FOR PUBLICATION

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

ALEXIS DEGELMANN; JOSEPH LIN, on behalf of themselves and all those similarly situated, *Plaintiffs-Appellants,* v. ADVANCED MEDICAL OPTICS INC., a Delaware corporation, *Defendant-Appellee.*	No. 10-15222 D.C. No. 4:07-cv-03107-PJH OPINION

Appeal from the United States District Court
for the Northern District of California
Phyllis J. Hamilton, District Judge, Presiding

Argued and Submitted
April 11, 2011—San Francisco, California

Filed September 28, 2011

Before: John T. Noonan and N. Randy Smith,
Circuit Judges, and Raner C. Collins, District Judge.*

Opinion by Judge Noonan

*The Honorable Raner C. Collins, District Judge for the U.S. District Court for Arizona, Tucson, sitting by designation.

COUNSEL

Jahan C. Sagafi, San Francisco, California, for the plaintiffs-appellants.

Ben D. Whitwell, San Francisco, California, for the defendant-appellee.

OPINION

NOONAN, Circuit Judge:

Alexis Degelmann and Joseph Lin ("Degelmann and Lin") represent a putative class ("the class") of purchasers of contact lens solution. They appeal the district court's order granting summary judgment for the defendant, Advanced Medical Optics, Inc. ("AMO"). They brought suit alleging AMO violated California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq.*, and False Advertising Law ("FAL"), *id.* at § 17500 *et seq.*, by marketing Complete MoisturePlus ("MoisturePlus") as a product that cleans and disinfects lenses. The district court ruled that Degelmann and Lin lack standing. AMO argues that the ruling was not error, and that even if it was, the suit was properly dismissed because the class' claims are preempted under 21 U.S.C. § 360k(a) of the Medical Devices Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq.*

The district court had jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2)(A). We have jurisdiction under 28 U.S.C. § 1291, and we affirm.

BACKGROUND

Between 2003 and 2007, AMO marketed and sold MoisturePlus. In May 2007, the Food and Drug Administration ("FDA") and the U.S. Centers for Disease Control and Prevention reported an increase of a serious eye infection called Acanthamoeba keratitis ("AK") associated with use of MoisturePlus. AMO recalled MoisturePlus and instituted a refund program for unused product.

Contact lens users who contracted AK after using MoisturePlus filed suit in various venues. The class of plaintiffs in this case were MoisturePlus users, but no member of this class contracted AK. The class members also did not lose

money by discarding unused MoisturePlus. Rather, Degelmann and Lin filed suit under California laws that proscribe false advertising and misleading marketing practices. Degelmann and Lin allege that AMO marketed MoisturePlus as an effective contact lens disinfectant and cleaner, but that in fact its users were seven times more likely than users of other contact lens solutions to suffer an AK infection. They also claim that AMO knew that MoisturePlus was a poor disinfectant compared to other similar products, and that the company misled consumers into believing MoisturePlus was as effective as other solutions. Degelmann and Lin aver that but for the inaccuracy of AMO's labeling practices, they would not have purchased MoisturePlus.

The district court invited AMO to file an "early motion for summary judgment" regarding standing and preemption. The court granted AMO's motion, ruling that the class does not have standing. The court found that the class members have not suffered an injury in fact because (1) they never contracted AK, so they suffered no harm from use of MoisturePlus, (2) they were not forced by the product recall to discard unused product, and (3) they did not lose money because if they had not bought MoisturePlus, they would have bought another lens solution. Because the district court ruled that the class does not have standing, it did not reach the issue of whether the class' claims are preempted.

This appeal followed.

STANDARD OF REVIEW

This Court's review of the district court's summary judgment order is *de novo*. *Papike v. Tambrands Inc.*, 107 F.3d 737, 739 (9th Cir. 1997). "In reviewing the court's order we must view the evidence in the light most favorable to [the non-movant] and determine whether there are any genuine issues of material fact and whether the court correctly applied the relevant substantive law." *Id.*

ANALYSIS

I. Standing

The jurisdiction of federal courts is limited by Article III of the Constitution to cases or controversies in which the plaintiff has standing. Standing requires an injury in fact, which is traceable to the defendant's acts and redressable by a court decision. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992). Injury in fact results from the "invasion of a legally protected interest which is [ ] concrete and particularized." *Id*. at 560 (citations omitted).

[1] A UCL plaintiff with standing is a person who "has suffered injury in fact and has lost money or property as a result of the unfair competition." Cal. Bus. & Prof. Code § 17204. "This provision requires [plaintiffs] to show that [they have] lost 'money or property' sufficient to constitute an 'injury in fact' under Article III of the Constitution." *Rubio v. Capital One Bank*, 613 F.3d 1195, 1203-1204 (9th Cir. 2010) (citing *Birdsong v. Apple, Inc.*, 590 F.3d 955, 959-60 (9th Cir. 2009) (internal footnote omitted)). Thus a UCL plaintiff must always have Article III standing in the form of economic injury.

Here, Degelmann and Lin, the class representatives, averred that they bought MoisturePlus, relying on the representation that it would disinfect their lenses, and would not have bought it had they known how poorly it actually worked. They have shown injury in fact, economic harm.

The California Supreme Court analyzed the economic harm suffered by a consumer who purchases a product based on misrepresentation in *Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310 (2011). In that case, plaintiffs brought UCL and FAL claims based on a lock manufacturer labeling its product as "Made in the U.S.A." when in fact some parts were foreign

made or involved foreign manufacture. The court's standing analysis is persuasive:

> For each consumer who relies on the truth and accuracy of a label and is deceived by misrepresentations into making a purchase, the economic harm is the same: the consumer has purchased a product that he or she *paid more for* than he or she otherwise might have been willing to pay if the product had been labeled accurately. This economic harm—the loss of real dollars from a consumer's pocket—is the same whether or not a court might objectively view the products as functionally equivalent.

Id. at 329.

[2] Here, as in *Kwikset*, the plaintiffs allege that they paid more for a product due to reliance on false advertising. The district court in this case was likely correct that Degelmann and Lin would have bought other contact lens solution had they not purchased MoisturePlus. However, as elucidated by the *Kwikset* court's discussion, it does not necessarily follow that they did not suffer economic harm. Degelmann and Lin presented evidence that they were deceived into purchasing a product that did not disinfect as well as it represented. Had the product been labeled accurately, they would not have been willing to pay as much for it as they did, or would have refused to purchase the product altogether. The district court's reasoning—that class members would have bought other contact lens solution, and therefore suffered no economic harm—conceived of injury in fact too narrowly.[1]

[1]The inquiry into injury in fact in this case, where the class makes claims under both the UCL's fraud prong and the FAL, is not controlled by *Birdsong v. Apple, Inc.*, 590 F.3d 955 (9th Cir. 2009). In that case, purchasers of iPod headphones pursued a claim under the UCL's "unfair" and "unlawful" prongs, asserting that listening to loud music on the headphones could result in hearing loss. They did not allege economic harm

[3] The district court's grant of summary judgment on standing grounds was in error.

II. Preemption

Though AMO argued below that this case was preempted, the district court did not address the issue. "The prevailing party may, of course, assert in a reviewing court any ground in support of his judgment, whether or not that ground was relied upon or even considered by the trial court." *Dandridge v. Williams*, 397 U.S. 471, 476 n.6 (1970) (citations omitted). This Court may address any issue "raised sufficiently for the trial court to rule on it. . . . [so long as the issue is] supported by the record, even if the [trial] court did not consider it." *In re E.R. Fegert, Inc.*, 887 F.2d 955, 957 (9th Cir. 1989) (citations omitted).

AMO argues that the FDA provides criteria for a contact lens solution to be labeled as a "disinfecting solution." AMO contends these criteria preempt any claims that AMO's use of the term "disinfects" was false or misleading.

[4] The Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"), contain a provision that expressly preempts some state and local causes of action regarding medical devices. It says that:

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from having purchased headphones in reliance on false advertising, but rather claimed that the inherent risk of the headphones reduced the value of their purchase and deprived plaintiffs of the benefit of their bargain. *Id.* at 961. The court in that case found that the claim of economic harm was not sufficient to plead injury in fact in part because, in distinct contrast to the MoisturePlus labeling at issue in this case, Apple had not represented that the headphones were safe at high volume. Rather, "Apple provided a warning against listening to music at loud volumes." *Id.* Because there is allegedly false labeling and advertising at issue in this case, *Birdsong* does not aid our disposition here.

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under [the FDCA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

[5] Under that provision, in order for a state law cause of action to be statutorily preempted, there must be (1) a federal requirement imposed on the device under the FDCA, and (2) the challenged state or local rule must impose a requirement that is different from, or adds additional obligations to, the federal requirement.

The first step of our preemption analysis is deciding whether the FDA has promulgated a specific requirement that applies to contact lens solution. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-322 (2008).

[6] "The [MDA] classifies medical devices in three categories based on the risk that they pose to the public." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). Lens care products for soft contact lenses, such as MoisturePlus, are classified as Class II devices. 21 C.F.R. § 886.5928. "Use of Class II devices involves some risk of injury . . . ." *Papike*, 107 F.3d at 739. Class II devices are not subject to the intensive premarket approval ("PMA") process. *See Lohr*, 518 U.S. at 477. In the PMA process, producers of Class III devices must provide the FDA with "reasonable assurance" that the device is both safe and effective. *Id.* In contrast, Class II devices are regulated through "special controls" issued by the FDA and must receive § 510(k) clearance, so named for the original number of the section in the MDA. *See id.* at 478; *Papike*, 107

F.3d at 739*; see also Riegel*, 552 U.S. at 322-23. The FDA reviews a device under § 510(k) to ensure only that it is substantially equivalent to a product that is already on the market. *Lohr*, 518 U.S. at 478.

The fact that lens solution is a Class II device that has come to market via the § 510(k) process, as opposed to the PMA process, does not necessarily determine whether it is subject to federal "requirements" for the purpose of § 360k. For example, *Papike* involved labeling requirements for tampons, which are Class II devices. 107 F.3d at 739. However, the FDA also requires tampon manufacturers to include a specific warning about Toxic Shock Syndrome in their packaging. *Id*. This court reviewed the regulations mandating those labeling requirements and found them to contain specific, substantive content on the risks of Toxic Shock Syndrome. *Id.* at 740. This court distinguished the kind of "general federal requirements" applicable to the device in *Lohr* from the device- and disease-specific labeling regulations the FDA had imposed on tampon producers, finding they were "requirements" for § 360k preemption purposes. *Id*. at 741.

A. Federal Requirement

AMO argues the "special controls" to which MoisturePlus was subject are federal requirements that apply to the testing, manufacture, and labeling of multipurpose contact lens solutions. AMO notes that the FDA has issued a document containing the special controls for lens solutions: *Guidance for Industry: Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products* ("*Guidance Document*") with which contact lens solution manufacturers must comply to receive § 510(k) clearance.

It mandates:

> In order for a contact lens care solution to be labeled as a contact lens "disinfecting solution," [1] it should

> meet the primary performance criteria of the stand-alone procedure for contact lens disinfecting products . . . . [2] This criteria [sic] may also be satisfied by a hydrogen peroxide (H_2O_2) disinfecting solution. . . . [3] An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulation, or both. . . . If alternative procedures are used, the applicant should be prepared to demonstrate the substantial equivalence in terms of safety and effectiveness to the predicate device.

Ctr. for Devices and Radiological Health, U.S. Dep't of Health and Human Servs., *Guidance Document*, 30, cover, 2 (1997).

AMO chose the first route to FDA approval of its labeling MoisturePlus as "disinfecting." It is undisputed that MoisturePlus met the primary performance criteria of the stand alone procedure. In doing so, MoisturePlus showed the prescribed level of efficacy in killing five representative microorganisms: *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli*, *Candida albicans*, and *Aspergillus niger*. *Id.* at 89.

[7] Accordingly, with regard to the labeling at issue in this law suit, the FDA has promulgated specific requirements, which MoisturePlus met.

B. Different or Additional State Requirement

[8] In order for the class to recover in this lawsuit, a court would have to hold that California's UCL and FAL required something different than what the FDA required in order for AMO to label MoisturePlus a disinfectant. Those California laws would have to require that AMO test for *Acanthamoeba*, and show that MoisturePlus kills it in sufficient quantities. That is, California law would have a requirement that is additional to the federal requirements.

[9] Accordingly, the class' claims are expressly preempted by § 360.

The district court was incorrect to conclude that this class of plaintiffs lacked standing, but "[w]e may affirm the district court's summary judgment on any ground supported by the record." *Hawn v. Exec. Jet Mgmt.*, 615 F.3d 1151, 1155 (9th Cir. 2010) (citation omitted). Here, the record demonstrates that the class' claims are preempted, so we affirm that grant of summary judgment.

CONCLUSION

For the reasons stated the judgment of the District Court is AFFIRMED.