[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 12-14309

D.C. Docket No. 1:08-cv-03773-CAP

STIEFEL LABORATORIES, INC.,

Plaintiff - Appellant,

versus

BROOKSTONE PHARMACEUTICALS, L.L.C.,

Defendant - Appellee.

Appeal from the United States District Court
for the Northern District of Georgia

(August 19, 2013)

Before MARTIN and FAY, Circuit Judges, and EDENFIELD,[*] District Judge.

PER CURIAM:

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[*] Honorable B. Avant Edenfield, United States District Judge for the Southern District of Georgia, sitting by designation.

Stiefel Pharmaceutical (Stiefel) sued Brookstone Pharmaceutical (Brookstone), claiming that Brookstone falsely advertised its acne gel, BPO Gel, as a generic equivalent to Stiefel's acne gel, Brevoxyl, in violation of section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B). The district court granted summary judgment in favor of Brookstone, determining that Stiefel did not present enough evidence for a reasonable jury to find that Brookstone violated the Lanham Act.[1] Stiefel appealed. After careful consideration, and having had the benefit of oral argument, we affirm.

I. BACKGROUND AND PROCEDURAL HISTORY

Stiefel and Brookstone are pharmaceutical companies who produce competing prescription topical acne gels. Even though BPO Gel and Brevoxyl are prescription drugs, they are "generally recognized as safe and effective" (GRAS/E) which means a non-name brand drug, such as BPO Gel, does not need approval from the Food and Drug Administration (FDA) before calling itself a "generic" for a name-brand drug, such as Brevoxyl. In fact, even if a pharmaceutical company asked the FDA for approval to call its GRAS/E drug a generic, the FDA would not give permission because it does not approve or accept comparative testing for this category of drugs. Because the FDA does not regulate the labeling of generics for

[1] Stiefel also alleged violations of Georgia state law. Because the same factual and legal analysis is used for these claims as the Lanham Act claims, the district court also found summary judgment appropriate on the state-law claims. Stiefel does not argue this on appeal, except to mention that if summary judgment is reversed for the federal-law claims, it should also be reversed for the state-law claims.

GRAS/E drugs, these drugs, including BPO Gel and Brevoxyl, are not found in the so-called "Orange Book," which is the FDA publication listing FDA-approved generics.

Brookstone competed with Stiefel by advertising its BPO Gel as a generic for Stiefel's Brevoxyl. Stiefel says that BPO Gel is not a generic for Brevoxyl, so Brookstone falsely advertised BPO Gel as a generic in violation of the Lanham Act. Specifically, Stiefel claims that three categories of Brookstone's advertisements violated the Lanham Act. First, Brookstone submitted "Labeling Statements" to a pharmaceutical database listing the product name as "Benzoyl Peroxide 4% Gel" and "Benzoyl Peroxide 8% Gel" instead of "BPO 4% Gel" and "BPO 8% Gel." Second, in "Marketing Statements," Brookstone announced through several communications that its BPO Gel was a generic for Brevoxyl. Third, on a Texas Medicaid Form, Brookstone indicated that BPO Gel was graded an "A" in the "Orange Book."

In granting summary judgment in favor of Brookstone, the district court found that Stiefel failed to produce enough evidence for a reasonable jury to conclude that Brookstone's Marketing Statements were false or misleading, as required to establish a violation of the Lanham Act. For the Labeling Statements and the Texas Medicaid form, the district court found that Steifel produced competent proof of falsity. However, the court concluded that Stiefel did not

present enough evidence of the material impact of these false statements to survive summary judgment.

II. DISCUSSION

We review a district court's grant of summary judgment de novo, applying the same legal standard as the district court. Whatley v. CNA Ins. Cos., 189 F.3d 1310, 1313 (11th Cir. 1999). Summary judgment should be granted only when "there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In making this decision, we view all evidence and draw all reasonable inferences in favor of the party opposing summary judgment. Whatley, 189 F.3d at 1313.

To establish a false advertising claim under section 43(A) of the Lanham Act, Stiefel must establish that 1) Brookstone's ads were false or misleading; 2) Brookstone's ads deceived, or had the capacity to deceive, consumers; 3) the deception had a material effect on purchasing choices; 4) BPO Gel affects interstate commerce; and 5) Stiefel has been, or is likely to be, injured because of the false advertising. See Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc., 299 F.3d 1242, 1247 (11th Cir. 2002).

Stiefel challenges three of the district court's conclusions. First, Stiefel contends that it presented evidence that Brookstone's statements were both false and misleading, and thus, the district court got it wrong by considering only

Stiefel's evidence that Brookstone's statements were false, and not whether Brookstone's statements were misleading. Second, Stiefel challenges the district court's conclusion that Stiefel did not present competent evidence that Brookstone's statements were literally false. Finally, for the statements on the Texas Medicaid form and the Labeling Statements, Stiefel argues that the district court erred in concluding there was insufficient evidence for a reasonable jury to decide that the false statements had a material impact. We consider each argument in turn.

A.

First, Stiefel argues the district court erred in only considering whether Brookstone's statements were literally false. Under the first element of the test for a violation of the Lanham Act, a plaintiff must show either that the statements were literally false or misleading. Hickson Corp. v. N. Crossarm Co., Inc., 357 F.3d 1256, 1261 (11th Cir. 2004). The evidence that a plaintiff must present to satisfy the first element depends on whether the plaintiff is claiming the statements were literally false or misleading. See Johnson & Johnson, 299 F.3d at 1247. A plaintiff alleging misleading statements must present evidence of consumer deception, while a plaintiff alleging literally false statements need not present evidence of deception. Id. Here, Stiefel was not explicit about whether it was claiming Brookstone's statements were false or misleading. Because Stiefel did

not point to evidence supporting any direct claims that Brookstone's statements were misleading, the district court decided that Stiefel was alleging Brookstone's statements were literally false. The district court then proceeded with the summary judgment analysis only on the theory of literal falsity.

Stiefel argues the district court erred in limiting its claims to literal falsity because its evidence included an expert report, which Stiefel says it offered for the purpose of proving the statements were misleading. However, Stiefel did not clearly identify this report as supporting, as the theory of the case, that Brookstone's statements were misleading. Instead, it appears that Stiefel argued that Brookstone's statements were false, and this report was cited to advance arguments in support of the falsity theory. While Stiefel points us to a few uses of the word "misleading" in its brief in opposition to summary judgment, none clearly support the conclusion that Stiefel was advancing a theory that Brookstone's statements were misleading within the meaning of the Lanham Act. While we draw all reasonable inferences in favor of Stiefel, we will not marshal evidence in support of arguments which were not supported in this way for the District Judge. Cf. Peppers v. Coates, 887 F.2d 1493, 1498 (11th Cir. 1989) ("[W]hen a motion for summary judgment is made and supported according to Rule 56, the nonmoving party's response must set forth specific facts showing a genuine issue

for trial."). For these reasons, we consider only whether Brookstone's statements were literally false.

B.

Stiefel next challenges the district court's conclusion that it did not produce competent evidence to show the literal falsity of Brookstone's marketing statements that BPO Gel is a generic for Brevoxyl. For two reasons, we conclude that Stiefel did not produce sufficient proof for a reasonable jury to conclude that Brookstone's statements were literally false.

First, Stiefel did not establish the meaning of the term "generic" in the relevant context. In considering false advertising claims under the Lanham Act, we "must analyze the message conveyed in full context," Johnson & Johnson, 299 F.3d at 1248 (quotation marks omitted), because it is only possible to determine the falsity of an advertisement when it is considered contextually. See, e.g., Osmose, Inc. v. Viance, LLC, 612 F.3d 1298, 1311 (11th Cir. 2010) ("This Court has [repeatedly] recognized the importance of context when analyzing false advertising claims.").

Thus, we must examine the context in which we consider the meaning of the term "generic." Since BPO Gel and Brevoxyl are prescription drugs, Stiefel urges us to look to the FDA definition of "generic" to derive the meaning of term. Brookstone counters that the FDA definition of "generic" is not relevant here,

because BPO Gel and Brevoxyl are GRAS/E drugs not subject to FDA approval. Brookstone allows that the term "generic" has a different meaning in the context of non-regulated drugs.

Our review of the record leads us to conclude that Stiefel did not present competent evidence to show that, in the context of drugs not regulated by the FDA, pharmacists understand the term "generic" to have the same meaning as it does in the regulated context. On appeal, Steifel points to several pieces of evidence in arguing that the FDA definition of "generic" should apply in the context of GRAS/E drugs not subject to FDA-approval. None are availing. In fact, Stiefel's evidence reflects uncertainty about the meaning of the term "generic" in the context of GRAS/E drugs. For example, three emails from Brookstone executives address the potential dual meaning of the term "generic" in the regulated and non-regulated context. Because Stiefel did not produce contextually appropriate evidence in support of its definition of the term "generic," a reasonable jury could not decide that Brookstone's statements were literally false.

Second, even if we assume that Stiefel did present evidence on the meaning of the term "generic," it did not present equivalency tests to show that Brookstone's BPO Gel was not a generic. While Stiefel argues that BPO Gel and Brevoxyl have different ingredients, Stiefel stresses the only way to establish whether a drug is "generic" as understood by the FDA is through bioequivalence

testing. However, in its own statement of facts, Stiefel concedes that "BPO Gel has never been tested for bioequivalence, pharmaceutical equivalence or therapeutic equivalence to Brevoxyl Gel." We agree with the district court's assessment that Stiefel's arguments and evidence are contradictory: On the one hand, Stiefel argues that Brookstone falsely stated that BPO Gel is a generic and that equivalency testing is required to determine whether or not BPO Gel is a generic. On the other hand, Stiefel presents no equivalency testing to show that BPO Gel is not a generic. Because there is no evidence from which a reasonable jury could conclude that Brookstone's marketing statements claiming generic equivalency were literally false, there is "an absence of evidence to support [Stiefel's] case," and summary judgment is appropriate. See Celotex Corp. v. Catrett, 477 U.S. 317, 325, 106 S. Ct. 2548, 2554 (1986).

C.

Finally, Stiefel argues the district court erroneously found that the false statements in the Texas Medicaid form and the Labeling Statements did not have a material impact on the consumer's purchasing decision. Stiefel says it offered evidence of materiality by showing that pharmacies "linked" BPO Gel and Brevoxyl, which caused pharmacists to substitute the less expensive BPO Gel for the more expensive Brevoxyl. Stiefel's argument based on this evidence fails because it shows only that Brookstone captured some of Stiefel's market share; it

does not show that Brookstone's false statements influenced pharmacists' purchasing choices. See Johnson & Johnson, 299 F.3d at 1250 ("The materiality requirement is based on the premise that not all deceptions affect consumer decisions."); Osmose, 612 F.3d at 1319 ("In order to establish materiality, the plaintiff must demonstrate that the defendant's deception is likely to influence the purchasing decision." (quotation marks omitted)). Because Stiefel did not show that Brookstone's false statements on the Texas Medicaid form and the Labeling Statements influenced consumer choices, the district court properly granted summary judgment. See Osmose, 612 F.3d at 1319 ("Even if an advertisement is literally false, the plaintiff must still establish materiality.").

III. CONCLUSION

For these reasons, summary judgment is appropriate in favor of Brookstone. The decision of the district court is **AFFIRMED**.