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

ELI LILLY AND COMPANY,	§	
	§	
Plaintiff,	§	
v.	§	CIVIL ACTION NO. H-23-3521
	§	
REVIVE RX, LLC,	§	
	§	
Defendant.	§	

ORDER

Eli Lilly and Company sued Revive RX, LLC, a Houston-based drug compounding pharmacy. Eli Lilly manufactures and sells an FDA-approved drug to treat diabetes. The drug, Mounjaro, contains tirzepatide as its key ingredient. Eli Lilly alleged that by compounding and selling medications also containing tirzepatide, Revive was unfairly competing, in violation of Texas common law. Revive RX moved to dismiss on the basis of implied preemption, arguing that Eli Lilly's claim would impermissibly impose state-law requirements on top of the federal requirements governing such drugs. (Docket Entry No. 14). Eli Lilly responded that "[i]f Revive's drugs comply with the limitations of section 503A [of the FDA], their sale does not violate Texas unfair competition law and Lilly's claim will fail on that state law basis, without any need to consider conflict preemption." (Docket Entry No. 16 at 15).

Fortunately, this court is not the first to consider this question. In a similar case alleging state-law unfair competition claims brought by a drug manufacturer selling its FDA-approved drugs against a compounder selling similar medications, the court dismissed the case as preempted because "Plaintiff's state law claims impinge on the FDA's sole authority over enforcement of the

FDCA's drug approval requirements." *Zyla Life Scis., LLC v. Wells Pharma of Houston, LLC*, No. 4:22-CV-04400, 2023 WL 6301651, at *4 (S.D. Tex. Sept. 27, 2023) (internal quotations omitted). Eli Lilly argued at the hearing on Revive's motion to dismiss that *Zyla Life Scis.* was not relevant because it did not involve a Texas state law. But *Zyla Life Scis*. involved state-law provisions in six other states that were similar to each other and to the Texas state law. *Zyla* is therefore relevant to the preemption analysis.

Zyla found that the challenge to the compounder prevailed because federal law controlled the requirements for manufacturing and selling the relevant drugs. The Ninth Circuit has taken a similar position, upholding dismissal of a challenge to an FDA approved drug brought by a compounder making a similar drug because the "[manufacturer's] claims would require litigation of whether [the defendant's] compounded drugs are 'essentially a copy' of [the drug] where the FDA has not itself so concluded." *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040, 1048 (9th Cir. 2022).

At the hearing on Revive's motion to dismiss, Eli Lilly argued that both *Zyla Life Scis.* and *Nexus Pharms.* were wrongly decided. (Docket Entry No. 35). These cases are only two of the dozens of cases brought by drug manufacturers against drug compounders pending around the country. Although the Fifth Circuit has not yet decided whether federal law preempts state-law claims that manufacturers bring against compounders, *Zyla Life Scis.* is currently on appeal to the Fifth Circuit, No. 23-20533. The Fifth Circuit's decision on the preemption question in *Zyla Life Scis.* is likely to determine if and how this case may proceed. The case is currently being briefed before the Fifth Circuit.

This case is stayed pending the decision by the Fifth Circuit in *Zyla*. Counsel are directed to promptly advise the court when the Fifth Circuit decision in *Zyla* is issued, and to advise the court of other cases resolving the same or similar issues.

SIGNED on December 27, 2023, at Houston, Texas.

Lee H. Rosenthal
United States District Judge