IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

EXEGI PHARMA, LLC, Plaintiff, v. ROBERTO PACIFICI, Defendant.	CIVIL ACTION FILE NO. 1:21-CV-2134-TWT

OPINION AND ORDER

This is a Lanham Act case. It is before the Court on the Defendant's Motion to Dismiss [Doc. 19]. For the reasons set forth below, the Defendant's Motion to Dismiss [Doc. 19] is GRANTED in part and DENIED in part.

I. Background

This case revolves around competing probiotic products used to treat certain gastrointestinal diseases. During the 1980s and 1990s, Professor Claudio De Simone researched the clinical uses and effects of certain bacterial strains. (Compl. ¶ 30.) One of the formulations De Simone created was an eight-strain combination probiotic product known as the De Simone Formulation. (*Id.*) In the early 2000s, De Simone formed VSL Pharmaceuticals, Inc. ("VSL") and licensed his patent on the De Simone Formulation to VSL, which launched the product in the United States commercially as "VSL#3." (*Id.*

¶ 31.) In 2014, De Simone resigned from VSL, but the company retained the license to the De Simone Formulation until January 2016. (*Id.* ¶ 34.) After VSL's license expired, De Simone licensed his formulation to the Plaintiff, ExeGi Pharma, LLC ("ExeGi"), which began to sell the formulation under the brand name "Visbiome." (*Id.*) After De Simone's departure, his co-founders at VSL attempted to reverse engineer the De Simone Formulation, and VSL began manufacturing a new formulation with Italian manufacturers. (*Id.* ¶ 35.) This formulation ("the Italian Formulation"), which the Plaintiff alleges was "demonstrably different" in several ways, was sold under the VSL#3 trademark by two of VSL's licensee distributors, Alfasigma USA, Inc. ("Alfasigma") and Sigma-Tau Pharmaceuticals, Inc. ("Leadiant"). (*Id.* ¶ 35–38.)

As a result of VSL's actions, De Simone brought suit against the company in Maryland federal district court ("the Maryland Action"). (*Id.* ¶ 74.) ExeGi later joined the suit, bringing claims against Alfasigma and Leadiant for false adverting under the Lanham Act. (*Id.*) After a three-week trial, the jury reached a verdict in favor of De Simone and ExeGi, awarding over $18 million in damages. (*Id.* ¶ 75.) Further, the court issued an injunction barring VSL from advertising the Italian Formulation as the same as the De Simone Formulation and from relying on studies performed on the De Simone Formulation. (*Id.* ¶ 78.) Having succeeded in that action, the Plaintiff now brings claims against the Defendant, Professor Roberto Pacifici. He is a professor at Emory University who has been studying the clinical application

of probiotics since at least 2012. (*Id.* ¶ 39.)

While VSL#3 was composed of the De Simone Formulation, Pacifici conducted a study on the probiotic's effect on bone loss of mice during menopause, and the study was published in April 2016. (*Id.* ¶¶ 40–42.) Shortly thereafter, the Plaintiff alleges that De Simone contacted Pacifici and informed him of the transition to the Italian Formulation and the differences between the two formulations. (*Id.* ¶ 43.) Later that year, VSL reached out to Pacifici about conducting another study on postmenopausal bone loss in women and whether he would become a scientific advisor for the company. (*Id.* ¶¶ 44, 46.) Pacifici became an advisor to VSL in early 2017, and later that year he gave a presentation in Rome, Italy about the Italian Formulation. (*Id.* ¶¶ 47–49.) In this presentation, the Plaintiff alleges that Pacifici presented data from studies performed on the De Simone Formulation as if the data represented analysis of the Italian Formulation. (*Id.* ¶ 51.)

In addition, VSL requested that Pacifici join a "GRAS Panel" regarding the Italian Formulation. (*Id.* ¶ 48.) "GRAS" is an acronym for "Generally Recognized as Safe." (*Id.* ¶ 2.) This GRAS Panel consisted of Dr. Pacifici and two other professors. (*Id.* ¶ 55.) In early 2017, a consulting company called Intertek presented Dr. Pacifici and the other members of the GRAS Panel with a draft report on the Italian Formulation ("the GRAS Report"), which Pacifici signed on May 3, 2017. (*Id.* ¶¶ 53, 56.) The Plaintiff alleges that the GRAS Report is "fatally flawed" by its reliance on studies performed on the De Simone

Formulation and its conclusions that the Italian formulation qualifies both as "GRAS" and as a "medical food" as defined by 21 U.S.C. § 360ee(b)(3). (*Id.* ¶¶ 57–59, 65–69.)

The Plaintiff contends that Pacifici's actions give credence to the notion that the Italian Formulation is GRAS, a "medical food," and equivalent to the De Simone Formulation. As a result, the Plaintiff brings four claims against Pacifici here: Contributory False Advertising under the Lanham Act (Count I), Unfair Competition under the Lanham Act (Count II); a violation of Georgia's Unfair Competition Statute, O.C.G.A. § 10-1-370 (Count III); and Tortious Interference with Business Relations (Count IV). Pacifici now seeks dismissal of all of the Plaintiff's claims pursuant to Federal Rule of Civil Procedure 12(b)(6).

II. Legal Standard

A complaint should be dismissed under Rule 12(b)(6) only where it appears that the facts alleged fail to state a "plausible" claim for relief. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009); Fed. R. Civ. P. 12(b)(6). A complaint may survive a motion to dismiss for failure to state a claim, however, even if it is "improbable" that a plaintiff would be able to prove those facts; even if the possibility of recovery is extremely "remote and unlikely." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007). In ruling on a motion to dismiss, the court must accept the facts pleaded in the complaint as true and construe them in the light most favorable to the plaintiff. *See Quality Foods de Centro Am., S.A.*

v. Latin Am. Agribusiness Dev. Corp., S.A., 711 F.2d 989, 994–95 (11th Cir. 1983); *see also Sanjuan v. Am. Bd. of Psychiatry & Neurology, Inc.*, 40 F.3d 247, 251 (7th Cir. 1994) (noting that at the pleading stage, the plaintiff "receives the benefit of imagination"). Generally, notice pleading is all that is required for a valid complaint. *See Lombard's, Inc. v. Prince Mfg., Inc.*, 753 F.2d 974, 975 (11th Cir. 1985), *cert. denied*, 474 U.S. 1082 (1986). Under notice pleading, the plaintiff need only give the defendant fair notice of the plaintiff's claim and the grounds upon which it rests. *See Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (citing *Twombly*, 550 U.S. at 555).

III. Discussion

The Defendant argues that the Plaintiff has failed to sufficiently plead each of its claims against him. (Def.'s Br. in Supp. of Def.'s Mot. to Dismiss, at 18–25.) In addition, the Defendant raises a variety of legal defenses to the Plaintiff's Lanham Act claims. In particular, the Defendant argues that the contributory false advertising claim is subject to claim preclusion as a result of the Maryland Action, and that the Plaintiff failed to allege the required "commercial speech" or contributory actions required for this claim. (*Id.* at 5–10, 15–18.) The Defendant also argues that the Federal Food, Drug, and Cosmetic Act ("FDCA") precludes both the Plaintiff's false advertising and unfair competition claims under the Lanham Act. (*Id.* at 10–15.) In response, the Plaintiff argues that its claims are not precluded by wither the FDCA or claim preclusion. (Pl.'s Br. in Opp'n to Def.'s Mot. to Dismiss, at 3–7, 11–15.)

The Plaintiff also argues that it has sufficiently pleaded all of its claims, including the element of "commercial speech" that it believes is not necessary to its contributory false advertising claim. (*Id.* at 7–11, 19–25.) The Parties' briefing focuses almost exclusively on Count I, and the Court starts its analysis there.

A. Count I: Contributory False Advertising

The Eleventh Circuit has held that "a plaintiff may bring a claim for contributory false advertising under § 43(a) of the Lanham Act." *Duty Free Americas, Inc. v. Estee Lauder Cos.*, 797 F.3d 1248, 1277 (11th Cir. 2015). There are two general elements to a contributory false advertising claim:

> First, the plaintiff must show that a third party in fact directly engaged in false advertising that injured the plaintiff. Second, the plaintiff must allege that the defendant contributed to that conduct either by knowingly inducing or causing the conduct, or by materially participating in it.

Id. With regards to the first element, the Plaintiff must plead and prove "an injury to a commercial interest in sales or business reputation caused by the misrepresentations." *Id.* (internal quotation marks and punctuation omitted). There are five elements that courts look to in determining whether a third party has inflicted the requisite injury: (1) false or misleading statements; (2) the statements deceived or could have deceived consumers; (3) the deception materially affected purchasing decisions; (4) the misrepresentations concerned goods or services in interstate commerce; and (5) the plaintiff has suffered or likely will suffer from the misrepresentations. *See id.* After the requisite injury

has been shown, a plaintiff must plead and prove that the defendant induced, caused, or "in some other way" supported the unlawful conduct. *Id.* Liability also requires "that the defendant had the necessary state of mind—in other words that it 'intended to participate in' or 'actually knew about' the false advertising." *Id.* Borrowing from the trademark infringement context, the Eleventh Circuit details several examples of potentially sufficient contributions, including one where a defendant provides "a necessary product or service, without which the false advertising would not be possible[.]" *Id.*

Before addressing the sufficiency of the Plaintiff's contributory false advertising allegations, the Court must assess whether these claims are precluded either by claim preclusion or the FDCA. First, regarding claim preclusion, the Defendant argues that the Maryland Action satisfies the four elements of claim preclusion. (Def.'s Br. in Supp. of Def.'s Mot. to Dismiss, at 5.) He argues that the Maryland Action clearly resulted in a final judgment rendered by a court of competent jurisdiction that involved the same causes of action and nucleus of operative facts. (*Id.*) Regarding the final requirement—the actions involve the same parties or their privies—the Defendant argues that because the claims here are derivative of and "inextricable from the false advertising claims" in the Maryland Action, the privity requirement is satisfied. (*Id.* at 6.) The Plaintiff counters this argument by noting that Pacifici signed the GRAS Report five days before it filed its Amended Complaint in the Maryland Action, and thus these claims could not have been brought in that

case. (Pl.'s Br. in Opp'n to Def.'s Mot. to Dismiss, at 3.) In his Reply, the Defendant argues that "any underlying theory of direct false advertising" raised by the Plaintiff in the Maryland Action cannot be raised here to support the claim of contributory false advertising by the Plaintiff. (Def.'s Reply Br. in Supp. of Def.'s Mot. to Dismiss, at 8–10.) The Court finds that Count I is not subject to claim preclusion. While the facts of the two cases overlap, the Plaintiff's allegations here involve separate conduct for which the Eleventh Circuit has recognized a cause of action: knowingly providing material support to a third party's false advertising efforts. This claim arises from a related but distinct nucleus of operative facts than the Maryland Action, and claim preclusion cannot apply as a result.

Second, the Defendant argues that the FDCA precludes both of the Plaintiff's Lanham Act claims. While the FDCA does not categorically preclude Lanham Act claims, such "claims may be barred if their resolution requires an original determination that is committed to the FDA, such as whether a drug is new, and whether it can be lawfully marketed under the FDCA." *Belcher Pharm., LLC v. Hospira, Inc.*, 1 F.4th 1374, 1380 (11th Cir. 2021) (internal quotation marks omitted). In other words, if a plaintiff brings a claim that requires an interpretation or application of the FDCA, such claims are precluded and must be enforced by the FDA itself. *See Hi-Tech Pharm., Inc. v. HBS Int'l Corp.*, 910 F.3d 1186, 1199 (11th Cir. 2018). The Defendant argues that the Plaintiff's Lanham Act claims here would require the Court "to

interpret and apply a complex web of statutory and regulatory provisions about the requirements for a 'medical food' and 'GRAS' substances." (Def.'s Br. in Supp. of Def.'s Mot. to Dismiss, at 14.) The Plaintiff argues in response that it "is not making a technical argument as to why the GRAS and medical food designations do not apply; rather, ExeGi's claim is that these designations are claimed fraudulently and wholly unsupported." (Pl.'s Br. in Opp'n to Def.'s Mot. to Dismiss, at 12–13.) However, an essential element of a contributory false advertising claim is a false or misleading statement. Even accepting the Plaintiff's allegations as true, the Defendant's use of data from the De Simone Formulation does not mean that the Italian Formulation is neither "medical food" nor "GRAS." Indeed, the Italian Formulation could satisfy both requirements if the proper tests were performed on the Formulation. This scientific inquiry is decidedly one left to the exclusive jurisdiction of the FDA under the FDCA. Thus, to the extent the Plaintiff raises its contributory false advertising claim as a result of the Defendant's "medical food" or "GRAS" statements, the claim is precluded by the FDCA.

However, the Plaintiff also predicates its contributory false advertising claim on the Defendant's claim of equivalence of the De Simone and Italian Formulations. Whether two substances are identical does not require an interpretation or application of the FDCA and is an inquiry well within this Court's competency. Thus, Count I is not precluded so long as it relies on the Defendant's alleged equivalence between the two formulations.

After determining that some of Count I escapes preclusion, the Court now turns to the sufficiency of the Plaintiff's allegations. The first element of a contributory false advertising claim—"that a third party in fact directly engaged in false advertising that injured the plaintiff"—is satisfied here. *Duty Free Americas, Inc.*, 797 F.3d at 1277. By pointing to the facts supporting the Plaintiff's case in the Maryland Action, the Plaintiff sufficiently alleges that the defendants in that case engaged in false advertising that harmed ExeGi. (Compl. ¶¶ 74–78, 90–91.) And despite the Defendant's claims to the contrary, the Plaintiff need not attach specific advertisements to the Complaint to render its allegations plausible at this stage in the proceedings. (*See* Def.'s Br. in Supp. of Def.'s Mot. to Dismiss, at 18–19.) Regarding Pacifici's participation in that false advertising, the Plaintiff alleges that the GRAS Report signed by Pacifici serves as the "underpinning of much of the false advertising engaged in" by the Maryland Action defendants. (Compl. ¶ 97.) Thus, the question before this Court is whether Pacifici's signature on the report and decision not to withdraw that signature constitutes participation in the alleged false advertising.

To survive a motion to dismiss, the Plaintiff must allege "that the defendant actively and materially furthered the unlawful conduct—either by inducing it, causing it, or in some other way working to bring it about." *Duty Free Americas, Inc.*, 797 F.3d at 1277. In its decision finding that the Lanham Act creates a cause of action for contributory false advertising, the Eleventh

Circuit detailed how courts should evaluate such allegations:

> It is also conceivable that there could be circumstances under which the provision of a necessary product or service, without which the false advertising would not be possible, could support a theory of contributory liability. In determining whether a plaintiff has adequately alleged facts to support such a claim, we look to whether the complaint suggests a plausible inference of knowing or intentional participation, examining the nature and extent of the communication between the third party and the defendant regarding the false advertising; whether or not the defendant explicitly or implicitly encouraged the false advertising; whether the false advertising is serious and widespread, making it more likely that the defendant knew about and condoned the acts; and whether the defendant engaged in bad faith refusal to exercise a clear contractual power to halt the false advertising.

Id. at 1278 (internal quotation marks and punctuation omitted). Given this framework and the Plaintiff's allegations regarding the GRAS Report, the Plaintiff has satisfied its burden at this stage in the litigation. The Plaintiff alleges that the GRAS Report materially supported a third party's false advertising, that Pacifici knew of the alleged false equivalence being expressed in the Report, that he was informed by De Simone and an attorney for a rival company that these statements indicated equivalence between the formulations, and that he refused to rescind his signature after being presented with this information. (Compl. ¶¶ 17, 43, 51, 55, 87, 97.) At this stage of the litigation, these allegations are sufficient. Thus, the Plaintiff has stated a claim of contributory false advertising related to claims that the De Simone and Italian Formulations were identical.

Pacifici argues that the Plaintiff should be required to allege that he

engaged in commercial speech. He argues that the Eleventh Circuit reads the Lanham Act narrowly to avoid any curtailment of First Amendment rights, and that narrow reading implies that a plaintiff must allege commercial speech to support a contributory false advertising claim. (Def.'s Br. in Supp. of Def.'s Mot. to Dismiss, at 7–8.) But as the Plaintiff points out, "contributory false advertising occurs when the defendant assists the commercial speech of a third party." (Pl.'s Br. in Opp'n to Def.'s Mot. to Dismiss, at 8.) Because contributory false advertising claims do not necessarily involve speech, and because the Eleventh Circuit's detailed explanation of the claim in *Duty Free Americas, Inc.* did not include this element, the Court will not impose such a requirement here.

B. Count II: Unfair Competition Under the Lanham Act

Under the Lanham Act:

> Any person who, on or in connection with any goods of services, . . . uses in commerce any word, term, symbol, or device, or any combination thereof, or any . . . false or misleading description of fact, or false or misleading representation of fact, which— (A) is likely to cause confusion, or to cause mistake, . . . shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1). The Plaintiff alleges that Pacifici's continued authorization of the GRAS Report causes confusion as to whether the Italian Formulation's is certified as GRAS and a medical food, whether the medical community has a consensus view that the Italian formation is safe for its intended use, and that the Italian Formulation "is of a particular standard and

quality." (Compl. ¶¶ 112–114.) However, absent from Count II is any allegation that the GRAS Report caused confusion as to the equivalence between the De Simone and Italian Formulations. As discussed above, any analysis of whether the Italian Formulation could be deemed either GRAS or a medical food is precluded by the FDCA. Unlike Count I, Count II appears entirely confined to inquiries reserved exclusively for the FDA. As a result, the Court finds that Count II is precluded by the FDCA and should be dismissed without prejudice.

C. Count III: Violation of Georgia Unfair Competition Statute

Georgia's Uniform Deceptive Trade Practices Act ("UDTPA") creates a cause of action against a person who, "in the course of his business, vocation, or occupation, [r]epresents that goods or services are of a particular standard, quality, or grade or goods that are of a particular style or model, if they are another[.]" O.C.G.A. § 10-1-372(a), (a)(7). The Plaintiff's allegations of a violation of the UDTPA mirror its allegations in Count II. These allegations are limited to whether the Italian Formulation was GRAS or a medical food, safe for its intended use, and of a particular quality and standard. (Compl. ¶ 127–129.) The evaluation of these questions is, as discussed above, within the province of the FDA. The Parties disagree about whether the FDCA precludes the Plaintiff's UDTPA claim. (Def.'s Br. in Supp. of Def.'s Mot. to Dismiss, at 24; Pl.'s Br. in Opp'n to Def.'s Mot. to Dismiss, at 24–25.) However, because the UDTPA is a state statute and not a federal one, the preclusion analysis performed as to the Lanham Act claim is inapposite. Instead, a

preemption analysis applies, a point not addressed by either Party. Without addressing this argument, the Defendant has failed to show a duty owed by the Plaintiff to the FDA or any other showing required that would support preemption of the UDTPA claim. As a result, this argument fails.

However, the Court finds the Plaintiff's UDTPA claim should be dismissed without prejudice. The Defendant argues that the UDTPA does not apply to "[c]onduct in compliance with . . . a statute administered by a federal, state, or local governmental agency[.]" O.C.G.A. § 10-1-374(a). The Defendant argues that in an analogous case, the Georgia Court of Appeals read this exception to mean that the UDTPA did not apply where an existing regulatory framework policed unfair trade practices within an industry and gave government officials "the power to investigate and act upon such claims[.]" *See Northeast Ga. Cancer Care, LLC v. Blue Cross & Blue Shield of Ga., Inc.*, 297 Ga. App. 28, 34–35 (2009). The Court finds that these facts give rise to a sufficiently similar circumstances: the FDCA gives the FDA the ability to monitor and enforce false claims of GRAS or medical food designations. Thus, under this construction of O.C.G.A. § 10-1-374(a), the UDTPA does not apply here. Given this case law, the Court finds that the Plaintiff's UDTPA claim should be dismissed without prejudice.

D. Count IV: Tortious Interference with Business Relations

In its Complaint, the Plaintiff alleges that Pacifici interfered with its business relationships "by endorsing the [GRAS Report] and the refusing to

rescind that endorsement[,]" resulting in Alfasigma's false advertising that caused the Plaintiff's customers to purchase the Italian Formulation over the Plaintiff's Visbiome product. (Compl. ¶ 144–45, 147.) To state a tortious interference with business relations claim in Georgia, a plaintiff must allege:

> (1) [I]mproper action or wrongful conduct by the defendant without privilege; (2) [that] the defendant acted purposely and with malice with the intent to injure; (3) [that] the defendant induced a breach of contractual obligations or caused a party or third parties to discontinue or fail to enter into an anticipated business relationship with the plaintiff; and (4) the defendant's tortious conduct proximately caused damage to the plaintiff.

Northeast Ga. Cancer Care, LLC, 297 Ga. App. at 33. Beyond proximately causing the damage to the Plaintiff's business, the Plaintiff must also allege "that the defendant directly induced adverse behavior by the third party." *St. Mary's Hosp. of Athens, Inc. v. Radiology Prof'l Corp.*, 205 Ga. App. 121, 125 (1992). Here, the Plaintiff makes no allegations that its Visbiome customers read the GRAS Report or made their purchasing decisions on that basis. Indeed, the Plaintiff explicitly alleges that the GRAS Report led to false advertising "that induced wholesalers, distributors, doctors, and end users of Visbiome to purchase" the Italian Formulation instead. (Compl. ¶ 145.) This allegation belies any direct action by Pacifici towards the Plaintiff's customers. The Plaintiff also makes no mention of Pacifici's presentation at industry conferences in Count IV. Without any allegations of Pacifici's direct influence on the purchasing decisions of the Plaintiff's customers, the Plaintiff's allegations of tortious interference with business relations fail. Count IV

should be dismissed without prejudice.

E. Count V: Attorneys' Fees Under O.C.G.A. § 13-6-11

Because some of the Plaintiff's claims may proceed, the Plaintiff's derivative claim for attorneys' fees may also proceed. The Defendant's Motion is denied as to Count V.

IV. Conclusion

For the reasons set forth above, the Defendant's Motion to Dismiss [Doc. 19] is GRANTED in part and DENIED in part. Counts II, III, and IV are dismissed without prejudice.

SO ORDERED, this 25th day of March, 2022.

THOMAS W. THRASH, JR.
United States District Judge