UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

STEVEN KALLAL,	)	
	)	
Plaintiff,	)	**No. 09 C 3346**
	)	
v.	)	**Judge Rebecca R. Pallmeyer**
	)	
	)	
CIBA VISION CORPORATION,	)	
a foreign Corporation	)	
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Steven Kallal experienced eye irritation and inflamation after using contact lenses manufactured by Defendant Ciba Vision Corporation ("Ciba"). Ciba recalled some of its contact lenses in 2006, and Kallal reasons that the problem that led Ciba to order a recall—poor ion permeability of the lenses—caused the inflamation in his eyes. Kallal charges Ciba with negligence (Count I), strict product liability (Count II), and breach of implied warranty (Count III). (2d Am. Compl. [33].) Ciba moves for summary judgment, arguing that since Kallal never used Ciba's recalled lenses, each of his claims fail. (Def. Ciba Vision's Mot. for Summ. J. [111], at ¶ 3.) For the reasons explained below, Ciba's motion for summary judgment is granted.

FACTUAL BACKGROUND

For three months in 2006, Ciba manufactured O2 Optix contact lenses in Indonesia. After later testing, Ciba concluded that a "substantial percentage" of eleven million lenses that had entered the market had ion permeability levels below 1.0. (Pl.'s Am. Counterstatement of Material Facts [151], hereinafter "Pl.'s 56.1", ¶¶ 6-8.) A medical assessment conducted by Ciba in December 2006 or January 2007 concluded that the low permeability levels created a "negligible" risk to consumers; Ciba nevertheless instituted a voluntary recall of the lenses on January 12, 2007. (Pl.'s 56.1 ¶¶ 9, 18; Pl.'s Am. Resp. to Def.'s Statement of Material Facts [150], hereinafter "Pl.'s

Resp. to Def.'s 56.1", at ¶¶ 14, 18.)

Between September 1, 2006 and April 15, 2007, Ciba shipped approximately 150 orders of O2 Optix lenses to Rose Optical in Godfrey, Illinois; of those, about 52 were later recalled. (Pl.'s 56.1 ¶ 11.) In December 2006, an optometrist at Rose Optical prescribed -3.75 diopters[1] O2 Optix lenses for Plaintiff Kallal, and he received a sample pack of the lenses. (Pl.'s Resp. to Def.'s 56.1 ¶ 21.) When he visited the optometrist in December 2006, Kallal was suffering from "some light sensitivity and some red eyes." (Pl.'s Resp. to Def.'s 56.1 ¶ 24.) He purchased the -3.75 diopters O2 Optix lenses from Rose Optical and began wearing them in January 2007. (Pl.'s Resp. to Def.'s 56.1 ¶¶ 12, 22.) Kallal had previously worn other types of contact lenses and had experienced difficulty with those lenses "off and on." (Pl.'s 56.1 ¶ 12; Pl.'s Resp. to Def.'s 56.1 ¶¶ 20, 23.)

Approximately a week after he began using the O2 Optix lenses, Kallal developed "symptoms of redness, light sensitivity, dryness, and sharp pain." Kallal continued wearing the lenses, but eventually limited his use to times when he was participating in athletic activities. (Pl.'s Resp. to Def.'s 56.1 ¶¶ 26-27.) By early February 2007, Kallal began to experience "severe discomfort" from eyes that were dry, irritated, and red. (Pl.'s Resp. to Def.'s 56.1 ¶ 25.) Though he continued to experience discomfort, Kallal purchased another set of -3.75 diopters O2 Optix contact lenses in March 2007. (Pl.'s Resp. to Def.'s 56.1 ¶ 28.) Kallal stopped wearing contact lenses after May 5, 2007. (Pl.'s Resp. to Def.'s 56.1 ¶ 29.)

More than two years later, on or around June 4, 2009, Kallal sought treatment from Dr. Anjali Pathak for severe eye inflammation. (Pl.'s 56.1 ¶ 14.) Dr. Pathak examined Kallal and determined that he had chronic ocular surface inflammation, mixed papillary and follicular

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[1] A diopter is a unit for the refractive power of lenses. The refractive power in diopters of a lens is the reciprocal of the focal length in meters. *Dorland's Illustrated Medical Dictionary* 529 (31st ed. 2007).

conjunctivitis,[2] and punctuate corneal erosions[3] on the surface of his corneas. (Pl.'s 56.1 ¶ 15; Pathak Dep., Ex. 2 to Am. Mem. in Support of Pl.'s Resp. in Opp'n to Def.'s Mot. for Summ. J. [149], hereinafter "Pl.'s Resp.", at 79:19-24, 80:1-2.) Dr. Pathak believes that Kallal's symptoms were "probably related to contact lens wear" and that his lenses "could have started this cycle of inflammation that [Kallal] experienced." (Pathak Dep. at 27:14-21, 69:17-18.) Dr. Panthak had no information beyond Kallal's own report concerning the type of contact lens he had worn two years earlier; was unaware that Kallal had suffered from eye irritation even before beginning to wear the O2 Optix lenses; and was not familiar with the concept of "ion permeability." (*Id*. at 62:6-65:18; 73:9-10.) Kallal's eye injuries have since resolved. (Pl.'s Resp. to Def.'s 56.1 ¶ 30.)

Some of the O2 Optix lenses Kallal wore were manufactured in Indonesia at the same manufacturing plant where the recalled lenses were produced. (Pl.'s 56.1 ¶ 13.) According to Dr. Pathak, Kallal's symptoms were "consistent with oxygen deprivation to his eyes, secondary to contact lens use" as well as limited motility, or movement, of the contact lenses. (Pathak Dep. at 78:9-12, 80:9-11). Kallal contends these symptoms are "directly linked" to ion permeability levels in lenses. (Pl.'s 56.1 ¶¶ 2-3.) Kallal admits, however, that Ciba's records show that Ciba did not ship any O2 Optix lenses subject to the recall to Rose Optical in Kallal's prescription, -3.75 diopters. (Pl.'s Resp. to Def.'s 56.1 ¶ 33.)

DISCUSSION

Summary judgment is appropriate when "there is no genuine issue as to any material fact" such that the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c). Summary judgment is the "'put up or shut up' moment in a lawsuit, when a party must show what

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[2] Follicular conjunctivitis is "non-specific inflammation of the conjunctiva, the mucous membrane of the eyes." (Pathak Dep. 79:16-18.)

[3] A punctuate corneal erosion is "a very fine area of eroded corneal epithelium." (Pathak Dep. at 80:3-8.)

evidence it has that would convince the trier of fact." *Arnett v. Webster*, 658 F.3d 742, 760 (7th Cir. 2011) (citations omitted). The court views the facts and draws all reasonable inferences in favor of the non-moving party. *Anderson v. Liberty Lobby,* Inc., 477 U.S. 242, 255 (1986). The nonmoving party may not rely on bare allegations unsubstantiated by specific evidence, however, to establish a genuine factual dispute. *Id.* at 248. Summary judgment may be appropriate when "a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Celotex Corp. v. Catrett,* 477 U.S. 317, 323 (1986). The court considers the pending motion with these standards in mind.

Kallal asserts that the O2 Optix lenses he used were defective. (Pl.'s 56.1 ¶ 12.) Kallal's second amended complaint asserts that the lenses were defective because they did not meet Ciba's 1.0 ion permeability standard, and thus were subject to Ciba's recall. (2d Am. Compl. [33] ¶ 29.) Now, in the face of Ciba's evidence that Kallal could not have been using O2 Optix lenses subject to the recall, Kallal has shifted his argument. He now contends that the fact that his lenses were not subject to the recall does not foreclose the possibility that they were defective for some other reason. (Pl.'s Resp. at 7-8.) This is, of course, possible, but Plaintiff has not presented evidence that the lenses were defective for any reason at all. Plaintiff suffered eye irritation after wearing O2 Optix lenses. The mere fact that a consumer suffers a negative reaction to a product, however, does not constitute evidence that the product is defective. *See Adelman-Tremblay v. Jewel Co.*, 859 F.2d 517, 522 (7th Cir. 1988) (citing Annotation, *Products Liability: Strict Liability in Tort Where Injury Results From Allergenic (Side-Effect) Reaction to Product*, 53 A.L.R.3d 298, § 3 (1973) ("[A] product, faultlessly manufactured and containing no impurities, is not rendered defective per se, within meaning of the doctrine of strict liability in tort, by the mere fact that it causes injury to certain individuals who, because of hypersensitivity or other peculiarity of makeup, suffer an allergenic or idiosyncratic reaction when exposed thereto.")). Penicillin, for example, is not a defective drug even though it produces serious allergic reactions in some patients. Without

evidence of some objective defect in the O2 Optix lenses he wore, Kallal's reaction to the lenses is not enough to show they were defective.

As the court understands his reasoning, Plaintiff appears to believe that the O2 Optix lenses he used must be defective because he experienced eye injuries after wearing them. His argument hints at reliance on the doctrine of *res ipsa loquitur*. A plaintiff can establish a negligence claim under this doctrine "by showing that even if there is no direct evidence of negligence, the circumstances of the accident indicate that it probably would not have occurred had the defendant not been negligent." *Clifford v. Crop Prod. Servs., Inc.*, 627 F.3d 268, 273 (7th Cir. 2010) (quoting *Aguirre v. Turner Constr. Co.*, 582 F.3d 808, 810-11 (7th Cir. 2009) (applying Illinois law)). Plaintiff lacks such evidence here, because he fails to show that his injuries are of a type that ordinarily would not occur without negligence. Plaintiff himself complained of similar, if less severe, symptoms even before being prescribed O2 Optix lenses. His bad reaction to the O2 Optix lenses alone is not enough to create an inference that they were defective in light of many possible alternative causes of eye irritation while wearing non-defective lenses.

Kallal relies on the fact that at least some of the lenses he wore were manufactured in the same place as the recalled lenses, but that wisp of circumstantial evidence is not enough to create a dispute of fact on the claim that the lenses he used were defective. Without any such evidence, Kallal is left to argue that the court should "question the reliability of Ciba Vision employees" (presumably because a former employee allegedly evaded service of a deposition subpoena) and should be suspicious of records showing that no recalled lenses in Kallal's prescription were shipped to Rose Optical. (Pl.'s Resp. at 8, 16-20.) Neither Plaintiff's unsupported allegations about the character of Ciba employees, nor his speculations concerning Ciba's shipping records, are sufficient to create a genuine issue of material fact.

Notably, Kallal might well not succeed here even if he could show that the lenses he used were subject to recall and purportedly defective because they did not meet ion permeability

standards. Federal law preempts state law tort claims for Class III medical devices, such as Ciba's lenses, which are approved by the Food and Drug Administration ("FDA") pursuant to the FDA's pre-market approval ("PMA") procedures, unless the claimant can show that his state tort claim is parallel to a federal violation. 21 U.S.C. § 360k; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *see also Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010) ("where state law is parallel to federal law, section 360k does not preempt the claim"). Plaintiff emphasizes that Ciba failed to include the "material characteristic" of ion permeability in its release specifications for O2 Optix lenses, though Ciba had included ion permeability levels in its applications to the FDA for approval. (Pl.'s Resp. at 16-17.) Ciba points out, however, that Kallal has not established a federal law violation, in part because "ion permeability was not a specification for the . . . lenses prior to the initiation of the recall." (Mem. of Law in Support of Def.'s Mot. for Summ. J. [112] at 13.) Ciba argues that ion permeability was a "material characteristic" of the lenses, but it was not a specification that the FDA required Ciba to meet. (*Id.* at 13.)

Finally, even if Kallal somehow established that Ciba violated federal standards with respect to ion permeability, he has still offered no basis for the conclusion that ion permeability levels explain his negative reaction to the O2 Optix lenses he wore. Dr. Pathak testified that Kallal's injuries were consistent with oxygen deprivation, which, Kallal asserts, is linked to low levels of ion permeability. In support of the claimed link, Kallal relies on an affidavit by Len Czuba, a plastics engineer who Kallal claims is an expert in medical devices (Czuba's qualifications make no mentionof any previous experience analyzing contact lenses). (Pl.'s Resp. at 11-12; Czuba Report, Ex. 3 to Pl.'s Resp., at 3-4.) Czuba's report asserts that ion permeability is "inextricably intertwined" with oxygen permeability, and that low ion permeability can decrease the motility of lenses. (*Id.* at 12.) Ciba contends that "ion permeability has nothing to do with the breathability or oxygen permeability of the lens." (Ciba Reply Memo at 10 n. 2).) But even if Czuba's opinion is admissible, Kallal still lacks admissible evidence that (1) Ciba violated federal law when it failed to include ion

permeability specifications on some of its lenses; (2) that the lenses Kallal himself wore were defective because they had low ion permeability; or (3) that his eye injuries resulted from the alleged low ion permeability. Without evidence that supports any of these conclusions, the record is insufficient to withstand a motion for summary judgment.

CONCLUSION

Defendant's motion for summary judgment [111] is granted as to all counts.

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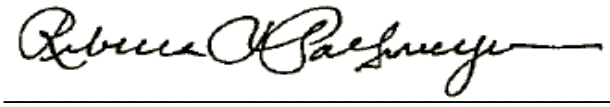

Dated: January 28, 2013

REBECCA R. PALLMEYER
United States District Judge