Biomet were made of in 2005. She did not test the trial liner cups used in 2005, only those of 2009 to 2012. She did not know the shelf life of the trial liner cups. Since 2005, she, along with other co-workers in the biomaterials group, have done investigations of devices that have broken. A complaint would be made to the complaint department in the regulatory group, located in Warsaw, Indiana. Information would then be relayed from the regulatory group, which would then investigate the product. The legal department and complaint department would investigate the circumstances and speak with witnesses.

Defendant South Nassau Communities Hospital expert, James Pugh, P.E., PhD, set forth that he is the president and director of Inter-City Testing & Consulting Corporation, and director of Biomedical Engineering, Material Science and Engineering of Inter-City Testing & Consulting Corporation in Mineola, New York. He set forth his education and work experience, and stated that he is a licensed professional engineer in the State of New York. He set forth that he reviewed various materials and documents relative to the care and treatment rendered to Louisa Venza, including her records from South Nassau Communities Hospital, co-defendant Biomet Orthopedics, Inc.'s recommendations for the care and handling of Biomet surgical instruments and instrument cases, the hospital's flash sterilization policy in effect in 2005. It is Dr. Pugh's opinion within a reasonable degree of engineering and biomedical certainty that under the circumstances then and there existing at the time of the total hip replacement procedure, it was totally appropriate to utilize the flash sterilization process to sterilize the acetabular trial liners for the plaintiff's hip replacement. Dr. Pugh also opined that in no way did the hospital's professional operating room staff deviate or depart from good and accepted medical and technical practice in using the flash autoclave machine to sterilize the trial liners for the subject procedure.

Dr. Pugh continued that according to the hospital's Flash Sterilization Policy in effect at the time, flash sterilization may be used when there is an immediate need for an individual item and there is no alternative. In this case, there was only one set of trial liners for two hip replacement procedures to be performed by Dr. Benatar on September 26, 2005, with no time to allow for the trial liners to go through the usual decontamination and sterilization process described by Robert Stevenson, the instrument reprocessing supervisor from Central Sterile Supply for defendant hospital. He did not see anything to indicate that the trial liners used in the Venza case were flash sterilized in any manner other than what was described by Stevenson and indicated in the hospital's policy.

Dr. Pugh stated that while Biomet's recommendations for the care and handling of Biomet surgical instruments indicates that instruments should not be flash autoclaved inside the instrument case, it was clear from Stevenson and Mr. Del Plato, the Biomet sales representative in attendance during the procedure, that the subject trial liners were not in an instrument case at the time they were flash autoclaved, and they would have been placed in a wire mesh instrument basket which would have been placed into a Flash Pack prior to autoclaving. Dr. Pugh stated that according to Biomet's recommendations for the care of their instruments, there was no reason to believe that the trial liners should not have been flash-autoclaved. Dr. Pugh stated that there were no identification numbers on the trial liners to keep track of the number used and sterilizations, although they were designed to be reused. However, Dr. Pugh stated, there was only one set of trial liners for hip replacement procedures.

Dr. Pugh stated that the trial liner was never subjected to any testing to determine the reason for its failure and the various pieces are missing after being brought back to the distributorship. No tests were performed on similar devices to determine whether flash-autoclaving and/or further cooling down of the trial liner in saline solution, as was done in this case, caused any adverse effect, or to determine the maximum number of permissible sterilizations. Dr. Pugh has not indicated that he performed testing of any like materials from which the trial liners were manufactured. His conclusion that flash autoclaving of Biomet's trial liner's was appropriate, and that in no way did the hospital's professional operating room staff deviate or depart from accepted practice in doing so, is conclusory and unsupported with any scientific or engineering basis for his opinion.

Biomet Orthopedics, Inc. has opposed defendant South Nassau Communities Hospital's motion for summary judgment by submitting, inter alia, the affidavit of its expert, Len Czuba. The plaintiffs have also opposed defendant South Nassau Communities Hospital's motion and have incorporated by reference the affidavit of Mr. Czuba.

In opposing this motion, Len Czuba, president of Czuba Enterprises, Inc., averred that he received a bachelor's degrees in biosciences from Southern Illinois University in 1973, then continued his studies with additional course work in polymer science, organic chemistry, physical chemistry, and plastics engineering, among others. He has also attended courses, classes, seminars, and conference programming that have permitted him to develop his understanding and expertise in polymer science and plastics engineering. He has worked in medical plastics and product development since 1974, and has published extensively on the selection of the plastic materials of construction and methods of processing and assembly, has spoken on sterilization, failure analysis, prevention, and the regulatory approval process. He has been issued fifteen U.S. Patents, along with associates, for designs and materials for construction for a variety of medical devices. At Czuba Enterprises, Inc., he provides expert consultation regarding polymer selection and processing for medical device product development.

Mr. Czuba continued that the trial liner used in Ms. Venza's surgery was manufactured of a plastic material or polymer known as polyoxymethylene (POM). In reviewing the records and materials, he ascertained that Ms. Venza's surgical procedure was begun before the trial liner was sterilized and ready for use because it had been used without incident during an immediately preceding surgery. SNCH utilized its prequalified flash sterilization procedure which requires a heating temperature between 270-272 degrees Fahrenheit. However, SNCH did not follow its own protocol and the trial

liner was not allowed to cool pursuant to the hospital procedure. The flash sterilized trial liner was very hot after the heating phase of the sterilization cycle and the hot liner was quenched cool in room temperature saline water solution instead of permitting it to cool naturally to room temperature. It was after this abbreviated sterilization cycle with rapid quench cooling that the trial liner cracked and broke when used by Dr. Benatar during his range of motion testing.

It is Mr. Czuba's opinion that, during the rapid quench cooling technique used by SNCH, the trial liner surface temperature was reduced, however, the interior of the trial liner was still hot. As a direct result, the temperature differential caused a significant weakness or stress, and the full physical properties of the polymer were not available to withstand the handling forces exerted on the trial liner during the range of motion testing. He continued that the trial liner was designed to be used at room temperature after adherence to qualified sterilization protocols. By deviating from the Biomet's instructions, and more importantly, the SNCH approved flash sterilization procedure, and using an unapproved rapid quench cooling technique, the trial liner was exposed to physical stresses beyond what it could be expected to withstand. In conclusion, Mr. Czuba opined to a reasonable degree of polymer science authority, that the trial liner was caused to fail because SNCH conducted an abbreviated flash sterilization procedure by rapidly cooling the trial liner, instead of allowing the trial liner to cool naturally, thereby creating an uncharacteristic weakness in the physical property of the polymer material.

Based upon the foregoing, it is determined that even if the moving defendant established prima facie entitlement to summary dismissal of the complaint, defendant Biomet Orthopedics, Inc. and the plaintiffs have raised factual issues to preclude summary judgment from being granted to defendant South Nassau Communities Hospital.

Accordingly, motion (001) by defendant South Nassau Communities Hospital is denied.

Dated: AUG 0 6 2014

HON. JOSEPH A. SANTORELLI
J.S.C.

FINAL DISPOSITION __X__ NON-FINAL DISPOSITION