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File Name: 07a0815n.06
Filed: November 21, 2007

No. 07- 3058

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

CYNTHIA YANOVICH and MICHAEL YANOVICH,	)	
Plaintiffs-Appellants,	)	
v.	)	**On Appeal from the United States District Court for the Northern District of Ohio**
ZIMMER AUSTIN, INC. and ZIMMER, INC.,	)	
Defendants-Appellees.	)	

Before: BOGGS, Chief Judge; MCKEAGUE, Circuit Judge; and COHN, District Judge.[*]

BOGGS, Chief Judge. Cynthia and Michael Yanovich brought an action in tort against the defendants, Zimmer Austin, Inc. and Zimmer, Inc., alleging that the artificial knees designed and manufactured by the defendants were defective under the Ohio Products Liability Act (OPLA). The defendants moved for summary judgment, arguing that: (1) Ohio law required Yanovich to submit expert medical testimony on the issue of causation; and, alternatively, (2) Yanovich's expert testimony did not sufficiently allege a defect. The district court adopted both of these arguments in

[*] The Honorable Avern Cohn, United States District Judge for the Eastern District of Michigan, sitting by designation.

granting summary judgment to the defendants. The Yanoviches now appeal, and we affirm.

I

We review a grant of summary judgment de novo, *Williams v. Ford Motor Co.*, 187 F.3d 533, 537-38 (6th Cir. 1999), under the familiar standard of Fed. R. Civ. P. 56(c) and *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986). Once the moving party has satisfied its initial burden of identifying those portions of relevant court documents that it believes demonstrate the absence of a genuine issue of material fact, the non-moving party must respond. Fed. R. Civ. P. 56(e). While the court must "afford all reasonable inferences, and construe the evidence in the light most favorable to the nonmoving party," if the evidence is "insufficient to reasonably support a jury verdict in favor of the nonmoving party, the motion for summary judgment will be granted." *Cox v. Kentucky DOT*, 53 F.3d 146, 150 (6th Cir. 1995) (internal citations omitted).

In September 2000, Dr. Stephen Helper performed a total knee replacement on Cynthia Yanovich's left and right knees The surgeon implanted the Intermedics Natural Knee II ("NK II") System, designed and manufactured by Zimmer Austin, Inc. and Zimmer, Inc. (collectively, "Zimmer").

After Yanovich's knee replacement surgery, she continued to experience considerable pain. On April 24, 2004, Yanovich sought the advice of Dr. Mary-Blair Matejczyk. Matejczyk observed that Yanovich's knees were in a valgus position or knock-kneed (meaning that Yanovich's knees bent in laterally toward the center of her body). A subsequent x-ray revealed lateral subluxation–a misalignment of the patella. Matejczyk recommended that Yanovich undergo surgery to revise the

placement of the patella and possibly to replace the right tibial insert. On October 20, 2004, Matejczyk discovered that the pegs of the patella button (which attached the synthetic patella to the natural patella) had fractured and that the patella buttons were "floating off to the side."

On July 12, 2005, Yanovich timely filed a complaint in the Common Pleas Court of Cuyahoga County, Ohio, against various defendants, including Dr. Helper, Hillcrest Hospital, and Zimmer. Yanovich alleged that: (1) the doctor and hospital had committed medical malpractice, and (2) the NK II was defective in both design and manufacture. In addition to Cynthia Yanovich's claims, her husband made several derivative claims including loss of Cynthia's wages, services, and consortium. After the doctor and hospital were dismissed from the suit, Zimmer removed the case to the United States District Court for the Northern District of Ohio on the basis of diversity jurisdiction.

Yanovich alleges that the NK II is defective in manufacture and design, and due to inadequate warning. Her claim of inadequate warning implicates the NK II as a whole, while her claims of manufacturing and design defect allege that a single component of the NK II is defective. Specifically, Yanovich argues that: (1) the patella was defective in manufacture because it lacked consistency in its strength; and (2) the patella was defective in design because the processes used to make the patella buttons did not adequately ensure that the product would be uniform in strength.

During discovery, Yanovich disclosed only a single expert witness, Dr. Erol Sancaktar, a professor who specializes in polymer engineering. Sancaktar's report focused on the mechanical and material properties of the patellar component. Sancaktar is not a medical doctor and his report contained no analysis of the potential medical causes for the patellas' breakage. After Yanovich

submitted Sancaktar's report, Zimmer moved for summary judgment on the basis that Yanovich had proffered insufficient evidence to support a jury verdict in her favor.

In her response to Zimmer's motion for summary judgment, Yanovich raised two new claims. First, she argued that Zimmer had breached the implied warranty of fitness. Second, she claimed that the NK II failed to conform to Zimmer's own specific representations. Disregarding the two new claims as improperly raised, the district court granted Zimmer's motion.

II

A. The products liability claims

Yanovich alleges that Zimmer's NK II system was defective and caused a tortious injury. Because the injury took place in Ohio, Ohio law applies. The Ohio Products Liability Act (OPLA), Ohio Revised Code §§ 2307.71-2370.80, which governs this dispute, states:

> A manufacturer is subject to liability for compensatory damages based on a product liability claim only if the claimant establishes, by a preponderance of the evidence, all of the following:
>
> (1) Subject to division (B) of this section, the manufacturer's product in question was defective in manufacture or construction as described in section 2307.74 of the Revised Code, was defective in design or formulation as described in section 2307.75 of the Revised Code, was defective due to inadequate warning or instruction as described in section 2307.76 of the Revised Code, or was defective because it did not conform to a representation made by its manufacturer as described in section 2307.77 of the Revised Code;
>
> (2) A defective aspect of the manufacturer's product in question as described in division (A)(1) of this section was a proximate cause of harm for which the claimant seeks to recover compensatory damages;
>
> (3) The manufacturer designed, formulated, produced, constructed, created, assembled, or rebuilt the actual product that was the cause of harm for which the claimant seeks to recover compensatory damages.

Ohio Rev. Code Ann. § 2307.73. In short, the plaintiff must show by a preponderance of the evidence that: (1) the product was defective; (2) the defective aspect of the product was the proximate cause of the injury; and (3) the defective product was actually manufactured by the defendant.

Zimmer admits that it manufactured the NK II implanted in Yanovich's knees, but argues that Yanovich has failed to proffer sufficient evidence that the NK II was defective in manufacture or design, or due to inadequate warning. Alternatively, Zimmer argues that even if Yanovich could prove that Zimmer's product was defective, Yanovich did not introduce sufficient evidence for a jury to find that the alleged defect was the actual cause of her injury.

Though a full mechanical explanation of the NK II is not necessary, a brief description of the NK II's manufacturing process and design is useful for understanding Yanovich's product liability claims. The NK II system comprises four elements: a femoral component, tibial baseplate, tibial insert, and patella button. The femoral component of the NK II attaches to the end of the upper leg bone, the femur. It wraps around the bone to provide a smooth surface that can rotate without friction. The tibial baseplate attaches to the end of the lower leg bone, the tibia. The tibial insert is placed in the tibial baseplate to provide the surface on which the femoral component rotates or articulates. The patella button attaches to the back of the patient's existing patella or knee cap, forming a single unit. The underside of the patella button is v-shaped and sits within a natural groove in the underlying femur, the trochlea or trochlear groove. This allows the fused patella to slide up and down the femur as the leg straightens and bends, but prevents the patella from moving

laterally. In a normally functioning human knee, the patella's motion is constrained by fibrous restraints that sit on either side of the patella and by the walls of the trochlear groove. However, if the patella is not properly aligned in the trochlear groove, it may partially come out of the groove. This is called subluxation.

The patella button, the focus of Yanovich's manufacturing and design defect claims, is made of a type of plastic called ultra-high molecular weight polyethylene ("UHMWPE"). Polyethylene is a polymer–a highly-structured, chain-like molecule. Zimmer uses two separate processes to harden the plastic. First, Zimmer bombards the plastic with electron beams or "E-beams." This irradiation induces crosslinking–the binding together of the individual chains of polyethylene at multiple points along the chains. Next, Zimmer anneals the plastic; this process of heating and slowly cooling the plastic induces crystallization of the polymers.

Sancaktar argues that "weakness and lack of consistent overall strength" in the patellas that were implanted in Yanovich constitutes a manufacturing defect and that the choice of plastic and the dual processes of using E-beam irradiation and tempering to harden that plastic is a design defect because it results in products that have inconsistent levels of hardness.

In opposing the motion for summary judgment, Yanovich submitted an affidavit by Sancaktar to supplement his initial report and deposition testimony. The district court discounted this affidavit on the basis that it contradicted Sancaktar's earlier testimony and report. We hold that it was error to discount Sancaktar's affidavit, but that summary judgment is nevertheless still warranted.

1. Sancaktar's affidavit

A party "cannot create a genuine issue of fact sufficient to survive summary judgment simply by contradicting his or her own previous sworn statement (by, say, filing a later affidavit that flatly contradicts that party's earlier sworn deposition) without explaining the contradiction or attempting to resolve the disparity." *Cleveland v. Policy Mgmt. Sys. Corp.*, 526 U.S. 795, 806 (1999).

A comparison of Sancaktar's deposition testimony with his affidavit demonstrates an apparent contradiction. In his deposition, Sancaktar answers as follows:

> Q. Did you compare Mrs. Yanovich's patellar components to the blueprints?
>
> A. Yes.
>
> Q. Okay. Did you undertake any effort to determine whether Mrs. Yanovich's patellar components conformed to the blueprints?
>
> A. They did conform, yes.
>
> Q. Okay. You are not sitting here today offering the opinion that in some way her patellar components deviated from [Zimmer's] design?
>
> A. No.
>
> . . .
>
> Q. If we define defective in manufacture as being devices that do not conform to a manufacturer's specification, with that definition in mind have you reached the conclusion on Pages 52 and 53 [of your report] that Mrs. Yanovich's devices were defective in manufacture?
>
> A. So you're asking whether they satisfy their own definition of how it should be? I don't really care about that frankly. In my opinion they were unsatisfactory. They may have satisfied themselves obviously because they are selling it.

> Q. You would agree with me, wouldn't you that Mrs. Yanovich's patellar components met Zimmer's manufacturing specifications correct?
>
> A. I'm sure they were satisfied with it, yes, but to me they are not satisfactory.

Thus, in his deposition testimony, Sancaktar concedes that the patellar components conformed to the manufacturing specifications. In Sancaktar's affidavit, however, he states two bases for asserting there was a manufacturing defect:

> Defendant's [patellas] are defective in design and manufacture in that they left the defendant after having been submitted in the manufacturing process to E-beam irradiation and annealing that resulted in wide variations in strength and hardness. Disparate strength of the product at various points caused it to scar, pit, and fracture prematurely while forces occasioned by the use of knee were imposed on the product.
>
> . . .
>
> It is also my opinion that the explanted polyethylene knee buttons and fixation pegs [the patellas removed from Yanovich's knees] were defective in manufacture or construction because they did not perform to the standards of the manufacturer and deviated from the design as shown by the greater hardness of the pristine sample kneecap button.

Thus, there is a *prima facie* contradiction between Sancaktar's position before Zimmer's motion for summary judgment and his position after. However, this apparent contradiction is arguably resolved upon consideration of the definition of "manufacturing defect" given by Zimmer's attorney during Sancaktar's deposition:

> If we define defective in manufacture as being devices that do not conform to a manufacturer's specification with that definition in mind have you reached the conclusion . . . that Mrs. Yanovich's devices were defective in manufacture?

This definition is not incorrect, but it is incomplete. Under OPLA, a product is defective in manufacture or construction if

> when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards. A product may be defective in manufacture or construction as described in this section even though its manufacturer exercised all possible care in its manufacture or construction.

O.R.C. § 2307.74(A).

Thus, Sancaktar could have identified a manufacturing defect by demonstrating that the extracted patellas deviated in a material way from *either* (1) Zimmer's design specifications/standards; *or* (2) otherwise identical units made by Zimmer. Zimmer's attorney asked Sancaktar whether or not the patellas deviated from design specifications, but he did not ask about any findings by Sancaktar as to whether the explanted or extracted patellas deviated from the sample patellas. Thus, though Sancaktar agrees that the extracted patellas conformed to Zimmer's blueprints, his opinion that there is a manufacturing defect based on the fact that the extracted patellas deviated from the sample patellas is not contradictory.

Even if the court was correct to construe Sancaktar's statements as contradictory, it was wrong to discount Sancaktar's affidavit. *Cleveland* does not hold that a district court can never consider a contradictory affidavit but only that a "party cannot create a genuine issue of fact sufficient to survive summary judgment simply by contradicting his or her own previous sworn statement . . . *without explaining the contradiction or attempting to resolve the disparity*." *Cleveland*, 526 U.S. at 806 (emphasis added).

In *Aerel, S.R.L. v. PCC Airfoils, L.L.C.*, 448 F.3d 899 (6th Cir. 2006), we explored the rationale behind *Cleveland* and developed a two-part inquiry for determining whether a party's apparently conflicting affidavit should be considered:

> [A] district court deciding the admissibility of a post-deposition affidavit at the summary judgment stage must first determine whether the affidavit directly contradicts the nonmoving party's prior sworn testimony. A directly contradictory affidavit should be stricken unless the party opposing summary judgment provides a persuasive justification for the contradiction. If, on the other hand, there is no direct contradiction, then the district court should not strike or disregard that affidavit unless the court determines that the affidavit "constitutes an attempt to create a sham fact issue." *See Franks* [*v. Nimmo*, 796 F.2d 1230, 1237 (10th Cir. 1986)]. A useful starting point for this inquiry is the nonexhaustive list of factors articulated by the Tenth Circuit in *Franks*, where the court noted that the existence of a sham fact issue turns on "whether the affiant was cross-examined during his earlier testimony, whether the affiant had access to the pertinent evidence at the time of his earlier testimony or whether the affidavit was based on newly discovered evidence, and whether the earlier testimony reflects confusion [that] the affidavit attempts to explain." *Id.*

Aerel, S.R.L., 448 F.3d at 908-09 (some internal citations omitted).

In this case, Yanovich attempted to resolve the apparent contradiction:

> All of Sancaktar's opinions were expressed in his report in a timely way. That which Zimmer claims are "new opinions" are not new at all. Sancaktar's basic relevant opinions are neither new or contradictory and any differences are explained as semantical.

(Appellants' Reply Br. 2).

Though Yanovich's argument is not particularly clear, she does hint at an important difference between a scientific expert contradicting previous scientific findings and a scientific expert contradicting previous *legal* analysis. Sancaktar's affidavit does not contradict his scientific findings, but only clarifies his legal interpretation of those findings. That is, his affidavit clarifies

that he is asserting a manufacturing defect, as defined under OPLA, based on his original findings that the extracted and sample patellas differed and his recently clarified understanding of the relevant law.

For these reasons, the district court should not have discounted Sancaktar's affidavit despite the fact that it appeared to contradict his early report and deposition testimony.

2. Manufacturing defect

Sancaktar admitted that there was no deviation from the design specifications; thus, the only question is whether Sancaktar's testimony raised a genuine issue of material fact that the extracted patellas "materially deviated" from the sample patellas. Sancaktar measured the hardness of the two patellas extracted from Yanovich's knees and the "pristine" or sample patella supplied by Zimmer using the Shore Durometer[2] test. His initial report lists the hardness values, measured on the Shore D scale, at various points on each of the patellas. He notes in his conclusions: "For Patella 1, the hardness values at front vary by as much as 57% from 58 [Shore D Hardness ("SDH")] to 25 [SDH]. For Patella 2, the hardness values at front vary by as much as 56% from 63 [to] 27.5." The hardness ratings for the pristine patella however, varied only from 60 SDH to 49 SDH.[3] Sancaktar's theory,

[2] The Shore Durometer test is a common method of determining hardness. There are two Shore scales, Shore A and Shore D, both of which measure the resistance of plastic materials to indentation and provide an empirical hardness value that does not correlate to other properties or fundamental characteristics. The Shore A scale is commonly used for soft plastics and the Shore D scale, used by Sancaktar, is appropriate for harder plastics.

[3] Sancaktar does not list the percentage of variation for the hardness ratings on the sample patella. This is because his initial report focused more on the variation of hardness *ratings* within a single patella as opposed to the variation in hardness *ranges* across patellas.

as stated in his deposition, is that this variation reflects the underlying variation in the crosslinking and crystallization of the plastic polyethylene from which the patellar component is formed:

> My opinion is that the electron beam, E-beam as referred, process used to crosslink the [patella's] ultra-high molecular weight polyethelene, does not produce a uniform crosslinking. . . . And subsequently the parts are annealed, they are heated and then cooled slowly to induce crystallization. And that also does not produce a uniform and desirable level or kind of crystallization, and as a result it's my opinion that from what I see from this particular component that there is a variation of properties in the patella and that is a result or artifact of the process–of the manufacturing process in my opinion.

Accordingly, it seems clear that Sancaktar's initial report proffers evidence that the extracted patellas did in fact deviate from the sample patellas. This is the basis for the conclusion, stated in his affidavit, that there is a manufacturing defect.

Mere deviation, however, is not enough to demonstrate a manufacturing defect. In order to prove that there was a manufacturing defect, Yanovich, via her experts, would also have to demonstrate that the deviation is "material." O.R.C. § 2307.74(A). Ohio courts have yet to fully define "materiality." It is clear, though, that, under Ohio law, not every variation or discrepancy rises to the level of a manufacturing defect. In *In re Air Crash Disaster at Sioux City*, 781 F. Supp. 1307 (N.D. Ill. 1991) (applying Ohio law as to the products liability claims), the court held that even though the plaintiffs had identified an undesirable metallurgical flaw in the relevant product, they had not established that the metallurgical flaw constituted a "defect" within the meaning of OPLA:

> Plaintiffs contend that the product in question, the General Electric fan disk, was defective because it was sold containing a hard alpha inclusion. The evidence is uncontroverted that the hard alpha inclusion contained in the fan disk had an undesirable metallurgical flaw. However, plaintiffs have not established that the metallurgical flaw constitutes a "defect" within the meaning of the statute.

> Ohio courts appear not to have had an opportunity to construe the meaning of the "material deviation" standard stated in § 2307.74 since the implementation of Ohio's product liability statutes in January 1988. A literal application of § 2307.74 requires that plaintiffs establish that the flaw constitutes a material deviation from design specification or industry performance standards. Evidence exists in the record that it is well known among users of titanium that titanium ingot has a certain incidence of hard alpha inclusion. Moreover, evidence in the record suggests that users of titanium ingot are generally aware that it is not possible to completely eliminate hard alpha inclusions and that these inclusions may pass the most rigorous inspection processes undetected. However, because of titanium's other metallurgical qualities, the aircraft industry often specifies the use of titanium over other metals despite the incidence of inclusions. This evidence inferentially suggests a general aircraft industry acceptance of titanium containing some degree of hard alpha inclusion in products manufactured from titanium.

Id. at 1310-11 (citations omitted).

The court in *Air Crash Disaster at Sioux City* distinguished acceptable differences in products from "material" deviations. Some level of imperfection was inevitable in the product, but that imperfection was tolerated because of the material's other good qualities. Based on this fact, the court reasoned that the plaintiffs had to introduce more than evidence of a mere deviation itself in order to show that the deviation was material. The same reasoning applies in the case at hand.

In Sancaktar's deposition, he admitted that Zimmer's specifications allowed for variation in the level of crosslinking, and thus, according to Sancaktar's theory, in the level of hardness. Accordingly, the mere fact that the extracted patellas deviated from the sample is not enough to demonstrate materiality.

Though proving that a deviation is *material* and proving that the deviation is the *cause* of the injury are related questions, they are nevertheless distinct inquiries. Of course, if Sancaktar introduced evidence that the deviation caused the injury, that would be evidence that the deviation

was material. But one could establish materiality without establishing causation. For example, Sancaktar could have tested whether a somewhat weaker patella could withstand the same forces as found in the human knee as the pristine patella. If the weaker patella could not withstand those forces, then such a weakness could be material. However, if the weaker patellas could withstand those same forces, then the fact that some patellas are stronger could be irrelevant and the deviation would be *immaterial*.

Unfortunately for Yanovich, Sancaktar's deposition testimony demonstrates that he made no inquiry into the materiality of the deviation he had identified:

> Q. Do you know statistically what level of hardness a patellar component must have before it will fail in clinical use?
>
> A. I did not determine that.
>
> Q. Okay. And again, with respect to the crosslinking, do you know what amount of crosslinking has to occur in a patellar component before there will be a failure of the component.
>
> A. I did not determine that.
>
> Q. And with respect to the crystallinity of a patellar component, at what level must the crystallinity be before the patellar component will fail.
>
> A. I did not determine that. I'm hoping Zimmer will.
>
> . . .
>
> Q. You told me already that you've not undertaken an effort to determine the amount of hardness that a device must have in order to avoid fracture, correct?
>
> Q. And the same thing is true with crosslinking and crystallinity, correct?
>
> A. Correct.

> Q. It is also accurate to say that you've not undertaken any effort to determine whether the hardness level of Mrs. Yanovich's device was such that it caused her patellar device to fracture?
>
> A. Correct. That's correct.
>
> Q. In other words, you know the hardness of her patellar components, correct?
>
> A. Correct.
>
> Q. But you don't know whether that hardness level caused the fracture of her devices?
>
> A. That's correct.
>
> Q. And I want to ask you the same thing about crosslinking and crystallinity. You told me earlier you don't now the amount of crosslinking that had occurred in her device, correct?
>
> A. Correct.
>
> Q. And that for that reason you don't know whether the lack of uniformity, if there is a lack of uniformity in Mrs. Yanovich's device caused her devices to fracture, correct?
>
> A. Correct.
>
> Q. And with respect to crystallinity, you observed the crystallinity of Mrs. Yanovich's devices, correct?
>
> A. Well, I did not observe the crystallinity but I do know that Zimmer does report that there may be some variation.

Yanovich attempts to overcome her lack of evidence by arguing that "the fact that the extracted patella[s] failed is significant evidence of a defect." Though this argument is not frivolous, it is ultimately without merit.

> Product defects may be proven by direct or circumstantial evidence. Where direct evidence is unavailable, a defect in a manufactured product existing at the time

> the product left the manufacturer may be proven by circumstantial evidence where a preponderance of that evidence establishes that the loss was caused by a defect and not other possibilities, although not all other possibilities need be eliminated.

State Farm Fire & Cas. Co. v. Chrysler Corp., 523 N.E.2d 489, 493-94 (Ohio 1988) (citing *Friedman v. General Motors Corp.*, 331 N.E.2d 702 (Ohio 1975) and *State Auto. Mut. Ins. Co. v. Chrysler Corp.*, 304 N.E.2d 891 (Ohio 1973)). However, before a plaintiff "can rely on circumstantial evidence or the process of elimination . . . the plaintiff must at least present evidence to show why the defendant's product should not be among the possible causes to be eliminated." *Indiana Ins. Co. v. General Electric Co.*, 326 F. Supp. 2d 844, 856 (N.D. Ohio 2004) (quoting *Truck Ins. Exch. v. MagneTek, Inc.*, 360 F.3d 1206, 1215 (10th Cir. 2004) (internal quotation marks omitted)). That is, in order to rely on circumstantial evidence to prove the existence of a defect, Yanovich must introduce other evidence that either (1) *eliminates* some of the other possible causes of the injury or (2) establishes that a defect-free product would not have performed the way the product at issue performed.

Sancaktar failed to eliminate other potential causes for the patellas' breakage. Thus, in order for Yanovich to rely on circumstantial evidence she must establish that defect-free patellas would not have performed the way her patellas performed. Yanovich has failed to make such a showing. Zimmer's position is that (1) the patellas were not defective; (2) they broke due to a combination of Yanovich's biometrics and the way they were implanted; (3) had other patellas been implanted in the same way that these patellas were implanted, they also would have been likely to fail. Yanovich, of course, provides an alternate theory, but she does not provide any evidence to support her

contention that non-defective patellas would not have broken had the other circumstances of her surgery and her biometrics remained the same.

This distinguishes Yanovich's situation from the cases in which Ohio courts have found that circumstantial evidence supported the existence of a defect. In those cases, there was some affirmative evidence that a non-defective product would not have failed in the manner of the product at issue.

In *Colboch v. Uniroyal Tire Co.*, 670 N.E.2d 1366 (Ohio Ct. App. 1995), for example, the plaintiff was mounting a tire on a wheel base when the tire exploded and injured him. The plaintiff introduced testimony that the tire was inflated to only 35 p.s.i. when it exploded. According to the defendant's own expert witness, a normal tire, conforming to the company's manufacturing standards, would have been able to withstand inflation up to 40 p.s.i. during the mounting process. Thus, if the plaintiff's testimony were true (that the tire was only at 35 p.s.i. when it exploded) then the mere fact of the tire's explosion would be circumstantial evidence that (1) there was a deviation between the tire at issue and manufacturer's specification; and (2) that the deviation was material.

In a similar case, *Pearce v. Fouad*, 766 N.E.2d 1057 (Ohio Ct. App. 2001), the court also concluded that the plaintiff provided sufficient circumstantial evidence "to allow a jury to find that, but for a defect which was present when the sixteen-inch, oscillating fan left its manufacturer, the fire would not have occurred." *Id.* at 1064.

> It is true that plaintiff provided no direct evidence that a defect in the sixteen-inch, oscillating fan caused the fire, or that such a defect was present when the fan left the control of its manufacturer. However, it is well-settled that the existence of a manufacturing defect may be established by circumstantial evidence. *Colboch v. Uniroyal Tire Co., Inc.* (1996), 108 Ohio App. 3d 448, 670 N.E.2d 1366. Here, the

> expert testimony, together with plaintiff's mother's testimony, established that the fire in plaintiff's bedroom was caused by something impeding the blades of the sixteen-inch, oscillating fan, which impedance caused the motor to stop and overheat. The expert testimony further established that UL safety guidelines for electric fans require such fans to be protected against overheating either by the installation of a thermal cutoff switch or an impedance protected motor design. Finally, plaintiff's expert testified that an electric fan which has a properly functioning thermal cutoff switch or a properly functioning impedance protected motor will not cause a fire. Defendant's expert did not offer an opinion as to the cause of the fire. Together, this evidence provides sufficient circumstantial evidence to allow a jury to find that, but for a defect which was present when the sixteen-inch, oscillating fan left its manufacturer, the fire would not have occurred.

Pearce, 766 N.E.2d at 1064-65.

In both *Colboch* and *Pearce*, the plaintiffs introduced evidence that if the device had conformed to the manufacturer's specifications, then the injury would not have occurred. In *Colboch*, that evidence came from the defendant's own expert witness who testified that a conforming tire would not have exploded at 40 p.s.i. Similarly, in *Pearce* the defendant conceded that according to its design specifications, the electric fan was supposed to be compliant with UL safety guidelines, which required either a thermal cutoff switch or an impedance protected motor design–either one of which would have prevented the fan from overheating. Thus, even though the experts in the above cases could not point to a *particular* defect in the product, there was circumstantial evidence that a defect existed and that the defect was the cause of the injury.

In this case, however, Sancaktar does not assert and Zimmer does not admit that had the extracted patellas had the same hardness as the pristine samples then they would not have failed. In fact, as noted above, Sancaktar specifically denies making any inquiry into the matter. Thus,

Yanovich has failed to proffer circumstantial evidence sufficient to raise a genuine issue of material fact, and Zimmer's motion for summary judgment should be granted.

3. Design Defect

> Under OPLA, a product is defective in design if
>
> at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation as determined pursuant to division (B) of this section exceeded the benefits associated with that design or formulation as determined pursuant to division (C) of this section.
>
> (B) The foreseeable risks associated with the design or formulation of a product shall be determined by considering factors including, but not limited to, the following:
>
> (1) The nature and magnitude of the risks of harm associated with that design or formulation in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product;
>
> (2) The likely awareness of product users, whether based on warnings, general knowledge, or otherwise, of those risks of harm;
>
> (3) The likelihood that design or formulation would cause harm in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product;
>
> (4) The extent to which that design or formulation conformed to any applicable public or private product standard that was in effect when the product left the control of its manufacturer.
>
> (5) The extent to which that design or formulation is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.
>
> (C) The benefits associated with the design or formulation of a product shall be determined by considering factors including, but not limited to, the following:
>
> (1) The intended or actual utility of the product, including any performance or safety advantages associated with that design or formulation;

> (2) The technical and economic feasibility, when the product left the control of its manufacturer, of using an alternative design or formulation;
>
> (3) The nature and magnitude of any foreseeable risks associated with an alternative design or formulation.

Ohio Rev. Code. Ann. § 2307.74(A)-(C).

In general, the determination of whether a design defect exists is a question of fact. *Nadel v. Burger King Corp.,* 695 N.E.2d 1185, 1191 (Ohio Ct. App. 1997). However, in order to survive summary judgment, the plaintiff must introduce evidence "on which the jury could reasonably find for the plaintiff." *Anderson*, 477 U.S. at 252. Taking into account Sancaktar's initial report, deposition testimony, and affidavit, there was insufficient evidence to submit the question of a design defect to the jury.

Yanovich asserts that the defect identified by Sancaktar is the "weakness and lack of consistent overall strength" in the patellas. Reading Sancaktar's statements in the light most favorable to Yanovich, we construe them as asserting a design defect in regard to the choice of plastic that forms the patellas and the two processes used to harden the plastic, E-beam irradiation and tempering. Sancaktar's argument is essentially that Zimmer's choice of plastic and hardening technique produced unpredictable levels of crosslinking that occasionally resulted in insufficiently strong products.

Zimmer points out that in Sancaktar's initial deposition testimony he does not assert that the hardening process made the patella's design defective, but only "unacceptable." Zimmer argued, and the district court agreed, that Sancaktar's statements of unacceptability were "insufficient to constitute expert opinion that the design of the patellas is defective."

This linguistic argument is not particularly persuasive because, as previously discussed, Sancaktar was unfamiliar with legal terms of art. Nevertheless, the district court was correct to point out that: (1) Sancaktar had found no literature reporting a failure of NK II patellas; (2) he knew of no other NK II patellas that had failed; and (3) he did not study the success rate of NK II patellas in isolation or in comparison to the other patellas available at the time. That is, Sancaktar failed to inquire about the foreseeable risks associated with the design or formulation of the patellas under Ohio Rev. Code. Ann. § 2307.74(B), and he failed to examine the benefits associated with the design or formulation of the patellas under Ohio Rev. Code. Ann. § 2307.74(C). Without having made such inquiries, Sancaktar had no legal basis for his conclusion that Zimmer's design choice in using E-beam and tempering to harden the polyethylene is defective. Even under the generous standard of review for a grant of summary judgment, we do not "accept as true legal conclusions or unwarranted factual inferences." *City of Monroe Employees Ret. Sys. v. Bridgestone Corp.*, 387 F.3d 468, 482 (6th Cir. 2004) (quoting *In re Sofamor Danek Group, Inc.*, 123 F.3d 394, 400 (6th Cir. 1997)). Thus, the district court was correct to hold that Yanovich failed to introduce evidence sufficient to survive summary judgment on the issue of design defect.

4. Causation

Before the district court analyzed whether Yanovich had adequately asserted a design or manufacturing defect, it held that summary judgment was appropriate on the grounds that the "plaintiffs have no expert medical evidence showing that Yanovich was injured as a proximate result of a defect in the patellas." We decline to decide the issue of whether Yanovich was required to introduce medical expert testimony on the issue of causation. Having determined that Yanovich's

expert did not proffer sufficient evidence of a manufacturing or design defect, we end our analysis of Yanovich's manufacturing and design defect claims.

5. Inadequate warning or instruction

Under OPLA, a product is defective due to inadequate warning or instruction at the time of marketing if, when it left the control of its manufacturer, both of the following applied:

> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
>
> (b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

Ohio Rev. Code Ann. § 2307.76(B)(2). A product is defective due to inadequate post-marketing warning or instruction if, at a relevant time after it left the control of its manufacturer, both of the following applied:

> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
>
> (b) The manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

Ohio Rev. Code Ann. § 2307.76(A)(2).

OPLA also states:

> An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.

Ohio Rev. Code Ann. § 2307.76(C).

This section embodies the "learned intermediary doctrine." Though this section discusses ethical drugs and is silent on prescription medical devices, the Ohio Supreme Court held that the same rationale applies to such devices. In *Vaccariello v. Smith & Nephew Richards, Inc.*, 763 N.E.2d 160, 164-65 (Ohio 2002), the Ohio Supreme Court concluded that (1) the common-law learned intermediary doctrine was not specifically eliminated or modified by the Ohio Products Liability Act and was therefore a viable doctrine; and (2) the doctrine should be extended to prescription medical devices.

Applying the doctrine to the case at hand, Zimmer was only under a duty to provide warning and instruction to the physician. Yanovich argues that Zimmer breached this duty because it offered "no warnings published . . . to the medical profession that remotely address the issues of not using its Natural Knee II in patients that are short, stocky, have big upper legs or are overweight." The product documentation in the record along with the testimony of Charles Clark, M.D., Zimmer's expert witness, flatly contradict Yanovich's unsupported assertions. Yanovich's doctors were adequately warned about the dangers inherent in Zimmer's NK II system. The district court was thus correct to dismiss Yanovich's claim based on inadequate warning.

B. Breach of warranty and failure to conform to representation claims

Yanovich raised two additional claims for the first time in her motion opposing summary judgment. She argued that Zimmer had breached the implied warranties of merchantability and fitness for a particular purpose and that the patellas are defective because they are not in conformity with a specific representation by Zimmer. "A party is not entitled to wait until the discovery cutoff date has passed and a motion for summary judgment has been filed on the basis of claims asserted in the original complaint before introducing entirely different legal theories . . . ." *Priddy v. Edelman*, 883 F.2d 438, 446 (6th Cir. 1989).

Because these claims were raised for the first time in Yanovich's brief opposing Zimmer's motion for summary judgment, the district court properly disregarded them.

C. Michael Yanovich's Claims

Michael Yanovich's claims for loss of wages, services, and consortium are derivative actions based on his wife's claims and can be maintained only so long as the underlying actions remain viable. *Messmore v. Monarch Mach. Tool Co.*, 463 N.E. 2d 108 (Ohio Ct. App. 1983) ("A cause of action based upon a loss of consortium is a derivative action. That means that the derivative action is dependent on the existence of a primary cause of action and can be maintained only so long as the primary action continues."). Because we find summary judgment was properly granted on Cynthia Yanovich's claims, the district court was correct to dismiss all of Michael Yanovich's claims.

III

For all of the above-stated reasons, we affirm the district court's grant of summary judgment.