

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

CATILINA NOMINEES PROPRIETARY)	
LTD., et al.,)	
)	
Plaintiffs,)	
)	No. 15-cv-10734
v.)	
)	Judge Andrea R. Wood
STERICYCLE, INC.,)	
)	
Defendant.)	

MEMORANDUM OPINION AND ORDER

Plaintiffs Catilina Nominees Proprietary Ltd. and Daniels Sharpsmart, Inc. initially sued Defendant Stericycle, Inc. (“Stericycle”) based on a single claim of patent infringement. During fact discovery, the Court granted Plaintiffs’ motion for leave to file the First Amended Complaint (“FAC”) to assert an additional claim for false advertising under the Lanham Act, 15 U.S.C. § 1125(a). (Dkt. No. 139.) Stericycle moved to dismiss the new claim. The Court granted the motion but also granted Plaintiffs leave to amend the FAC to attempt to cure pleading deficiencies relating to the Lanham Act claim. (Mar. 26, 2021 Mem. Op. & Order Granting Mot. to Dismiss, Dkt. No. 161.) Plaintiffs subsequently filed the Second Amended Complaint (“SAC”). (Dkt. No. 163). Now before the Court is Stericycle’s motion to dismiss Count II of the SAC pursuant to Federal Rules of Civil Procedure 12(b)(6) and (9)(b). (Dkt. No. 169.) For the reasons stated below, Stericycle’s motion is denied.

BACKGROUND

In this case, Plaintiffs allege that they participate in the market for reusable containment solutions for the collection of regulated medical waste. (SAC ¶ 11.) Stericycle is their competitor

in the medical waste market. (*Id.* ¶ 25.) Both Plaintiffs and Stericycle offer a reusable sharps disposal container as part of a sharps management service. (*Id.* ¶¶ 12–13, 22.)

In their original complaint, Plaintiffs asserted a single count against Stericycle for alleged patent infringement. After conducting discovery, Plaintiffs filed the FAC to add a second count with a false advertising claim. Specifically, the FAC alleged that statements contained within Stericycle’s Section 510(k) submission to the Food and Drug Administration (“FDA”)¹ and promotional materials are false and misleading in violation of the Lanham Act. Stericycle filed a motion to dismiss the Lanham Act claim in the FAC, which the Court granted. Although the Court dismissed the false advertising claim for failure to meet the heightened pleading standards of Rule 9(b), it also ruled on the actionability of certain specific statements. In particular, the Court held that statements in Stericycle’s Section 510(k) submissions were not actionable under the Lanham Act and that several statements in the promotional materials were non-actionable puffery. Additionally, the Court noted that, while a statement that Stericycle markets its products as “hav[ing] marketing clearance from the FDA” could be a quantifiable and actionable statement of fact, it interpreted the FAC as challenging not that statement itself but the statements upon which Stericycle relied to obtain the clearance. (Mar. 26, 2021 Mem. Op. & Order Granting Mot. to Dismiss at 11.)

¹ A Section 510(k) submission seeks to show that a new device does not need preapproval from the FDA to be marketed as safe and effective because it is “substantially equivalent” to another legally marketed device. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008); 21 U.S.C. §§ 360c(f)(1)(A)(ii), (i)(1)(A), 360e(b)(1).

Plaintiffs have now filed the SAC, in which they replead the Lanham Act claim to add more detail (including date ranges and the names of specific customers). Plaintiffs again assert a false advertising claim based on the following nine statements:²

Statement (1): Accused container “keep[s] . . . anyone from reaching into the container to retrieve sharps waste” (SAC ¶ 32);

Statement (2): Accused container raises “no new issues of safety or effectiveness” (*id.* ¶ 33);

Statement (3): Accused containers “have marketing clearance from the FDA” (*id.* ¶ 36);

Statement (4): Accused container is “designed for ease of use and increasing safety” (*id.* ¶ 35);

Statement (5): Accused container is “[i]deal for patient rooms and treatment areas where security and convenience are critical” (*id.* ¶ 35);

Statement (6): “IF NEEDLESTICKS ARE A PROBLEM, WE HAVE THE SOLUTION” (*id.* ¶ 36);

Statement (7): Accused container provides “tangible results and sustainable benefits” that include “100% sustained reduction in needlesticks . . . [b]ased on an independent national study” (*id.* ¶ 37);

Statement (8): “Design utilizes safety/engineering controls that prevents access to the contents of the contents of the container” (*id.* ¶ 35); and

Statement (9): Accused container “incorporates safety/engineering controls that include limited access to the contents of the container” (*id.* ¶ 38).

And once again, Stericycle moves to dismiss the Lanham Act claim, arguing, among other things, that the SAC fails to meet the heightened pleading standard in Rule 9(b).

DISCUSSION

To survive a Rule 12(b)(6) motion, a complaint must contain sufficient factual allegations to “state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). In evaluating a motion to

² For ease of reference, the Court adopts the numbering convention provided by Stericycle and adopted by Plaintiffs in their Response to the motion.

dismiss, the Court accepts as true all well-pleaded facts and draws all reasonable inferences from those facts in the plaintiff's favor. *Bell v. City of Country Club Hills*, 841 F.3d 713, 716 (7th Cir. 2016). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft*, 556 U.S. at 678. When plaintiffs allege fraud, they must also comply with the heightened standard of Rule 9(b), which requires the complaint to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). This Court previously concluded that the heightened pleading requirements of Rule 9(b) apply to Plaintiffs' Lanham Act claim. (Mar. 26, 2021 Order Granting Mot. to Dismiss at 4.)

I. Actionable Statements

The Court first clarifies which of the statements listed in the SAC are potentially actionable. To state a false advertising claim under the Lanham Act, the plaintiff must allege that:

- (1) The defendant made a material false statement of fact in a commercial advertisement;
- (2) the false statement actually deceived or had the tendency to deceive a substantial segment of its audience; and
- (3) the plaintiff has been or is likely to be injured as a result of the false statement.

Eli Lilly & Co. v. Arla Foods, Inc., 893 F.3d 375, 381–82 (7th Cir. 2018). In the SAC, Plaintiffs repeat essentially the same list of allegedly false and actionable statements as included in the FAC. As noted above, however, the Court has already held that certain of those statements are not actionable in its ruling dismissing Count II of the FAC.

The Court has already found that Statements (1) and (2), which are contained in Stericycle's Section 510(k) submission to the FDA, were not used in commercial advertising and promotion and thus cannot form the basis for a false advertising claim under the Lanham Act. Plaintiffs accept that Statements (1) and (2) are not actionable and maintain that the statements were only included in the SAC to provide context. Such a purpose is permissible, but the Court

reiterates that Statements (1) and (2) may not serve as the basis for an independent claim for false advertising.

The Court also previously considered whether Statement (3), which states that the accused container “[has] marketing clearance from the FDA,” is actionable. Finding that it is not, the Court explained that it interpreted the FAC, with regards to Statement (3), to challenge the statements upon which Stericycle relied to obtain the marketing clearance, not the veracity of the Statement (3) itself. (Mar. 26, 2021 Mem. Op. & Order Granting Mot. to Dismiss at 11.) In briefing the motion to dismiss the FAC, Plaintiffs stated that they were not arguing that Statement (3) is actionable but instead included that statement in the FAC as context. (Pls.’ Resp. to Mot. to Dismiss at 20, Dkt. No. 144.) However, for purposes of the present motion to dismiss, Plaintiffs no longer claim that Statement (3) is included in the SAC merely as context. Instead, they now assert that Stericycle changed the design of its sharps container after the issuance of the FDA marketing clearance, and thus it was false or misleading to market the second version as being approved by the FDA. Although Stericycle contends that this Court has already held that Statement (3) is both true and based on non-actionable statements, that is not so. To the contrary, in its prior ruling, the Court recognized that the allegation that Stericycle markets its products as “hav[ing] marketing clearance from the FDA” is a quantifiable and actionable statement of fact. (Mar. 26, 2021 Order Granting Mot. to Dismiss at 11.) As Plaintiffs now challenge Statement (3) itself, and not just those statements upon which Stericycle relied to obtain the marketing clearance, the Court finds it to be actionable.

Additionally, the Court previously determined that Statements (4), (5), and (6)—that the containers are “designed for ease of use and increasing safety,” “ideal for patient rooms and treatment areas,” and serve as a solution to needlesticks—are mere puffery. (*Id.*) Nonetheless,

Plaintiffs now argue otherwise and maintain that whether those statements are puffery is a matter for summary judgment, appearing to imply that this Court has already ruled to that effect.

Plaintiffs are mistaken. The Court's prior decision clearly concluded that, while several of Stericycle's statements amount to more than mere puffery, Statements (4), (5), and (6) are not among them. (*Id.*)

Plaintiffs may not relitigate the Court's decision simply by filing an amended complaint and re-asserting matters that have already been decided. "The law of the case doctrine is based on the policy that 'when an issue is once litigated and decided, that should be the end of the matter.'" *Rustom v. Rustom*, No 17 C 9061, 2019 WL 4034620, at *7 (N.D. Ill. Aug. 27, 2019) (quoting *Barrett v. Baylor*, 457 F.2d 119, 123 (7th Cir. 1972)). Absent a compelling reason, "a single court should not revisit its earlier rulings" so as to "further consistency, to avoid constantly revisiting rulings, and to conserve judicial resources." *Sharp Elecs. Corp. v. Metro Life Ins. Co.*, 578 F.3d 505, 510 (7th Cir. 2009). Plaintiffs may not ignore the Court's prior ruling and attempt to relitigate an issue already decided. Statements (4), (5), and (6) are not actionable.

II. Sufficiency of the Allegations

The Court next turns to whether Plaintiffs have sufficiently pleaded claims relating to the remaining, actionable statements: Statements (3), (7), (8), and (9). To plead a fraud claim successfully consistent with Rule 9(b), the complaint must "describe the who, what, when, where, and how of the fraud." *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 776 (7th Cir. 2016) (internal quotation marks omitted). The goal of "these heightened pleading requirements [is to] 'force the plaintiff to do more than the usual investigation before filing his complaint'" in order to "ensure[] that the claim is 'responsible and supported, rather than defamatory and extortionate.'" *Conditioned Ocular Enhancement, Inc. v. Bonaventura*, 458

F. Supp. 2d 704, 709 (N.D. Ill. 2006) (quoting *Ackerman v. Nw. Mut. Life Ins. Co.*, 172 F.3d 467, 469 (7th Cir. 1999)). Generally, “[t]his requirement includes the identity of the person making the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated . . .” *Rocha v. Rudd*, 826 F.3d 905, 911 (7th Cir. 2016) (internal quotation marks omitted). But the information a plaintiff must provide to satisfy the standard “may vary on the facts of a given case.” *Pirelli Armstrong Tire Corp. Retiree Med. Benefits Tr. v. Walgreen Co.*, 631 F.3d 436, 442 (7th Cir. 2011). Indeed, the Seventh Circuit has warned against “erroneously tak[ing] an overly rigid view of the formulation.” *Id.*

Stericycle asserts that the SAC fails to meet the heightened pleading standards required by Rule 9(b). Specifically, Stericycle contends that Plaintiffs fail to specify the “where” and “how” of the alleged fraud. But Plaintiffs do plead “where” the fraud allegedly occurred; they provide a list of targeted customers and, in fact, name specific hospitals. And although Stericycle insists that Plaintiffs have not described “how” the fraud occurred, it is clear from the pleadings that the method by which the fraud was allegedly perpetrated was via the distribution of promotional materials containing the false statements. In fact, Plaintiffs have provided an exhibit consisting of Stericycle’s promotional template form with customizable fields to better target individual customers. (SAC, Ex. C, STERI_0001861, Dkt. No. 164.) From this, it is reasonable to infer that Stericycle actually distributed the promotional material to potential customers—such inferences are allowed even under Rule 9(b). *See, e.g., United State v. Omnicare, Inc.*, No. No. 11-cv-8980, 2014 WL 1458443, at *10 (N.D. Ill. Apr. 14, 2014) (noting that, in the context of Medicaid fraud, a lack of specific examples of actual false claims submitted on specific dates can be overcome by facts which support an inference that such claims were submitted.)

Even if a plaintiff is unable to “plead the specific date, place, or time of the fraudulent acts,” the plaintiff may be able to state a valid fraud claim if they are able to “use some alternative means of injecting precision and some measure of substantiation into their allegation of fraud.” *Pirelli*, 631 F.3d at 442. In fact, Rule 9(b)’s particularity requirement “must be relaxed where the plaintiff lacks access to all facts necessary to detail his claim.” *Corley v. Rosewood Care Ctr., Inc.*, 142 F.3d 1041, 1051 (7th Cir. 1998). Courts have established that such pleading is appropriate if “(1) the facts constituting the fraud are not accessible to the plaintiff and (2) the plaintiff provides the grounds for his suspicions.” *Berkowitz v. Automation Aids, Inc.*, 896 F.3d 834, 841 (7th Cir. 2018) (internal quotation marks omitted).

Therefore, it is not dispositive that Plaintiffs plead certain facts, such as the dates on which the allegedly false or misleading statements were made and the customers to which they were directed, “on information and belief.” *See Goldberg v. Rush Univ. Med. Ctr.*, 929 F. Supp. 2d 807, 817 (N.D. Ill. 2013) (noting that courts must “remain sensitive to information asymmetries that may prevent a plaintiff from offering more detail” and recognizing that a plaintiff may plead fraud based on information and belief so long as the grounds for their suspicions makes the allegations plausible) (quoting *Pirelli*, 631 F.3d at 443). Here, Plaintiffs do not have access to specific communications between Stericycle and its potential or actual customers. As Plaintiffs note, Stericycle has not produced such information during discovery. Stericycle counters that Plaintiffs could have reached out to individual customers and requested the records, or even issued subpoenas to the customers to obtain the information. But Stericycle itself has consistently maintained that its customer relationships are confidential and covered by a protective order and that it would be improper for Plaintiffs to solicit information about Stericycle from a third party

with whom Stericycle asserts a confidential relationship. In sum, Plaintiffs have shown that details about specific customer interactions relating to the alleged fraud are inaccessible to them.

Similarly, Plaintiffs have provided grounds for their suspicions. Stericycle contends that Plaintiffs fail to point to any instance for which they have firsthand knowledge of each element detailing the “who, what, when, where, and how” of the alleged fraud. But Plaintiffs do allege that Stericycle has used specifically identified promotional materials from specific dates, identified using the date of printing, which contain the specified allegedly false or misleading statements to target individually named customers, after which those customers began purchasing Stericycle’s products. This is enough to state a plausible claim, even under Rule 9(b)’s heightened standards. *See Medscript Pharmacy, LLC v. My Script, LLC*, 77 F. Supp. 3d 788, 793 (N.D. Ill. 2015) (holding that the plaintiff satisfied Rule 9(b) where it alleged that the defendants made false statements by attempting to pass themselves off as the plaintiff, and the complaint specified the allegedly false statements, described how the defendant used prescription pads to pass themselves off as the plaintiff, asserted the targets were identified via a patient list, and stated that the representations were made beginning in January 2014).

Finally, Stericycle maintains that not only have Plaintiffs have failed to demonstrate that the relevant statements are false or misleading, but further that the statements are in fact demonstrably true. But the determination of whether a statement is false or misleading is a fact-based inquiry and thus not appropriately determined at this stage of the proceedings. *See Leiner v. Johnson & Johnson Consumer Cos.*, 215 F. Supp. 3d 670, 673 (N.D. Ill. 2016) (holding that the defendant’s argument that allegedly false statements were actually true “is a merits argument outside the scope of what [the Court] may appropriately decide on a motion to dismiss”). For instance, although Stericycle seeks to rely on a market study attached to Plaintiffs’ SAC to argue

that the statement about a “100% sustained reduction in needlesticks” is demonstrably true, Plaintiffs contend not that it is false, but that it is misleading. And Plaintiffs specifically allege the reasons why this may be so. But again, that is a matter to be resolved at a later point in the proceedings. *See Heredia v. Cap. Mgmt. Servs., L.P.*, 942 F.3d 811, 814 (7th Cir. 2019) (“Generally, the question of whether a disputed statement is false, deceptive, or misleading is a fact-laden one and therefore a district court may not dismiss a complaint unless the disputed statement is plainly, on its face, not misleading or deceptive.”) For now, Plaintiffs have done enough to state a claim.

CONCLUSION

For the reasons stated above, Stericycle’s motion to dismiss Count II of Plaintiffs’ Second Amended Complaint (Dkt. No. 169) is denied.

Dated: November 4, 2021



Andrea R. Wood
United States District Judge