

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

DOUGLAS KAYE,

Plaintiff,

vs.

SYNTHES (U.S.A.),

Defendants.

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CIVIL ACTION NO. H-05-2809

MEMORANDUM AND RECOMMENDATION

This product liability personal injury case is before the court on defendant Synthes (U.S.A.)’s motion to strike plaintiff’s experts (Dkt. 31) and motion for summary judgment (Dkt. 32).¹ Having considered the parties’ submissions and all matters of record, the court recommends that Synthes’s motion to strike be granted, its motion for summary judgment be denied, and this case be set for trial.

Background

Plaintiff Douglas Kaye was seriously injured in a skiing accident in March 2003. He broke his left clavicle in the accident. When Kaye’s clavicle did not heal on its own, an orthopedic surgeon, Dr. Timothy Sitter, surgically implanted a 6-hole bone fixation plate to assist in the healing process. Kaye is a thin man, and the plate created an irritating bump on his shoulder. On June 23, 2003, Dr. Sitter performed a second surgery to implant the smaller,

¹ The district court referred this case to this magistrate judge for pre-trial management (Dkt. 8).

thinner profile bone plate manufactured by Synthes that is the subject of this suit. During the June 2003 operation, Dr. Sitter also performed an osteotomy, a procedure in which the surgeon cuts and realigns the bone. A few days after the surgery, Kaye returned to work as a manual scissor sharpener.

On July 28, 2003, Kaye moved a refrigerator away from the wall to clean behind it. A few hours later, while attending a friend's wedding, he began to feel pain. The next day he went to Dr. Sitter's office and got x-rays. The x-rays revealed that the Synthes plate was broken. Dr. Sitter promptly performed a third surgery to remove and replace the broken plate. The removed broken plate is lost and is not available for observation or testing. A contemporaneous operating room note indicates that the broken plate was sent to Synthes. An attending nurse, Valerie Vaughan, testified that she remembers the Synthes representative who was present during the surgery, John Adams, taking possession of the plate. John Adams denies taking possession of the plate, and another Synthes representative denies receiving it in the mail.

Dr. Sitter subsequently performed a fourth surgery to remove the plate that was implanted in July 2003. Kaye has had no further surgeries or complications from his clavicle. Kaye is suing Synthes for damages related to his third surgery in which the broken plate was removed and replaced.² Kaye has asserted causes of action based on negligence, strict products liability, negligent failure to warn, and breach of warranty.

² Kaye is not suing for lost wages or for future medical care.

Synthes moves to strike the experts Kaye designated to testify regarding the cause of the plate failure because he has not served expert reports. Synthes moves for summary judgment on the grounds that Kaye has no evidence of a manufacturing, marketing, or design defect, and cannot prove a causal link between a product defect and his damages.

Analysis

A. Motion to Strike

Kaye timely designated Salah Mahmoud PE, PhD and William B. Aiken, PE as experts in this case. Kaye's deadline for serving his experts's reports was June 27, 2006. Discovery was closed September 29, 2006. Plaintiff does not deny that he has not prepared or served expert reports from Mahmoud or Aiken.

Kaye designated Mahmoud and Aiken to testify regarding the failure mechanism for the plate. Kaye anticipated that the experts would photograph the plate and record their visual observations of it, perform nondestructive testing using magnetic particle inspection, examine the fracture surfaces under optical and scanning electron microscopes, and conduct metallurgical testing. Without the plate none of this can be done.

The reason for Kaye's failure to prepare and serve expert reports is understandable, but Mahmoud and Aiken cannot testify as to work they have not done, opinions they have not formed, and reports that have not been served on Synthes. Therefore, Synthes's motion to strike the designation of Mahmoud and Aiken is granted.³

³ If the plate shows up before trial, and there is a very good, plausible reason why it was not
(continued...)

B. Motion for Summary Judgment

1. Summary Judgment Standards

Summary judgment is appropriate if no genuine issues of material fact exist, and the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c). The party moving for summary judgment has the initial burden to prove there are no genuine issues of material fact for trial. *Provident Life & Accident Ins. Co. v. Goel*, 274 F.3d 984, 991 (5th Cir. 2001). Dispute about a material fact is “genuine” if the evidence could lead a reasonable jury to find for the nonmoving party. *In re Segerstrom*, 247 F.3d 218, 223 (5th Cir. 2001). “An issue is material if its resolution could affect the outcome of the action.” *Terrebonne Parish Sch. Bd. v. Columbia Gulf Transmission Co.*, 290 F.3d 303, 310 (5th Cir. 2002)

If the movant meets this burden, “the nonmovant must go beyond the pleadings and designate specific facts showing that there is a genuine issue for trial.” *Littlefield v. Forney Indep. Sch. Dist.*, 268 F.3d 275, 282 (5th Cir. 2001) (quoting *Tubacex, Inc. v. M/V Risan*, 45 F.3d 951, 954 (5th Cir. 1995)). If the evidence presented to rebut the summary judgment is not significantly probative, summary judgment should be granted. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249-50 (1986). In determining whether a genuine issue of material fact exists, the court views the evidence and draws inferences in the light most favorable to the nonmoving party. *Id.* at 255.

³ (...continued)
found sooner, Kaye may ask the court to reconsider this ruling and seek whatever relief he feels is appropriate.

2. Products Liability Law and Kaye's claims

Texas law applies to this product liability case that is before the court based on diversity jurisdiction. *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938). A product may be unreasonably dangerous for purposes of a strict products liability action because of defects in marketing, design, or manufacturing. *American Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 426 (Tex. 1997). Kaye bears the burden of proving that the marketing, design, or manufacturing defect caused his injuries. *Id.*; *Prudential Ins. Co. v. Jefferson Assoc. Ltd.*, 896 S.W.2d 156, 161 (Tex. 1995).

a. Marketing Defect

In order to prevail on his claim that the plate had a marketing defect, Kaye must prove that Synthes's failure to provide adequate instructions and warnings rendered the plate unreasonably dangerous. *Grinnell*, 951 S.W.2d at 426. A manufacturer generally has a duty to warn if it knows or should know about the dangers of its product. *Id.* However, no duty to warn arises if the dangers associated with a product are matters of ordinary common knowledge. *Id.* A product is unreasonably dangerous if it is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *Id.* at 426-27 (citing the Restatement (Second) of Torts § 402A cmt. i (1965)).

In the context of a prescriptive medical device, such as the bone plate at issue here, the "learned intermediary" doctrine applies. Under the learned intermediary doctrine, the

manufacturer's duty to warn is fulfilled by giving warnings to the consumer's physician, who based on training and experience, decides what warnings to pass along to his patient. However, the learned intermediate doctrine does not absolve a manufacturer from liability; the manufacturer's warnings to the physician must still be adequate. *Wyeth-Ayerst Labs. v. Medrano*, 28 S.W.2d 87, 91 (Tex. App.—Texarkana, 2000, no pet.).

Synthes warned in the package insert that was available to Dr. Sitter that the subject plate “cannot withstand activity levels or loads equal to those placed on normal healthy bone,” “was not designed to withstand the unsupported stress of full weightbearing or load-bearing,” and “can break when subjected to the increased loading associated with delayed union or non-union” of the fractured bone.⁴ Dr. Sitter testified that he was aware at the time he implanted the plate that it was not designed to withstand the unsupported stress of full loading. However, he does not consider moving a refrigerator on castors to constitute full load bearing activity for an upper extremity.⁵

Kaye argues that Synthes should have given warnings indicating that the level of activity associated with moving a refrigerator on castors could cause the plate to break. However, Kaye has not offered any evidence of what level of activity that would be. Dr. Sitter is not qualified, nor did he purport, to give an opinion as to the forces involved in

⁴ Labbé aff., defendant's exhibit 2, at exhibit C.

⁵ Sitter dep., defendant's exhibit 1, at 120-21. The record is not well-developed on the facts surrounding the refrigerator move. Dr. Sitter assumes that the refrigerator was on castors.

moving a refrigerator. But even if he were, there is no evidence in the current record that the refrigerator Kaye moved was in fact on castors, how much it weighed, or numerous other factors Dr. Sitter acknowledged bear on the issue.⁶ Moreover, Kaye has not presented any evidence of what warnings or instructions Dr. Sitter gave him at the time the plate was implanted, so he cannot prove that his actions were permitted under the restrictions and warnings Dr. Sitter provided.⁷ The court recommends that Kaye's claims based on Synthes's failure to issue adequate warnings be dismissed.

b. Design Defect

In order to prevail on his claim that the plate possessed a design defect that caused him harm, Kaye must prove that the plate was unreasonably dangerous as designed, taking into consideration the utility of the product and the risk involved in its use. *Grinnell*, 951 S.W.2d at 432. Whether a seller has breached this duty, *i.e.* whether a product is unreasonably dangerous, is a question of fact. *Id.* The types of evidence admissible in a design defect case include: “(1) the utility of the product to the user and to the public as a whole weighed against the gravity and likelihood of injury from its use; (2) the availability of a substitute product which would meet the same need and not be unsafe or unreasonably expensive; (3) the manufacturer's ability to eliminate the unsafe character of its product

⁶ Sitter dep., at 87-89.

⁷ Kaye's ability to present evidence on this claim is not hindered by the loss of the plate. There does not appear to be any dispute over what warnings were contained in the package insert, and nothing prevented Kaye or Dr. Sitter from testifying as to precisely what warnings Kaye was given.

without seriously impairing its usefulness or significantly increasing its costs; (4) the user's anticipated awareness of the dangers inherent in the product and the ability to avoid those dangers because of general public knowledge or the obvious condition of the product, or of the existence of suitable warnings or instructions; and (5) the expectations of the ordinary consumer." *Id.* Liability for a design defect may attach even if the defect is apparent. *Id.* at 433.

Kaye has presented no evidence that the subject plate suffered from a design defect.⁸ Kaye has not even identified or offered a description of the alleged design defect (was is too thin? too thick? too short? too long? too wide? too narrow? made of an inappropriate material?). Kaye has presented no evidence that a safer alternative design is available, or that the utility of the plate does not justify the risks inherent in using it. In fact, Kaye's only expert, Dr. Sitter, testified that he believes the plate was an appropriate choice for the care and treatment of Kaye, that he continues to use the type of plate at issue here, and that such a plate "remains an appropriate choice for certain patients."⁹ Dr. Sitter's testimony is

⁸ Kaye's ability to develop and present evidence of a design defect is not hindered by the loss of the plate. Experts could have examined any plate of the exact same kind to offer opinions as to the reasonableness of the design and specifications for the plate, they did not have to examine the actual plate that was used in Kaye.

⁹ Sitter dep., at 37.

consistent with the opinion of Synthes's expert, Dr. Labbé, who testified that he extensively uses the type of plate at issue here and has no doubts as to the plate's design.¹⁰

The court recommends granting Synthes summary judgment on Kaye's claims based on an alleged design defect.

c. Manufacturing Defect

In order to prevail on his claim that the plate had a manufacturing defect that lead to his injury, Kaye must prove that the plate deviated in construction or quality from specifications or planned output in a manner that rendered it unreasonably dangerous. *Grinnell*, 951 S.W.2d at 434. The common knowledge defense does not apply to this type of claim because a user does not anticipate a manufacturing defect. *Id.*

Kaye argues that he should be allowed to go to trial on his manufacturing defect claim based on circumstantial evidence. Kaye further argues that he is entitled to an inference of a defect due to Synthes's spoliation of evidence. Synthes argues that Dr. Sitter's testimony is something less than sufficient circumstantial evidence to create any fact issue as to Kaye's manufacturing defect claim. Synthes also takes issue with Kaye's argument that it is entitled to an inference based on spoliation of evidence.

Kaye relies on Dr. Sitter's testimony that he was surprised that the plate broke where it did. Dr. Sitter testified that his experience and training lead him to expect that a plate would break at the fracture site where stresses are concentrated, but in this case the plate

¹⁰ Labbé aff., at 4.

broke laterally to the fracture itself.¹¹ Dr. Sitter further testified that moving a refrigerator would not cause the breakage that occurred here because that kind of stress would cause the screws to rip out of the bone with the plate intact.¹² Dr. Sitter cannot explain why the plate broke where it did.¹³

Synthes has presented expert testimony from Dr. Marc Labbé that plates can and do break even where there is no design or manufacturing defect. Also, plates generally break in the area of the screw holes, as did the plate at issue here.¹⁴ This testimony is consistent with that of Dr. Sitter. Labbé does not offer an opinion to counter Dr. Sitter’s position that plates usually break in the area of the fracture.

Dr. Labbé also does not offer an opinion that moving the refrigerator caused the plate to break.¹⁵ He says only that activities such as sharpening scissors and moving a refrigerator “can place significant loads on the clavicle and, in this case, the plate.” Because a manufacturing defect could certainly cause a plate to break, Labbé’s affidavit is not conclusive evidence that a manufacturing defect did not cause the plate to break in this case.

¹¹ Sitter dep., at 42-43; *id.* at 59 (“Where this one broke didn’t necessarily fit the usual patters.”); *id.* at 115 (the location of the plate break “does not quite make sense”).

¹² Sitter dep., at 43-44; *id.* at 91 (“an acute full load typically doesn’t break the plate. The screws pull out of the bone, because that’s the weak link.”).

¹³ *Id.*, at 63, 92, 115.

¹⁴ Labbé aff., ¶¶ 7-8.

¹⁵ Labbé’s affidavit and expert report indicate that the break was to due to fatigue from being “repetitively bent or undergoing repeated loading over time,” not due to one time acute stress. Labbé aff., ¶ 7 and exhibit B, at 2.

In fact, Labbé’s expert report does not purport to give an opinion as to the existence of a manufacturing defect, but states “It is my opinion that the plate fracture is due to fatigue and not due to *design* defect.”¹⁶

Synthes has also presented the expert testimony of Dr. Jack Lemons. Like Labbé, Lemons opines that “plates can and do occasionally break without being in any way defective.”¹⁷ Dr. Lemons is of the opinion that the plate broke “due to a combination of many loading cycles leading to localized stress and strain hardening within the plate followed by a high load that induced local stresses within the plate that exceeded the strength of the plate.” Lemons further says that such breaks generally occur at screw hole locations, as here.¹⁸ However, like Labbé, Lemons does not address the significance of the break occurring laterally to the bone fracture. Lemons concludes that “in all probability, this plate system was not defective due to design, metallurgy, or manufacturing.”¹⁹ Of course, this testimony does not rule out the possibility that the plate in this case broke because it was defective. Synthes’s experts are no more able than Kaye’s were to offer a competent opinion as to the failure mechanism of the subject plate without examining the plate itself.

¹⁶ Labbé aff., at exhibit B, p. 2 (emphasis added).

¹⁷ Lemons aff., defendant’s exhibit 3, ¶ 6.

¹⁸ *Id.* ¶ 5.

¹⁹ *Id.* ¶ 7.

The court recognizes that the burden to prove the existence of a defect and causation rests on Kaye. While the circumstantial evidence in this case is hardly overwhelming, the court concludes that Dr. Sitter's testimony is sufficient to create a fact issue and avoid summary judgment on Kaye's manufacturing defect claim.

There is clearly a fact issue as to whether the broken plate was returned to Synthes after Kaye's July 2003 surgery. Dr. Sitter does not know what happened to the plate, but testified that it is his usual policy not to give a broken plate back to a patient, but to return it to the manufacturer.²⁰ Synthes argues that it instructed Dr. Sitter not to send it the plate because Kaye had already hired a lawyer. But the letter Synthes references was written and mailed on July 30, the same day as the surgery.²¹ There is no way the hospital, much less the personnel in the operating room, could have known about it at the time. Synthes also characterizes Valerie Vaughan's recollection as vague. There is nothing vague about the statement "[a]fter the procedure was over I remember John Adams taking possession of the plate."²²

The court is unwilling to recommend denying Kaye his day in court where his inability to present more evidence may be Synthes's fault and not his own. At trial, the district court may exercise its discretion to instruct the jury as to evidence spoliation and adverse

²⁰ Sitter dep., at 65, 71.

²¹ Temple aff., defendant's reply exhibit 2, ¶ 6.

²² Vaughan aff, plaintiff's exhibit 2.

inferences, or not.²³ But this court recommends that resolution of Kaye's claims based on an alleged manufacturing defect await trial.

d. Warranties of Merchantability and Fitness

Kaye did not respond to Synthes's motion regarding his breach of warranty claim. Those claims should be dismissed.

To the extent Kaye's breach of warranty claim is based the theories of defective design and defective warnings, the claim also fails for the same reasons as his strict liability claims based on those theories. *See Smith v. Louisville Ladder Corp.*, 237 F.3d 515, 518 (5th Cir. 2001).

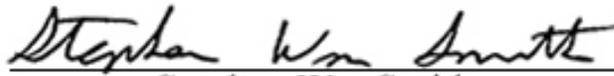
Conclusion

For the reasons discussed above, the court orders that Synthes's motion to strike (Dkt. 31) is granted, and recommends that Synthes's motion for summary judgment (Dkt. 32) be granted in part and denied in part, and that this case be set for trial.

²³ A district court has discretion to admit evidence of spoliation and to instruct the jury on adverse inferences. *United States v. Wise*, 221 F.3d 140, 156 (5th Cir. 2000).

The parties have ten days from service of this Memorandum and Recommendation to file written objections. Failure to file timely objections will preclude appellate review of factual findings or legal conclusions, except for plain error. *See* FED. R. CIV. P. 72.

Signed at Houston, Texas on May 11, 2007.



Stephen Wm Smith
United States Magistrate Judge