

An EpiPen is a product that contains a dose of the drug epinephrine, which is used to treat anaphylactic shock. Najib's physician had prescribed the drug for him to use when he suffered an acute asthma attack. On or about April 19, 1997, he suffered such an attack, but when he opened the EpiPen, he discovered that it had prematurely ejected. He apparently suffered no injury as a result of this attack. Shortly thereafter, on or about April 26, 1997, Najib suffered another acute asthma attack and his fiancée, Julie Campbell, attempted to assist him by unboxing a new EpiPen and removing it from its outer tube. However, Ms. Campbell was unable to remove the gray safety cap, and while Najib was attempting to remove it, the EpiPen "fell apart" (Deposition of Julie Campbell, J.A. 598) and became unusable. As a result, Ms. Campbell and Najib were unable to administer the shot and Najib lost consciousness while waiting for an ambulance. (*Id.* at 603). Ms. Campbell was able to resuscitate him, and he was taken to the emergency room for treatment. (*Id.* at 609-612). Dr. Kenneth Bain, a neuropsychologist, opined that the second incident caused hypoxic brain damage. (Deposition of Kenneth Bain, J.A. 526-528).

Najib's Complaint alleged the following: in Counts One and Two, negligence in design, manufacture, and failure to warn; in Count Three, failure to conform to representation; in Count Four, supplier liability; and in Count Five, breach of implied warranty of merchantability. (J.A. 15-22). Counts Two, Three and Four included violations of Ohio's products liability statute. (*Id.*).

The district court granted summary judgment on all of Najib's claims. In so doing, the district court held that the testimony of Jack Raber, a pharmacist, was irrelevant. The district court also held that the testimony of Najib's expert, Dr. Reese, was inadmissible because it

would not help the trier of fact and further held that this failure to produce admissible expert testimony was fatal to his claims.

II. STANDARD OF REVIEW

This court reviews *de novo* a district court's award of summary judgment. *Barrett v. Harrington*, 130 F.3d 246, 251 (6th Cir. 1997). Summary judgment is proper if the evidence submitted shows that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). This Court must view the entire record in the light most favorable to the non-moving party. *Smith v. Chrysler Corp.*, 155 F.3d 799, 804 (6th Cir. 1998). This court reviews the district court's decisions to exclude the testimony of Dr. Reese and Mr. Raber for abuse of discretion. *See, e.g., General Electric Co. v. Joiner*, 522 U.S. 136, 141, 118 S.Ct. 512, 517, 139 L.Ed.2d 508 (1997).

III. ANALYSIS

A. Admissibility of Dr. Reese's testimony

The district court's Opinion and Order (J.A. 473) indicates that, although it found Dr. Reese to be qualified to receive an expert designation, it did not find that his testimony would be helpful to a jury in "determin[ing] whether and how the EpiPens were defective." (J.A. at 480-81). With regard to Najib's claims of negligent design and manufacture, the district court listed three ways in which a product's design could be defective. One is where the product "is more dangerous than an ordinary consumer would expect ... or ... the benefits of the challenged design do not outweigh the risk inherent in such design." (J.A. at 481, *quoting City of Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1146 (Ohio 2002)). A second is "where the

manufacturer fails to incorporate feasible safety features to prevent injuries.” (J.A. at 482, *citing Perkins v. Wilkinson Sword, Inc.*, 700 N.E.2d 1247 (Ohio 1998)). The third such situation occurs when “a product ... differs in a material way from its design specifications or from otherwise identical units.” (J.A. at 482, *citing Kemp v. Medtronic, Inc.*, 1999 U.S. Dist. LEXIS 22470, at * 24 (S.D. Ohio 1999)).

In light of these possibilities, the district court examined Dr. Reese’s testimony and determined that it amounted to his “opinion ... that something malfunctioned, but he did not know what.” (J.A. at 482-3). The district court noted that Dr. Reese “did not even review the EpiPen’s design specifications or manufacturing procedures,” which it said “prevented him from addressing whether and how the EpiPen differed in a material way from its design specifications or from otherwise identical units.” (J.A. at 483). It also said that Dr. Reese’s testimony did not address the first or third possible bases for a finding of negligence in design or manufacture listed above. (*Id.*). As to the failure to warn, the district court said that because Dr. Reese was “unable to identify the alleged defect,” Najib had “failed to prove that Defendants knew or should have known about a defect” and granted summary judgment on that claim. (J.A. at 484). Similarly, with respect to the claim of failure to provide usable instructions, the district court said that “[b]ecause [Dr. Reese’s] report fails to detail how the instructions were unclear, his conclusion [that they were inadequate] is irrelevant.” (*Id.*).

Addressing the claim of a defect in manufacture or construction, the district court found that Najib could not satisfy the first prong of the test set forth in the statute (which requires him to establish by a preponderance of the evidence that there was a defect in the product) because “[Dr.] Reese cannot state what the alleged defect was.” (J.A. at 485). The district court granted

summary judgment on that claim, as well as the claims for failure to conform to representations and the breach of implied warranty of merchantability, on essentially the same grounds. Examination of Dr. Reese's report (J.A. 348) and deposition testimony (J.A. 762) indicates that the district court correctly interpreted Dr. Reese's testimony. Although Dr. Reese did discuss possible alternate designs and alternate labeling/packaging possibilities in his report, such discussion amounts essentially to speculation where the actual defect in a product is not identified. Therefore, it appears that the district court did not abuse its discretion in excluding Dr. Reese's testimony.

B. Sufficiency of Najib's admissible evidence

A separate issue, addressed although not so delineated by the parties, is whether, even exclusive of Dr. Reese's testimony, summary judgment on Najib's claims was appropriate. Najib argues that the circumstantial evidence of a defect in the case (i.e., the evidence that the gray cap became stuck and the EpiPen fell apart) is sufficient to create an issue for the jury. In response, Meridian argues only that "Plaintiff is not qualified to testify regarding the technical aspects of the Epi-pen's design or components, its manufacture ..." and that "Plaintiff's testimony by itself is insufficient, as a matter of law, to sustain his claim for design or manufacturing defect." (Defendant-Appellant's Brief, at 15).

A careful reading of the district court's opinion indicates that it did not consider the possibility that the circumstantial evidence could be sufficient to withstand the summary judgment motion. As Plaintiff correctly asserts, Ohio law provides for this possibility. In *State Farm Fire & Cas. Co. v. Chrysler Corp.*, the Supreme Court of Ohio said that

[w]here direct evidence [of a product defect] 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.

523 N.E.2d 489, 493-94, 37 Ohio St. 3d 1, 5 (Ohio 1988). In that case, which involved a fire of unknown origin that broke out in the plaintiff's vehicle while it was parked, the Supreme Court of Ohio affirmed a directed verdict in favor of the car's manufacturer because the circumstantial evidence that did exist failed to rule out a number of causes (maintenance, etc.) and therefore could not causally link the fire to a defect in the car's manufacture. *Id.* at 495. In this case, the destruction of the EpiPen as a result of its failure rendered direct evidence unavailable, meaning circumstantial evidence may be used to establish that the EpiPen was defective. The district court's opinion, however, does not address this possibility. Rather, it examines only the expert testimony offered by Plaintiffs and grants summary judgment on the basis of its exclusion of that testimony. This is understandable in light of the fact that the arguments before the district judge concerned primarily the admissibility of the expert testimony. However, Najib did raise the circumstantial evidence argument. The district court said:

...the Court holds that [Dr. Reese's] testimony and report will not help the trier of fact determine whether the EpiPen was negligently designed or manufactured. Accordingly, the Court grants the Defendants' motion for summary judgment on these claims.

(J.A. at 483). The district court made similar statements in its analysis of several of Najib's other claims. (J.A. at 484, 485, 487).

We believe, however, that the circumstantial evidence in Najib's case is significantly different from that presented in *State Farm* because he presented testimony that excludes other possible causes for the EpiPen's malfunction. He and his fiancée both testified that the EpiPen in question was new, had not previously been removed from its box, and that they knew how to

remove the cap. Therefore, we believe that Najib's case is more similar to the situation described by the Ohio Court of Appeals in *Hickey v. Otis Elevator Co.* in which proof of causation by circumstantial evidence was held to be appropriate for jury determination. 840 N.E.2d 637, 641-42, 163 Ohio App.3d 765, 770-71 (Ohio Ct. App. 2005). In that case, the Court of Appeals distinguished between cases in which the issue of causation is complicated by virtue of the nature of the product at issue (*Hickey* dealt with a malfunctioning elevator) and those in which a jury could reasonably infer causation from the circumstantial evidence because the product itself was relatively simple (citing *Porter v. Gibson Greetings, Inc.*, 1997 WL 761851 (Ohio App. 2 Dist. 1997), which dealt with an ordinary balloon). *Id.* Therefore, we believe that the district court's opinion inappropriately granted summary judgment on the issue of defect where an issue of material fact exists. We note that we express no opinion on the issue of causation, as that issue is not before us at this time.

We note, however, that, under Ohio law, the use of circumstantial evidence to prove the element of defect is allowable in the context of products liability claims, but is insufficient to prove negligence. *Gast v. Sears Roebuck & Co.*, 313 N.E.2d 831, 39 Ohio St.2d 29 (Ohio 1974). Therefore, as to Najib's negligence claims, the district court's grant of summary judgment for failure to introduce evidence of breach was appropriate in light of its evidentiary rulings.

C. Admissibility of Mr. Raber's testimony

Plaintiff offered the testimony of Jack Raber, a pharmacist. As to the admissibility of Mr. Raber's testimony, the district court's opinion says:

Plaintiff offers the deposition testimony of Raber, a pharmacist, to establish that the EpiPen could be used to treat asthma attacks. Thus, Raber did not testify to Plaintiff's manufacturing or design defect claims, nor did his testimony address Plaintiff's inadequate warning and instruction claims. Because the Court

excluded [Dr. Reese's] report and testimony above, Plaintiff is unable to establish that the EpiPen malfunctioned. Consequently, [Mr. Raber's] testimony becomes irrelevant and the Court grants the Defendants' motion for summary judgment for lack of evidence.

(J.A. 488). The district court based its evaluation of Mr. Raber's testimony's relevance on its conclusion that Plaintiff had failed to survive summary judgment due to the shortcomings of Dr. Reese's testimony. However, as discussed in Section B, *supra*, the district court erroneously failed to consider circumstantial evidence in making this determination. Therefore, the relevance of Mr. Raber's testimony may also need to be reconsidered in light of the district court's consideration of that evidence.

D. Supplier-liability claim

As noted above, count four of Najib's complaint alleged supplier-liability against Meridian. Under Ohio law, Meridian cannot be considered both the EpiPen's manufacturer and its supplier. Ohio's products liability statute specifically provides, in its definition of "supplier," that the term "does not include ... a manufacturer." *Ohio Rev. Code Ann.* § 2307.71(15)(b). Therefore, the district court's grant of summary judgment on this claim was proper.

III. CONCLUSION

For the foregoing reasons, we **AFFIRM** the district court's order granting summary judgment to the Defendants on Najib's supplier-liability claim and negligence claims, and **REVERSE** the grant of summary judgment on the issue of defect as to the remaining claims. We therefore **REMAND** the case for further proceedings consistent with this opinion.