# **CERTIFIED FOR PUBLICATION**

# IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

## SECOND APPELLATE DISTRICT

# DIVISION THREE

TODD GARRETT,

Plaintiff and Appellant,

v.

HOWMEDICA OSTEONICS CORPORATION et al.,

Defendants and Respondents.

B234368

(Los Angeles County Super. Ct. No. SC104332)

APPEAL from a judgment of the Superior Court of Los Angeles County,

Cesar S. Sarmiento, Judge. Reversed with directions.

Law Offices of Martin N. Buchanan, Martin N. Buchanan; Girardi | Keese,

Thomas V. Girardi and Amanda H. Kent for Plaintiff and Appellant.

Sedgwick, Ralph A. Campillo, Steven D. Di Saia and Hall R. Marston for

Defendants and Respondents.

Todd Garrett appeals a summary judgment in favor of Howmedica Osteonics Corporation (Howmedica) and Stryker Corporation (Stryker) in a products liability action involving an implanted prosthetic device.<sup>1</sup> He contends the defendants failed to satisfy their burden to show that the prosthesis was not defective, the exclusion of portions of his expert's declaration was error and his expert's declaration creates triable issues of fact precluding summary judgment.

We hold that (1) the doctrine of strict products liability based on a design defect is inapplicable to implanted medical devices available only through the services of a physician and cannot provide a basis for the defendants' liability, and (2) the exclusion of portions of the plaintiff's expert's declaration was error. We conclude that the expert's declaration creates triable issues of fact precluding summary adjudication of two counts alleged in the complaint. We therefore will reverse the judgment with directions.

## FACTUAL AND PROCEDURAL BACKGROUND

## 1. Factual Background

Garrett was treated for cancer in his left femur (thigh bone). Jeffrey Eckardt, an orthopedic surgeon, ordered a prosthetic device to replace the middle portion of the femur. Howmedica and Stryker allegedly participated in some manner in the design or manufacture of the prosthesis. Eckardt implanted the prosthesis in August 2007, attaching it to the two remaining ends of the femur using an adhesive and cross-pins.

<sup>&</sup>lt;sup>1</sup> The defendants acknowledge that this action is not preempted by the federal Medical Device Amendments of 1976 (21 U.S.C. § 360c et seq.).

Garrett reported pain in his thigh beginning in February 2009. Eckardt investigated and detected a fatigue fracture in the prosthesis. Eckardt replaced the fractured prosthesis with a different type of prosthesis in March 2009. The new prosthesis included an artificial joint, and the second surgery required a considerably longer recovery time than the first.

#### 2. Trial Court Proceedings

Garrett filed a complaint in August 2009 and filed a third amended complaint against Howmedica, Stryker and others in September 2010. He alleges counts against Howmedica and Stryker for (1) strict products liability based on manufacturing and design defects; (2) strict products liability based on failure to warn; (3) breach of express warranty; and (4) negligence.<sup>2</sup>

Howmedica and Stryker filed a motion for summary judgment or summary adjudication in March 2011. They argued that Garrett's discovery responses showed that he had no evidence to establish the essential elements of his claims. They also argued that the evidence presented in support of their motion showed that the prosthesis was not defective and that they had no duty to warn as a matter of law. They filed a declaration by Albert H. Burstein, a mechanical engineer, stating his opinion that the prosthesis was not defective in design or manufacture, that the fracture was caused by a cyclical rotational force resulting from normal human activity and that the force

<sup>&</sup>lt;sup>2</sup> Garrett also alleged a count against Howmedica and Stryker for fraudulent concealment, but he later dismissed that count.

simply exceeded the load that the product could bear over time. They also presented Garrett's discovery responses and other evidence in support of the motion.

Garrett opposed the motion, except that he did not oppose the attack on his count for strict products liability based on failure to warn. Garrett filed a declaration by Lawrence Kashar, a metallurgist, stating that he had determined through destructive testing and other examinations that the portion of the prosthesis that suffered a fracture "was softer tha[n] 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 was less than the expected hardness of the third specification." Kashar stated that (1) hardness was a direct indication of the strength of the material; (2) a portion of the prosthesis was not made from the cobalt-chromium-molybdenum alloy, but instead was made from a titanium alloy; and (3) he had detected "a layer of polymeric-like material" in holes surrounding the cross-pins and noted that the defendants' deponent had "stated that no polymeric material should be involved with this implant." Kashar characterized these as "anomalies" and stated his opinion that, based on these purported anomalies, the prosthesis was defective in manufacture and/or design and that there were "strong arguments" that the purported defect had caused the prosthesis to fail.

Howmedica and Stryker filed evidentiary objections to most of the substantive portions of the Kashar declaration on various grounds, including lack of expert qualification, lack of an explanation or reasoning to support an expert opinion, "lacks foundation" (capitalization omitted) and relevance.

The trial court concluded that Garrett's discovery responses showed that he had no evidence that the prosthesis was defective or that the defendants had breached an express warranty or were negligent. The court stated that Garrett was relying on the mere fact that the product had failed, which was insufficient evidence to establish a basis for liability, and that after litigating this case for almost two years, he could not reasonably expect to obtain evidence of a product defect, breach of warranty, negligence or causation. The court stated further that the Burstein declaration filed by the defendants also supported the conclusion that Garrett could not establish either the existence of a product defect or causation.

The trial court also found that the Kashar declaration failed to satisfy the requirements for admissibility of expert opinion because it lacked a reasoned analysis and an adequate foundation for his opinions.<sup>3</sup> The court sustained objections to all of the challenged portions of the Kashar declaration, with only one exception. The court concluded that Garrett had failed to create a triable issue of material fact and that the defendants were entitled to summary judgment as a matter of law. The court entered a judgment in favor of Howmedica and Stryker in June 2011. Garrett timely appealed the judgment.

<sup>&</sup>lt;sup>3</sup> The minute order ruling on the defendants' motion for summary judgment or summary adjudication stated this reason for sustaining the objections to the Kashar declaration and later stated more generally as to each objection "Sustained."

#### **CONTENTIONS**

Garrett contends (1) the evidence that the prosthesis failed less than two years after the surgery creates a triable issue of fact as to the existence of a design defect and causation, and the defendants failed to satisfy their burden of presenting evidence that the prosthesis was not defective under the risk-benefit test; (2) a triable issue of fact exists as to the existence of a design defect under the consumer expectations test; (3) Kashar adequately stated the basis for his opinion, and the exclusion of portions of his declaration was error; and (4) the Kashar declaration creates triable issues of fact as to the existence of a design or manufacturing defect, negligence and causation.<sup>4</sup>

#### DISCUSSION

#### 1. Standard of Review

A court may grant a summary judgment only if there is no triable issue of material fact and the moving party is entitled to judgment in its favor as a matter of law. (Code Civ. Proc., § 437c, subd. (c).) A defendant moving for summary judgment must show that one or more elements of the plaintiff's cause of action cannot be established or that there is a complete defense. (*Id.*, subd. (p)(2).) The defendant can satisfy its burden by presenting evidence that negates an element of the cause of action or evidence that the plaintiff does not possess and cannot reasonably expect to obtain evidence needed to establish an essential element. (*Miller v. Department of Corrections*)

<sup>&</sup>lt;sup>4</sup> Garrett does not challenge the granting of summary judgment as to the counts for failure to warn strict products liability and breach of express warranty. He therefore abandons any claim of error with respect to those counts. (*Angeloti v. The Walt Disney Co.* (2011) 192 Cal.App.4th 1394, 1402, fn. 3.)

(2005) 36 Cal.4th 446, 460 (*Miller*).) If the defendant meets this burden, the burden shifts to the plaintiff to present evidence creating a triable issue of material fact. (Code Civ. Proc., § 437c, subd. (p)(2).)

We review the trial court's ruling on a summary judgment motion de novo, liberally construe the evidence in favor of the party opposing the motion, and resolve all doubts concerning the evidence in favor of the opponent. (*Miller, supra*, 36 Cal.4th at p. 460.) A different standard of review applies to the court's evidentiary rulings in connection with the motion, which we review for abuse of discretion. (*Miranda v. Bomel Construction Co., Inc.* (2010) 187 Cal.App.4th 1326, 1335.)

We must affirm a summary judgment if it is correct on any of the grounds asserted in the trial court, regardless of the trial court's stated reasons. (*Conte v. Wyeth*, *Inc.* (2008) 168 Cal.App.4th 89, 113.) Even if the grounds entitling the moving party to a summary judgment were not asserted in the trial court, we must affirm if the parties have had an adequate opportunity to address those grounds on appeal. (*Johnson v. United Cerebral Palsy/Spastic Children's Foundation* (2009) 173 Cal.App.4th 740, 754; *Western Mutual Ins. Co. v. Yamamoto* (1994) 29 Cal.App.4th 1474, 1481; see Gov. Code, § 68081; Code Civ. Proc., § 437c, subd. (m)(2).)

# Design Defect Strict Products Liability Is Inapplicable to Implanted Medical Devices<sup>5</sup>

The doctrine of strict products liability imposes strict liability in tort on the manufacturer of a defective product and others in the product's chain of distribution. (*Jimenez v. Superior Court* (2002) 29 Cal.4th 473, 477-478; *Greenman v. Yuba Power Products, Inc.* (1963) 59 Cal.2d 57, 63.) The purpose of the imposition of liability is to ensure that the loss is borne not by injured consumers but by manufacturers, retailers and others in the chain of distribution who are better able to reduce the risks of injury and can equitably distribute the loss to the consuming public. (*Jimenez, supra*, at pp. 477-478; *Vandermark v. Ford Motor Co.* (1964) 61 Cal.2d 256, 262-263.)

Strict products liability has been imposed for defects arising from flaws in the manufacturing process (manufacturing defects), defects in the design rendering a product unsafe (design defects) and inadequate warnings or failure to warn (warning defects). (*O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, 347; *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1057 (*Brown*).) 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 foreseeable manner (consumer expectations test). (*Barker v. Lull Engineering Co.* (1978) 20 Cal.3d 413, 418.)

<sup>&</sup>lt;sup>5</sup> Howmedica and Stryker argue for the first time in their respondents' brief that design defect strict products liability is inapplicable to implanted medical devices. We will address this argument despite the defendants' failure to raise the issue in the trial court because it is potentially dispositive of part of the appeal and involves a purely legal question.

The California Supreme Court in *Brown*, *supra*, 44 Cal.3d 1049, held that a manufacturer of prescription drugs cannot be strictly liable for a design defect and that the appropriate test for determining a prescription drug manufacturer's liability for a design defect involves an application of the ordinary negligence standard. (*Id.* at pp. 1061, 1069.) Under the negligence standard as reflected in comment k to section 402A of the Restatement Second of Torts, adopted in *Brown*, a manufacturer is liable for a design defect only if it failed to warn of a defect that it either knew or should have known existed. (*Brown, supra*, at p. 1059.)

*Brown* explained that the consumer expectations test is inappropriate for prescription drugs because an ordinary consumer would have no safety expectations with respect to a prescription drug apart from the information provided by his or her physician. (*Brown, supra*, 44 Cal.3d at pp. 1061-1062.) A prescription drug manufacturer that has provided appropriate warnings to the physician cannot be liable for the physician's failure to convey those warnings to the patient, and cannot be liable if the patient relies on information provided by others as to the side effects of the drug. (*Id.* at p. 1062.)

*Brown* also noted that the risk-benefit test is inappropriate for prescription drugs for public policy reasons. (*Brown, supra*, 44 Cal.3d at pp. 1062-1065.) Unlike other products for which strict liability has been imposed, prescription drugs "may be necessary to alleviate pain and suffering or to sustain life." (*Id.* at p. 1063.) But, "unlike other important medical products (wheelchairs, for example), harm to some users from prescription drugs is unavoidable. Because of these distinctions, the broader

public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability for injuries resulting from their use." (*Ibid.*) In many cases, to withhold a drug from the market in order to enhance its safety would not serve the public welfare, and public policy favors the development of new drugs despite the presence of some risks, even serious risks, "because drugs can save lives and reduce pain and suffering." (*Ibid.*) The potential for strict liability could cause drug manufacturers to refrain from researching and developing beneficial drugs for fear of liability, and the cost of insurance to protect against strict liability could increase the cost of medication beyond the reach of those who need it most. (*Ibid.*) *Brown* therefore concluded that application of the risk-benefit test would be against the public interest. (*Id.* at p. 1065.)

*Brown* rejected a case-by-case approach to determining whether a particular drug was exceptionally beneficial and "unavoidably dangerous," and therefore exempt from strict liability, concluding instead that prescription drugs as a class are *exempt* from strict liability for design defects regardless of whether the particular drug at issue is found to be "beneficial to the public health." (*Brown, supra*, 44 Cal.3d at p. 1065, fn. 10 & pp. 1066-1069.) Drug manufacturers, however, are *not* exempt from liability for manufacturing defects, failure to warn or negligence. (*Id.* at p. 1069, fn. 12.)

*Hufft v. Horowitz* (1992) 4 Cal.App.4th 8 (*Hufft*) held that the rule from *Brown*, *supra*, 44 Cal.3d 1049, also applies to "implanted prescription medical devices."<sup>6</sup>

<sup>&</sup>lt;sup>6</sup> *Hufft*, *supra*, 4 Cal.App.4th 8, apparently used the terms "implanted prescription medical devices" (*id.* at p. 11), "implanted prescription medical products" (*id.* at pp. 11,

(*Hufft, supra*, at p. 11.) *Hufft* stated that, like prescription drugs, implanted medical devices are available only through the services of a physician and can alleviate pain and suffering, sustain life or provide other important benefits. (*Hufft, supra*, at p. 18.) As is true of prescription drugs, harm to some users from implanted medical devices is unavoidable. (Id. at pp. 18-19.) Hufft stated, however, that unlike prescription drugs, an ordinary consumer might have a reasonable expectation as to the performance of an implanted medical device apart from the information provided by his or her physician. (Id. at pp. 17-18 & fn. 8.) Notwithstanding this, Hufft concluded that 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. (Id. at p. 19.) As in Brown, the Hufft court held that the exemption applies to all implanted medical devices, including the penile prosthesis involved in *Hufft*, and that a court need not determine whether the particular device at issue is unavoidably dangerous or exceptionally beneficial. (*Hufft, supra*, at p. 19.)

Plenger v. Alza Corp. (1992) 11 Cal.App.4th 349 followed Hufft, supra,
4 Cal.App.4th 8, concluding that the public policy considerations articulated in Brown,
supra, 44 Cal.3d 1049, are equally applicable to "prescription implanted medical devices." (Plenger, supra, at p. 360.) Plenger held that design defect strict products
liability is inapplicable to an intrauterine device (IUD). (Id. at pp. 360-361.)

<sup>19-20)</sup> and "implanted medical devices" (*id.* at pp. 11, 17-19) interchangeably, and assumed that all implanted medical devices "require a physician's prescription" (*id.* at p. 19, fn. 10).

*Artiglio v. Superior Court* (1994) 22 Cal.App.4th 1388 (*Artiglio*) also followed *Hufft, supra*, 4 Cal.App.4th 8, concluding that design defect strict products liability is inapplicable to implanted medical devices that are available only through the services of a physician. (*Artiglio, supra*, at p. 1397.) As in *Brown, supra*, 44 Cal.3d 1049, and *Hufft, supra*, 4 Cal.App.4th 8, *Artiglio* concluded that the exemption is categorical and is not determined on a case-by-case basis. (*Artiglio, supra*, at pp. 1395-1397.) *Artiglio* noted that the devices there at issue, breast implants, were provided directly by the physician and therefore were not, strictly speaking, "prescribed." (*Id.* at p. 1397.)

In this case, Garrett argues that the exemption from design defect strict products liability established in *Hufft*, supra, 4 Cal.App.4th 8, and its progeny, is limited to implanted medical devices that are available only by prescription. He argues that whether the prosthesis here was available only by prescription was not at issue in the trial court and the evidence in the record is inconclusive on this point, so summary judgment cannot be affirmed on this basis. We hold, however, that the exemption is not so limited. It is undisputed that the prosthesis here was both ordered by a physician and surgically implanted by a physician, and it cannot reasonably be disputed that the implant was available only through the services of a physician. As the court concluded in Artiglio, supra, 22 Cal.App.4th 1388, the reasoning of Brown, supra, 44 Cal.3d 1049, and *Hufft*, supra, 4 Cal.App.4th 8, applies to an implanted medical device in these circumstances regardless of whether, strictly speaking, it was available only by prescription and regardless of whether it is properly characterized as a "prescription" implanted medical device. 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*, *supra*, 22 Cal.App.4th at p. 1397; see *Hufft*, *supra*, 4 Cal.App.4th at p. 18.)

We therefore conclude that Howmedica and Stryker cannot be strictly liable for a design defect under either the risk-benefit or consumer expectations test and that Garrett has shown no prejudicial error in the granting of summary judgment with respect to his claim for strict products liability based on a design defect.<sup>7</sup> That, however, does not dispose of Garrett's entire case.

- 3. The Kashar Declaration Creates Triable Issues of Fact as to the Existence of a Manufacturing Defect and Negligence
  - a. The Exclusion of Portions of the Kashar Declaration Based on Evidence Code Section 801, Subdivision (b) Was Error

The trial court stated that the Kashar declaration "lacks adequate factual foundation" and "is entirely devoid of any reasoned analysis to support his opinion." Regarding Kashar's statement that the prosthesis was softer than the "minimum required hardness" in two of the three ASTM specifications covering Cobalt-28% Chromium-6% Molybdenum alloy for use in an implant and was less than the "expected

<sup>&</sup>lt;sup>7</sup> Garrett alleges design defect strict products liability and manufacturing defect strict products liability together in a single count. However, because these are two separate theories of liability that properly could have been alleged as separate counts, we will treat them as separate counts and conclude that summary adjudication is proper as to the count for design defect strict products liability. (*Mathieu v. Norrell Corp.* (2004) 115 Cal.App.4th 1174, 1188; *Lilienthal & Fowler v. Superior Court* (1993) 12 Cal.App.4th 1848, 1854-1855.)

hardness" of the third specification, the court stated that Kashar failed to "describe the testing process he used to arrive at this conclusion or describe the results of the testing." The court also stated that Kashar failed to describe what the ASTM specifications were and failed to state that the prosthesis should have complied with the ASTM specifications for that particular alloy. The court stated that therefore there was no basis for Kashar's opinion that the prosthesis was defective. The court also stated that Kashar offered no opinion that the purported defect caused any injury.

"An expert opinion has no value if its basis is unsound. (People v. Lawley (2002) 27 Cal.4th 102, 132 [115 Cal.Rptr.2d 614, 38 P.3d 461]; People v. Bassett (1969) 69 Cal.2d 122, 141, 144 [70 Cal.Rptr. 193, 443 P.2d 777].) Matter that provides a reasonable basis for one opinion does not necessarily provide a reasonable basis for another opinion. Evidence Code section 801, subdivision (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.' (Italics added.) We construe 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. (Smith v. ACandS, Inc. (1994) 31 Cal.App.4th 77, 93 [37 Cal.Rptr.2d 457], disapproved on another point in Camargo v. Tjaarda Dairy (2001) 25 Cal.4th 1235, 1245 [108 Cal.Rptr.2d 617, 25 P.3d 1096]; see Cal. Law Revision Com. com., 29B West's Ann. Evid. Code (1995 ed.) foll. § 801, p. 20 ['irrelevant or speculative matters are not a proper basis for an expert's opinion'].)

"A trial court exercises discretion when ruling on the admissibility of expert testimony under Evidence Code section 801, subdivision (b). If the court excludes expert testimony on the ground that there is no reasonable basis for the opinion, we review the exclusion of evidence under the abuse of discretion standard. (*People v. Mickey* (1991) 54 Cal.3d 612, 687-688 [286 Cal.Rptr. 801, 818 P.2d 84]; *People v. Bui* (2001) 86 Cal.App.4th 1187, 1196 [103 Cal.Rptr.2d 908].) To the extent the ruling is based on the trial court's conclusion of law, we review the legal conclusion de novo. (*Penner v. County of Santa Barbara* (1995) 37 Cal.App.4th 1672, 1676 [44 Cal.Rptr.2d 606].)" (*Lockheed Litigation Cases* (2004) 115 Cal.App.4th 558, 564.)

A trial court determining whether there is a reasonable basis for an expert opinion under Evidence Code section 801, subdivision (b) must examine the matter that the expert relied on in forming an opinion. This limited analysis involves reviewing the matter relied on and understanding the matter to the extent necessary to determine whether it can provide a reasonable basis ("reasonably may be relied upon" (*ibid*.)) for the expert's opinion. A court conducting this analysis must not weigh the probative value of the opinion, substitute its own opinion for the expert's opinion or presume to be an expert. Rather, the analysis is limited to determining whether the matter relied on can provide a reasonable basis for the opinion or, on the other hand, reveals that the opinion is based on a leap of logic, conjecture, or artifice. (See *ibid.*; *Lockheed Litigation Cases, supra*, 115 Cal.App.4th at p. 564.)

In this case, Kashar declared that he "conducted extensive examinations of the portions of the prosthetic device that were removed from Mr. Garrett using visual

examination, optical microscopic examination, x-ray radiography, fluorescent dye penetrant examination, scanning electron microscopy, and such destructive testing as hardness testing, micro hardness testing, microstructural analysis, and chemical analysis." He declared that he had determined, based on his examinations, that the fractured portion of the prosthesis was softer than the "minimum required hardness" in two of the three ASTM specifications covering the alloy for use in an implant and was less than the "expected hardness" of the third specification.

We believe that this explanation is sufficient to support his opinion for purposes of opposing the summary judgment motion. In our view, Kashar's failure to describe the particular testing processes that he used to arrive at his conclusions regarding the hardness of the prosthesis and his failure to more particularly describe the results of that testing do not in any manner indicate that his conclusions are speculative, conjectural or lack a reasonable basis. Whatever shortcomings that cross-examination may or may not reveal in Kashar's testing methods and opinion, we believe that the absence of more specific information as to the testing methods used and the results obtained would not provide any grounds for the trial court to conclude that there was no reasonable basis for Kashar's opinion.

Our conclusion is the same with respect to Kashar's failure to identify the particular ASTM specifications that he considered. The absence of that information does not render the declaration conclusory and cannot justify the conclusion that there was no reasonable basis for Kashar's opinion.

Kashar's 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. We therefore hold that the trial court failed to liberally construe the declaration, as required (*Miller*, *supra*, 36 Cal.4th at p. 460), and that the sustaining of the objections to the declaration based on Evidence Code section 801, subdivision (b) was an abuse of discretion.

# b. The Sustaining of the Objections Cannot Be Affirmed on Other Grounds

Howmedica and Stryker also objected to portions of the Kashar declaration on the grounds that he was not qualified to testify as an expert. "A person is qualified to testify as an expert if he has special knowledge, skill, experience, training, or education sufficient to qualify him as an expert on the subject to which his testimony relates." (Evid. Code, § 720, subd. (a).) Kashar stated in his declaration that he was "a metallurgist with more than 30 years of experience in materials analysis, failure analysis and material trade-off evaluation." He testified in his declaration 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 defendants' objections to portions of the Kashar declaration on grounds of lack of foundation and relevance, to the extent that they did not merely reiterate the same grounds that we have already rejected, were similarly meritless. No preliminary fact or other foundational matter was lacking, and Kashar's testimony clearly is relevant and creates triable issues of fact, as we will explain.

#### c. The Kashar Declaration Creates Triable Issues of Fact

A product has a manufacturing defect if it differs from the manufacturer's intended result or from other ostensibly identical units of the same product line. (*Barker v. Lull Engineering Co., supra,* 20 Cal.3d at p. 429.) In other words, a product has a manufacturing defect if the product as manufactured does not conform to the manufacturer's design. (*In re Coordinated Latex Glove Litigation* (2002) 99 Cal.App.4th 594, 607.) A manufacturing defect was a legal cause of injury only if the defect was a substantial factor in producing the injury. (*Soule v. General Motors Corp.* (1994) 8 Cal.4th 548, 572.)

The defendants' expert Burstein stated in his declaration filed in support of the summary judgment motion that he "conducted a detailed examination of the subject prosthesis" and reviewed Howmedica's records with regard to its design and manufacture. Based on his examination of the prosthesis and review of the records, he opined that the prosthesis "entirely met the specifications provided by Dr. Eckardt," that it "was manufactured by proper means and methods of the proper materials, as also accepted in the industry, for this product and application" and that it "was not defective in design or manufacture."

Kashar stated in his declaration filed in opposition to the summary judgment motion that he had determined through destructive testing and other examinations that the portion of the prosthesis that suffered a fracture "was softer tha[n] 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 was less than the expected hardness of the third specification." He stated that hardness was a direct indication of the strength of the material. Kashar also stated that a portion of the prosthesis was not made from the cobalt-chromium-molybdenum alloy, but instead was made from a titanium alloy. He stated that these "anomalies" made the prosthesis defective in manufacture or design.

Although Kashar did not expressly state that the design specifications for the prosthesis provided for use of the Cobalt-28% Chromium-6% Molybdenum alloy, Garrett presented deposition testimony by Daniel G. Barcenas of Stryker stating that the prosthesis was designed to be made from "cobalt chrome" and not titanium. Eckardt also testified in his deposition that he designed the prosthesis to be constructed of "alloys of vitallium, which is the ingredient or secret proprietary, and of cobalt, chrome molybdenum."

We must construe the evidence liberally in favor of Garrett as the party opposing summary judgment and must resolve all doubts in the evidence in his favor. (*Miller*, *supra*, 36 Cal.4th at p. 460.) Accordingly, we conclude that the evidence, liberally construed, supports the proposition that the prosthesis was designed to be constructed of Cobalt-28% Chromium-6% Molybdenum alloy and not titanium alloy, and that it was intended to comply with the ASTM specifications for hardness covering the former alloy for use in an implant, but that a portion of the prosthesis was made from titanium alloy, and the portion that failed did not comply with the applicable ASTM

specifications for Cobalt-28% Chromium-6% Molybdenum alloy. This creates 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. In light of the evidence that the hardness of the material also affects its strength, the evidence also creates a triable issue of fact as to whether the purported manufacturing defect was a substantial factor in bringing about the failure of the prosthesis resulting in Garrett's injury. The triable issues of fact as to the existence of a manufacturing defect and causation preclude summary adjudication of the count for strict products liability based on a manufacturing defect and the count for negligence (see fn. 7, *ante*).

## **DISPOSITION**

The judgment is reversed with directions to the trial court to vacate the order granting summary judgment and enter a new order granting summary adjudication of the counts for failure to warn strict products liability, design defect strict products liability and breach of express warranty and otherwise denying the motion for summary judgment or summary adjudication. Garrett is entitled to recover his costs on appeal.

## **CERTIFIED FOR PUBLICATION**

CROSKEY, J.

WE CONCUR:

KLEIN, P. J.

KITCHING, J.