

ENTERED

April 29, 2026

Nathan Ochsner, Clerk

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

ELI LILLY AND COMPANY,	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION NO. H-25-3464
	§	
EMPOWER CLINIC SERVICES, LLC	§	
D/B/A EMPOWER PHARMACY,	§	
	§	
Defendant.	§	

MEMORANDUM OPINION AND ORDER

Plaintiff, Eli Lilly and Company ("Lilly" or "Plaintiff"), brings this action against Defendant, Empower Clinic Services, LLC, d/b/a Empower Pharmacy ("Empower" or "Defendant"), for false or misleading advertising and promotion in violation of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), and for related claims based on the statutory or common law of the states of Alaska, Colorado, Connecticut, Hawaii, North Carolina, South Carolina, Tennessee, Texas, and Washington.¹ Lilly seeks declaratory, injunctive, and monetary relief.² Lilly alleges that this court has subject matter jurisdiction under 28 U.S.C. § 1331 based on the Lanham Act cause of action, and also under 28 U.S.C. § 1332 based on diversity because the matter in controversy exceeds the value of \$75,000 and is between citizens of different states. Lilly also alleges that the court has supplemental jurisdiction over the state law causes

¹Complaint, Docket Entry No. 1, pp. 54-74 ¶¶ 161-290. Page numbers for docket entries refer to the pagination inserted at the top of the page by the court's electronic filing system.

²Id. 75-78.

of action under 28 U.S.C. § 1367(a) because they belong to the same case or controversy as the Lanham Act cause of action.³

Pending before the court is Defendant Empower Clinic Services, L.L.C. d/b/a Empower Pharmacy's Motion to Dismiss for Failure to State a Claim and Memorandum in Support ("Defendant's Motion to Dismiss") (Docket Entry No. 34), Defendant Empower Clinic Services, L.L.C. d/b/a Empower Pharmacy's Motion to Stay Discovery ("Defendant's Motion to Stay Discovery") (Docket Entry No. 46), and Defendant Empower Clinic Services, L.L.C. d/b/a Empower Pharmacy's Motion for Protective Order ("Defendant's Motion for Protective Order") (Docket Entry No. 73). Plaintiff has responded to Defendant's motions by filing Plaintiff Eli Lilly and Company's Opposition to Defendant's Motion to Dismiss for Failure to State a Claim ("Plaintiff's Opposition to Defendant's Motion to Dismiss") (Docket Entry No. 49), and Plaintiff Eli Lilly and Company's Opposition to Empower Pharmacy's Motion to Stay Discovery ("Plaintiff's Opposition to Defendant's Motion to Stay") (Docket Entry No. 47). Defendant has replied by filing Defendant Empower Clinic Services, L.L.C. d/b/a Empower Pharmacy's Reply in Support of Its Motion to Stay Discovery ("Defendant's Reply in Support of Motion to Stay") (Docket Entry No. 51), and Defendant Empower Clinic Services, L.L.C. d/b/a Empower Pharmacy's Reply in Support of Its Motion to Dismiss for Failure to State a Claim and

³Id. at 8 ¶ 22. See also Disclosure of Interested Parties, Docket Entry No. 32 (disclosing that Lilly is an Indiana corporation, and Empower is a limited liability company with two members, one of whom is a citizen of Texas, and the other is a citizen of New York).

Memorandum in Support (“Defendant’s Reply in Support of Motion to Dismiss”) (Docket Entry No. 53). For the reasons stated below, Defendant’s Motion to Dismiss will be granted as to the Lanham Act claim and the claim asserted under Texas common law, and otherwise denied. Defendant’s Motion to Stay and Motion for Protective Order will be denied as moot.

I. Factual Allegations⁴

Lilly is a pharmaceutical company responsible for developing, testing, and gaining approval from the United States Food and Drug Administration (“FDA”) for two medications containing the active ingredient tirzepatide: MOUNJARO® and ZEPBOUND®. Tirzepatide is a micromolecule discovered by Lilly that targets the patient’s GLP-1 and GIP receptors to improve blood sugar control and reduce appetite. The FDA approved MOUNJARO® to treat type 2 diabetes, and ZEPBOUND® to treat chronic weight management and obstructive sleep apnea in certain adults. MOUNJARO® and ZEPBOUND® have been tested and FDA-approved only as single-ingredient medications for subcutaneous (i.e., under the skin) injection. Because Lilly was the first to gain FDA approval for tirzepatide-based medications, Lilly enjoys a period of market exclusivity through at least May of 2027.

⁴Unless otherwise noted, the facts in this section are alleged in the “General Allegations” section of Lilly’s Complaint, Docket Entry No. 1, pp. 9-54 ¶¶ 26-160, and restated in Plaintiff’s Opposition to Defendant’s Motion to Dismiss, Docket Entry No. 49, pp. 14-18.

Empower is a licensed compounding pharmacy located in Houston, Texas, authorized to ship drugs across the country to every state except California. Empower makes and sells two versions of tirzepatide medications: Tirzepatide ODT, dissolving tablets taken orally; and injections containing fixed-dose combinations of tirzepatide and niacinamide (a form of vitamin B-3). Lilly alleges that, unlike its tirzepatide medications, Empower's compounded medications have not been tested in clinical trials or approved by the FDA, and that Empower has a history of regulatory violations, including failure to comply with sanitation and sterility requirements by use of non-pharmaceutical grade components.

Lilly alleges that Empower's marketing and sale of its untested and unapproved compounded tirzepatide medications is unfair, deceptive, false, and misleading, and creates a significant risk to patient safety and to the brand-image of tirzepatide-based medications that Lilly spent billions of dollars to develop. Lilly alleges three main issues with Empower's advertisements of its tirzepatide-based products. First, Lilly alleges that Empower unfairly and deceptively markets and sells its tirzepatide medications (1) as safe and effective treatments for both type 2 diabetes and weight management, despite the fact that they have never been studied clinically; (2) as custom-made, "personalized" medications, despite the fact that Tirzepatide ODT is manufactured in three standardized strengths, and tirzepatide in combination

with niacinamide is manufactured in two standardized strengths, none of which are altered for individual patients, and (3) as manufactured in adherence "to stringent regulatory standards," despite the fact that federal and state regulators, and whistle blowers, have observed deficiencies in Empower's safety practices. Lilly alleges that Empower's unfair and deceptive practices have caused harm by luring patients away from Lilly's safe and effective FDA-approved medications in favor of Empower's untested and unapproved drugs, and that if left unchecked these harms will continue. Asserting that Empower's sales of compounded tirzepatide products would have been made by Lilly but for Empower's unlawful and unfair competition, Lilly alleges that it has suffered financial harm in the form of lost sales as a direct result of Empower's unfair competition. Lilly also alleges that Empower's deceptive practices have caused irreparable harm to its brand and customer goodwill by promising results that consumers will not obtain from Empower's products.

II. Standard of Review

Citing Federal Rule of Civil Procedure 12(b)(6), Empower seeks dismissal of all causes of action asserted in Lilly's Complaint. A Rule 12(b)(6) motion tests the formal sufficiency of the plaintiff's pleadings and is "appropriate when a defendant attacks the complaint because it fails to state a legally cognizable

claim.” Ramming v. United States, 281 F.3d 158, 161 (5th Cir. 2001), cert. denied sub nom. Cloud v. United States, 122 S. Ct. 2665 (2002). To defeat a motion to dismiss pursuant to Rule 12(b)(6), a plaintiff must plead “enough facts to state a claim to relief that is plausible on its face.” Bell Atlantic Corp. v. Twombly, 127 S. Ct. 1955, 1974 (2007). “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 v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (citing Twombly, 127 S. Ct. at 1965). Labels, conclusions, and “a formulaic recitation of the elements of a cause of action will not do.” Twombly, 127 S. Ct. at 1974.

When considering a motion to dismiss, the court must accept the factual allegations of the complaint as true, view them in a light most favorable to the plaintiff, and draw all reasonable inferences in the plaintiff’s favor. Id. The court “must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice.” Funk v. Stryker Corp., 631 F.3d 777, 783 (5th Cir. 2011) (quoting Tellabs, Inc. v. Makor Issues & Rights, Ltd., 127 S. Ct. 2499, 2509 (2007)). “A judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within

the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.” Id. (citing Fed. R. Evid. 201(b)). In Funk the Fifth Circuit held that “the district court took appropriate judicial notice of publicly-available documents and transcripts produced by the FDA, which were matters of public record directly related to the issue at hand.” Id.

III. Empower’s Motion to Dismiss

Lilly alleges that it “files this action to stop Empower from engaging in false and deceptive sales and practices and selling its knockoff, unapproved tirzepatide drugs in violation of state and federal law.”⁵ Asserting that Lilly’s Complaint is a thinly veiled attempt to eliminate compounding with tirzepatide, Empower argues that Lilly’s claims are all subject to dismissal under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim for which relief may be granted.⁶ Lilly responds that Empower’s attacks on the sufficiency of the Complaint all fail.⁷

⁵Complaint, Docket Entry No. 1, p. 3 ¶ 7.

⁶Defendant’s Motion to Dismiss, Docket Entry No. 34, p. 12.

⁷Plaintiff’s Opposition to Defendant’s Motion to Dismiss, Docket Entry No. 49, p. 14.

A. Lilly's Lanham Act Claims

Lilly's only federal law claim is an unfair competition claim against Empower for false or misleading advertising under § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). Lilly alleges that

283. Empower's commercial advertising claims described herein are false and misleading in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B). Empower deceptively promotes its tirzepatide products as "safe" and "effective" based on Lilly studies, deceptively promotes its tirzepatide products as "personalized" when they are mass-manufactured, and falsely advertises that it complies with regulations, despite the fact that regulatory authorities have concluded otherwise on multiple occasions.
284. Empower has made materially false statements to sell its Tirzepatide ODT and its tirzepatide/niacinamide injection. These statements have influenced and are likely to continue to influence consumers' purchasing decisions – specifically, decisions to purchase Empower's Tirzepatide ODT and tirzepatide/niacinamide products instead of Lilly's FDA-approved medicines. Empower is steering patients with serious diseases like diabetes and obesity away from obtaining safe, effective, available, and FDA-approved treatments. Empower's unlawful conduct is putting health, safety, and lives at risk.
285. Empower's advertisements and business practices actually deceive or have the tendency to deceive consumers.
286. Empower has caused its false statements to enter interstate trade or commerce.
287. As a direct and proximate result of Empower's false and deceptive campaign, Lilly is suffering immediate and continuing irreparable injury for which there is no adequate remedy at law.
288. As a direct and proximate result of Empower's false and deceptive campaign, Lilly has suffered and will

continue to suffer significant monetary damages and discernible competitive injury by loss of goodwill.⁸

Empower argues that this claim fails because Lilly has not plead facts capable of establishing statutory standing or most elements of a false advertising claim.⁹ Lilly responds that it has alleged facts capable of establishing a Lanham Act claim.¹⁰

1. Applicable Law

In pertinent part, § 43(a) of the Lanham Act states that

[a]ny person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—

. . .

(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, 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)(B). This section creates liability for "false advertising, § 1125(a)(1)(B)." Lexmark International, Inc. v. Static Control Components, Inc., 134 S. Ct. 1377, 1384 (2014).

⁸Plaintiff's Complaint, Docket Entry No. 1, pp. 73-74 ¶¶ 283-88.

⁹Defendant's Motion to Dismiss, Docket Entry No. 34, p. 23. See also Defendant's Reply in Support of Motion to Dismiss, Docket Entry No. 53, pp. 20-31.

¹⁰Plaintiff's Opposition to Defendant's Motion to Dismiss, Docket Entry No. 49, pp. 14, and 30-51.

In Lexmark the Supreme Court addressed the issue of statutory standing under the Lanham Act. Observing that this section of the Lanham Act is meant to protect businesses from “injuries to business reputation and present and future sales,” id. at 1390, the Court articulated a two-step inquiry for determining whether a plaintiff has a right to sue under the Lanham Act. The first step asks whether the plaintiff comes within “the zone of interest” implicated by the statute. The Court held that “to come within the zone of interests in a suit for false advertising under § 1125(a), a plaintiff must allege an injury to a commercial interest in reputation or sales.” Id. The second step asks whether the plaintiff’s injuries are proximately caused by defendant’s alleged violation of the statute. Id. at 1390-91. The Court held that to establish proximate cause, a plaintiff “must show economic or reputational injury flowing directly from the deception wrought by the defendant’s advertising; and that occurs when deception of consumers causes them to withhold trade from the plaintiff.” Id. at 1391. Thus the Court concluded that to have statutory standing to invoke the Lanham Act’s cause of action for false advertising “a plaintiff must plead (and ultimately prove) an injury to a commercial interest in sales or business reputation proximately caused by the defendant’s misrepresentations.” Id. at 1395.

To succeed on a claim of false advertising under the Lanham Act,

a plaintiff must show: (1) A false or misleading statement of fact about a product; (2) [s]uch statement either deceived or had the capacity to deceive a substantial segment of potential consumers; (3) [t]he deception was material, in that it is likely to influence the consumer's purchasing decision; (4) [t]he product is in interstate commerce; and (5) [t]he plaintiff has been or is likely to be injured as a result of the statement at issue.

Molzan v. Bellagreen Holdings, L.L.C., 112 F.4th 323, 334 (5th Cir. 2024) (quoting IQ Products Co. v. Pennzoil Products Co., 305 F.3d 368, 375 (5th Cir. 2002), cert. denied, 123 S. Ct. 1632 (2003)). See also Pizza Hut, Inc. v. Papa John's International, Inc., 227 F.3d 489, 495 (5th Cir. 2000), cert. denied, 121 S. Ct. 1355 (2001) (articulating the same elements for a Lanham Act claim).

2. Application of the Law to the Alleged Facts

Empower argues that Lilly's Lanham Act claim should be dismissed for lack of statutory standing because "Lilly [d]oes [n]ot [p]lead [f]acts [d]emonstrating Empower's [a]dvertisements [c]aused Lilly [h]arm."¹¹

Citing ¶¶ 159 and 160 of its Complaint, Lilly responds that it alleges injuries that fall within the zone of interests protected by the Lanham Act – specifically, lost sales and damage to its brand and customer good will. . . . Lilly alleges that these injuries are proximately caused by Empower's false advertisements, which lure patients away from Lilly's FDA-approved tirzepatide medicines in favor of Empower's untested, unapproved products.¹²

¹¹Defendant's Motion to Dismiss, Docket Entry No. 34, p. 23.

¹²Plaintiff's Opposition to Defendant's Motion to Dismiss, Docket Entry No. 49, p. 31.

In pertinent part these paragraphs allege:

. . . Empower's unlawful, false and deceptive sales and practices lure consumers away from obtaining safe and effective treatment with MOUNJARO® and ZEPBOUND® on the false promises that (i) untested and unapproved Empower oral disintegrating tablets and tirzepatide/niacinamide injections are safe and effective in treating diabetes and addressing chronic weight management, (ii) Empower's untested and unapproved compounded tirzepatide/niacinamide injections and tirzepatide oral disintegrating tablets fit patients' unique needs, when, in truth, Empower is marketing and selling the same tirzepatide/niacinamide injections and tirzepatide oral disintegrating tablets to every consumer, and/or (iii) Empower is in compliance with regulatory requirements.

. . . Empower's false and deceptive practices cause irreparable harm to Lilly's brand and consumer goodwill by promising results that consumers will not obtain from Empower's products. Empower promotes its Tirzepatide ODT and tirzepatide/niacinamide injections by trading on the credibility of Lilly and its FDA-approved MOUNJARO® and ZEPBOUND® – earned through decades of safe and effective pharmaceutical manufacturing and years of clinical research and testing on tirzepatide specifically – including by specifically citing studies of Lilly's medicines as support for its untested and unapproved knockoffs. When consumers fail to achieve desired results from Empower's Tirzepatide ODT and combination injection, consumers are likely to conclude that tirzepatide is ineffective in general – an outcome made more likely given Empower's reliance on Lilly's clinical studies. Worse still, consumers are likely to be harmed using compounded tirzepatide products from a pharmacy like Empower that has a long record of safety lapses, and when they are, consumers are likely to draw unwarranted conclusions about the safety and effectiveness of Lilly's FDA-approved tirzepatide medicines.¹³

Citing Lexmark, 134 S. Ct. 1393, Lilly argues that these allegations constitute

¹³Complaint, Docket Entry No. 1, pp. 53-54 ¶¶ 159-60.

a “classic Lanham Act false-advertising claim” “in which one competitor directly injures another by making false statements about his own goods . . . inducing customers to switch.” . . . That is exactly what Lilly has alleged: Empower’s tirzepatide-based drugs directly compete with Lilly’s tirzepatide-based medicines, luring Lilly’s customers away. See Compl. ¶¶ 92, 112, 159, 209, 235, 248, 264.¹⁴

Citing Colorado Biolabs, Inc. v. Three Arrows Nutra, LLC, No. 3:25-CV-0601-D, 2025 WL 2524313, at *15 (N.D. Tex. September 2, 2025), Lilly argues that its allegations are “sufficient to show Lanham Act standing under Fifth Circuit law.”¹⁵ In the cited section of Colorado Biolabs the court held the defendant’s allegations sufficient to establish statutory standing to assert a Lanham Act counterclaim after quoting the following passage from Lujan v. Defenders of Wildlife, 112 S. Ct. 2130, 2137 (1992) (quoting Lujan v. National Wildlife Federation, 110 S. Ct. 3177, 3189 (1990)): “At the pleading stage, general factual allegations of injury resulting from the defendant’s conduct may suffice, for on a motion to dismiss we ‘presum[e] that general allegations embrace those specific facts that are necessary to support the claim.’” Colorado Biolabs, 2025 WL 2524313, at *14.

Lilly’s reliance on Colorado Biolabs is misplaced for at least two reasons. First, the authorities on which the Colorado Biolabs court relied address the standard for establishing Constitutional

¹⁴Plaintiff’s Opposition to Defendant’s Motion to Dismiss, Docket Entry No. 49, p. 31.

¹⁵Id.

standing under Article III, not statutory standing under the Lanham Act, which is more demanding. See Lexmark, 134 S. Ct. at 1388 (“[r]ead literally . . . [the Lanham Act’s] broad language might suggest that an action is available to anyone who can satisfy the minimum requirements of Article III . . . [H]owever . . . the unlikelihood that Congress meant to allow all factually injured plaintiffs to recover persuades us that [§ 1125(a)] should not get such an expansive reading”). Second, the authorities on which the Colorado Biolabs court relied predate the “plausibility” pleading standard established by the Supreme Court in Twombly, 127 S. Ct. at 1974, and Iqbal, 129 S. Ct. at 1949.

Lilly does not argue that its allegations of harm satisfy the standards for pleading statutory standing to assert Lanham Act claims set forth in Lexmark, Twombly and Iqbal. Instead, citing ¶¶ 158 and 175 of the Complaint Lilly merely argues that it “alleges direct harm to Lilly.”¹⁶ Paragraph 158 of the Complaint alleges that “[s]ome sales made by Empower of its compounded tirzepatide products would have been made by Lilly but for Empower’s unlawful and unfair competition, and Lilly has suffered financial harm as a direct result.”¹⁷ Paragraph 175 of the Complaint alleges that

¹⁶Id. at 32.

¹⁷Complaint, Docket Entry No. 1, p. 53 ¶ 158.

[a]s a direct result and proximate result of Empower's unlawful, unfair, and deceptive business practices, Lilly has suffered and will continue to suffer monetary damages and discernible competitive injury by the loss of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® tirzepatide medicines.¹⁸

Lilly argues that "these allegations directly link Empower's conduct to Lilly's loss of sales and goodwill, adequately pleading a direct causation theory."¹⁹ While these allegations sufficiently allege injury to a commercial interest in reputation or sales needed to satisfy the zone of interest requirement for establishing statutory standing under the Lanham Act, they are not sufficient to satisfy the proximate cause requirement.

To allege proximate cause under the Lanham Act, a plaintiff "ordinarily must show economic or reputational injury flowing directly from the deception wrought by the defendant's advertising; and that occurs when deception of consumers causes them to withhold trade from the plaintiff." Lexmark, 134 S. Ct. at 1391. Lilly premises its injury from Empower's conduct on lost sales and reputational harm, but Lilly's Complaint fails to allege facts that plausibly support an inference that Lilly has lost sales or suffered irreparable harm to its brand or goodwill traceable to Empower's allegedly false advertising. Absent such allegations of fact there is no statutory standing under the Lanham Act.

¹⁸Id. at 56 ¶ 175.

¹⁹Plaintiff's Opposition to Defendant's Motion to Dismiss, Docket Entry No. 49, p. 32.

(a) Reputational Injury

Lilly alleges that Empower's false and deceptive practices irreparably harm its brand and consumer goodwill by promising results that consumers will not obtain from Empower's products, and that Empower's products are likely to harm consumers because "Empower . . . has a long record of safety lapses."²⁰ Lilly alleges that "[w]hen consumers fail to achieve desired results" or are harmed from Empower's products, they "are likely to draw unwarranted conclusions about the safety and effectiveness of Lilly's FDA-approved tirzepatide medicines."²¹ But Lilly fails to allege facts supporting an inference that Empower's compounded medications harm consumers or fail to meet consumer expectations. The only mention of a consumer complaining about Empower's tirzepatide medicines is found in ¶ 105 of Plaintiff's Complaint where Lilly asserts that "Empower's false claims have actually deceived the marketplace. . . Consumers . . . have been deceived, and they have voiced complaints about ineffective Empower tirzepatide products."²² Footnote 70 at the end of that paragraph cites to a tiktok video posted by an Empower customer,²³ but fails to allege the contents of the video, fails to link the contents of

²⁰Complaint, Docket Entry No. 1, p. 54 ¶ 160.

²¹Id.

²²Id. at 33 ¶ 105.

²³Id. n. 70.

the video to Empower's allegedly false advertisements, and fails to allege facts raising an inference that the allegedly false advertisements caused the video's creator to attribute any negative experience with Empower's tirzepatide medicines to Lilly. Moreover, Lilly does not allege that its name is on any of Empower's products or mentioned in any of Empower's allegedly false advertisements. Lilly's allegations do not support a plausible inference that Empower's compounded tirzepatide medications are not safe and effective, that consumers taking them do not achieve desired results, or that Empower's customers are likely to draw unwarranted conclusions about the safety and effectiveness of Lilly's tirzepatide medications. The court concludes that Lilly's allegations of fact do not raise a plausible inference that Lilly suffered any reputational injury to its brand or goodwill proximately caused by Empower's allegedly false advertising.

(b) Lost Sales

Lilly alleges that Empower's false and deceptive practices irreparably harm Lilly by luring consumers away from obtaining safe and effective treatment with Lilly's MOUNJARO® and ZEPBOUND®. To satisfy the proximate cause requirement based on lost sales, Lilly must allege facts supporting an inference that Empower's allegedly false advertising caused customers to withhold trade from Lilly. Id. In Lexmark the Court held that proximate causation for lost

sales may be adequately alleged when “there is likely to be something very close to a 1:1 relationship between” a plaintiff’s lost sales and the sales diverted to a defendant. Id. at 1394. The allegations in Lilly’s Complaint do not show a 1:1 relationship – or anything approaching it – between Empower’s sales of tirzepatide medications and Lilly’s lost sales. Instead, Lilly merely alleges that “[s]ome sales made by Empower of its compounded tirzepatide products would have been made by Lilly but for Empower’s unlawful and unfair competition.”²⁴ Lilly also alleges that Empower’s “false and deceptive sales and practices lure consumers away from obtaining safe and effective treatment with MOUNJARO® and ZEPBOUND.®”²⁵ These allegations are not enough to avoid dismissal.

For example, in Austin’s Natural Frozen Pops, Inc. v. JonnyPops, LLC, No. 1:24-CV-716-RP, 2025 WL 888560 (W.D. Tex. March 13, 2025), a case cited by Lilly, the plaintiff alleged that “where retailers have limited space to stock either [plaintiff’s product] or [defendant’s product] in their better-for-you section, retailers have chosen [defendant’s product] due to its deceptive sales presentations, because [defendant’s product] is not truly a better-for-you product,” and that “when [defendant’s product] began selling next to [plaintiff’s product] as a better-for-you product

²⁴Id. at 53 ¶ 158.

²⁵Id. ¶ 159.

in one health grocer, [plaintiff's] sales velocity declined by about 25%." Id. at *4. The court relied on these factual allegations to find that the plaintiff had sufficiently pled defendant's advertising caused plaintiff to lose sales. Id.

Lilly alleges that Empower's false advertisements cause Lilly to lose sales and lure patients away from Lilly's tirzepatide medicines to Empower's products. But Lilly's Complaint does not allege facts linking Empower's advertisements to consumers who have been lured away – or switched – from Lilly's tirzepatide medicines to Empower's products. Thus, even if as Lilly alleges, Empower's advertisements were false and misleading, Lilly has failed to allege facts raising a plausible inference that Empower's allegedly false advertisements cause Lilly to lose sales or cause consumers to withhold trade from Lilly. See Eli Lilly and Co. v. Willow Health Services, Inc., No. 2:25-cv-03570-AB-MAR, 2026 WL 639976, *8 (C.D. Calif. February 3, 2026) (dismissing Lanham Act claim for lack of statutory standing because "proximate causation fails absent allegations showing a direct link between advertising and lost sales"). See also United States ex rel. University Loft Co. v. Avteq, Inc., No. SA-14-CA-528-OLG, 2015 WL 13548950, at *9 (W.D. Tex. December 22, 2015) (dismissing Lanham Act claim for lack of statutory standing because "plaintiff had not pleaded that defendants' alleged false advertising was the proximate cause of plaintiff failing to win bids"), report and recommendation adopted, 2016 WL 9461763 (W.D. Tex. January 8, 2016).

(c) Conclusions as to Lilly's Lanham Act Claim

Because Lilly alleges injury to a commercial interest in reputation and sales, Lilly's allegations are sufficient to satisfy the zone of interest requirement for statutory standing to pursue a Lanham Act claim against Empower. See Lexmark, 134 S. Ct. at 1390. But because Lilly's Complaint fails to allege facts that plausibly support an inference that Lilly has lost sales or suffered irreparable harm to its brand or consumer goodwill traceable to Empower's allegedly false advertising, Lilly has failed to plead facts sufficient to satisfy the proximate cause requirement for statutory standing to pursue a Lanham Act claim against Empower. See id. at 1391. Because plaintiffs asserting Lanham Act claims must allege facts capable of proving that they have been or are likely to be injured as a result of the advertisements at issue, Molzan, 112 F.4th at 334, and because Lilly has failed to allege facts capable of proving that Empower's allegedly false and deceptive advertisements caused Lilly to lose sales or harmed Lilly's brand or consumer goodwill, the court also concludes that Lilly has failed to state a Lanham Act claim for which relief may be granted. Therefore, Empower's Motion to Dismiss Lilly's Lanham Act claims will be granted.

B. Lilly's State Law Claims

Lilly asserts state law claims for unfair competition and false advertising under the common law of Texas, and state statutes of Alaska, Colorado, Connecticut, Hawaii, North Carolina, South Carolina, Tennessee, and Washington. Empower argues that Lilly cannot establish its state law claims because they are all preempted by federal law, because Lilly cannot use common law to enforce the Texas Food, Drug, and Cosmetic Act, and because the states' unfair competition laws exempt drug compounding.²⁶ Asserting that Empower violates state unfair competition laws by selling unapproved compounded tirzepatide medications, Lilly responds that the Fifth Circuit has rejected Empower's preemption argument, Empower's conduct is actionable under Texas law, and Empower's conduct is not protected by state-law safe harbors.²⁷

1. Lilly's State Law Claims Are Not Preempted by Federal Law

Asserting that "Lilly's state law claims each improperly seek to enforce [§] 503A of the [Food, Drug, and Cosmetic Act] ("FDCA"),"²⁸ 21 U.S.C. § 353a, and citing Buckman Co. v. Plaintiffs'

²⁶Defendant's Motion to Dismiss, Docket Entry No. 34, pp. 41-51. See also Defendant's Reply in Support of Motion to Dismiss, Docket Entry No. 53, pp. 8-20.

²⁷Plaintiff's Opposition to Defendant's Motion to Dismiss, Docket Entry No. 49, pp. 19-30.

²⁸Defendant's Motion to Dismiss, Docket Entry No. 34, pp. 49-

Legal Committee, 121 S. Ct. 1012 (2001), Empower argues that Lilly's state law claims should all be dismissed because they are all impliedly preempted by the FDCA's prohibition against non-federal enforcement of its drug-related provisions, i.e., 21 U.S.C. § 337(a).²⁹ Empower argues that

Lilly attempts to circumvent FDCA's private enforcement prohibition by cloaking its federal claims under state laws that require "new drugs" to undergo federal approval prior to sale. See e.g., Compl. ¶¶ 168, 180, 194, 207, 219, 231, 244, 259, and 272. Lilly alleges that Empower violates these state laws by selling compounded medications into these states. Id. Lilly, therefore seeks to avoid implied preemption by relying on parallel state laws that mirror and incorporate federal new drug approval requirements. But, by Lilly's own admission, the above state laws are **only** relevant if Empower's compounded medications do **not** comply with [§] 503A, which would thereby make Empower's compounded medications "unapproved drugs." See Compl. ¶ 80 (asserting that Empower cannot invoke [§] 503A as a defense because Empower allegedly violates [§] 503A's requirements). What Lilly is actually seeking to do is to enforce [§] 503A of the FDCA. . .

[Because] Lilly's state law claims are entirely dependent upon proving noncompliance with [§] 503A; Lilly's state law claims cannot be proven in [§] 503A's absence. This is precisely what [§] 337(a) forbids. Further, Lilly has not cited (nor could it) any parallel state law basis for its true claims (violation of [§] 503A) because **none** of these states have incorporated parallel versions of [§] 503A into their state law. Thus, the issue is not that Lilly is enforcing state laws that have made federal laws their own . . . , but that these states have not made the federal law that Lilly is **actually enforcing** their own. . . The Fifth Circuit's recent Zyla[Life Sciences, L.L.C. v. Wells Pharma of

²⁸ (...continued)
50.

²⁹Id. at 49-51.

Houston, L.L.C., 134 F.4th 326 (5th Cir. 2025)], opinion is therefore inapposite. No matter how Lilly packages its claim, it “is effectively suing for a violation of the FDCA . . . and the claim is thus impliedly preempted under Buckman. . . . Therefore, Lilly’s state law claims fail.”³⁰

Citing Zyla, 134 F.4th at 330-31 and 338, Lilly responds that the Fifth Circuit has rejected Empower’s preemption argument.³¹ Asserting “Zyla held that there is ‘no preemption’ of state-law claims that ‘make federal law their own,’” and “Empower relies on Buckman . . . which Zyla distinguished,”³² Lilly argues that

[t]o avoid Zyla, Empower claims that Lilly is not enforcing “new drug approval requirements” at all. . . . Since those laws are “only relevant if Empower’s compounded medications do not comply with [§] 503A,” Empower claims Lilly is “actually seeking to . . . enforce [§] 503A” of the FDCA and so its claim is preempted. . . . Zyla rejected that argument, too. The defendant in that case also argued that it “did not need to obtain approval if it satisfied” federal compounding regulations. 134 F.4th at 331 n.2. But in the Fifth Circuit’s words, “[t]hat is a big if.” Id. The Court explained that “to establish this theory of preemption,” the defendant must “have proven that it satisfies [federal law’s] many requirements.” Id. Since it had “only moved to dismiss under 12(b)(6),” it “cannot have” made that showing. Id.³³

³⁰Id. at 50-51. See also Defendant’s Reply in Support of Motion to Dismiss, Docket Entry No. 53, pp. 7-12 (reasserting the same argument).

³¹Plaintiff’s Opposition to Defendant’s Motion to Dismiss, Docket Entry No. 49, pp. 19-21.

³²Id. at 20 (citing Zyla, 134 F.3d at 332).

³³Id. at 20-21.

(a) Applicable Law

Congress enacted the FDCA to “promote the public health,” 21 U.S.C. § 393(b)(1), by among other things, ensuring that “human . . . drugs are safe and effective.” 21 U.S.C. § 393(b)(2)(B). Provisions of the FDCA relevant to the allegations in this action include the prohibition against introducing new drugs into interstate commerce without approval of the FDA, 21 U.S.C. § 355(a), and the allowance of drug compounding performed by licensed pharmacists, physicians, and outsourcing facilities under the direct supervision of a licensed pharmacist, 21 U.S.C. §§ 353a-353b.³⁴ Congress gave the FDA the sole authority to police violations of the FDCA and foreclosed any private right of action by requiring that “all . . . proceedings for the enforcement, or to restrain violations” of the FDCA “shall be by and in the name of the United States.” 21 U.S.C. § 337(a). Citizens may petition the FDA to take administrative action, 21 C.F.R. §§ 10.25(a), 10.30, but may not privately enforce the FDCA. See POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2235 (2014) (“Private parties may not bring enforcement suits [for FDCA violations].”).

States across the country have adopted their own food-and-drug laws that often mirror the FDCA. See Zyla, 134 F.4th at 330. As

³⁴Title 21 §§ 353a and 353b are often referred to as §§ 503A and 503B, respectively, as drawn from the FDA Modernization Act of 1997, Pub. L. No. 105-115 (1997). These sections articulate conditions drug compounders must meet.

relevant here, Alaska, Colorado, Connecticut, Hawaii, North Carolina, South Carolina, Tennessee, Texas, and Washington have incorporated federal new-drug approval requirements into their own regulatory regimes. See Alaska Stat. Ann. § 17.20.110(a)(1)-(2); Colo. Rev. Stat. § 12-280-131(1); Conn. Gen. Stat. Ann. § 21a-110(a); Hawaii Rev. Stat. §§ 328-17(a)(1)-(2); N.C. Gen. Stat. § 106-135(a)(1)-(2); S.C. Code § 39-23-70(a); Tenn. Code Ann. § 53-1-110(a); Tex. Health & Safety Code § 431.114(a); Wash. Rev. Code § 69.04.570.

Although the FDCA contains express preemption provisions covering food, 21 U.S.C. § 343-1; medical devices, 21 U.S.C. § 360k, non-prescription drugs, 21 U.S.C. § 379r, and cosmetics, 21 U.S.C. § 379s, there is no express preemption provision covering prescription drugs. See Wyeth v. Levine, 129 S. Ct. 1187, 1196, 1200 (2009). The issue is thus whether Lilly's state law claims are impliedly preempted by the FDCA's exclusive enforcement provision, 21 U.S.C. § 337(a). The leading case on implied preemption under the FDCA is Buckman, 121 S. Ct. at 1012. The Supreme Court held that the FDCA impliedly preempts state law claims premised on FDCA violations. See Zyla, 134 F.4th at 337 (citing Buckman, 121 S. Ct. at 1017). The Buckman preemption analysis depends on whether plaintiffs "sought to wield state law to vindicate a wrong committed against the Federal Government." See Zyla, 134 F.4th at 337 (emphasis in the original). If so, the

claim is impliedly preempted because it inevitably conflicts with the federal government's exclusive enforcement authority over the FDCA's regulatory scheme. However, Zyla held that if a claim relies on an independent state law duty, then it is not preempted under Buckman. Id. at 338 (citing Wyeth, 129 S. Ct. at 1200, for "permitting distinct state regulation under the FDCA").

(b) Application of the Law to the Alleged Facts

Empower's argument that Lilly's state law claims are preempted is premised on the contention that Lilly's claims are not based on violations of state laws that parallel the FDCA but, instead, on violations of § 503A of the FDCA, 21 U.S.C. § 353a, which imposes conditions on compounders not found in the state statutes.³⁵ This argument is not persuasive because it mischaracterizes Lilly's state law claims, which are all based on allegations that Empower engages in unfair methods of competition by selling unapproved drugs, including its Tirzepatide ODT and tirzepatide/niacinamide injections, in each of the named states in violation of state laws that proscribe the sale of unapproved new drugs.³⁶ None of Lilly's

³⁵Defendant's Motion to Dismiss, Docket Entry No. 34, pp. 49-51.

³⁶See Complaint, Docket Entry No. 1, pp. 55 ¶ 168 (citing Alaska Stat. Ann. §§ 17.20.110(a)(1)-(2), proscribing sale of unapproved new drugs), 57 ¶ 180 (citing Colo. Rev. Stat. § 12-280-131(1), prohibiting sale of "any new drug not authorized to move in interstate commerce under appropriate federal law"), 59 ¶ 194 (continued...)

state law claims allege violation of conditions imposed on compounders by § 503A, i.e., 21 U.S.C. § 353a.

Section 503A is cited in four paragraphs of Lilly's Complaint, but none of those four paragraphs contain allegations of illegal conduct. Three of the four paragraphs merely present background information about the FDCA and reasons for the addition § 503A.³⁷ The fourth paragraph is ¶ 80, where Lilly alleges that

Empower cannot defend its conduct by claiming that its sale of unapproved compounded tirzepatide is authorized by [§] 503A of the FDCA. Section 503A allows true compounders to compound and sell prescription drugs under narrowly confined conditions. Empower routinely and regularly does not comply with several of those conditions.³⁸

Asserting that ¶ 80 of Lilly's Complaint admits that the state laws on which Lilly bases its unfair competition and deceptive practice claims are only relevant if Empower's compounded medications do not comply with § 503A, Empower argues that Lilly's state law claims are preempted because they are dependent upon

³⁶(...continued)
(citing Conn. Gen. State. Ann. §§ 21a-110(a)-(b), governing the sale of new drugs), 61 ¶ 207 (citing Haw. Rev. Stat. §§ 328-17(a)(1)-(2), requiring approvals to sell new drugs), 63 ¶ 219 (citing N.C. Gen. Stat. Ann. § 106-135, prohibiting sale of unapproved drugs), 65 ¶ 231 (citing S.C. Code Ann. § 39-23-70, requiring approval to sell new drug products), 67 ¶ 244 (citing Tenn. Code Ann. § 53-1-110, requiring approval to sell new drugs), 70 ¶ 259 (citing Tex. Health & Safety Code Ann. § 431.114(a), requiring approval to sell new drugs), and 72 ¶ 272 (citing Wash. Rev. Code Ann. § 69.04.570, requiring approval to sell new drugs).

³⁷Id. at 17 ¶ 58, 18 ¶ 60, 19 ¶ 62.

³⁸Id. at 24 ¶ 80.

proving noncompliance with § 503A. The court disagrees. Paragraph 80's assertion that "Empower cannot **defend** its conduct by claiming that its sale of unapproved tirzepatide is authorized by [§] 503A," merely anticipates that Empower may advance as an affirmative defense that it does not need approval to sell tirzepatide medicines in the named states if it satisfies the FDCA's conditions for compounding pharmacists. But as the Fifth Circuit said in response to a similar argument made by the defendant in Zyla, "[t]hat's a big if" that cannot be shown on a Rule 12(b)(6) motion because the court cannot draw factual inferences in the defendant's favor. 134 F.4th 331 at n.2. The court concludes, therefore, that Lilly's state law claims are not impliedly preempted by the FDCA's prohibition against non-federal enforcement of the its prescription drug-related provisions.

2. Lilly's Texas Common Law Claim Will be Dismissed

Lilly asserts a claim in violation of Texas common law by alleging:

263. Empower has engaged in unfair competitive acts or practices by advertising, promoting, selling and offering for sale in Texas its unapproved new drugs in violation of the Texas Food, Drug, & Cosmetic Act, Tex. Health & Safety Code Ann. § 431.114(a).
264. In doing so, Empower lures consumers away from obtaining safe and effective treatment, such as Lilly's FDA-approved tirzepatide medicines, thereby interfering with Lilly's ability to conduct business.

265. Empower's unlawful and unfair conduct puts health, safety, and lives at risk, harming Lilly by creating a risk that customers will draw unwarranted conclusions about the safety and effectiveness of Lilly's FDA-approved tirzepatide medicines.
266. As a direct and proximate result of its unlawful and unfair business practices, Empower has obtained an unfair and illegal business advantage, benefitting and profiting from sales made as a result of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® tirzepatide medicines. Lilly has suffered and will continue to suffer monetary damages that can be measured and quantified as well as discernible competitive injury by the loss of goodwill.
267. Empower's unfair conduct is interfering with Lilly's ability to conduct its business. As a direct and proximate result of Empower's unfair business practices, Lilly is suffering immediate and continuing, competitive, irreparable injury for which no adequate remedy at law exists.³⁹

Empower argues that Lilly's claims based on Texas common law should be dismissed because Lilly cannot use common law to create a private cause of action under the Texas Food, Drug, and Cosmetic Act ("TFDCA"), Texas Health & Safety Code § 431.114(a), which bans the sale of unapproved new drugs.⁴⁰ Lilly responds that Empower's alleged conduct is actionable under Texas law because it has alleged that Empower is selling unapproved new drugs in Texas, and that "illegal act . . . interfered with [Lilly's] ability to conduct its business."⁴¹

³⁹Complaint, Docket Entry No. 1, pp. 70-71 ¶¶ 263-67.

⁴⁰Defendant's Motion to Dismiss, Docket Entry No. 34, pp. 46-49. Empower also argues that these claims should be dismissed because they are preempted by § 337(a) of the FDCA, 21 U.S.C. § 337(a). But for the reasons stated above in § III.B.1, the court has already rejected that argument.

⁴¹Plaintiff's Opposition to Defendant's Motion to Dismiss, (continued...)

(a) Applicable Law

"Unfair competition under Texas law 'is the umbrella for all statutory and nonstatutory causes of action arising out of business conduct which is contrary to honest practice in industrial or commercial matters.'" Taylor Publication Co. v. Jostens, Inc., 216 F.3d 465, 486 (5th Cir. 2000) (quoting American Heritage Life Insurance Co. v. Heritage Life Insurance Co., 494 F.2d 3, 14 (5th Cir. 1974)). To state an unfair competition claim under Texas law, plaintiffs must allege (1) an illegal act by the defendant; (2) that interfered with the plaintiff's ability to conduct its business. Id. "Although the illegal act need not necessarily violate criminal law, it must at least be an independent tort." Id. Thus, under Texas law, a claim for unfair competition is not an independent tort and must be based on the defendant's breach of some independently recognized legal duty. Id. (citing Schoellkopf v. Pledger, 778 S.W.2d 897, 904-05 (Tex. App. – Dallas 1989, writ denied) ("Without some finding of an independent substantive tort or other illegal conduct, we hold that liability cannot be premised on the tort of 'unfair competition.'"")).

⁴¹ (...continued)
Docket Entry No. 49, p. 28.

(b) Application of the Law to the Alleged Facts

To establish the first element of its unfair competition claim under Texas law Lilly alleges that "Empower has engaged in an illegal act by selling unapproved new drugs in Texas in violation of . . . the [TFDCA], Tex. Health and Safety Code § 431.114(a)."⁴² That statute prohibits the sale of new drugs unless they are otherwise approved by federal or state law:

- (a) A person shall not sell, deliver, offer for sale, hold for sale or give away any new drug unless: (1) an application with respect thereto has been approved and the approval has not been withdrawn under Section 505 of the federal Act; (2) a copy of the letter of approval or approvability issued by the United States Food and Drug Administration is on file with the department if the product is manufactured in this state.

. . .

- (c) This section shall not apply: (1) to any drug that is not a new drug as defined by the federal Act; (2) to any drug that is licensed under the Public Health Service Act (42 U.S.C. 201 et seq.); or (3) to any drug approved by the department by the authority of any prior law.

Tex. Health & Safety Code § 431.114(a), (c).

In Eli Lilly and Co. v. Revive RX, LLC, 812 F. Supp. 3d 708, 723-29 (S.D. Tex. 2025), Lilly asserted an almost identical claim for unfair competition based on violation of the TFDCA, Tex. Health and Safety Code § 431.114. The Revive defendant sought dismissal under Rule 12(b)(6), and following an in depth analysis of the

⁴²Id. (citing Complaint, Docket Entry No. 1, p. 70 ¶¶ 259, 263).

TFDCA, the statute's enforcement scheme, and relevant case law, the court concluded that Texas courts likely would not allow a tort claim based on violations of the TFDCA. Reasoning that "[t]he Texas FDCA is a comprehensive regulatory scheme, enforced by various officials from the local to the state level," id. at 726, that the statute "supplies an exhaustive list of thirty-seven prohibited categories of activity," id., that "[m]any of those prohibited activities . . . provide specified exceptions to the prohibition," id. at 726-27, and that the statute "provides a sliding scale of remedies for violations. . . including criminal prosecutions, . . . administrative and civil monetary penalties[,] . . . and . . . injunctions," id. at 727, the court concluded that "the structure of the Texas FDCA's enforcement scheme forecloses private enforcement through common-law unfair-competition torts." Id. The court reasoned that its conclusion was bolstered by the purpose behind the TFDCA, the availability of other protections for the harms Lilly sought to redress, and comparison of unfair competition law in Texas and other states.

Observing that "[t]he Texas legislature enacted the FDCA to protect patients from unsafe and ineffective drugs," id. at 728, the court reasoned that "Eli Lilly does not belong to the class of persons the statute was designed to protect and did not suffer the type of injury the statute was designed to prevent." Id. Observing that Lilly alleged sales of tirzepatide products made by the defendant would have been made by Lilly but for the defendant's

unlawful and unfair competition, and that the poor quality of the defendant's tirzepatide products harmed its goodwill because "consumers are likely to conclude that tirzepatide is ineffective in general," id. at 729, the court reasoned that "Texas law already includes the tort of misappropriation, which prevents competitors from using a product that the plaintiff developed through extensive time, labor, skill, and money." Id. at 728. The court also reasoned that the tort of misappropriation "impos[es] liability on defendants who use 'a trade name similar to that of the plaintiff on products that are markedly inferior or of a different quality and nature than those of the plaintiff.'" Id. at 729. Because the Texas tort of misappropriation "generally fit the allegations in Eli Lilly's complaint," the court concluded that "there is little reason to expand tort liability through the Texas FDCA." Id. Observing that "[o]nly 'consumers,' not competitors . . . may enforce Texas' Deceptive Trade Practices Act, Tex. Bus. Com. Code § 17.50(a)," id., and that "other states' unfair competition laws include far broader protections, allowing 'a person' or 'any person' to file suit," id., the court reasoned that Lilly was relying on a novel common-law claim precisely because Texas does not have a comparably broad unfair competition statute. Id.

Because the claims that Lilly has asserted against Empower under the common law of Texas in this action are virtually identical to those that Lilly asserted against the defendant in Revive, and because the court finds the observations, reasoning, and conclusions reached by the Revive court persuasive, the court

concludes the unfair competition claims that Lilly has asserted against Empower under the common law of Texas are subject to dismissal because Texas courts likely would not allow Lilly to pursue such claims based on violation of the Texas FDCA. Thus the court will dismiss Lilly's claims against Empower for violation of Texas common law for failure to state a claim for which relief may be granted.

3. Lilly's State Law Claims Are Not Barred by Exemptions to the State Laws at Issue

Empower argues that Lilly cannot state claims for unfair competition and deceptive practices based on its unapproved drug theory under the laws of Alaska, Connecticut, Colorado, Hawaii, North Carolina, South Carolina, Tennessee, or Washington because

under both state and federal law, compounded medications are not required to undergo federal drug approval. Therefore, Empower's conduct falls under state exemptions permitting state-sanctioned activity, excluding Empower's conduct from liability under deceptive practices and unfair competition acts in these states. . . Thus Lilly's Unapproved Drug Theory fails.⁴³

Citing Zyla, 134 F.4th at 331 n. 2, Lilly responds that Empower's argument fails because under the state laws at issue this argument is recognized as an affirmative defenses that cannot be established on a motion to dismiss.⁴⁴

⁴³Defendant's Motion to Dismiss, Docket Entry No. 34, p. 41-42. See also Defendant's Reply in Support of Motion to Dismiss, Docket Entry No. 53, pp. 12-13.

⁴⁴Plaintiff's Opposition to Defendant's Motion to Dismiss, Docket Entry No. 49, p. 21.

(a) Alaska

Lilly alleges that

[i]n the course of trade and commerce in Alaska, Empower engages in unfair methods of competition and unfair practices in violation of Alaska Stat. Ann. § 45.50.471(a). Empower does so by unlawfully selling unapproved drugs in Alaska, including its Tirzepatide ODT and tirzepatide/niacinamide injections, in violation of Alaska Stat. Ann. §§ 17.20.110(a)(1)-(2), which proscribes the sale of unapproved new drugs.⁴⁵

Lilly also alleges that "Empower's tirzepatide tablets and injections are new drugs within the meaning of Alaska Stat. Ann. § 17.20.370[(14)] because they are not generally recognized among experts as safe for use under the conditions prescribed, recommended, or suggested in their labeling."⁴⁶

Empower argues that Lilly fails to state a claim under Alaska's Unfair Trade Practices and Consumer Protection Act ("UTPA"), Alaska Stat. Ann. §§ 45.50.471 et seq., because its "supposed 'unlawful sale of unapproved¶ drugs' falls squarely within [a] . . . statutory exemption[]." ⁴⁷ Empower argues that

[t]he relevant statute provides that UTPA does not apply to "an act or transaction regulated by a statute or regulation administered by the state, including a state regulatory board or commission, unless the statute or regulation does not prohibit the practices declared unlawful in AS 45.50.471." Alaska Stat. Ann. § 45.50.481(a)(1).⁴⁸

⁴⁵Complaint, Docket Entry No. 1, p. 55 ¶ 168.

⁴⁶Id. ¶ 169. See also id. at 54-56 ¶¶ 161-77.

⁴⁷Defendant's Motion to Dismiss, Docket Entry No. 34, p. 44.

⁴⁸Id.

In pertinent part Alaska Statute § 45.50.481(a)(1) states that

[n]othing in AS 45.50.471-45.50.561 applies to . . . an act or transaction regulated by a statute or regulation administered by the state, including a state regulatory board or commission, unless the statute or regulation does not prohibit the practices declared unlawful in AS 45.50.471.

Quoting Adkins v. Collens, 444 P.3d 187, 195 (Alaska 2019), cert. denied, 140 S. Ct. 2508 (2020), Empower argues that this exemption applies to Lilly's claim for violation of Alaska law because

Lilly alleges that "Empower failed to file[] any application seeking approval for its tirzepatide tablets or injections with any regulator," Compl. ¶ 164, and "no regulator has ever approved [Empower's drugs] for sale." Compl. ¶ 165. According to Lilly, this conduct violates Alaska Stat. Ann. §§ 17.20.110(a)(1)-(2) (Compl. ¶ 168), a part of Alaska's comprehensive Food, Drug, and Cosmetic Act. Alaska Stat. Ann. § 17.20.005. Lilly's Complaint, therefore, concedes that the sale of "new drugs" is subject to a "separate and distinct statutory scheme." . . . As Lilly admits, this separate and distinct statutory scheme prohibits the exact conduct relied upon for the UTPA claim: the sale of "unapproved drugs." . . . Thus, Lilly's UTPA claim fails because Empower's conduct falls within the relevant statute's exemption.⁴⁹

Lilly responds that Alaska's exemption "does not apply to conduct that is defined as per se unfair or deceptive under Alaska's UTPA. See Alaska Stat. §§ 45.50.471(b)[(48)], 45.50.481(c)."⁵⁰ Lilly argues that "Empower's conduct is per se unfair and deceptive,"⁵¹ because it violates prohibitions against

⁴⁹Id. at 44-45. See also Defendant's Reply in Support of Motion to Dismiss, Docket Entry No. 53, pp. 15-16.

⁵⁰Plaintiff's Opposition to Defendant's Motion to Dismiss, Docket Entry No. 49, p. 25.

⁵¹Id.

“causing a likelihood of confusion or misunderstanding as to the . . . approval of . . . goods,” Alaska Stat. § 45.50.471(b)(3), “representing that goods . . . have . . . approval . . . that they do not have,” Alaska Stat. § 45.50.471(b)(4), and “representing that goods are of a particular standard, quality, or grade . . . if they are of another,” Alaska Stat. § 45.50.471(b)(6).⁵² Lilly also responds that Empower is unable to prove that the exemption applies because proof “requires factual evidence not cognizable at this stage.”⁵³ Citing White v. NYLIFE Securities, LLC, 551 F.Supp.3d 974, 983 (D. Alaska 2021), Lilly argues Empower “must prove that the [regulatory] scheme is enforced in an ongoing, careful way,” but that “Empower submits no evidence about ‘state enforcement.’”⁵⁴

Empower replies that Lilly cannot rely on per se violations of Alaska law because “Lilly’s Opposition does not cite to a single place in its Complaint where it sets forth these supposed per se violations – because Lilly **did not** plead a per se claim,”⁵⁵ and because “Lilly has not pled a single factual allegation to support violations of the[prohibitions]” that Lilly contends constitute per se violations.⁵⁶ Citing inter alia White, 551 F.Supp.3d at 974, Empower asserts that

⁵²Id. at 25-26.

⁵³Id. at 26.

⁵⁴Id.

⁵⁵Defendant’s Reply in Support of Motion to Dismiss, Docket Entry No. 53, p. 15.

⁵⁶Id. n. 4.

numerous Alaska courts evaluate the applicability of the exemption at the Rule 12(b)(6) stage, and none have categorically held that the exemption cannot be so established. . . [T]he pertinent question is whether the exemption is evident from the face of the Complaint. Here, it is. Lilly's basis to allege Empower's compounded medications violate UTPCA is Empower's alleged failures to "conduct preclinical trials," to file "any application seeking approval," and to demonstrate its medications are "safe and effective." ECF 1 ¶¶ 162-165. Lilly claims these failures violate Alaska Stat. § 17.20.110(a), which requires an application for the "new drug" to be effective under the federal act. But as Lilly extensively pleaded, new drug approval is highly regulated (ECF 1 ¶¶ 26-38), demonstrating that the specific conduct complained of is subject "to ongoing, careful regulation." Adkins v. Collens, 444 P.3d 187, 195 (Alaska 2019). And as Lilly has also pleaded, Empower's alleged failure to obtain new drug approval for its compounded medications violates Alaska Stat. § 17.20.110(a). Lilly pleaded itself into the exemption and dismissal is warranted.⁵⁷

The Alaska FDCA prohibits "sell[ing], deliver[ing], offer[ing] for sale, hold[ing] for sale, or giv[ing] away a new drug" without meeting the approval requirements in the statute, Alaska Stat. Ann. § 17.20.110(a), and incorporates federal new-drug approval requirements. Alaska Stat. Ann. § 17.20.110(a)(1)-(2). Thus, to sell a new drug in Alaska – the specific prohibition at issue – Empower must obtain permission from a state or federal regulator. See Matanuska Maid, Inc. v. State, 620 P.2d 182, 186 (Alaska 1980) (citing State v. Reader's Digest Association, Inc., 501 P.2d 290, 303 (Alaska 1972)). Alaska's exemption facially applies to Empower's alleged illegal conduct. Nevertheless, in the case that

⁵⁷Id. at 16.

both parties cite, i.e., White, the court doubted that the exemption should apply if the regulatory scheme is "seldom used by the state or individual plaintiffs to seek redress in factually similar . . . cases," 551 F.Supp.3d at 983, and concluded "that mere citation to a broad regulatory scheme is insufficient to support dismissal of a UTPA claim." Id. at 985. Since, moreover, exemption is an affirmative defense that Empower must plead and prove, the court concludes that Lilly's claims under Alaska law survive dismissal. If, however, Empower asserts Alaska Stat. Ann. § 45.50.481(a)(1) as an affirmative defense in its answer, and if Lilly seeks to avoid the statutory exemption by asserting per se violations of Alaska's UTPA, then Lilly would be required to prove that the violations alleged in its Complaint are, in fact, per se violations of Alaska's FDCA. See Revive, 812 F.Supp.3d at 740.

(b) North Carolina

Lilly alleges:

Empower engages in unfair methods of competition in or affecting commerce, and unfair practices in or affecting commerce, when it unlawfully sells unapproved and potentially dangerous drugs in North Carolina, including its Tirzepatide ODT and tirzepatide/niacinamide injections, in violation of the North Carolina Food, Drug, and Cosmetic Act. See N.C. Gen. Stat. Ann. §§ 106-135.⁵⁸

⁵⁸Complaint, Docket Entry No. 1, p. 63 ¶ 219.

Lilly also alleges that “Empower’s tirzepatide tablets and injections are unapproved new drugs within the meaning of N.C. Gen. Stat. Ann. § 106-121 because they are not generally recognized among experts as safe for use under the conditions prescribed, recommended, or suggested in their labeling.”⁵⁹

Empower argues that Lilly fails to state a claim under the North Carolina Unfair and Deceptive Trade Practices Act (“NCUDTPA”), N.C. Gen. Stat. Ann. § 75-1.1(a) because

“professional services rendered by a member of a learned profession,” such as pharmacy services, are exempt from [NC]UDTP[A] liability. Specifically, [NC]UDTP[A] provides that “[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are declared unlawful.” N.C. Gen. Stat. Ann. § 75-1.1(a). However, [NC]UDTP[A] defines “commerce” to exclude “professional services rendered by a member of a learned profession.” N.C. Gen. Stat. Ann. § 75-1.1(b).⁶⁰

Citing Sykes v. Health Network Solutions, Inc., 828 S.E.2d 467, 472-73 (N.C. 2019), Empower argues that “[t]his is known as the ‘learned profession’ exemption.”⁶¹ Citing Church Ekklesia Sozo Inc. v. CVS Health Corp., No. 3:20-cv-382-RJC-DSC, 2022 WL 1572732, at *14 (W.D.N.C. Feb. 25, 2022), Empower argues that “North Carolina courts broadly apply the ‘learned profession [exemption]’ to medical professionals . . . including pharmacists.”⁶²

⁵⁹Id. ¶ 220.

⁶⁰Defendant’s Motion to Dismiss, Docket Entry No. 34, p. 45.

⁶¹Id.

⁶²Id. at 45-46. See also Defendant’s Reply in Support of (continued...)

Lilly responds that Empower's motion to dismiss the unfair competition claim asserted under North Carolina law should be denied because although "Empower claims it engages in the learned profession of 'pharmacy services,'" Lilly alleges that

"Empower is not 'compounding' tirzepatide," Comp. ¶ 8 (emphasis added), but "instead is mass-manufacturing its untested tirzepatide products at a commercial scale." id. ¶¶ 8, 19, 75-76 (using automated, commercial-scale equipment to produce 70,000 drugs per week). The conduct in question is drug manufacturing, not drug compounding, and drug manufacturing is not exempt from the NCUDTPA.⁶³

Quoting Sykes, 828 S.E.2d at 473, Lilly argues that

[e]ven if Empower could ignore Lilly's well-pleaded allegations that it is not acting as a pharmacy, "the mere status of a defendant as a member of a 'learned profession' does not shield that defendant from any claim under [the NCUDTPA] regardless of how far removed the claim is from that defendant's professional practice."⁶⁴

In pertinent part the NCUDTPA states:

- (a) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are declared unlawful.
- (b) For purposes of this section, "commerce" includes all business activities, however denominated, but does not include professional services rendered by a member of a learned profession.
- . . .
- (d) Any party claiming to be exempt from the provisions of this section shall have the burden of proof with respect to such claim.

⁶² (...continued)
Motion to Dismiss, Docket Entry No. 53, pp. 16-18.

⁶³Plaintiff's Opposition to Defendant's Motion to Dismiss, Docket Entry No. 49, p. 27.

⁶⁴Id.

N.C. Gen. Stat. Ann. § 75-1.1. Courts in North Carolina conduct a two-part inquiry to determine whether the “learned profession” exemption applies: “First, the person or entity performing the alleged act must be a member of a learned profession. Second, the conduct in question must be a rendering of professional services.” Sykes, 828 S.E.2d at 472 (quoting Wheless v. Maria Parham Medical Center, Inc., 768 S.E.2d 119, 123 (N.C. 2014)). The Supreme Court of North Carolina has held that members of health care professions fall within the learned profession exemption to § 75-1.1, and that “[t]his exception for medical professionals has been broadly interpreted.” Sykes, 828 S.E.2d at 472 (citing Shelton v. Duke University Health System, Inc., 633 S.E.2d 113, 117 (N.C. App. 2006), rev. denied, 643 S.E.2d 590 (N.C. 2007)). But “the mere status of a defendant as a member of a ‘learned profession’ does not shield that defendant from any claim under N.C.G.S. § 75-1.1.” Id. at 473. At issue is whether the activity alleged constitutes rendering of professional services under the statute. In cases like this that involve medical professions, the North Carolina Supreme Court has said that the issue is whether “the heart of th[e] action is directly related to providing patient care.” Id.

Empower argues that it engages in the learned profession of “pharmacy services” because it holds pharmacy licenses and

compounds tirzepatide products.⁶⁵ But Lilly alleges that “Empower is not ‘compounding’ tirzepatide,” and “instead is mass-manufacturing . . . tirzepatide products at commercial scale without seeking, or obtaining, approval from FDA or any state agency.”⁶⁶ Lilly alleges that Empower engages in unfair methods of competition in violation of North Carolina law by selling unapproved and potentially dangerous drugs in North Carolina,⁶⁷ engaging in deceptive trade practices “by marketing and selling its Tirzepatide ODT and tirzepatide/niacinamide injections to treat weight issues while misciting inapplicable clinical trials and materially omitting that no data exists to support its use for any purpose,”⁶⁸ and falsely stating that its tirzepatide products are “personalized formulations . . . tailored to fit individual patients.”⁶⁹ In other words Lilly alleges that Empower is not engaged in compounding pharmaceuticals, a practice of the learned profession of pharmacy, see N.C.G.S.A. § 90-85.3A, but instead, that Empower is manufacturing and selling unapproved pharmaceuticals, which are not practices of a learned profession.

⁶⁵Defendant’s Motion to Dismiss, Docket Entry No. 34, p. 46.

⁶⁶Complaint, Docket Entry No. 1, p. 3 ¶ 8. See also id. at 7 ¶ 19, and 22-23 ¶¶ 75-76.

⁶⁷Id. at 63 ¶ 219.

⁶⁸Id. ¶ 221.

⁶⁹Id. at 64 ¶ 222.

Because the basis for Lilly's NCUDEPA claim is that Empower is manufacturing unapproved pharmaceuticals, and using false and deceptive statements to market and sell its unapproved pharmaceuticals in North Carolina, the court concludes that the conduct at the heart of this action is not sufficiently related to the provision of patient care to fall within the exemption afforded to the "learned profession" of pharmacy. The "learned profession" exemption does not entitle Empower to dismissal of the claims that Lilly has asserted under North Carolina law.

(c) Colorado, Connecticut, Hawaii, South Carolina, Tennessee, and Washington

Empower argues that Lilly's unfair competition and deceptive practice claims for violation of the laws of Colorado, Connecticut, Hawaii, South Carolina, Tennessee, and Washington should all be dismissed because "conduct that is permitted by regulatory agencies cannot form the basis of an unfair competition or deceptive practice claim."⁷⁰ Asserting that "[n]ot one of these states requires compounded medications to undergo new drug approval prior to sale,"⁷¹ Empower argues that

⁷⁰Defendant's Motion to Dismiss, Docket Entry No. 34, p. 42.

⁷¹Id. at 43 (citing Conn. Gen. Stat. § 20-633b (setting forth the licensing requirements for pharmacies dispensing sterile compounded medications); 3 Colo. Code Regs. 719-1:21.00.20(b) (authorizing nonresident prescription drug outlets registered in Colorado to dispense compounded medications); Haw. Rev. Stat. (continued...))

[a]s demonstrated by these state . . . regulatory schemes, Empower's compounded medication[s] are not required to undergo new drug approval prior to sale. In fact, the specific conduct upon which Lilly predicates Empower's violations of the Acts – shipment of compounded drugs without new drug approval – is expressly **permitted** by these statutes and regulations. As a result of its state licenses, Empower is authorized to sell compounded medications and is not required to obtain new drug approval prior to doing so, exempting Empower from liability under the state statutes under which Lilly sues.⁷²

Lilly responds that the existence of state laws exempting compounded medications from new drug approval is not sufficient reason for the court to conclude that Empower is entitled to the protection of those laws. Asserting that the crux of its Complaint is that Empower is not complying with state regulations governing sale of new drugs, Lilly argues that Empower's reliance on exemptions accorded by state law raise affirmative defenses that cannot be decided on a motion to dismiss.⁷³ Without disputing that its exemption argument is an affirmative defense, Empower replies that "affirmative defenses that are apparent on the face of the

⁷¹(...continued)

§ 461-15(6) (requiring any entity engaged in the sale of compounded medications to first obtain a permit from the board to do so); S.C. Code Ann. § 40-43-86(CC) (setting forth requirements for compounding of medication by pharmacies permitted in South Carolina); Tenn. Code Ann. § 63-10-216 (setting forth Tennessee's licensing requirements for pharmacies engaged in compounding); Wash. Admin. Code § 246-945-100 (setting forth Washington's minimum standards for pharmacies engaged in compounding)).

⁷²Id. at 43-44.

⁷³Plaintiff's Opposition to Defendant's Motion to Dismiss, Docket Entry No. 49, pp. 22-24.

Complaint may be considered at this stage.”⁷⁴ Asserting that it “sought judicial notice of its active nonresident pharmacy licenses in each state,”⁷⁵ Empower replies that its

state licenses and the pharmacy regulatory schemes in these states authorize the exact conduct of which Lilly complains – selling and dispensing compounded medications absent undergoing new drug approval. The regulatory exemptions, therefore, apply.

. . . Lilly hedges that Empower must “prove” compliance with each states’ compounding requirements to invoke these exemptions – but that argument wildly misstates these exemptions. The exemptions turn on whether the complained of activity is “permitted” or “authorized.” The statutes and Empower’s judicially noticeable licenses resolve that question on the pleadings; they show the specific challenged activity – selling and dispensing compounded medications absent new drug approval – is authorized and regulated and thus not actionable as “unapproved drug” sales under these states’ consumer statutes. Empower need not “prove” compliance with each states’ compounding requirements because Lilly’s complained of conduct rests on the general assertion that new drug approval is necessary for compounded medications. ECF 1 ¶¶ 168, 182, 194, 207, 219, 231, 244, and 272.⁷⁶

Empower’s argument that Lilly’s state law claims are exempted is premised on the contention that “Lilly’s complained of conduct rests on the general assertion that new drug approval is necessary

⁷⁴Defendant’s Reply in Support of Motion to Dismiss, Docket Entry No. 53, p. 13 (citing inter alia American Precision Ammunition, L.L.C. v. City of Mineral Wells, 90 F.4th 820, 824 (5th Cir. 2024) (“[a] Rule 12(b)(6) dismissal may also ‘be appropriately based on a successful affirmative defense’ provided that the affirmative defense ‘appear[s] on the face of the complaint’”)(internal citation omitted)).

⁷⁵Id. at 14.

⁷⁶Id.

for compounded medications.”⁷⁷ This argument is not persuasive because it mischaracterizes Lilly’s state law claims. Lilly’s state law claims are all based on allegations that Empower engages in unfair competition by selling unapproved new drugs, specifically its Tirzepatide ODT and tirzepatide/niacinamide injections, in each of the named states in violation of state laws that proscribe the sale of unapproved new drugs.⁷⁸ Moreover, Lilly also alleges that Empower engages in unfair competition under the laws of Colorado, Connecticut, South Carolina, Tennessee, and Washington, but not Hawaii, by marketing and selling its tirzepatide medications as unique, personalized, compounded medicine, when, in fact, Empower does not tailor its drugs to patients’ needs.⁷⁹ Empower’s arguments do not justify relief on a Rule 12(b)(6) motion to dismiss because – as the parties concede – each state’s exemption constitutes an affirmative defense that Empower is required to plead and prove. See Fed. R. Civ P. 8(c)(1) (requiring defendants “[i]n responding to a pleading,” to “affirmatively state any avoidance or affirmative defense”). As the Fifth Circuit stated in Zyla, on a motion to dismiss, a defendant “cannot have proven that it

⁷⁷Id.

⁷⁸Complaint, Docket Entry No. 1, pp. 57 ¶¶ 181-82 (Colorado); 59 ¶ 194-95 (Connecticut); 61 ¶¶ 207-08 (Hawaii); 65 ¶¶ 231-32 (South Carolina); 67 ¶¶ 244-45 (Tennessee), and 72 ¶¶ 272-73 (Washington).

⁷⁹Id. at 58 ¶ 184 (Colorado); 60 ¶ 198 (Connecticut); no Hawaiian corollary; 65-66 ¶ 234 (South Carolina); 68 ¶ 247 (Tennessee); 72 ¶ 275 (Washington).

satisfies” the statutory requirements for authorized compounding because courts must “draw factual inferences in” the plaintiff’s favor on the question of the defendant’s “compliance with” federal and state law. 134 F.4th at 331 n. 2 (discussing compliance with 21 U.S.C. § 353b’s many requirements). Lilly’s Complaint needs to – and does – allege that Empower violates state law, but does not need to allege that Empower does not qualify for a statutory exemption. See Revive, 812 F. Supp. 3d at 736 (citing Cunningham v. Cornell University, 145 S. Ct. 1020 (2025) (addressing a similar issue with respect to the Employee Retirement Income Security Retirement Act). See also Federal Trade Commission v. Morton Salt Co., 68 S. Ct. 822, 827 (1948) (recognizing as a “general rule of statutory construction that the burden of proving justification or exemption under a special exception to the prohibitions of a statute generally rests on one who claims its benefits”). The court concludes, therefore, that Empower is not entitled to dismissal of Lilly’s claims for violation of the unfair competition laws of Colorado, Connecticut, Hawaii, South Carolina, Tennessee, and Washington, merely because those laws exempt regulated conduct such as drug compounding that Empower contends it practices. See Zyla, 134 F.4th at 331 n.2 (recognizing that courts cannot draw factual inferences in favor of a defendant like Empower seeking dismissal under Rule 12(b)(6)). See also Revive, 812 F. Supp. 3d at 736–37 (denying motion to dismiss analogous claims under Alaska, Connecticut, North Carolina, Tennessee, and Washington law).

IV. Empower's Motions to Stay Discovery and for Protective Order

Empower's Motion to Stay Discovery (Docket Entry No. 46), seeks a stay pending a ruling of its Motion to Dismiss.⁸⁰ Because the court has now ruled on Empower's Motion to Dismiss, Empower's Motion to Stay Discovery is moot.

Empower's Motion for Protective Order (Docket Entry No. 73), seeks an order abating discovery pending a ruling on Empower's Motion to Dismiss.⁸¹ Because the court has now ruled on Empower's Motion to Dismiss, Empower's Motion for Protective Order is moot.

V. Conclusions and Order

For the reasons stated above in § III.A, the claims that Lilly has asserted against Empower under the Lanham Act are **DISMISSED** for failure to allege facts capable of establishing the proximate cause requirement for statutory standing to pursue that claim.

For the reasons stated above in § III.B.1, the court concludes that the state law claims Lilly has asserted against Empower are not preempted by federal law.

For the reasons stated above in § III.B.2, the claims that Lilly has asserted against Empower under Texas common law are **DISMISSED** for failure to state a claim for which relief may be granted.

⁸⁰Defendant's Motion to Stay Discovery, Docket Entry No. 46, p. 1. See also Proposed Order, Docket Entry No. 46-1.

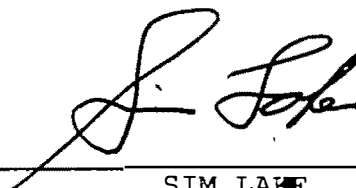
⁸¹See Defendant's Motion for Protective Order, Docket Entry No. 73, p. 1. See also Proposed Order, Docket Entry No. 73-2.

For the reasons stated above in § III.B.3, the court concludes that the claims Lilly has asserted against Empower under the state laws of Alaska, Colorado, Connecticut, Hawaii, North Carolina, South Carolina, Tennessee, and Washington are not subject to dismissal because they are not barred by exemptions to the state laws at issue.

Therefore, Empower's Motion to Dismiss, Docket Entry No. 34, is **GRANTED in PART and DENIED in PART**.

For the reasons stated above in § IV, Defendant's Motion to Stay, Docket Entry No. 46, is **DENIED** as **MOOT**, and Defendant's Motion for Protective Order, Docket Entry No. 73, is **DENIED** as **MOOT**.

SIGNED at Houston, Texas, this 29th day of April, 2026.



SIM LAKE
SENIOR UNITED STATES DISTRICT JUDGE