UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 20-CV-10280-RWZ

AZURITY PHARMACEUTICALS, INC.

v.

EDGE PHARMA, LLC

MEMORANDUM & ORDER

May 18, 2021

ZOBEL, S.D.J.

Plaintiff, a specialty pharmaceutical company, alleges that defendant, a compounding facility, has made false representations on its website in violation of the Lanham Act, 15 U.S.C. § 1125(a)(1), and the Massachusetts consumer protection statute, Mass. Gen. Laws ch. 93A. It claims that defendant has been compounding an antibiotic nearly identical to plaintiff's and falsely marketing it as complying with the Food & Drug Administration's ("FDA") requirements. Defendant has moved to dismiss the complaint. (Docket # 20).

I. Background

"Drug compounding is often regarded as the process of combining, mixing, or altering ingredients to create a sterile or non-sterile medication . . . ." FDA, Human Drug Compounding Progress Report at 4 (Jan. 2017), available at https://www.fda.gov/media/102493/download. Under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, compounded drugs are exempt from the FDA's drug

approval process. Nevertheless, in 2013 Congress established certain requirements for both compounded drugs and the companies that manufacture them. 21 U.S.C. §§ 353a, 353b.[1] For example, manufacturers can now elect to become "outsourcing facilities" that "compound drugs intended to meet the needs of specific patients for whom an approved or over-the-counter drug is not medically appropriate." Supra, Human Drug Compounding Progress Report at 7. In addition, outsourcing facilities may sell compounded drugs using "bulk drug substance" only if the FDA has identified a clinical need, or if the compounded drug is on the FDA's drug shortage list, 21 U.S.C. § 353b(a)(2)(A)(i)–(ii), and they may not compound drugs that are "essentially a copy" of an FDA-approved drug, id. § 353b(a)(5).

Plaintiff alleges that, as an outsourcing facility, defendant is compounding a product, vancomycin hydrochloride, that does not comply with these requirements, even though the FDA has not cited defendant for non-compliance or pursued an enforcement action against it.[2] Given defendant's alleged violations, plaintiff asserts that statements on defendant's website are false and therefore violate the Lanham Act.

II. Standard of Review

To survive a motion to dismiss under Rule 12(b)(6), 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

[1] Although the FDA has not yet promulgated regulations interpreting these requirements, in January 2017 and January 2018 it issued guidance setting out its interim policies.

[2] Plaintiff cites recent FDA inspection reports that identified several compliance violations at defendant's facility, but none of those violations are related to defendant's vancomycin hydrochloride product. (Docket # 1 ¶¶ 5, 53–56, 58; Docket # 41-3).

U.S. 544, 570 (2007)). For purposes of this motion, the court must accept all factual allegations in the complaint as true and construe all reasonable inferences in the plaintiff's favor. See Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993).

III. Analysis

The Lanham Act provides a remedy for plaintiffs who are injured by

> [a]ny person who, on or in connection with any goods or services, or any container for goods, uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her . . . goods, services, or commercial activities . . . .

15 U.S.C. § 1125(a)(1)(B). To bring a successful Lanham Act claim,

> a plaintiff must demonstrate that (1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about his own or another's product; (2) the misrepresentation is material, in that it is likely to influence the purchasing decision; (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience; (4) the defendant placed the false or misleading statement in interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products.

Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave., 284 F.3d 302, 310–11 (1st Cir. 2002).

Plaintiff alleges that defendant's website misrepresents defendant as complying with the FDCA when it does not. Plaintiff's Lanham Act claim would require the court to determine whether defendant is violating the FDCA and the FDA's interim policies, including whether defendant's vancomycin hydrochloride product is, as plaintiff alleges, "essentially a copy" of plaintiff's own product. Again, the FDA itself has not determined that defendant is violating the requirements plaintiff identifies in its complaint.

"Enforcement of the FDCA and the detailed prescriptions of its implementing regulations is largely committed to the FDA," POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102, 115 (2014), thus "there are some circumstances when the FDCA . . . preclude[s] Lanham Act claims," Hi-Tech Pharms., Inc. v. Hodges Consulting, Inc., 230 F. Supp. 3d 1323, 1330 (N.D. Ga. 2016). "Because the FDCA forbids private rights of action under that statute, a private action brought under the Lanham Act may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation." PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 924 (9th Cir. 2010); see Sandoz Pharm. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 231 (3d Cir. 1990) ("[W]hat the [FDCA] . . . do[es] not create directly, the Lanham Act does not create indirectly, at least not in cases requiring original interpretation of th[is] Act[] or [its] accompanying regulations.").

It would be inappropriate for the court to resolve plaintiff's Lanham Act claim, which necessitates resolution of "thorny questions that may require the FDA's expertise. For instance, . . . what the FDCA means by . . . 'essentially a copy' . . . ." Allergan United States v. Imprimis Pharm., Inc., No. 17-cv-01551, 2017 U.S. Dist. LEXIS 223117, at *20 (C.D. Cal. Nov. 14, 2017) (citing 21 U.S.C. § 353b(a)(5)); see also Nexus Pharm., Inc. v. Quva Pharma, Inc., No. 20-cv-07518, 2020 U.S. Dist. LEXIS 208832, at *10 (C.D. Cal. Oct. 29, 2020) (citing recent FDA testimony on § 353b as "highlight[ing] the fact that determination of whether Defendants' product is 'essentially a copy' . . . in violation of the FDCA, must be left to the FDA"); JHP Pharm., Ltd. Liab. Co. v. Hospira, Inc., 52 F. Supp. 3d 992, 1004 (C.D. Cal. 2014) ("In short, unlike the binary

factual determination of whether [a party's] products are, in fact, FDA-approved, the question of legality directly implicates the FDA's rulemaking authority. The determination . . . whether a drug . . . can be lawfully marketed under the FDCA, involves complex issues of history, public safety, and administrative priorities that Congress has delegated exclusively to the FDA."). This claim is therefore precluded by the FDCA.[3]

Plaintiff's Chapter 93A claim likewise fails as it is premised on the same allegations. See Reed v. Zipcar, Inc., 883 F. Supp. 2d 329, 334–35 (D. Mass. 2012) ("Chapter 93A supplies an independent cause of action . . . . [a]s long as a litigant offers separate arguments in support of her Chapter 93A claim . . . ." (citation omitted)), aff'd 527 F. App'x 20 (1st Cir. 2013).

IV. Conclusion

Defendant's motion to dismiss (Docket # 20) is ALLOWED. Plaintiff's motion for preliminary injunction (Docket # 2) is therefore DENIED as moot.

May 18, 2021
DATE

RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE

[3] As another court has noted, plaintiff has another avenue available to advance its claims.

> If the Plaintiff were to pursue the matter with the FDA through its administrative procedures and obtain a clear statement from the agency that the Defendants are selling their products illegally or otherwise breaking the law, *and* if the Defendants at that point chose to affirmatively declare in their advertising that their products comply with the law, a federal court could hear a Lanham Act claim for false advertising.

JHP Pharm., 52 F. Supp. 3d at 1004.