UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

STEVEN KALLAL,	)	
	)	
Plaintiff	)	
	)	
v.	)	**No. 09 cv 3346**
	)	
CIBA VISION CORPORATION, A foreign corporation; NOVARTIS PHARMACEUTICALS CORPORATION, A foreign corporation; and STEPHEN MARTIN, an individual,	)	**Judge Rebecca R. Pallmeyer**
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Steven Kallal filed this action in state court against Defendants Ciba Vision Corporation, the manufacturer and distributer of O_2 Optix contact lenses; Novartis Pharmaceuticals Corporation, the owner and parent corporation of Ciba Vision; and Stephen Martin, President of Ciba Vision.[1] Plaintiff alleges that his use of O_2 Optix lenses caused various injuries to his eyes, including grating, abrading, puncturing, tearing, and dehydration of the eyes. He filed suit in state court, and Defendants removed the case to federal court based on diversity jurisdiction. The court then dismissed the complaint without prejudice for failure to state a claim that was not preempted by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq*. Plaintiff has filed aan amended complaint alleging claims for negligence, strict liability, and breach of implied warranty, and Defendants have renewed their motion to dismiss based on preemption. For the reasons that follow, Defendants' motion is granted in part and denied in part.

[1] In their brief, Defendants refer to discussions regarding the voluntary dismissal of Defendants Novartis and Martin, but no such motion has been filed.

FACTUAL BACKGROUND

The following facts, drawn from the pleadings, are presumed true for the purposes of Defendants' motion. O_2 Optix soft contact lenses are produced by Ciba Vision. (Second Amended Compl. ¶ 1.) O_2 Optix lenses are classified as Class III medical devices under the MDA. (Order of Nov. 2, 2009) (taking judicial notice of that fact). Class III devices, which include such devices as replacement heart valves and pacemaker pulse generators in addition to the O_2 Optix lenses, receive the highest degree of government oversight and must pass a rigorous FDA premarket approval process before being marketed and sold. 21 U.S.C. § 360c(a)(1)(C). In contrast, Class I and Class II devices are subject to lesser oversight that may include labeling requirements, performance standards, and postmarket surveillance. *Id.* § 360c(a)(1)(A)-(B); *see generally Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316-17 (2008).

The FDA granted Defendant Ciba Vision's application for premarket approval of the O_2 Optix lenses on September 27, 2004. (Second Amendment Compl., Ex. 1.) Some two-and-a-half years later, around January 12, 2007, Ciba Vision notified medical facilities and distributors of a voluntary recall of several lots of their O_2 Optix soft contact lenses. (*Id.* at ¶ 20.) The recall notice explained:

> We are taking this voluntary action because we identified that some lenses in these lots may fall below our standard for ion permeability, a material characteristic that correlates with lens movement on the eye. Reduced ion permeability in O_2 OPTIX (lotrafilcon B) lenses may lead to reduced lens movement, symptoms of discomfort and/or foreign body irritation.

(*Id.*, Ex. 3., at 1) The letter also states that Ciba Vision was conducting the recall with the knowledge of the FDA. (*Id.*)

On January 8, 2007, shortly before the recall, Plaintiff's mother bought O_2 Optix contact lenses for her son, which he used. (*Id.* ¶¶ 23, 25.) He alleges that the contact lenses "were negligently and defectively manufactured in violation and noncompliance of the approved standards of the FDA pre-market approval order issued under the Medical Devices Act." (*Id.* ¶ 26.) As a result, the contact lenses "caused and promoted grating, abrading, puncturing, tearing and

dehydration of Plaintiff's eyes and further prevented adequate oxygen within approved standards to reach the corneal area and other eye surface." (*Id.* ¶ 27.)

Plaintiff's Complaint includes three claims: negligence, strict liability, and breach of the implied warranty of merchantability. In support of Count One, the negligence claim, Plaintiff alleges that Defendants failed to exercise reasonable care and due diligence in the "manufacturing, testing, quality assurance, sale, marketing, and/or distribution into the stream of commerce" of O_2 Optix contact lenses. (*Id.* at ¶ 29.) Plaintiff refers to Defendants' duty to ensure that the lenses were manufactured within the standards of the premarket approval order and to provide the notifications and reports required by the order. (*Id.* ¶ 29-30.) The only specific standard that Plaintiff refers to is the standard for ion permeability, which the Complaint seems to suggest was part of the order giving premarket approval to the lenses. He further alleges that Defendants failed to take timely action to warn vendors and consumers of their noncompliance with the premarket approval order. (*Id.* ¶ 31(c).)

Count Two makes similar allegations under a strict liability theory. Specifically, Plaintiff alleges that Defendants manufactured defective and unsafe O_2 Optix lenses, failing to comply with the standards required by the premarket approval process. (*Id.* ¶¶ 34, 35.) Plaintiff further alleges that Defendants failed to adequately test the lenses as required under the premarket approval order and failed to provide adequate warnings. (*Id.* ¶¶ 37, 40, 43.) Finally, in Count Three, Plaintiff charges Defendants with breach of the implied warranty of merchantability. He alleges that he relied on an implied warranty that the lenses were compliant with the premarket approval but that the lenses did not comply. (*Id.* at ¶ 46.) Defendants have moved to dismiss all three claims as preempted by the MDA.

ANALYSIS

Defendants' argument for dismissal falls at the intersection of two developing areas of law: preemption of certain medical-device claims following *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and the pleading standard articulated in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009).

In *Riegel*, the Supreme Court addressed MDA's explicit preemption of state law claims that would impose any requirement "different from, or in addition to, any requirement applicable" to the device under federal law and that "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." 21 U.S.C. § 360k(a). The Court held that the premarket approval process imposes federal "requirements" triggering MDA's preemption clause because "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 322-23. Thus, any common-law claim under state law that imposes different or greater "requirements" through liability is preempted by MDA. *Id.* at 324-25. On the other hand, so-called "parallel" claims that provide "a damages remedy for claims premised on a violation of FDA regulations" are not preempted because they do not add to federal requirements. *Id.* at 330.

In *Twombly* and *Iqbal*, the Supreme Court introduced a "plausibility" standard to Federal Rule of Civil Procedure 8(a)(2)'s requirement that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Although detailed factual allegations are not required, the plaintiff must provide sufficient facts "to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. In other words, the claim must have facial plausibility; the plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 129 S. Ct. at 1949; *see also Brooks v. Ross*,

578 F.3d 574, 580-81 (7th Cir.2009).

In this case, Plaintiff has pleaded that Defendants failed to comply with federal requirements. As *Riegel* makes clear, such claims are not preempted by MDA because they would not impose different or greater requirements than those under federal law.[2] Defendant argues that even though the claims allege the violation of federal requirements only, they must be dismissed because they fail to state *which* requirements were violated. Plaintiff's complaint, however, does refer to a specific requirement: the standard for ion permeability. (Second Amended Compl. ¶ 29, 30, 35, 37-39, 41.) Plaintiff repeatedly suggests that the ion permeability standard is a federal requirement. Defendants insists that it is merely an internal standard, and the language of the recall letter—"some lenses in these lots may fall below our standard for ion permeability"—supports this argument. At this stage in the litigation, though, the court cannot determine the relationship, if there is one, between Defendants' internal standards and federal standards. Accordingly, at this stage, Plaintiff's allegations that Defendants are liable for violating an ion permeability standard alleged to be a federal requirement is sufficient to state a claim that is not preempted by the MDA. In light of that conclusion, the court declines to determine whether a plaintiff can state a non-preempted claim without identifying a specific federal requirement that the defendant has violated. *Compare Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 837-38 (S.D. Ind. 2009) (holding that no such specificity is required) *with Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588-89 (E.D.N.Y. 2009) (requiring a pleading to state more than a general violation of federal requirements).

Defendants also argue that Plaintiff has failed to plead sufficient facts connecting the contact lenses that he used to the lenses that were recalled. It is curious that Plaintiff's complaint includes the container numbers for lenses his mother purchased after the recall but not for lenses she

[2] Some of Plaintiff's claims—those relating to premarket design and testing—are indeed preempted. Plaintiff calls its design allegations "inadvertent," and has withdrawn them.

purchased before the recall. (Second Amended Compl. ¶¶ 23-24.) That number might demonstrate that the lenses Plaintiff used were among those that were recalled. Nevertheless, such detail is not necessary in a complaint. Plaintiff has alleged that contact lenses he purchased before the recall caused him injuries that Defendants identified as possible results from use of the recalled lenses. Plaintiff must eventually provide proof, but at this stage, it is hardly unreasonable to infer from those allegations that Plaintiff used lenses that were recalled. *Iqbal*, 129 S. Ct. at 1949.

CONCLUSION

Defendants' Motion to Dismiss [35] is granted with respect to the portion of Plaintiff's claims related to premarket design and testing; it is denied with respect to claims that the lenses Plaintiff used violated an ion permeability standard alleged to be a federal requirement. Defendant is directed to answer relevant allegations within 21 days. A status conference is set for Monday, July 19, 2010, at 9:00 a.m.

ENTER:

Dated: June 9, 2010

REBECCA R. PALLMEYER
United States District Judge