United States Court of Appeals
For the First Circuit

No. 21-1492

AZURITY PHARMACEUTICALS, INC.,

Plaintiff, Appellant,

v.

EDGE PHARMA, LLC,

Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Rya W. Zobel, U.S. District Judge]

Before

Barron, Chief Judge,
Howard and Thompson, Circuit Judges.

James H. Hulme, with whom Nadia A. Patel, Valerie C. Samuels, and Arent Fox LLP were on brief, for appellant.

Robert J. Fluskey, Jr., with whom Linda L. Morkan, William J. Egan, Julianna M. Charpentier, Robinson & Cole LLP, and Hodgson Russ LLP were on brief, for appellee.

August 12, 2022

BARRON, Chief Judge. Azurity Pharmaceuticals, Inc. ("Azurity") is a specialty pharmaceutical company. It markets a hydrochloride vancomycin drug that received pre-market approval from the United States Food and Drug Administration ("FDA"). Edge Pharma, LLC ("Edge") is a drug compounding company. It markets a hydrochloride vancomycin drug that competes with Azurity's but has not been given pre-market FDA approval.

In 2020, Azurity filed suit in the United States District Court for the District of Massachusetts against Edge under both the Lanham Act and a Massachusetts consumer protection law, Mass. Gen. Laws. ch. 93A ("Chapter 93A"), based on statements that Edge allegedly made on its website. The suit alleges that a number of these statements represent or convey the impression that Edge is not in violation of section 503B of the Food, Drug, and Cosmetic Act ("FDCA"), which authorizes drug compounders who meet certain conditions to market their compounded drugs without first obtaining FDA approval. The suit alleges that these statements are literally false and/or misleading. The suit further alleges that another one of Edge's statements on its website is false and/or misleading because it holds out Edge's vancomycin drug as being superior to Azurity's.

Edge moved to dismiss Azurity's claims for, among other things, failure to state a claim on which relief could be granted under Federal Rule of Civil Procedure ("Rule") 12(b)(6). The

District Court granted Edge's Rule 12(b)(6) motion as to Azurity's Lanham Act claim on the ground that the FDCA precluded Azurity's claim. The District Court based this ruling on the determination that the claim would require a court to interpret the meaning of section 503B in a way that would interfere with the FDA's authority to administer and enforce the FDCA. Azurity Pharms., Inc. v. Edge Pharma, LLC, 540 F. Supp. 3d 141, 144 (D. Mass. 2021). The District Court also ruled that, because the FDCA precluded Azurity's Lanham Act claim, Azurity's Chapter 93A claim "likewise fails as it is premised on the same allegations" as Azurity's Lanham Act claim.[1] Id. (citing Reed v. Zipcar, Inc., 883 F. Supp. 2d 329, 334–35 (D. Mass. 2012)).[2] We affirm in part (albeit on an alternative ground) and vacate in part.

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[1] Azurity's complaint contains two counts, one for violation of the Lanham Act and another for unfair and deceptive trade practices under Chapter 93A. The District Court treated Azurity as having made one "claim" under each statute. See Azurity, 540 F. Supp. 3d at 144. On appeal, Azurity frames its complaint has having stated four distinct claims under the Lanham Act. Following the District Court, we use the singular "claim" to encompass all of the theories that Azurity argues for finding Edge to have violated the Lanham Act, and we do the same with respect to Chapter 93A.

[2] In granting Edge's motion to dismiss, the District Court also denied Azurity's motion for a preliminary injunction as moot. Azurity, 540 F. Supp. 3d. at 145. Azurity referred to this denial in its notice of appeal, but it makes no mention of it in its briefing to us so any challenge to that ruling is waived. See United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990).

I.

Because this appeal is from the grant of a motion to dismiss Azurity's complaint for failure to state a claim under Rule 12(b)(6), we accept all well-pleaded facts in Azurity's operative complaint as true. See Clorox Co. P.R. v. Proctor & Gamble Com. Co., 228 F.3d 24, 30 (1st Cir. 2000). We also draw all reasonable inferences in Azurity's favor. Id.

A.

The FDCA requires the FDA's pre-approval to market any drug. However, the FDCA exempts "compounded" drugs -- which are drugs that are produced by "combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering . . . a drug or bulk drug substance," 21 U.S.C. § 353b(d)(1) -- from the FDCA's pre-approval requirements in some circumstances.

The circumstances are set forth in section 503B of the FDCA, 21 U.S.C. § 353b. That section provides that certain pre-approval requirements "shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility if each of the . . . conditions [set forth in section 503B] is met." 21 U.S.C. § 353b(a). The FDCA defines an "outsourcing facility" as a facility that "is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies

with all of the requirements of [section 503B of the FDCA]." Id. § 353b(d)(4)(A)(i)-(iii).

In specifying the conditions that an outsourcing facility must meet, section 503B provides that an "outsourcing facility" may not compound a drug that is "essentially a copy of one or more approved drugs." Id. § 353b(a)(5). Section 503B defines "essentially a copy" to mean:

> (A) a drug that is identical or nearly identical to an approved drug . . . unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 356e of this title at the time of compounding, distribution, and dispensing; or
>
> (B) a drug, a component of which is a bulk drug substance that is a component of an approved drug . . . , unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Id. § 353b(d)(2).

Another portion of section 503B concerns the use by "outsourcing facilities" of a "bulk drug substance." Id. § 353b(a)(2). That provision requires, as a "condition" for an "outsourcing facility" to market a compounded drug without prior FDA approval, that:

> The drug is compounded in an outsourcing facility that does not compound using bulk drug substances . . ., unless--

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