CASE STUDY PREPARED FROM ORIGINAL PUBLISHED OPINION

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Garrett v Howmedica Osteonics Corporation (03/2013)

Products Liability; Summary Judgment; Expert Declarations

Plaintiff was treated for cancer in his left femur, eventually receiving a prosthetic to replace the middle portion of the bone in 2007. Defendants allegedly participated in the design or manufacture of the prosthesis. In 2009, Plaintiff reported pain in his thigh, and upon investigation by his orthopedist, a fatigue fracture was detected. A second surgery was required to replace the first prosthesis, leading to a considerably longer recovery time than the first surgery. Plaintiff filed suit against several defendants, including Howmedica and Stryker, alleging strict products liability based on manufacturing and design defects, failure to warn, breach of express warranty and negligence.

Howmedica and Stryker filed a summary judgment motion in March 2011, arguing that plaintiff could not establish essential elements of his claim. Their expert's declaration opined the prosthesis was not defective in design or manufacture, and that the fracture occurred from normal human activity that exceeded the load the product could bear over time. Plaintiff opposed, filing a declaration by Lawrence Kashar, a metallurgist, stating that he had determined through destructive testing that the portion of the prosthesis that fractured was softer than the minimum required hardness in two of the three ASTM specifications that cover Cobalt-28% Chromium-6% Molybdenum alloy for use as an implant material, and less than the expected hardness of the third specification. Kashar stated that (1) hardness was an indication of strength, (2) a portion of the prosthesis was made of a titanium alloy and not the alloy specified, and (3) contained a polymeric material that should not have been in the prosthesis. Based on these anomalies, Kashar stated the device was defective in manufacture and/or design, and that such defects caused the failure.

Defendants objected to portions of the declaration on lack of expert qualification, lack of explanation or reasoning to support an expert opinion, and relevance. The trial court agreed with defendants, finding plaintiff had no evidence the prosthesis was defective. The mere fact the product failed was insufficient to establish liability, and plaintiff could not prove a design or manufacturing defect. The negligence and warranty claims were also lacking any evidentiary basis. The trial court found the Kashar declaration failed to satisfy the requirements for admissibility of expert opinion because it lacked a reasoned analysis and an adequate foundation to support the opinions he expressed. The court sustained objections to the challenged portions of the declaration. Absent a triable issue of fact, the summary judgment was granted as to Howmedica and Stryker. Plaintiff filed a timely appeal.

The Second District Court of Appeal noted a product is defective in design if the benefits of the design do not outweigh the risk of danger inherent in the design (risk-benefit test), or if the product fails to perform as safely as an ordinary consumer would expect when used in an intended or reasonably forseeable manner (consumer expectations test). (*Barker v Lull Engineering Co.* (1978) 20 Cal.3d 413) A later Appellate Court opinion found that implanted prescription medical devices, like prescription drugs, are available only through the services of a physician. Like prescription drugs, harm to users of implanted medical devices is unavoidable. In the interest of the development, availability and affordability of implanted medical devices, an exemption from design defect liability for all implanted medical devices was justified. (*Hufft v Horowitz* (1992) 4 Cal.App.4th 8)

Accordingly, the Second DCA in this appeal held the public interest in the development, availability and affordability of implanted medical devices justifies an exemption from design defect strict products liability for all implanted medical devices that are available only through the services of a physician. (*Artiglio v Superior Court* (1994) 22 Cal.App.4th 1388) As such, Howmedica and Stryker could not be strictly liable for a design defect, and the trial court ruling on this issue was correct.

The Justices then turned to the manufacturing defect issue where the trial

court stated the Kashar declaration lacked a reasoned analysis and failed to include a description of the testing. Evidence Code section 801 (b) states that a court must determine whether the matter that the expert relies on is of a type that an expert reasonably can rely on "in forming an opinion upon the subject to which his testimony relates." The Court construes this to mean that the matter relied on must provide a reasonable basis for the particular opinion offered, and that an expert opinion based on speculation or conjecture is inadmissible. (*Sargon Enterprises, Inc. v University of Southern California* (2012) 55 Cal.4th 747)

The trial court's gatekeeping responsibility with respect to expert testimony is governed not only by section 801(b), but also by section 802, which allows the trial court to inquire into the reasons for an expert's opinion and to exclude expert opinion testimony if it is based on reasons unsupported by the material on which the expert relies. (*Sargon*, p. 771) Courts must also be cautious in excluding expert testimony. The trial court's gatekeeping role does not involve choosing between competing expert opinions. The high court warned that the gatekeeper's focus must be solely on principles and methodology, not on the conclusions they generate. (*Daubert v Merrell Dow Pharmaceuticals, Inc.* (1993) 509 U.S. 579) The court must not weigh an opinion's probative value or substitute its own opinion for the expert's opinion. Rather, the court must simply determine whether the matter relied on can provide a reasonable basis for the opinion or whether that opinion is based on a leap of logic or conjecture.

The goal of the trial court gatekeeping is simply to exclude clearly invalid and unreliable expert opinion. It must assure the expert brings to the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field. (*Sargon*, p. 772) In this case, plaintiff's expert, Mr. Kashar, declared that he conducted extensive examinations of the prosthetic device, including visual exam, scanning electron microscopy, x-ray radiography, fluorescent dye penetrant exam and destructive testing such as hardness testing, microstructural analysis and chemical analysis. He declared that he had determined from these examinations that the minimum required hardness in two of the three ASTM specifications covering the alloy for use in an implant were absent and the third test was less than the expected hardness.

The Justices opined that the failure by Kashar to describe particular testing

processes that he used to arrive at his conclusions, and his failure to more particularly describe the results of the testing do not in any manner indicate his conclusions are speculative or lack a reasonable basis. The failure to expressly state that the prosthesis should have complied with the ASTM specifications for Cobalt-28% Chromium-6% Molybdenum alloy and his failure to expressly state that the purported defect was a cause of the device's failure are immaterial because those matters are readily inferable from the facts and opinion expressly stated.

Defendants argued the absence of a description of the testing methods employed made it impossible for the trial court to determine whether the material relied upon supported Kashar's opinion. They argued that *Sargon* requires the trial court to scrutinize the reasons for an expert's opinion and must determine whether the analytical gap between the data and the opinion is too great. The Second DCA explained that *Sargon* involved the exclusion of expert testimony at trial. There, the court had an eight day evidentiary hearing mostly involving testimony from the expert witness. The court ruled the expert's methodology was too speculative for the evidence to be admissible.

Here the case involves the exclusion of expert testimony presented in opposition to a summary judgment motion. The trial court here did not conduct an evidentiary hearing, and there was no examination of the expert pursuant to section 802. Absent more specific information on the testing methods used and the results obtained, the trial court here could not scrutinize the reasons for Kashar's opinion to the same extent as did the court in *Sargon*. The rule that the trial court must liberally construe the evidence submitted in opposition to a summary judgment motion applies in ruling on both the admissibility of the expert testimony and its sufficiency to create a triable issue of fact. (*Jennifer C. v Los Angeles Unified School Dist.* (2008) 168 Cal.App.4th 1320) A reasoned explanation required in an expert declaration filed in opposition to a summary judgment motion need not be as detailed or extensive as that required in expert testimony presented in support of a summary judgment motion or at trial. (*Powell v Kleinman* (2007) 151 Cal.App.4th 112)

The Justices concluded that the explanation provided for Kashar's opinion was sufficient and that the trial court could not properly exclude the expert

testimony based on Kashar's failure to identify the particular tests employed or describe the test results. Defendants also objected to portions of the declaration on the basis that Kashar was not qualified to testify as an expert. (Evidence code section 702(a)) Kashar stated that he had been a metallurgist for 30 years doing materials analysis, failure analysis and material trade-off evaluation. The Court stated his testimony was on the nature and hardness of the materials used in the prosthesis, a subject for which his experience as a metallurgist undoubtedly qualified him as an expert.

The defense expert stated the prosthesis was not defective in manufacture. Kashar stated that his testing and other examinations showed the fracture occurred on a portion of the prosthesis that was softer than the required minimum hardness, and short of meeting two of the three ASTM standards for hardness. He stated that a portion of the prosthesis was not made from cobalt-chromium-molybdenum, but instead from a titanium alloy. He stated that these anomalies made the prosthesis defective in manufacture or design.

Plaintiff also presented testimony from two defense representatives that the prosthesis was to be made from cobalt chrome and not titanium. Construing the evidence liberally, in favor of the party opposing summary judgment, the Justices found it created a triable issue of fact as to whether the prosthesis as manufactured failed to conform to its intended design and therefore creates a triable issue of fact as to the existence of a manufacturing defect. The evidence also creates a triable issue as to whether the manufacturing defect was a substantial factor in bringing about the failure of the prosthesis resulting in plaintiff's injury.

Accordingly, summary adjudication of the count for strict products liability based on a manufacturing defect and the count for negligence is precluded. The judgment is reversed with directions to vacate the summary judgment. Plaintiff is to recover his costs on appeal.

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