J. S11036/06

2006 PA Super 152

JOSEPH CREAZZO AND DARLENE CREAZZO, husband and wife, Appellants	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
v.	:	
MEDTRONIC, INC., Appellee	:	No. 1843 EDA 2005

Appeal from the Order Entered June 3, 2005, Court of Common Pleas, Northampton County, Civil Division, at No. C0048CV2001008832.

BEFORE: FORD ELLIOTT, P.J., ORIE MELVIN, and JOHNSON, JJ.

OPINION BY JOHNSON, J: Filed: June 27, 2006

¶ 1 Joseph Creazzo ("Plaintiff-Husband") and Darlene Creazzo, his wife, (collectively "the Creazzos"), appeal the trial court's order granting summary judgment in favor of Medtronic, Inc. on the Creazzos' claims of product defect, failure to warn, and strict liability. The Creazzos contend that the court erred when it dismissed their product defect claim based on their inability to retrieve the product, and dismissed their remaining claims based on the inadequacy of their expert opinion and the "learned intermediary" doctrine. Upon review of the trial court's disposition, we do not find reversible error. Therefore, we affirm the court's entry of summary judgment.

¶ 2 This matter arose out of the failure of a medical device implanted in the body of Plaintiff-Husband that Medtronic designed and manufactured. The device, known as the Model 7425 Itrel 3 Implantable Neurological Electrical Pulse Generator (the Itrel 3), was designed to alleviate chronic pain by passing an electrical stimulus through nerve structures in the dorsal aspect of the patient's spinal cord by way of a stimulation lead. Plaintiff-Husband's treating physician implanted him with such a device and lead in December 1998, after unsuccessful treatment with medication and other therapies. Although the device operated as expected for some period of time, it ultimately malfunctioned, necessitating its removal on October 1, 2002.

¶ 3 Significantly, the Creazzos commenced this litigation ten months prior to the explantation surgery and filed the Complaint asserting their substantive claims almost eight months prior on February 22, 2002. Medtronic, thus alerted to the Creazzos' allegations, communicated through counsel, requesting that the Itrel 3 be preserved and proposed a stipulation for the examination and inspection of the device "to avoid any issues of spoliation of evidence, whether inadvertent or purposeful[.]" Letter of John P. Lavelle, Jr., Esq. to Kristen M. Harvey, Esq., 9/19/02. Plaintiffs' counsel declined the proposed stipulation but did request that the staff at Thomas Jefferson Hospital, where the explantation was conducted, retain the Itrel 3

for further examination. The Creazzos took no active steps to preserve the device, however, and when current counsel sought to retrieve it from Thomas Jefferson in September 2004, the hospital responded that it could not be located. Consequently, a gross pathology examination carried out at the hospital constitutes the only inspection conducted of the device; neither party was able to submit the Itrel 3 to a retained expert.

¶ 4 Nevertheless, the Creazzos did submit an expert report based upon review by a consulting engineer specializing in medical products. This expert considered multiple medical reports compiled during Plaintiff-Husband's treatment, as well as the Jefferson pathology report, numerous Medtronic technical documents concerning the Itrel 3, a "[j]ournal article examining prior failures associated with fabrication defects with the Medtronic Pisces leadwire sheathing[,]" and documentation of over 600 other failures of the epidural wire. Report of Ted Milo, B.E.E.E., 2/14/05, at 12 of 13. He rendered an opinion that Plaintiff-Husband's complications were "the direct result of a defective Medtronic Model 4387A-33 epidural stimulation lead resulting in the eventual premature failure of that lead." Report of Ted Milo, B.E.E.E., 2/14/05, at 12 of 13.

¶ 5 Subsequently, Medtronic filed the motion for summary judgment that underlies this appeal claiming that the Creazzos' product defect and manufacturing defect claims should be dismissed on the basis of spoliation of

the evidence, and their failure to warn claims dismissed on the basis of the learned intermediary doctrine. The trial court, the Honorable F.P. Kimberly McFadden, granted Medtronic's motion, concluding that no less a sanction was appropriate given the circumstances surrounding the disappearance of the Itrel 3. The Creazzos now file this appeal, raising the following questions for our review:

> 1. Whether the court erred in granting summary judgment?
>
> 2. Whether the court erred in ruling that as a result of spoilation of the evidence summary judgment must be granted in favor of [Medtronic]?
>
> 3. Whether the court erred in ruling that [the Creazzos'] expert "offers no opinion that the [Itrel 3] was defectively designed"?
>
> 4. Whether the court erred in ruling that strict liability is not a basis for liability and that [Medtronic's] motion for summary judgment based on strict liability must be granted[?]
>
> 5. Whether the court erred in granting summary judgment on the basis of the learned intermediary doctrine?
>
> 6. Whether [the Creazzos'] product liability claim is not precluded under the medical device amendments (MDA) to the Food, Drug and Cosmetic Act?

Brief for Appellants at 3.

¶ 6 The Creazzos' questions challenge the trial court's exercise of discretion in granting Medtronic's motion for summary judgment. "Our scope of review of an order granting summary judgment is plenary." ***Pappas v. UNUM Life***

Ins. Co., 856 A.2d 183, 186 (Pa. Super. 2004) (citation omitted). Accordingly, we must consider the order in the context of the entire record. ***See Stanton v. Lackawanna Energy, Ltd.,*** 820 A.2d 1256, 1258 (Pa. Super. 2003). "Our standard of review is the same as that of the trial court; thus, we determine whether the record documents a question of material fact concerning an element of the claim or defense at issue." ***Id.***

> [A] proper grant of summary judgment depends upon an evidentiary record that either (1) shows the material facts are undisputed or (2) contains insufficient evidence of facts to make out a *prima facie* cause of action or defense[.] Thus, a defendant may establish a right to summary judgment by demonstrating the plaintiff's inability to show an element essential to his claim. If the plaintiff fails to contravene the defendant's claim with evidence raising a factual dispute as to that element, the defendant is entitled to entry of judgment as a matter of law.

Pappas, 856 A.2d at 186 (internal citations and quotation marks omitted). Conversely, if the plaintiff demonstrates a question of material fact, the court must defer the question for consideration of a jury and deny the motion for summary judgment. ***See Stanton***, 820 A.2d at 1259. "We will reverse the resulting order only where it is established that the court committed an error of law or clearly abused its discretion." ***Id.*** (citation omitted).

¶ 7 In support of their first question, the Creazzos offer only a generic statement that the trial court erred in granting summary judgment for

Medtronic, without case-specific analysis, citing caselaw only to document the required standard of review. Brief for Appellants at 8 ("There is a genuine issue of material fact, if not many, namely whether the device in question was defectively designed and as a result, [Medtronic] is not entitled to judgment as a matter of law."). Because the Creazzos' discussion of this question is so substantially truncated as to deprive us of grounds for review, we deem their first question waived. ***See*** Pa.R.A.P. 2101, 2119(a); ***see also Borough of Mifflinburg v. Heim***, 705 A.2d 456, 467 (Pa. Super. 1997) (deeming question waived [b]ecause appellant's discussion of this issue in the argument portion of his brief is limited to one sentence and includes no supporting citations to law . . .).

¶ 8 In support of their second question, the Creazzos assert that the trial court erred in dismissing their product defect claims on the basis of spoliation of the evidence. Brief for Appellants at 8-9. Although the Creazzos do not seriously dispute the loss of the Itrel 3, they argue that some lesser sanction was appropriate and that the trial court abused its discretion in imposing the ultimate sanction of dismissal. Brief for Appellants at 10-12. They ground this assertion on the conclusion that their claim is one for design defect rather than manufacturing defect and that, as such, Medtronic could have conducted an adequate examination by examining the stimulation leads of other Itrel 3 units. Brief for Appellants at 10-11 (citing

O'Donnell v. Big Yank, Inc., 696 A.2d 846 (Pa. Super. 1997)). We find this argument unsubstantiated by the record and, consequently, unconvincing.

¶ 9 "When reviewing a court's decision to grant or deny a spoliation sanction, we must determine whether the court abused its discretion." ***Mount Olivet Tabernacle Church v. Wiegand***, 781 A.2d 1263, 1269 (Pa. Super. 2001) (citing ***Croydon Plastics Co. v. Lower Bucks Cooling & Heating***, 698 A.2d 625, 629 (Pa. Super. 1997) (recognizing that "[t]he decision whether to sanction a party, and if so the severity of such sanction, is vested in the sound discretion of the trial court")). Such sanctions arise out of "the common sense observation that a party who has notice that [evidence] is relevant to litigation and who proceeds to destroy [evidence] is more likely to have been threatened by [that evidence] than is a party in the same position who does not destroy [the evidence]." ***Mount Olivet***, 781 A.2d at 1269 (quoting ***Nation-Wide Check Corp. v. Forest Hills Distributors, Inc.***, 692 F.2d 214, 218 (1st Cir. 1982)). Our courts have recognized accordingly that one potential remedy for the loss or destruction of evidence by the party controlling it is to allow the jury to apply its common sense and draw an "adverse inference" against that party. ***See Schroeder v. Commonwealth of Pa., Dep't of Transp.***, 710 A.2d 23, 28 (Pa. 1998). Although award of summary judgment against the offending

party remains an option in some cases, its severity makes it an inappropriate remedy for all but the most egregious conduct. ***See Tenaglia v. Proctor & Gamble, Inc.***, 737 A.2d 306, 308 (Pa. Super. 1999) ("[S]ummary judgment is not mandatory simply because the plaintiff bears some degree of fault for the failure to preserve the product.").

¶ 10 To determine the appropriate sanction for spoliation, the trial court must weigh three factors:

> (1) the degree of fault of the party who altered or destroyed the evidence; (2) the degree of prejudice suffered by the opposing party; and (3) whether there is a lesser sanction that will avoid substantial unfairness to the opposing party and, where the offending party is seriously at fault, will serve to deter such conduct by others in the future.

Mount Olivet, 781 A.2d at 1269-70 (quoting ***Schmid v. Milwaukee Elec. Tool Corp.***, 13 F.3d 76, 79 (3d Cir. 1994)). In this context, evaluation of the first prong, "the fault of the party who altered or destroyed the evidence," requires consideration of two components, the extent of the offending party's duty or responsibility to preserve the relevant evidence, and the presence or absence of bad faith. ***See Mt. Olivet***, 781 A.2d at 1270. The duty prong, in turn, is established where: "(1) the plaintiff knows that litigation against the defendants is pending or likely; and (2) it is foreseeable that discarding the evidence would be prejudicial to the defendants." ***Id.*** at 1270-71.

¶ 11 In this case, the trial court determined that the Creazzos bore substantial responsibility for the loss of the Itrel 3. Trial Court Opinion, 2/10/05, at 9. The court reasoned that, notwithstanding the actual loss of the Itrel 3 by a third party (Thomas Jefferson Hospital), responsibility for its preservation remained with the Creazzos, who were fully aware of their pending action and the need to preserve the device but failed to take active steps to do so for a period of two years. Trial Court Opinion, 6/3/05, at 4-5. The court reasoned further that the absence of the device caused Medtronic substantial prejudice, concluding that the Creazzos asserted a claim of manufacturing defect (not design defect), the defense of which requires inspection of the individual device. Trial Court Opinion, 6/3/05, at 5. The court determined accordingly that no lesser a sanction than dismissal would be adequate.

¶ 12 We find no error in the trial court's analysis and determination of this issue. Contrary to the Creazzos' rather summary argument, they and not Medtronic bore responsibility for the preservation of the Itrel 3. The fact that the actual loss occurred while the device was in the custody of a third-party does not ameliorate that responsibility, given the Creazzos' knowledge of their own pending claim and the nature of their claim as one based on a manufacturing defect. The Creazzos cite no authority to the contrary. Unlike the claim for design defect in ***Big Yank***, which could be investigated

with reference to other products of the same design, ***see*** 696 A.2d at 849, or claims of negligence to which the continued existence of the product is not critical given the focus of legal inquiry on conduct rather than inherent defect, ***see Mt. Olivet***, 781 A.2d at 1270, a claim of manufacturing defect is untenable in the absence of the product itself. Where, as in this case, the actual device has not been examined even by the plaintiff's own expert both proof and defense of the claim are severely compromised. Given the paucity of direct evidence that such an absence imposes on the action, per force, we cannot conclude that the trial court erred in dismissing the Creazzos' product defect claim on the basis of spoliation.

¶ 13 The Creazzos attempt to circumvent this inevitable conclusion by arguing in support of their third question that the opinion of their engineering witness, Ted Milo, B.E.E.E., adequately established a claim of design defect and that the trial court erred in refusing to so interpret his report. Brief for Appellants at 11. To support their claim, the Creazzos rely on Milo's statement "it is my professional opinion that complications of intermittent stimulation, shocking sensation in Mr. Creazzo's lower back . . . was the direct result of a defective 'Medtronic Model 4387A-33' . . . ." Brief for Appellants at 11. This language, they argue, asserts "that the lot was defectively designed and not just this particular unit." Brief for Appellants at 11. To buttress this claim, the Creazzos argue that Milo's report identified

37 complaints involving broken leads on other Itrel 3 units, that the pathology report showed that the lead wires of this particular unit had broken, a defect consistent with those in some 600 other cases. Brief for Appellants at 11-12.

¶ 14 We find the Creazzos' analysis of this point unconvincing, as it requires that we accept as true an inference of design defect based merely on the numbers of complaints logged concerning Itrel 3 units and the fact that the pathology report showed broken lead wires. The Creazzos fail to identify any portion of the report that expressly supports their interpretation of it. The only express language they cite, reproduced above, is no more indicative of a design defect than of a manufacturing defect. Moreover, the numbers of complaints they cite concerning the devices invite rank speculation and are not demonstrably relevant to the failure of the individual unit at issue here. Indeed, the expert's report, while it opines that broken leads and/or leadwires cause the Itrel 3 to malfunction, says nothing to establish why those components themselves malfunctioned. Accordingly, we find no merit in the Creazzos' assertion that the trial court erred in refusing to accept their expert report as substantiation for a theory of design defect as opposed to manufacturing defect. Thus, the Creazzos' third question does not provide grounds for relief.

¶ 15 In support of their fourth question, the Creazzos challenge the trial court's determination that their strict liability claim is barred by Restatement 2d of Torts section 402A, comment k. Brief for Appellants at 12-13. Comment k excludes certain products from the definition of "unreasonably dangerous" used in section 402A on the basis that they are incapable of being made safe for their intended use, but are useful nonetheless. The express language of the comment provides as follows:

> *k. Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an

> apparently useful and desirable product, attended with a known but apparently reasonable risk.

RESTATEMENT (SECOND) OF TORTS, § 402A cmt. k.

¶ 16 In this case, the trial court applied this section to the Itrel 3, citing our Supreme Court's decision in ***Hahn v. Richter***, 673 A.2d 888, 890-91 (Pa. 1996), in which the high court adopted comment k, to conclude that strict liability could not be applied to prescription drugs where adequate warnings of the drugs' potential risks had been provided. In applying comment k here, the trial court reasoned that given the potential utility of the Itrel 3, no significant distinction can be drawn between the device and the drug upon which the Supreme Court based its decision in ***Hahn***. Trial Court Opinion, 6/3/05, at 8. The court concluded accordingly that strict liability could not be a basis for liability in this case. Trial Court Opinion, 6/3/05, at 8. The Creazzos contend that the trial court misconstrued ***Hahn***, and that comment k does not apply to medical devices because the comment text does not mention them. Brief for Appellants at 13. They cite no authority, however, for so restrictive an interpretation either of comment k or of ***Hahn***, nor do they provide significant analysis of the language they seek to apply. We find no reason why the same rational applicable to prescription drugs may not be applied to medical devices. Accordingly, we conclude that the Creazzos have

failed to demonstrate reversible error in the trial court's treatment of this issue. Their fourth question is without merit.

¶ 17 In their fifth question, the Creazzos challenge the trial court's application of the "learned intermediary" doctrine, which allows that where a manufacturer provides adequate warning of the risks attendant to an unavoidably dangerous product to a learned intermediary, such as the Creazzos' physician, failure to provide warnings to the end user is not grounds for liability. Brief for Appellants at 13-14. As above, the trial court supported its decision by likening the Itrel 3 to prescription medication, in the context of which this Court has previously applied the learned intermediary doctrine. Trial Court Opinion, 6/3/05, at 6-7 (citing ***Taurino v. Ellen***, 579 A.2d 925, 927 (Pa. Super. 1990). Again, however, the Creazzos' argument presents only a facile conclusion that because existing cases have not applied the learned intermediary doctrine in that context, there exists no basis for its application here. We find this rationale unsubstantiated and unconvincing. To the extent that our court's have previously applied the doctrine in relation to prescription drugs, we find no compelling reason why it may no be so applied here. Accordingly, we find no merit in the Creazzos' fifth question.

¶ 18 Finally, in their sixth question, the Creazzos argue, in less than ten lines, that their product liability claim is not precluded under the Medical

Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C § 360k(a). Brief for Appellants at 15. We find no reference to this claim in the trial court's opinion and order; nor do the Creazzos provide citation to any point in the record where they offered it. Consequently, we can only conclude that they raise this argument for the first time here. We therefore deem it waived and will not consider it further. ***See Devine v. Hutt***, 863 A.2d 1160, 1170 (Pa. Super. 2004) (concluding that argument in opposition to summary judgment not raised before the trial court will be deemed waived and cannot be presented for the first time on appeal).

¶ 19 For the foregoing reasons, we affirm the trial court's order granting summary judgment in favor of Medtronic.

¶ 20 Order granting summary judgment **AFFIRMED**.