



IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

WAYNE V. JASKE,)	
)	
Plaintiff,)	
)	
vs.)	No. 03 C 2939
)	
ZIMMER, INC.,)	
)	
Defendant.)	

MEMORANDUM OPINION AND ORDER

Plaintiff Wayne Jaske had his left knee replaced with a prosthesis to alleviate recurring pain. When the prosthesis failed, he filed suit against the manufacturer, defendant Zimmer, Inc., and alleged strict products liability and negligence. On March 19, 2008, we granted defendant's motion to exclude the testimony of two of plaintiff's experts, Donald E. Duvall, PhD, and Riad Gobran, PhD, and also struck the affidavit of another of plaintiff's experts, Lyle R. Jacobs, PE. Plaintiff now asks us to reconsider our decision. For the following reasons, we grant plaintiff's motion subject to limitations outlined in this opinion.

BACKGROUND

At issue here is a Miller Galante II prosthetic knee ("MG II") manufactured by defendant. In 1995, plaintiff had an MG II implanted in his left knee. By the beginning of 2002, he began to experience activity-related knee pain, and in June 2002 he underwent implant replacement surgery. At this time, his surgeon discovered that the metal tibial base plate of the MG II was loose and had fractured. Plaintiff contends that either a manufacturing or design defect in the plastic tibial articulating surface ("TAS") caused the tibial base plate

to fracture.¹

In our earlier opinion we rejected defendant's contention that Duvall and Gobran, both experts in polymer science, were not qualified to offer any opinions about the MG II. However, we had concerns that the test used as the basis for their opinions was not reliable. Duvall performed a Fourier Transform Infrared Spectroscopy ("FTIR") on the MG II after it was explanted from plaintiff in order to determine levels of oxidation in the ultra high molecular weight polyethylene ("UHMWPE") that made up the TAS. We had two concerns regarding the test. First, whether the results of the test were skewed because lipids and proteins from plaintiff's body had permeated the TAS. Second, we noted that if the test results were accurate, they did not determine when the oxidation took place. Because we believed that the FTIR formed the foundation of the testimony of Duvall, and in turn Gobran and Jacobs, we excluded the testimony and affidavit. We, however, indicated that it was possible that plaintiff would be able to supplement his filing and alleviate our concerns, and he has accepted our invitation to do so.

ANALYSIS

This case, like most cases, comes down to two competing theories. Plaintiff contends that the plastic TAS oxidized as a result of the gamma irradiation process used to sterilize the MG II after manufacture. That oxidation caused the TAS to become brittle, and through use and wear it became severely degraded and uneven. The deformation of the TAS then caused stress on the tibial base plate that over time caused it to fracture. As support for his theory,

¹ Total knee replacement, the procedure plaintiff underwent, involves the replacement of three bone surfaces with artificial components: the lower end of the femur (thigh bone); the top surface of the tibia (shin bone); and the back surface of the patella (knee cap). The MG II system consists of a metal femoral replacement component, a metal tibial base plate attached to a plastic tibial articular surface that covers the tibia, and a dome-shaped patellar component.

plaintiff proposes to offer the following expert opinions. Duvall will testify to the existence and potential causes of oxidation in the TAS (plf's mem. in opp. to def.'s mo. to exclude (dkt 58) at 10). Gobran will testify that the most likely cause of oxidation in the TAS is the gamma irradiation sterilization process employed by defendant (*id.* at 14). Jacobs, a registered professional engineer specializing in metallurgical science, will opine that the forces that caused the fracture of the tibial base plate originated from the TAS (*id.* at 19-20). Finally, Lawrence D. Weis, MD, plaintiff's medical doctor, will testify that failures such as this are rare, and that plaintiff's personal characteristics, by themselves, cannot explain the cause of the failure (*id.* at 18-19.)

Defendant proffers a different reason for the fracture. According to its expert, plaintiff's weight and activity level caused bone resorption, or a breakdown of the bone in the tibia. He contends that the resorption of the underlying bone caused stress on the tibial base plate, which ultimately caused it to fracture.

Which theory is correct? Now is not the appropriate time to make that determination. Our present task is to determine only if the proffered expert testimony is relevant and reliable. *See Fed. R. Evid. 702; Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993) (explaining that the court's role is that of gatekeeper, to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable"). In order to make this determination, we consider "whether the expert is qualified in the relevant field and whether the methodology underlying the expert's conclusions is reliable." *Zelinski v. Columbia 300, Inc.*, 335 F.3d 633, 640 (7th Cir. 2003).

Defendant argues, as it did in the motion to exclude Duvall and Gobran's testimony, that they are not qualified to offer opinions in this matter because they have no experience in

physical anatomy, biomechanics, or orthopedics. As explained in our original opinion, Duvall and Gobran are not offering an opinion in those three areas. Instead, they are testifying to matters of polymer science, and after we examined their credentials we found that they are qualified to render such opinions. We also note that the proposed testimony about the oxidation level of the UHMWPE is relevant to plaintiff's proffered cause of the MG II's failure. Our previous concern was whether the underlying methodology Duvall and Gobran used to form their opinion was sound.

The analysis that we undertake in order to determine reliability is flexible, depending on the particular case at hand. Kumho Tire Co. Ltd. v. Carmichael, 526 U.S. 137, 142 (1999). Daubert provides a number of non-exclusive factors to consider, including whether the methodology (1) has been tested, (2) has been subjected to peer review and publication, (3) has a potential or known rate of error, and (4) has been accepted by the relevant professional community. 509 U.S. at 593-94. The 2000 Advisory Committee's Notes to Rule 702 suggest additional factors, including:

(5) whether "maintenance standards and controls" exist; (6) whether the testimony relates to "matters growing naturally and directly out of research they have conducted independent of the litigation," or developed "expressly for purposes of testifying"; (7) "[w]hether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion"; (8) "[w]hether the expert has adequately accounted for obvious alternative explanations"; (9) "[w]hether the expert is being as careful as he would be in his regular professional work outside his paid litigation consulting"; and (10) "[w]hether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give."

Fuesting v. Zimmer, Inc., 421 F.3d 528, 534-35 (7th Cir. 2005).

Our first concern was that lipids and proteins from plaintiff's body may have skewed the FTIR results. Originally, plaintiff offered us nothing but Duvall's deposition testimony to allay our concern. Plaintiff now informs the court that any biological material present on

the UHMWPE would absorb the infrared spectrum used in the FTIR at a different frequency than oxidized polyethylene, and that the FTIR is the accepted standard of the American Society of Testing and Manufacturing for this purpose.² *See* ASTM F2102, Standard Guide for Evaluating the Extent of Oxidation in Ultra-High-Molecular-Weight Polyethylene Fabricated Forms Intended For Surgical Implants, (2006). This demonstrates that the FTIR test has acceptance in the professional community as a method to determine the level of oxidation in surgical implants made from UHMWPE. The effects of infrared spectroscopy on biological material, such as lipids and proteins, has been well studied as well. *See, e.g.*, Barbara Stuart, Biological Applications of Infrared Spectroscopy, § 6.2 (Proteins and Peptides) - § 6.3 (Lipids), (John Wiley & Sons 1997). Thus we conclude that the FTIR test is a reliable method to provide the level of oxidation present in the UHMWPE. To the extent that the parties disagree on how to interpret these results, that disagreement is a matter best left for trial. *See* Smith v. Ford Motor Co., 215 F.3d 713, 719 (7th Cir. 2005).

That is not the end of the inquiry, however. We noted in our earlier opinion that an FTIR test measures the amount of oxidation present in a substance only at the time the test is conducted. The test cannot provide historical readings and plaintiff has offered no form of regression analysis based on the current test results to pinpoint when the oxidation occurred. Because our understanding was that Duvall and Gobran's theory that the oxidation began immediately after sterilization was based on the results of the FTIR, they needed to provide more than their own deposition testimony as support.

Plaintiff's latest submission clarifies the matter. Duvall and Gobran's theory is

² The American Society for Testing and Materials (ASTM) is a not-for-profit organization that provides a global forum for the development and publication of voluntary consensus standards for various materials, products, systems, and services in over 130 varied industry areas.

independent of the results of the FTIR. Instead of relying on the FTIR to arrive at their theory, the FTIR simply provides support for it. In other words, the results of the FTIR are consistent with the theory. The theory that gamma irradiation sterilization in air causes oxidation in UHMWPE has been recognized for some time in the scientific community. *See, e.g.,* Thierry A. Blanchette & Brian R. Burroughs, "Numerical Oxidation Model for Gamma Radiation-Sterilized UHMWPE: Consideration of Dose-Depth Profile," Journal of Biomedical Materials Research, 58(6), 684-93 (2001). Defendant's expert disagrees with the theory. While that shows that the theory is not universally accepted, universal acceptance is not a prerequisite for the admission of scientific testimony.

We, however, agree with the defendant that the opinions of Duvall and Gobran should be limited. Plaintiff asserts that Duvall and Gobran will be asked to testify on very limited matters, and we have limited our examination of their proposed testimony accordingly. Therefore, Duvall and Gobran's testimony will be limited to the existence, characteristics, and potential causes of oxidation in the TAS.

We turn now to the affidavit of Jacobs, which requires a different analysis. We originally struck Jacobs' affidavit because it relied on Duvall and Gobran's opinions, which at that time had been excluded. Because we now allow their testimony, we must examine defendant's alternative contention that Jacobs' most recent affidavit is untimely and contradicts his earlier deposition testimony.

Jacobs' affidavit was filed on September 19, 2007. In that affidavit he, for the first time, offered an opinion that oxidation of the TAS caused the forces on the tibial base plate that led to its fracture. In his September 18, 2002, expert report, and in his August 4, 2005, deposition, he expressed no opinion as to the cause of the forces on the tibial base plate and

ultimate fracture. What changed in the interim? Plaintiff contends that Jacobs received new information: the final opinion of Duvall and the knowledge that the TAS is affixed to the top surface of the tibial plate. Defendant argues that its motion for summary judgment, filed July 27, 2007, prompted Jacobs' new opinion. In defendant's view, plaintiff realized that he had no evidence of the causal link between the oxidation of the UHMWPE and the fracture of the tibial base plate, so he submitted this new opinion of Jacobs to make that connection.


The timing of the affidavit is troubling. In his defense of the affidavit, plaintiff asserts that Jacobs did not receive the new information until after his deposition. With regard to the position of the TAS in relation to the tibial base plate, that information is at the heart of the design of the MG II and was available since the beginning of this case. Indeed, a description of how these parts attach is included in Duvall's February 16, 2005, report. In any event, Duvall issued his final report in December 2005, and plaintiff offers us no reason to explain why Jacobs waited over 20 months to submit his new opinion.

However, the defendant's characterization of this new information as "inconsistent" with Jacobs' deposition testimony is not entirely accurate. It is true that a party cannot attempt to create a genuine issue of material fact through the use of "[s]elf-serving affidavits without factual support in the record." Patterson v. Chicago Ass'n for Retarded Citizens, 150 F.3d 719, 724 (7th Cir. 1998). But the focus of this analysis does not rest entirely on the timing of the affidavit. Also important is the reliability of the evidence. See Unterreiner v. Volkswagen of American, Inc., 8 F.3d 1206, 1210-11 (7th Cir. 1993). While it is true that at his deposition Jacobs testified that he had planned to offer no opinion as to the cause of the forces on the tibial base plate (Jacobs dep. at 71:13-72:14), there is factual support in the record for his revised testimony, and at least a portion of that support (Duvall's final report) was not

available to him at the time of his prior deposition. We hold that although the timing of the affidavit is suspect, Jacobs should not be foreclosed from expressing opinions based on the newly acquired information.³

CONCLUSION

For the foregoing reasons, plaintiff's motion for reconsideration is granted as outlined above.



JAMES B. MORAN
Senior Judge, U. S. District Court

Jan 20, 2009

³ Defendant indicates in a footnote that, should we reject its attempt to strike Jacobs's affidavit on timeliness grounds, it will challenge the opinion contained in the affidavit on Daubert grounds because Jacobs is not qualified to render an opinion on plastics. While that is certainly defendant's right, at present we fail to see how such a challenge would be successful. The opinion contained in the affidavit is not about the characteristics of plastics, rather it is about how an uneven surface caused stress to be placed on the metal tibial plate, which ultimately caused the fracture of the plate. Jacobs's engineering background specializing in metallurgical consulting which includes the evaluation of medical and orthopaedic devices appears to qualify him to offer such an opinion.