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U.S. COURT OF APPEALS

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UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

THERMOLIFE INTERNATIONAL, LLC, Plaintiff-counter-defendant - Appellant, v. GASPARI NUTRITION INC., Defendant-counter-claimant - Appellee.	No. 14-15180 D.C. No. 2:11-cv-01056-NVW MEMORANDUM*

Appeal from the United States District Court
for the District of Arizona
Neil V. Wake, District Judge, Presiding

Argued and Submitted February 10, 2016
San Francisco, California

Before: SILVERMAN, FISHER and TALLMAN, Circuit Judges.

ThermoLife International, LLC (ThermoLife) appeals from an adverse judgment in its suit against Gaspari Nutrition Inc. (GNI), a competitor in the dietary supplement market. As relevant here, ThermoLife sued GNI for six counts of false advertising under the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), and unfair

* This disposition is not appropriate for publication and is not precedent except as provided by 9th Cir. R. 36-3.

competition under Arizona common law. ThermoLife alleges that from 2005 to 2010 GNI falsely advertised its testosterone boosters as "safe," "natural," "legal" and compliant with the Food, Drug & Cosmetic Act, (FDCA), as amended by the Dietary Supplement Health Education Act (DSHEA). The district court excluded four of ThermoLife's experts as unreliable; granted summary judgment because the FDCA precluded or preempted all but one of ThermoLife's claims and ThermoLife could not establish the elements of falsity, materiality and injury; and denied ThermoLife's requests for discovery sanctions and Rule 59(e) relief.

We have jurisdiction under 28 U.S.C. § 1291, and we vacate the judgment and remand for further proceedings on all six of the Lanham Act claims and the unfair competition claim.

I. FDCA preclusion and preemption

We review de novo the district court's grant of summary judgment based on its interpretation of the FDCA, *see PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 923 (9th Cir. 2010), and hold the FDCA neither precludes ThermoLife's Lanham Act claims nor preempts its unfair competition claim.

A. In deciding whether the FDCA precludes ThermoLife's claims, the district court did not have the benefit of *Pom Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014), which squarely controls the issue. *Pom Wonderful*

established that the FDCA generally does not preclude Lanham Act claims for false labeling of food. *Id.* at 2241. Both of the Court's rationales applies to ThermoLife's claims: neither the FDCA nor the Lanham Act expressly bars ThermoLife's claims, *id.* at 2237; and whereas the FDCA protects public health by relying on the FDA's expertise, Lanham Act claims like ThermoLife's protect commercial interests by relying on the market expertise of competitors, *id.* at 2238-39. Indeed, *Pom Wonderful* expressly rejected most of GNI's arguments on preclusion.[1]

GNI contends *Pom Wonderful* is distinguishable because ThermoLife's claims "require litigation of the alleged underlying FDCA violation . . . where the FDA has not itself concluded that there was such a violation." *PhotoMedex*, 601 F.3d at 924. But ThermoLife's claims that GNI falsely advertised its products as "safe" and "natural" require no interpretation of the FDCA; and, as we explain below, ThermoLife need not demonstrate a FDCA violation to prevail on its claims that GNI falsely advertised its products as "legal" or "DSHEA-compliant." Whatever the precedential value of the *PhotoMedex* rule after *Pom Wonderful* – an

[1] *See Pom Wonderful*, 134 S. Ct. at 2239 (explaining that a Lanham Act plaintiff seeks to enforce unfair competition rules, not the FDCA); *id.* (explaining that the FDCA's exclusive federal enforcement authority "does not indicate that Congress intended to foreclose private enforcement of other federal statutes").

issue we do not decide – that rule would not bar ThermoLife's claims. Accordingly, the FDCA does not preclude ThermoLife's Lanham Act claims.

B. The unfair competition claim also is not preempted. Although the FDCA expressly preempts state-law requirements that conflict with certain FDCA provisions, *see* 21 U.S.C. § 343-1, those provisions do not include § 343(a), which governs the misbranding of food through false or misleading labeling. Nor does the FDCA's bar against private enforcement impliedly preempt the unfair competition claim. There is a general "presumption against pre-emption," *Wyeth v. Levine*, 555 U.S. 555, 565 n.3 (2009), and the FDCA does not impliedly preempt claims where, as here, "the state-law duty 'parallels' the federal-law duty," *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1231 (9th Cir. 2013) (en banc).

The district court's ruling that ThermoLife abandoned its unfair competition claim was clearly erroneous. At summary judgment, ThermoLife responded to each of GNI's arguments by contending the unfair competition claim was not preempted, the elements of that claim (and the false advertising claims) were established and the claim was timely.

II. Exclusion of Expert Opinion Evidence

Reviewing for an abuse of discretion, *see Lust ex rel. Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 596-97 (9th Cir. 1996), we hold the district court

improperly excluded Dr. Sox's and Berger's opinion evidence but properly excluded Hornbuckle's and Epperson's opinion evidence.

A. The district court erred in excluding Dr. Sox's opinion on the safety of GNI's products. Each of the district court's rationales essentially faulted Dr. Sox for not opining on whether GNI's products were, in fact, safe. But that reasoning "applied too high a relevancy bar." *Messick v. Novartis Pharm. Corp.*, 747 F.3d 1193, 1197 (9th Cir. 2014). Dr. Sox's opinion needed only to "logically advance[]" the issue, *id.* at 1196 (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995)), which it did by opining the dietary supplement industry would not have deemed GNI's products "safe." Contrary to the district court's conclusions, moreover, Dr. Sox did provide a standard for determining what is "safe" – *i.e.*, the industry standard – and his presumption that GNI's ingredients were not safe was sufficiently valid in light of the industry's strict reliance on establishing safety through certain procedures GNI had not used.

B. The district court also erred in excluding Berger's survey evidence on materiality. "[S]urvey evidence should be admitted 'as long as [it is] conducted according to accepted principles and [is] relevant." *Fortune Dynamic, Inc. v. Victoria's Secret Stores Brand Mgmt., Inc.*, 618 F.3d 1025, 1037 (9th Cir. 2010) (second and third alterations in original) (quoting *Wendt v. Host Int'l, Inc.*, 125

F.3d 806, 814 (9th Cir. 1997)). By asking consumers of testosterone boosters whether they would have continued using GNI's products (or switched to another testosterone booster) after learning GNI's advertisements were false, Berger's survey was "probative on whether the advertisements influenced consumers' purchasing decisions." *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1143 (9th Cir. 1997). Although the district court faulted the survey's biased questions and unrepresentative sample, neither defect was so serious as to preclude the survey's admissibility. *See Fortune Dynamic*, 618 F.3d at 1037-38 (holding that a survey with "highly suggestive" questions was admissible); *Southland Sod Farms*, 108 F.3d at 1143 (holding that objections as to "leading questions" and an unrepresentative sample "go only to the weight, and not the admissibility, of the survey").

Scott Fetzer Co. v. House of Vacuums Inc., 381 F.3d 477 (5th Cir. 2004), is distinguishable. Berger's survey sample did not "severely limit[] the probative value of the survey's results" by omitting a "large proportion" of the class of potential consumers, but included both consumers of GNI's products and consumers of other testosterone boosters. *Id.* at 487-88. Nor was the survey unreliable simply because it was not validated. Berger reasonably explained why the survey could not be validated and concluded it was nevertheless a "good

survey" based on respondents' "consistent, across-the-board answers." GNI also asserts Berger's conclusions were not based on sufficient facts or data, but none of his conclusions involved "too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). We therefore conclude the district court improperly excluded Berger's opinion and survey evidence.

C. The district court did not abuse its discretion in excluding Hornbuckle's opinion on injury as too subjective to be reliable. A trial court has broad discretion to decide "how to determine reliability." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Although the reliability of a non-expert opinion can "depend[] heavily on the knowledge and experience of the expert," *United States v. Hankey*, 203 F.3d 1160, 1169 (9th Cir. 2000), the district court was not required to base Hornbuckle's reliability on his knowledge and experience. Because Hornbuckle used a novel and wholly subjective methodology, the district court could exercise its discretion to exclude his opinion evidence.

D. The district court did not err in excluding Epperson's opinion on damages. Epperson's model for calculating actual damages relied on Hornbuckle's report to establish the market share ThermoLife could have captured absent GNI's allegedly false advertising. Given the exclusion of that report, Epperson's model

required a substitute estimate of ThermoLife's market share. Yet ThermoLife points to no evidence in the record from which a reasonable jury could conclude a specific percentage of customers would have purchased ThermoLife's testosterone boosters. Because a jury would be unable to supply this essential input, Epperson's model of actual damages was not "based on sufficient facts or data" and would not have been helpful to the jury. Fed. R. Evid. 702.

Epperson's disgorgement calculations likewise were unreliable because they included sales revenue for five years before the first allegedly false statement. Although Epperson could assume the issue of causation, his assumption still had to be "based on sufficient facts or data," *id.*, and there is no evidence that GNI profited from 2000 to 2004 from false advertising that commenced in 2005. Epperson's assumption, which was never explained, relied on "simply too great an analytical gap between the data and the opinion proffered" for the disgorgement calculations to be reliable. *Joiner*, 522 U.S. at 146.

III. Falsity, materiality and injury elements of the Lanham Act claims

We review de novo the district court's grant of summary judgment on the Lanham Act claims – including the determination that ThermoLife failed to establish injury, *see Southland Sod Farms*, 108 F.3d at 1145-46 – and ask whether the evidence, when viewed in the light most favorable to ThermoLife, establishes a

triable issue of material fact. *See id.* at 1138. We hold there is a triable issue of falsity, materiality and injury on all six Lanham Act claims.

A. The district court erroneously concluded there is no triable issue of falsity for each type of GNI's advertisements.

1. Counts 1, 2 and 5 involve advertisements that GNI's products were "legal" or "DSHEA-compliant." The district court was correct that such statements are generally inactionable opinion because they "purport to interpret the meaning of a statute or regulation." *Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 731 (9th Cir. 1999). But there is a "well-established exception" that an opinion "by a speaker who lacks a good faith belief in the truth of the statement" is actionable. *PhotoMedex*, 601 F.3d at 931. Because every opinion "explicitly affirms . . . that the speaker actually holds the stated belief," a CEO's statement about legal compliance "would falsely describe her own state of mind if she thought her company was breaking the law." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus.*, 135 S. Ct. 1318, 1326 (2015). Here, ThermoLife points to numerous emails indicating GNI was aware its products were not DSHEA-compliant. Therefore there is a triable issue of falsity on Counts 1, 2 and 5.

2. There is also a triable issue of falsity on Counts 4 and 6, concerning GNI's statements that its products were "safe." Because those statements do not "purport to interpret the meaning of a statute or regulation," they are statements of fact, not opinion. *Coastal Abstract Serv.*, 173 F.3d at 731. GNI asserts its products were presumed safe until the FDA proved otherwise. But the statutory provision on which GNI relies, 21 U.S.C. § 342(f), neither mentions a presumption of safety nor establishes whether a dietary supplement is safe, but defines when a supplement is safe enough that it is not an "adulterated food." On the merits, a reasonable jury could find GNI's products were not safe based on the recall evidence and Dr. Sox's report.[2]

3. Finally, there is a triable issue of falsity on Count 3, concerning GNI's statements that Novedex is "natural" and its ingredients are "naturally occurring and are found in natural foodstuffs." These statements were not inactionable opinion. Because the statements were "capable of . . . being reasonably interpreted as a statement of objective fact" – namely, that the ingredients were taken from or

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[2] We reject GNI's contention that the recall evidence is inadmissible. Unlike in *Toole v. McClintock*, 999 F.2d 1430, 1434-35 (11th Cir. 1993), the FDA's finding on the safety of aromatase inhibitors was neither "proposed" nor based on outside research. And unlike in *Werner v. Upjohn Co.*, 628 F.2d 848, 853 (4th Cir. 1980), ThermoLife seeks to introduce the recall evidence to prove the falsity of GNI's statements, not GNI's negligence.

could be found in nature – they were statements of fact, not opinion. *Coastal Abstract Serv.*, 173 F.3d at 731. Based on Dr. Sox's opinion evidence, a reasonable jury could conclude that the dietary ingredients in GNI's products were not natural or naturally occurring and hence GNI's statements in Count 3 were false.

B. The district court erred with respect to materiality, as well. A statement is material if it is "likely to influence the purchasing decision." *Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv. Inc.*, 911 F.2d 242, 244 (9th Cir. 1990). ThermoLife pointed to GNI's survey results, Berger's survey results and Internet message board posts, all of which indicated that the safety, legality and natural ingredients of GNI's products were – to varying degrees – important factors in consumer purchasing decisions. This evidence establishes a triable issue of materiality.[3]

C. There is a triable issue on injury. "We have generally presumed commercial injury when defendant and plaintiff are direct competitors and defendant's misrepresentation has a tendency to mislead consumers." *TrafficSchool.com, Inc. v. Edriver Inc.*, 653 F.3d 820, 826 (9th Cir. 2011). This

[3] Because we conclude there is a triable issue on materiality, we do not reach ThermoLife's argument that GNI's statements were material as a matter of law.

presumption is warranted even in false advertising cases because, when competitors vie for the same customers, "a misleading ad can upset their relative competitive positions" and thereby cause injury. *Id.* at 827.

GNI contends this presumption is inconsistent with our observation that "actual evidence of some injury *resulting from the deception* is an essential element of the plaintiff's case." *Harper House Inc. v. Thomas Nelson, Inc.*, 889 F.2d 197, 210 (9th Cir. 1989). But *Harper House* held only that a court cannot assume injury without any evidence of causality and consumer deception. *See id.* at 209-10. Consistent with that observation, *TrafficSchool.com* permits a jury to infer injury based on evidence of direct competition (which provides a causal link) and a likelihood of consumer deception. *See* 653 F.3d at 826.

GNI argues the presumption applies only in the context of standing, but the two standards – which are derived from the same statutory language – are one and the same. *See id.* ("The Lanham Act permits 'any person' to sue if he 'believes that he . . . is *likely* to be damaged.'" (alterations in original) (quoting 15 U.S.C. § 1125(a))); *Southland Sod Farms*, 108 F.3d at 1139 ("The elements of a Lanham Act § 43(a) false advertising claim are: . . . the plaintiff has been or is likely to be injured as a result of the false statement. . . ." (footnote omitted)).

A reasonable jury could infer ThermoLife has established a presumption of commercial injury. GNI does not dispute it directly competed with ThermoLife in the market for testosterone booster products; and GNI's literally false statements necessarily misled consumers. Because GNI has not attempted to rebut the presumption, ThermoLife has established a triable issue on injury. *See TrafficSchool.com*, 653 F.3d at 827.

D. The district court decided only the issue of injury ("actual harm"), but not damages ("amount of harm"). Thus we decline to decide whether ThermoLife has presented sufficient evidence to establish entitlement to damages.

IV. Discovery sanctions and Rule 59(e) relief

We review for an abuse of discretion the district court's denial of discovery sanctions, refusal to reopen discovery and denial of Rule 59(e) relief based on newly discovered evidence. *See Panatronic USA v. AT&T Corp.*, 287 F.3d 840, 846 (9th Cir. 2002) (request to reopen discovery); *Dixon v. Wallowa County*, 336 F.3d 1013, 1022 (9th Cir. 2003) (Rule 59(e) relief); *Fjelstad v. Am. Honda Motor Co.*, 762 F.2d 1334, 1337 (9th Cir. 1985) (discovery sanctions). We hold that the district court properly exercised its discretion on each ruling.

A. Case-dispositive sanctions for spoliation were not proper because the evidence was too speculative to make the requisite finding of willfulness, fault, or

bad faith. *See Leon v. IDX Sys. Corp.*, 464 F.3d 951, 958 (9th Cir. 2006). Even ThermoLife's expert concluded intentional deletion was merely the "typical explanation" – but not the only explanation – for the number of deleted files found on the CEO's hard drive. The district court's finding of lack of willfulness was a "permissible view[] of the evidence." *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 574 (1985).

B. ThermoLife failed to "show how allowing additional discovery would have precluded summary judgment." *Panatronic USA*, 287 F.3d at 846 (quoting *Chance v. Pac-Tel Teletrac Inc.*, 242 F.3d 1151, 1161 n.6 (9th Cir. 2001)). The district court considered all of the evidence ThermoLife now points to – and in any case no additional discovery was needed to preclude summary judgment because ThermoLife raised a triable issue on each element of its claims.

C. ThermoLife was not entitled to Rule 59(e) relief based on newly discovered evidence. ThermoLife has not shown how "the outcome would likely have been different" had GNI disclosed the evidence sooner, *Dixon*, 336 F.3d at 1022, and the evidence was not "newly discovered" because it was "available before disposition of the motion for summary judgment," *Frederick S. Wyle Prof'l Corp. v. Texaco, Inc.*, 764 F.2d 604, 609 (9th Cir. 1985).

V. Costs

Because we vacate the district court's grant of summary judgment to GNI, we also vacate the award of costs to GNI.

VI. Conclusion

In sum, the district court properly excluded the opinions of Hornbuckle and Epperson and properly denied discovery sanctions and Rule 59(e) relief. But the district court improperly excluded Dr. Sox's and Berger's opinion and erred in granting summary judgment on ThermoLife's six Lanham Act claims and unfair competition claim. Because the FDCA neither precludes nor preempts those claims and factual issues preclude summary judgment, we vacate the judgment and remand for further proceedings. Each party shall bear its own costs on appeal.

AFFIRMED in part; VACATED and REMANDED in part.