

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

ELI LILLY AND COMPANY,

Plaintiff,

v.

J. BERGERON, M.D., P.A. D/B/A
HOUSTON WEIGHT LOSS CENTER,

Defendant.

Case No. 4:24-cv-2313

JURY TRIAL DEMANDED

**PLAINTIFF ELI LILLY AND COMPANY'S COMPLAINT
FOR TRADEMARK INFRINGEMENT, FALSE ADVERTISING,
AND FALSE DESIGNATION OF ORIGIN**

INTRODUCTION

1. This is an action to protect patients from unstudied, unapproved, and unsafe drugs masquerading as Plaintiff Eli Lilly and Company’s (“Lilly”) FDA-approved medicines for adults with type 2 diabetes, obesity, or excess weight and weight-related medical problems. Defendant J. Bergeron, M.D., P.A. d/b/a Houston Weight Loss Center (“Defendant”) has designed its website, social media, and advertising materials to deceive patients into thinking Defendant offers a way to obtain Lilly’s clinically studied medicines, when in reality Defendant offers no such thing.¹ Lilly therefore brings this action under federal and state law to protect patients from Defendant’s dangerous, deceptive, and unlawful practices.

2. For nearly 150 years, Lilly has worked tirelessly to develop and deliver trusted and innovative medicines that meet critical and unmet patient needs. Lilly’s proprietary MOUNJARO[®] and ZEPBOUND[®] are two such first-of-their-kind medicines, which are indicated for the serious conditions afflicting many tens of millions of Americans. To advance treatment of these chronic conditions, Lilly used its extensive experience with world-class medicines to develop the brand-new class of GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulintropic polypeptide) dual-receptor agonists, which includes tirzepatide, the active ingredient in Lilly’s MOUNJARO[®] and ZEPBOUND[®]. Lilly’s MOUNJARO[®] and ZEPBOUND[®] are the only FDA-approved GLP-1/GIP medicines.

3. Before obtaining FDA approval, Lilly’s new medicines underwent years-long clinical trials, which tested them for safety, quality, and effectiveness on thousands of patients. When approving these medicines, the FDA called Lilly’s “novel” MOUNJARO[®] an “important

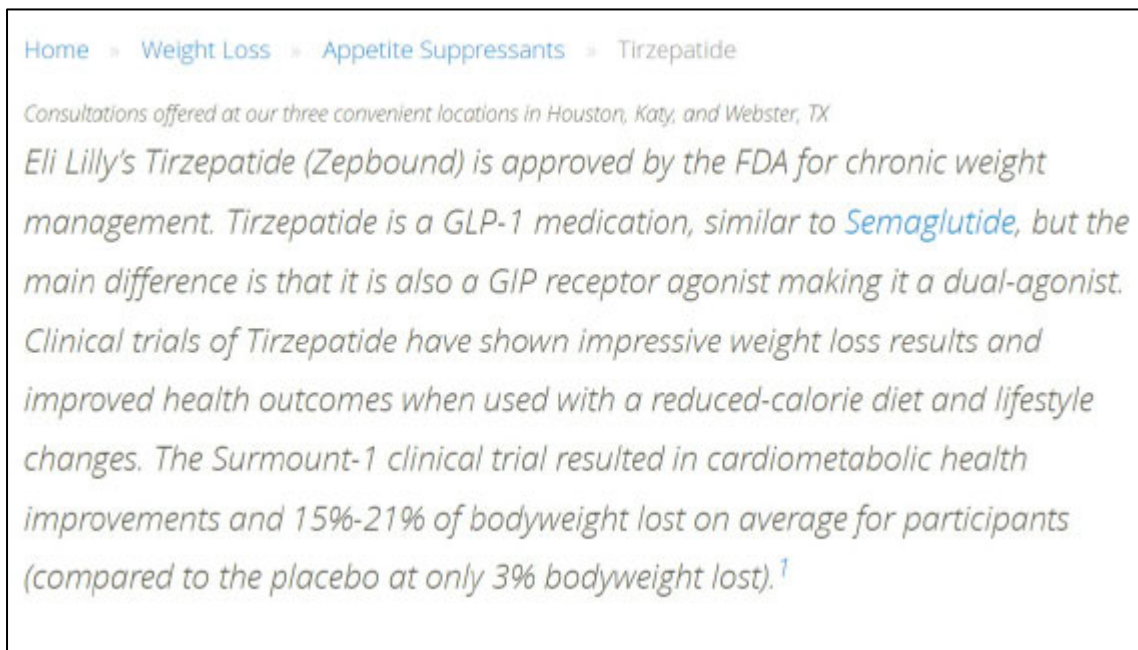
¹ In support of this Complaint, Lilly’s allegations are upon actual knowledge with respect to itself and its own acts, and upon information and belief as to all other matters.

advance” and observed that Lilly’s ZEPBOUND® “addresses an unmet medical need.” <https://web.archive.org/web/20221028212253/https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes> (archived FDA MOUNJARO® approval press announcement); <https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management> (FDA ZEPBOUND® approval press announcement).

4. Compounded products sold as “tirzepatide,” meanwhile, are not approved or even reviewed by the FDA. Pharmacies currently offering compounded versions of tirzepatide are not required to follow the FDA’s “good manufacturing practices,” nor to comply with the same controls on sterility and safe storage as manufacturers of FDA-approved medicines. They are also not required to report adverse events—an important regulatory requirement imposed on manufacturers of FDA-approved medicines for patient safety. Compounded drugs are not tested for safety, quality, or efficacy in clinical trials. Accordingly, and as the FDA has warned, “compounded drugs pose a higher risk to patients than FDA-approved drugs,” such as MOUNJARO® and ZEPBOUND®. <https://www.fda.gov/drugs/human-drug-compounding/drug-compounding-and-drug-shortages> (FDA explainer on Drug Compounding).

5. Defendant falsely and unlawfully trades on Lilly’s work, reputation, and goodwill, offering unproven and unapproved compounded drugs as if they were genuine Lilly medicines. But Defendant does not offer Lilly’s proprietary MOUNJARO® and ZEPBOUND® medicines. Indeed, Defendant’s drugs have undergone *none* of the rigorous studies or approval processes that Lilly’s medicines have. Passing Defendant’s compounded drugs off as Lilly’s MOUNJARO® and ZEPBOUND® is not merely deceptive—it’s dangerous.

6. Defendant’s intentional deception of patients starts from the top of its “Tirzepatide” webpage, where it boldly proclaims “Eli Lilly’s Tirzepatide (Zepbound) is approved by the FDA for chronic weight management,” before citing to “Clinical trials,” including Lilly’s SURMOUNT® clinical trials, as shown below:



7. Despite this impossible-to-miss headline, Defendant does not offer ZEPBOUND®. Nor is Defendant’s product purporting to contain tirzepatide produced by Eli Lilly, approved by the FDA, or tested for safety, quality, and effectiveness in any clinical trial, including Lilly’s SURMOUNT® clinical trials.

8. Lilly therefore brings this action pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, and for violation of Texas common law. Lilly’s claims arise out of Defendant’s infringement of Lilly’s rights in the MOUNJARO® and ZEPBOUND® trademarks and Defendant’s acts of false designation of origin, false advertising, and unfair competition.

THE PARTIES

9. Plaintiff Lilly is a corporation organized and existing under the laws of Indiana

and has its principal place of business in Indiana.

10. Defendant is a Texas professional association with a principal place of business at 1941 W T C Jester Boulevard, Houston, Texas 77008, in this District. Its president, registered agent, and sole reported director or officer is John Bergeron, with registered agent address 1941 W T C Jester Boulevard, Houston, Texas 77008.

11. Defendant additionally does business as “Houston Weight Loss Center” and at its website, “<https://www.houstonweightloss.com>.”

12. According to Defendant’s website, Defendant offers services “at our three convenient locations in Houston, Katy, and Webster, Tx.”
<https://www.houstonweightloss.com/weight-loss/appetite-suppressant-programs/tirzepatide-for-weight-loss>. These locations have addresses at:

- a. 1941 W T C Jester Boulevard #101, Houston, Texas 77008
- b. 23217 Red River Drive, Katy, Texas 77494
- c. 17630 State Highway 3, Webster, Texas 77598

JURISDICTION AND VENUE

13. The Court has subject matter jurisdiction over the Lanham Act causes of action pleaded herein pursuant to 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331 and 1338(a). The Court has supplemental jurisdiction over the state and common law causes of action pleaded herein pursuant to 28 U.S.C. §§ 1338(b) and 1367(a).

14. Venue is proper in this District and division pursuant to 28 U.S.C. § 1391 because Defendant operates and conducts business in this District and division. Defendant is subject to personal jurisdiction in this District.

**LILLY’S FDA-APPROVED TIRZEPATIDE MEDICINES:
MOUNJARO® AND ZEPBOUND®**

15. Lilly’s MOUNJARO® is a novel treatment for type 2 diabetes, a chronic and progressive condition facing more than 30 million Americans. As the FDA has noted, “Despite the availability of many medications to treat diabetes, many patients do not achieve the recommended blood sugar goals.”

<https://web.archive.org/web/20221028212253/https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes> (archived FDA MOUNJARO® approval press announcement). MOUNJARO® targets this problem head-on using an innovative active pharmaceutical ingredient, tirzepatide. Before it received FDA approval, Lilly’s MOUNJARO® was clinically proven to improve blood sugar control “more effective[ly] than the other diabetes therapies with which it was compared in clinical studies.”

Id.

16. The FDA approved MOUNJARO® and indicated it in addition to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. As part of the approval process, Lilly submitted data on safety, quality, and effectiveness collected through clinical trials involving thousands of patients. Lilly’s MOUNJARO® is thus proven safe and effective when used as directed.

17. In addition to MOUNJARO®, Lilly markets and sells ZEPBOUND®, another proprietary, FDA-approved treatment option containing the active pharmaceutical ingredient tirzepatide. With ZEPBOUND®, Lilly aims to help the many dozens of millions of American adults with obesity or with excess weight and weight-related medical problems lower their risks of cardiovascular disease and other leading causes of death. As the FDA has noted, ZEPBOUND® “addresses an unmet medical need” by targeting “chronic weight management

(weight reduction and maintenance)” through a new method of hormone receptor activation.

<https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management> (FDA ZEPBOUND[®] approval press announcement).

18. As with MOUNJARO[®], the safety, quality, and effectiveness of ZEPBOUND[®] was established through rigorous clinical trials featuring thousands of patients. The FDA recently approved ZEPBOUND[®] and indicated it for adults with obesity (with a BMI of 30 kg/m² or greater) or those who are overweight (with a BMI \geq 27 kg/m² or greater) and also have at least one weight-related additional condition, such as hypertension (high blood pressure), dyslipidemia (high cholesterol or fats in blood), type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease, to lose weight. It should be used with a reduced-calorie diet and increased physical activity.

19. Lilly’s tirzepatide medicines are the result of billions of dollars of investments in research and development, which included dozens of studies and trials.

20. Countless highly specialized personnel ensure Lilly medicines meet quality and safety standards. Lilly manufactures its medicines under strict controls in state-of-the-art facilities. Transforming tirzepatide API to medicine is a complex, methodical, and science-based process. Lilly follows Good Manufacturing Practices (GMP), which are regulations that “provide[] for systems that assure proper design, monitoring, and control of manufacturing processes and facilities.” <https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp> (FDA explainer on GMP). GMPs include “establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations,

and maintaining reliable testing laboratories.” *Id.* GMPs help “prevent instances of contamination, mix-ups, deviations, failures, and errors.” *Id.*

21. Each step in Lilly’s process to manufacture its tirzepatide medicines—from sourcing and chemical synthesis of the API to formulation and device assembly and packaging—requires extensive testing and controls and specialized equipment. Lilly’s medicines must be, and always are, accompanied with important, FDA-approved labels, instructions, and warnings.

22. Lilly now promotes, offers, and sells MOUNJARO[®] and ZEPBOUND[®] medicines in Texas and throughout the United States.

LILLY’S MOUNJARO[®] AND ZEPBOUND[®] TRADEMARKS

23. Lilly uses the trademarks MOUNJARO[®] and ZEPBOUND[®] (the “Lilly Marks”) to identify and promote Lilly’s proprietary, FDA-approved medicines with the active pharmaceutical ingredient tirzepatide. Lilly markets and sells MOUNJARO[®] and ZEPBOUND[®] throughout the United States using the Lilly Marks.

24. Lilly first adopted and used the MOUNJARO[®] mark at least as early as June 3, 2022, and has used the MOUNJARO[®] mark continuously since that time. Lilly has extensively promoted, advertised, and marketed its prescription-only diabetes medicine bearing the MOUNJARO[®] mark in many different channels, directed both to healthcare professionals and to patients.

25. Lilly is the owner of two federal trademark registrations for MOUNJARO[®], U.S. Reg. Nos. 6,809,369 (issued August 2, 2022) and 7,068,463 (issued May 30, 2023). True and correct copies of Plaintiff Lilly’s registrations for the MOUNJARO[®] mark are attached hereto as part of **Exhibit A**. Lilly additionally has several pending applications to register its MOUNJARO[®] mark in connection with more classes, services, and goods, including U.S.

Trademark Ser. Nos. 97/596,856, 97/668,206, and 98/253,743. As a result of its use of the MOUNJARO[®] mark, Lilly also owns valuable common law and other rights in and to the MOUNJARO[®] mark.

26. Lilly first adopted and used the ZEPBOUND[®] mark at least as early as November 30, 2023, and has used the ZEPBOUND[®] mark continuously since that time. Lilly has extensively promoted, advertised, and marketed its prescription-only weight-loss medicine bearing the ZEPBOUND[®] mark in many different channels, directed both to healthcare professionals and to patients.

27. Lilly is the owner of one federal trademark registration for ZEPBOUND[®], U.S. Reg. No. 7,288,373 (issued January 23, 2024). A true and correct copy of Plaintiff Lilly's registration for the ZEPBOUND[®] mark is attached hereto as part of **Exhibit A**. Lilly additionally has several pending applications to register its ZEPBOUND[®] mark, including U.S. Trademark Ser. Nos. 97/530,451, 97/530,456, and 98/295,137. As a result of its use of the ZEPBOUND[®] mark, Lilly also owns valuable common law and other rights in and to the ZEPBOUND[®] mark.

28. Lilly conceived the Lilly Marks to stand out in the marketplace. The Lilly Marks do not describe any attributes of either medicine and are accordingly inherently distinctive.

29. Lilly promotes, advertises, and markets MOUNJARO[®] and ZEPBOUND[®] both to healthcare professionals and to patients, among others, through various channels, including on the websites mounjaro.com, mounjaro.lilly.com, zepbound.com, and zepbound.lilly.com, in social media, in online advertisements, and on television.

30. As a result of Lilly's use, promotion, advertising, and marketing of MOUNJARO[®] and ZEPBOUND[®], the Lilly Marks are exclusively associated with Lilly, serve to identify genuine Lilly products, and are valuable assets of Lilly.

THE RISKS OF COMPOUNDING

31. Upon information and belief, Defendant markets and sells to patients compounded drug products that purport to contain tirzepatide and that are not approved by the FDA or any other global regulatory agency ("Unapproved Compounded Drugs").

32. Typically, prescription medicines must undergo a rigorous premarket approval process. Federal law creates a narrow exception for compounding, which the FDA defines as a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient." <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding> (FDA guidance on drug compounding law compliance). This narrow exception applies, for instance, where a patient cannot safely take a commercially manufactured FDA-approved drug due to an allergy to a particular dye.

33. The Food, Drug, and Cosmetic Act (FDCA), in section 503A, prescribes a rigid set of requirements that compounding pharmacies must meet, including a requirement that compounding occur only "on the prescription order that a compounded product is necessary for the identified patient." This restriction is important because compounding pharmacies are not required to comply with GMP, so they are only permitted to produce a small amount based on the specific needs of specific patients. The FDA has explained the importance of this

requirement to ensure that compounding pharmacies “are not actually operating as conventional manufacturers”:

The longer a compounded sterile drug product that has been contaminated is held by a pharmacist or physician before distribution, or held in inventory in a health care facility before administration, the greater the likelihood of microbial proliferation and increased patient harm. Because of these and other risks, the FD&C Act places conditions on compounding that must be met for compounded drugs to qualify for the exemptions in section 503A, [including that] compounding is for an identified individual patient, drugs compounded in advance of receiving prescriptions are compounded only in limited quantities, and drugs are distributed pursuant to a valid patient-specific prescription. These conditions are meant to help ensure that compounding under section 503A is based on individual patient needs, and that entities purportedly operating under section 503A are not actually operating as conventional manufacturers.

<https://www.fda.gov/media/97347/download> (FDA prescription requirement compliance guidance for industry).

34. As the FDA further explained, “The *prescription requirement* under section 503A is a critical mechanism to distinguish compounding by a licensed pharmacist or licensed physician from conventional manufacturing, and to ensure that drug products compounded under section 503A, which are not FDA-approved, are not subject to the requirement that labeling bear adequate directions for use, and are not subject to [GMP requirements, are provided to a patient only based on individual patient need.” *Id.* (emphasis in original).

35. Compounders are also limited in their ability to engage in a practice called anticipatory compounding, which is when, “based on a history of receiving prescriptions for a particular drug product to be compounded for an identified individual patient, and in the context of an established relationship with a particular prescriber or patient, a pharmacist or physician will compound a batch of drugs in anticipation of receiving another patient-specific prescription. The compounder then provides the drugs to a patient or health care provider when a prescription for an identified individual patient is received.” *Id.* As the FDA further explained:

[A]nticipatory compounding [] has risks. For example, if a problem occurs during compounding, such as contaminating a drug product that is supposed to be sterile, or producing subpotent or superpotent sterile or non-sterile drugs, it could affect numerous patients, and not just one. Because drug products compounded in accordance with section 503A are exempt from CGMP requirements, there is an inherently greater chance of a production mistake or contamination. Restricting anticipatory compounding to limited quantities serves to limit the number of patients likely to be affected if there are drug product mix-ups or contamination. The limitations on anticipatory compounding in section 503A (i.e., compounding must be in “limited quantities” and based on an “established relationship”) help to protect patients from product quality issues. ***These limitations on anticipatory compounding also help to distinguish licensed pharmacists or licensed physicians compounding drug products under section 503A for individual patients from conventional manufacturers, who generally produce larger quantities of drugs that are distributed without a prescription.***

Id. (emphasis added).

36. According to the FDA, “[c]ompounded drugs are not FDA-approved. This means that FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients.” The FDA has warned that: “Compounded drugs . . . do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs unnecessarily exposes patients to potentially serious health risks. Because compounded drugs are not FDA-approved, FDA does not verify their safety, effectiveness, or quality before they are marketed.” <https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers> (FDA drug compounding FAQ).

37. Health risks from compounded drugs are serious. In 2021, a pharmacist pled guilty to providing adulterated compounded drugs to cataract surgery patients. The adulterated compounds contained “an excessive amount of an inactive ingredient” that can damage sensitive eye tissue. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/texas-pharmacist-pleads-guilty-adulterating-drug-used-cataract-surgeries> (FDA press announcement re guilty plea). At least 68 patients were injected with the adulterated compounds, at two different surgery centers, over a period of months, even though

patients suffered near-immediate adverse events, including permanent blindness.

<https://www.wfaa.com/article/news/do-not-publish-yet/287-5f002ed3-e110-4063-9959-a2e5f54b5097> (WFAA article re outbreak). One patient had believed “every pill you take, every shot you take is tested” and was surprised to learn that compounded drugs were neither fully tested nor deemed safe or otherwise approved by the FDA. *Id.*

38. There are countless other examples of people experiencing serious injury from taking unregulated medicines. Inappropriate drug compounding caused at least 73 reported compounding errors between 2001 and 2019. These errors led to more than 1,562 adverse events and at least 116 deaths. <https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2020/us-illnesses-and-deaths-associated-with-compounded-or-repackaged-medications-2001-19> (U.S. Illnesses and Deaths Associated With Compounded or Repackaged Medications, 2001–19).

39. Lilly has seen problems first-hand for compounded tirzepatide. Lilly has discovered compounded drugs advertised as tirzepatide with safety, sterility, and efficacy problems. Some contain bacteria, high impurity levels, different colors (pink, instead of colorless), or a chemical structure different from the tirzepatide in Lilly’s FDA-approved medicines. In at least one instance, Lilly saw nothing more than sugar alcohol. Lilly also has received reports of patients experiencing significant adverse events after being injected with non-Lilly tirzepatide, including a patient who experienced a seizure and was admitted to the Intensive Care Unit and other patients who experienced severe allergic reactions. According to the FDA’s Adverse Events Reporting System (FAERS), to date, over 150 adverse events associated with compounded or so-called (but not actually) “generic” tirzepatide have been reported, including over 100 “serious cases” and at least 5 deaths.

40. Consequences from compounded drugs may be deadly. In October 2012, compounded drugs contaminated with a fungus were shipped throughout the country and later injected into patients' spines and joints. After these contaminated products were injected into nearly 14,000 patients, more than 60 people died of fungal meningitis. *Id.* Regarding this outbreak, the FDA has written:

The 2012 fungal meningitis outbreak was not an isolated event. It was the most serious in a long history of serious adverse events associated with contaminated, super-potent, mislabeled, or otherwise poor quality compounded drugs. In addition, many serious adverse events linked to poor quality compounded drugs, including outbreaks of infections and deaths have occurred since then. And, because most compounders do not report adverse events to FDA, the agency may not be aware of adverse events associated with compounded drugs unless a health care provider submits an adverse event report regarding his or her patients or a state official notifies FDA.

<https://www.fda.gov/media/102493/download> (FDA Compounding Progress Report).

**WIDESPREAD SAFETY CONCERNS
ABOUT COMPOUNDED TIRZEPATIDE**

41. Regulators and law enforcement across the United States and abroad have recognized the safety concerns with compounded tirzepatide and other incretins. They have issued warnings, and in at least one instance, banned incretin compounding.

42. The FDA, for example, has consistently and repeatedly raised its concerns with compounding generally and compounded incretins more specifically.

<https://www.fda.gov/media/97347/download> (FDA prescription requirement compliance guidance for industry). The FDA specifically has targeted compounded tirzepatide as a threat to consumer safety. The Director of the FDA's Office of Unapproved Drugs and Labeling Compliance has issued multiple warning letters to compounding pharmacies purportedly selling compounded tirzepatide products because they are not safe or effective.

<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning->

letters/us-chem-labs-669074-02072024 (FDA warning letter re US Chem Labs);
<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/synthetix-inc-dba-helix-chemical-supply-668918-02072024> (FDA warning letter re Synthetix Inc. DBA Helix Chemical Supply).

43. Across the country, at least nine state pharmacy boards, along with several state poison centers, have issued guidance and warnings regarding the risks to patients of compounded incretins. The Alabama Board of Pharmacy notified all licensed pharmacists and pharmacies that “even when compounding of [incretins] is allowable under [federal law], . . . the use of any non-pharmaceutical grade active pharmaceutical ingredient (API), or one not produced by an FDA-registered establishment, is prohibited.” <https://www.albme.gov/press-release/concerns-with-semaglutide-and-other-glp-1-receptor-agonists> (Alabama Board of Medical Examiners press release). And the Maryland Poison Control Center warned that buying compounded incretins “online puts people at risk due to the medicine not being regulated and/or being sold from a source that is not licensed,” including because those compounded products “have not been evaluated for safety and effectiveness by the FDA.” <https://blog.mdpoison.com/2024/03/semaglutide> (Blog of the Maryland Poison Center).

44. The issue of unsafe compounded drugs purporting to contain tirzepatide has also received international attention. Australia recently banned the development and sale of compounded anti-obesity medications because of “increasing community concern” and “increasing reports of patients coming to harm from” compounded incretin drugs. The ban—effective October 2024—targets compounded drugs that are “being misrepresented and sold as replica [] Mounjaro®.” <https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/protecting-australians-from-unsafe-compounding-of-replica-weight-loss-products>

(Australia Minister for Health and Aged Care press release). As Mark Butler, Australia’s Minister for Health, said, “Australians should be able to have faith in the medications they use, including compounded medicines,” and the ban “will protect Australians from harm and save lives.” *Id.*

45. Doctors and patient groups recognize the problems with compounded incretins, and they are sharing their concerns, too. The Obesity Society, Obesity Action Coalition, and Obesity Medicine Association, for example, issued a joint statement warning that when people use incretin “alternatives, you may not be getting what you hoped for. You may also get something you did not want (other active substances have been found in some compounded versions).” https://www.obesityaction.org/wp-content/uploads/GLP-1-Compounded-Alternative-Statement_Final_Logos-1.pdf (joint statement from leading obesity expert organizations).

46. Lilly itself has issued multiple public warnings about compounded tirzepatide, including by publishing an open letter.

**DEFENDANT’S FALSE ADVERTISING
AND TRADEMARK INFRINGEMENT**

47. Lilly does not sell MOUNJARO® or ZEPBOUND® to Defendant for resale or redistribution. Nor has Lilly authorized Defendant to use the Lilly Marks in connection with any of Defendant’s offered goods or services. On information and belief, therefore, the Unapproved Compounded Drugs sold by Defendant are made by compounding pharmacies, which deliver them to Defendant for prescription, administration, or other dispensing to patients.

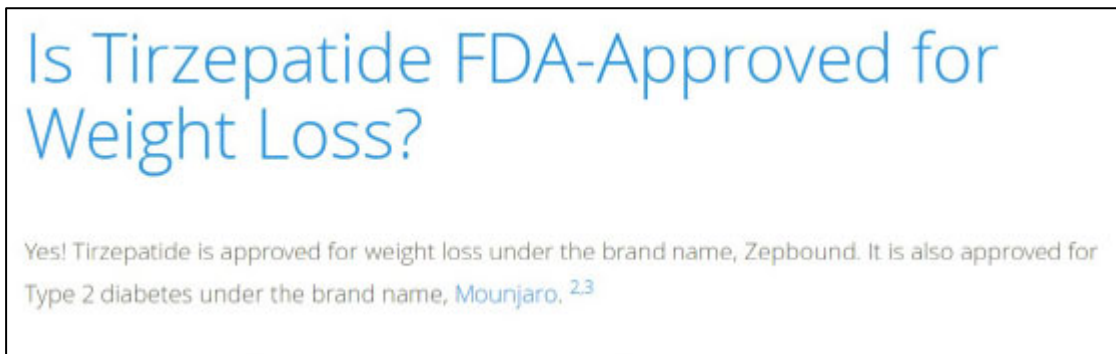
48. On information and belief, Defendant does not sell Lilly’s MOUNJARO® and ZEPBOUND® and has no association with Lilly. Yet Defendant boldly and falsely appropriates the Lilly Marks to market and sell Unapproved Compounded Drugs purporting to contain

tirzepatide. These drugs are *not* MOUNJARO[®] or ZEPBOUND[®]. Rather, Defendant passes off Unapproved Compounded Drugs as MOUNJARO[®] or ZEPBOUND[®]. Defendant's unlawful use of the Lilly Marks can only be intended to deceptively lure in patients in pursuit of revenues and profits.

49. Because Defendant is not offering genuine MOUNJARO[®] or ZEPBOUND[®], Lilly has no control over the safety, quality, or effectiveness of the Unapproved Compounded Drugs sold by Defendant.

50. Examples of Defendant's trademark infringement and false advertising are shown below and are attached hereto as **Exhibit B**.

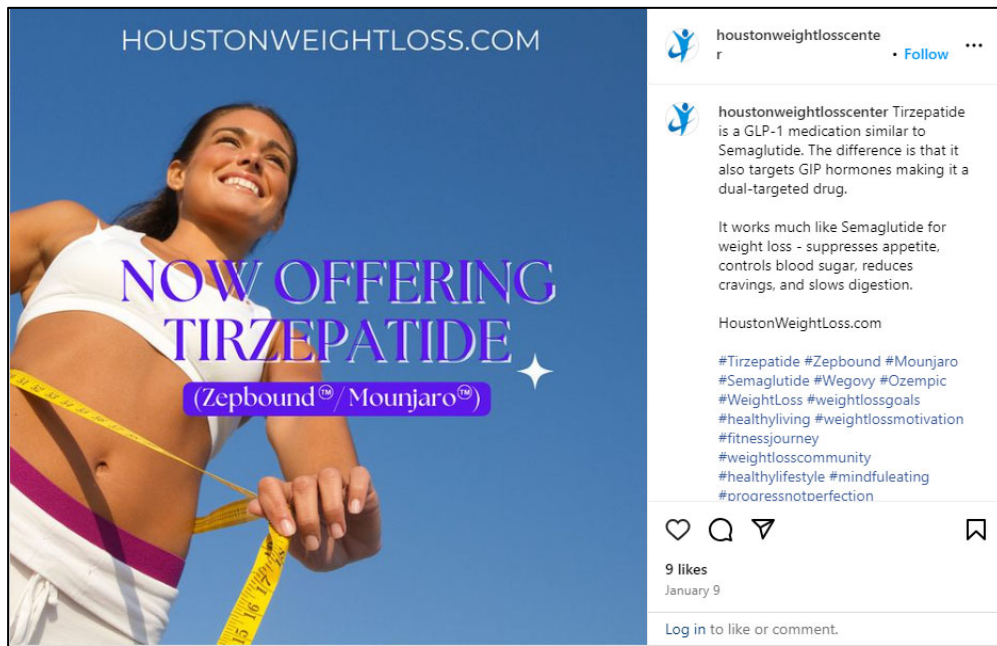
51. An example of Defendant's unauthorized use of the Lilly Marks, on the "Tirzepatide" page of Defendant's website (houstonweightloss.com/weight-loss/appetite-suppressant-programs/tirzepatide-for-weight-loss), is shown below.



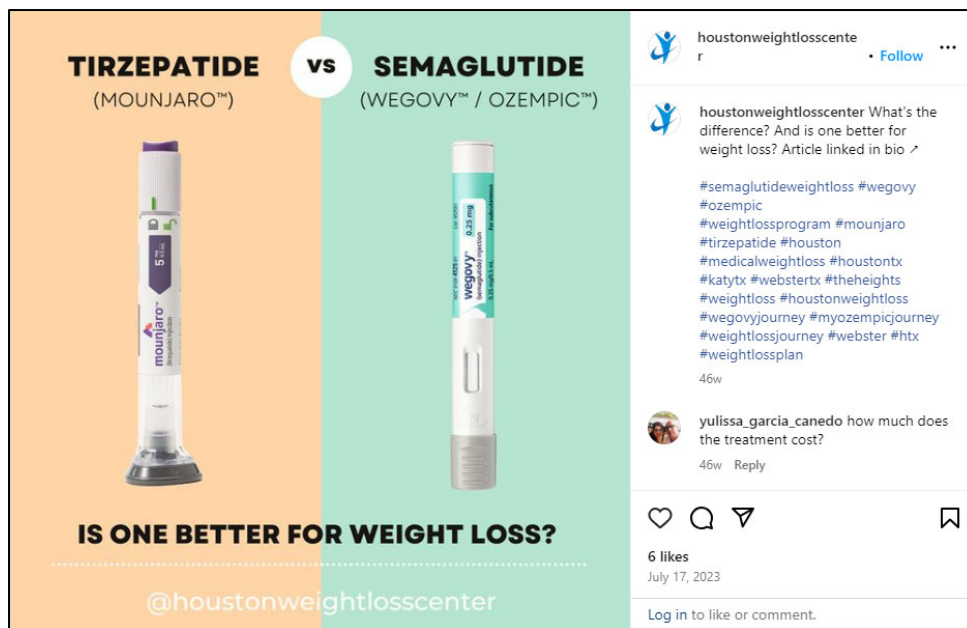
52. As the image shows, Defendant promotes its Unapproved Compounded Drugs as "approved for weight loss under the brand name Zepbound. It is also approved for Type 2 diabetes under the brand name, Mounjaro." Defendant's Unapproved Compounded Drugs are *not* sold under the brand name "Zepbound" or "Mounjaro," because they are not ZEPBOUND[®] or MOUNJARO[®].

53. On this “Tirzepatide” webpage, which Defendant uses to sell its Unapproved Compounded Drugs, Defendant uses Lilly’s coined terms MOUNJARO® and ZEPBOUND® repeatedly, despite the fact that Defendant does not offer either of these Lilly medicines.

54. Defendant invokes Lilly’s MOUNJARO® and ZEPBOUND® trademarks on its social media accounts as well. For example, and as shown below, on January 9, 2024 Defendant posted a graphic to Instagram that reads in large font “NOW OFFERING TIRZEPATIDE (Zepbound™ / Mounjaro™).” This post is also “tagged” #Zepbound and #Mounjaro, as shown below.



55. In another post from July 17, 2023, Defendant showed an image of Lilly’s MOUNJARO® autoinjector pen under the words “TIRZEPATIDE (MOUNJARO™).” This post, too, was tagged #Mounjaro.



56. Defendant’s website and social media conveys the unmistakable impression that Defendant is offering for sale Lilly’s MOUNJARO® and ZEPBOUND®, a product originating from the same source as Lilly’s MOUNJARO® and ZEPBOUND®. But Lilly is the only approved source of MOUNJARO® and ZEPBOUND® in the United States, and Lilly does not sell either medicine to Defendant for resale or redistribution.

57. Defendant first started using the Lilly Marks to advertise its Unapproved Compounded Drugs long after Lilly had adopted them. Defendant’s use can only have been intended to benefit from the goodwill Lilly generated around the Lilly Marks.

58. Defendant also falsely advertises its Unapproved Compounded Drugs on its website and social media by making statements that claim or imply that its Unapproved Compounded Drugs are FDA-approved and have been proven to achieve certain therapeutic outcomes. These statements rely on the FDA’s approval of *Lilly’s* medicines and clinical trials for *Lilly’s* medicines. These studies and approvals have no bearing on, and cannot substantiate

claims about, Defendant's Unapproved Compounded Drugs, which upon information and belief are sold without having undergone any clinical trials on safety and effectiveness.

59. For example, as shown below, Defendant's same Tirzepatide webpage includes an entire section devoted to relaying the results of Lilly's "Surmount 1 clinical trial," proclaiming that "Tirzepatide was shown to have impressive results for weight loss and improved cardiometabolic health."

The screenshot shows a webpage with the following content:

Clinical Trial Results – Tirzepatide for Weight Loss

In the Surmount 1 clinical trial, Tirzepatide was shown to have impressive results for weight loss and improved cardiometabolic health. The trial was a randomized, double blind, placebo-controlled study lasting 72 weeks that included 2,539 participants. Participants were required to have a BMI of 30 or greater, or, BMI of 27 or greater with at least one weight-related health problem.

- Tirzepatide 5-mg doses – Average change in weight was -15%
- Tirzepatide 10-mg dose – Average change in weight was -19.5%
- Tirzepatide 15-mg dose – Average change in weight was -20.59%

Placebo – Average change in weight was -3%

Along with these significant weight loss results there were also improvements in all prespecified cardiometabolic measures for participants taking Tirzepatide.¹

60. Moreover, Defendant's Unapproved Compounded Drugs are not FDA approved for any indication, despite Defendant's exclamatory "Yes!" shown above. See ¶50.

61. As shown below, Defendant's webpage also contains a "References" section, which cites to (1) a medical journal article discussing the results of the Lilly-funded SURMOUNT[®] trial, (2) ZEPBOUND[®]'s FDA approval announcement, (3) MOUNJARO[®]'s FDA approval announcement, and (4) Lilly's zepbound.lilly.com website.

References

1. Jastreboff, Ania M., et al. (2022). Tirzepatide Once Weekly for the Treatment of Obesity. *New England Journal of Medicine*.
2. FDA Office of Media Affairs (2023). FDA Approves New Medication for Chronic Weight Management. *FDA.gov*.
3. FDA Office of Media Affairs (2022). FDA Approves Novel, Dual-Targeted Treatment for Type 2 Diabetes. *FDA.gov*.
4. Eli Lilly. (2023). Zepbound [package insert].

62. As with Defendant’s trademark infringement, Defendant’s false and/or misleading advertising extends to Defendant’s social media pages as well. For example, on May 15, 2024, Defendant posted a graphic on Instagram that, as shown below, stated that “Patients lost **up to 21% of starting body weight** on average during the clinical trial” in answer to the question “How much weight can you lose on Tirzepatide?” Defendant’s caption indicates these were the results from Lilly’s SURMOUNT® clinical trials.



63. Upon information and belief, these statements are false and/or misleading as to Defendant’s Unapproved Compounded Drugs, which are **not** FDA approved, were **not** the subject of Lilly’s SURMOUNT® clinical trials, were **not** the subject of any other clinical trials,

are *not* clinically proven to achieve any results, and are *not* described on Lilly's zepbound.lilly.com website.

64. Defendant continues to use the Lilly Marks, including in advertising and promotion on its website and social media, to deceive patients who, upon information and belief, are seeking to buy but are in fact not buying genuine FDA-approved MOUNJARO[®] and/or ZEPBOUND[®] to treat their serious health conditions.

65. Defendant's prominent and misleading use of the Lilly Marks is likely to cause consumers to falsely believe that they are purchasing MOUNJARO[®] and/or ZEPBOUND[®], that Defendant is a source for Lilly's FDA-approved treatment options MOUNJARO[®] and/or ZEPBOUND[®], that Defendant's Unapproved Compound Drugs are as safe and effective as Lilly's FDA-approved treatment options MOUNJARO[®] and ZEPBOUND[®], and/or that Defendant's services are provided, licensed, sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly.

66. Defendant's use of the Lilly Marks is without the permission, consent, or authorization of Lilly. Defendant has no right to use, and Defendant knows that it has no right to use, the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs or otherwise. Defendant's advertising and promotional materials are false and misleading where they suggest and/or state an association with Lilly's FDA-approved MOUNJARO[®] and ZEPBOUND[®], because no such association exists.

67. There is no need for Defendant to use the Lilly Marks to advertise or promote its Unapproved Compounded Drugs purporting to contain tirzepatide, other than to trade upon the reputation of Lilly and to create confusion in the marketplace and/or mislead patients with

serious health conditions regarding the origin, identity, or source of Defendant's Unapproved Compounded Drugs.

68. Defendant's unauthorized use of the Lilly Marks is intended—and likely—to cause confusion, to cause mistake, or to deceive, and infringes Lilly's established exclusive rights in the Lilly Marks.

69. Upon information and belief, unless enjoined by this Court, Defendant will continue to use the Lilly Marks and/or otherwise falsely advertise its Unapproved Compounded Drugs as associated with or being MOUNJARO[®] and ZEPBOUND[®], all in violation of Lilly's rights.

HARM TO THE PEOPLE OF TEXAS AND LILLY

70. Lilly's FDA-approved MOUNJARO[®] and ZEPBOUND[®] medications have undergone extensive clinical trials and approval processes. But these clinical studies and FDA approvals only apply to genuine Lilly MOUNJARO[®] and ZEPBOUND[®] used as directed by a prescribing physician. The clinical trials and approval processes do not inform the safety, quality, or effectiveness of Defendant's Unapproved Compounded Drugs.

71. Defendant's unlawful, misleading business model may expose patients to the serious risks described above. Critically, because Defendant falsely advertises and, without Lilly's consent, uses the Lilly Marks in connection with its Unapproved Compounded Drugs, patients are unlikely to know the unique risks associated with Defendant's untested, unapproved drugs.

72. Defendant advertises itself as providing MOUNJARO[®] and ZEPBOUND[®], when in reality Defendant provides untested Unapproved Compounded Drugs. Defendant's promotional tactics are *intended* to mislead patients into believing that Unapproved

Compounded Drugs are backed by clinical trials and have been approved by the FDA, when no such studies have been conducted, and neither the FDA nor any other regulatory body has approved them. Patients who take Defendant's Unapproved Compounded Drugs and suffer harm will have had no forewarning.

73. Not only does this deceitful content expose the people of Texas to serious health risks, but Defendant's unlawful tactics undermine the name, goodwill, and reputation that Lilly has invested heavily in developing. Moreover, Defendant's unfair methods allow it and its suppliers of Unapproved Compounded Drugs to unjustly profit from sales to patients looking for MOUNJARO[®] and ZEPBOUND[®].

FIRST CAUSE OF ACTION
Trademark Infringement
in Violation of 15 U.S.C. § 1114

74. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

75. Lilly is the owner of all right, title, and interest in federal trademark registrations for the inherently distinctive Lilly Marks and has standing to maintain an action for trademark infringement under 15 U.S.C. § 1114.

76. Without Lilly's consent, Defendant has used and continues to use in commerce the Lilly Marks in connection with the offering, sale, and advertising of its Unapproved Compounded Drugs purporting to contain tirzepatide. Consumers who encounter Defendant's unauthorized use of the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs and related goods and services are likely to think that they are provided, licensed, sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly.

77. Defendant's actions are likely to cause confusion, or to cause mistake, or to deceive, and thus constitute trademark infringement of the registered Lilly Marks, in violation of Section 32 of the Lanham Act, 15 U.S.C. § 1114.

78. Defendant had actual and/or constructive knowledge of Lilly's rights prior to its infringing use of the Lilly Marks. The actions of Defendant alleged above have at all times relevant to this action been willful.

79. As a direct and proximate result of the actions of Defendant alleged above, Lilly has been damaged and will continue to be damaged. Defendant's conduct, unless enjoined by the Court, will further impair the value of the Lilly Marks' name, reputation, and goodwill. This harm constitutes an injury for which Lilly has no adequate remedy at law.

80. This is an exceptional case under 15 U.S.C. § 1117.

81. Based on such conduct, Lilly is entitled to injunctive relief as well as monetary damages, and other remedies provided by Sections 1116, 1117, and 1118, including Defendant's profits, treble damages, reasonable attorneys' fees, costs, and prejudgment interest.

SECOND CAUSE OF ACTION
**Trademark Infringement, False Designation of Origin
and Unfair Competition in Violation of 15 U.S.C. § 1125**

82. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

83. Lilly is the owner of all right, title, and interest in the inherently distinctive Lilly Marks and has standing to maintain an action for trademark infringement, false designation of origin, and unfair competition under 15 U.S.C. § 1125.

84. Without Lilly's consent, Defendant has used and continues to use in commerce the Lilly Marks in connection with the offering, sale, and advertising of its Unapproved

Compounded Drugs purporting to contain tirzepatide. Consumers who encounter Defendant's unauthorized use of the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs and related goods and services are likely to think that they are provided, licensed, sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly.

85. Defendant's actions are likely to cause confusion, or to cause mistake, or to deceive as to the origin, sponsorship, or approval of the products and services and commercial activities of Defendant, and thus constitute trademark infringement, false designation of origin, and unfair competition with respect to the Lilly Marks, in violation of Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A).

86. Defendant had actual and/or constructive knowledge of Lilly's rights prior to its infringing use of the Lilly Marks. The actions of Defendant alleged above have at all times relevant to this action been willful.

87. As a direct and proximate result of the actions of Defendant alleged above, Lilly has been damaged and will continue to be damaged. Defendant's conduct, unless enjoined by the Court, will further impair the value of the Lilly Marks' name, reputation, and goodwill. This harm constitutes an injury for which Lilly has no adequate remedy at law.

88. This is an exceptional case under 15 U.S.C. § 1117.

89. Based on such conduct, Lilly is entitled to injunctive relief as well as monetary damages, and other remedies provided by Sections 1116, 1117, and 1118, including Defendant's profits, treble damages, reasonable attorneys' fees, costs, and prejudgment interest.

THIRD CAUSE OF ACTION
False and Misleading Advertising and Promotion
in Violation of 15 U.S.C. § 1125(a)(1)(B)

90. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

91. Defendant'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).

92. Defendant has knowingly and willfully made material false and misleading statements in its commercial advertisements for its Unapproved Compounded Drugs, and these statements regarding the Unapproved Compounded Drugs' safety, quality, effectiveness, and regulatory status have influenced and are likely to continue to influence consumers' purchasing decisions.

93. Defendant's statements—including its various literally false claims—have the tendency to deceive a substantial segment of consumers, who have relied or likely will rely on Defendant's false statements in making their tirzepatide-based medicine purchase decisions.

94. Defendant has caused its false statements to enter interstate trade or commerce.

95. As a direct and proximate result of Defendant's false and deceptive campaign, Lilly is suffering immediate and continuing irreparable injury for which there is no adequate remedy at law.

96. As a direct and proximate result of Defendant's false and deceptive campaign, Lilly has suffered and will continue to suffer significant monetary damages and discernible competitive injury by the direct diversion of sales from Lilly to Defendant and Defendant's suppliers and by a loss of goodwill associated with Lilly's MOUNJARO[®] and ZEPBOUND[®] and the Lilly Marks.

97. This is an exceptional case under 15 U.S.C. § 1117.

98. Lilly is entitled to injunctive relief as well as monetary damages, and other remedies provided by Sections 1116, 1117, and 1118, including Defendant's profits, treble damages, reasonable attorneys' fees, costs, and prejudgment interest.

FOURTH CAUSE OF ACTION
Unfair Competition
in Violation of Texas Common Law

99. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

100. The above-described acts of Defendant constitute unfair competition in violation of Texas common law.

101. Without Lilly's consent, Defendant has used and continues to use in commerce the Lilly Marks to pass off its Unapproved Compounded Drugs purporting to contain tirzepatide as genuine MOUNJARO[®] and ZEPBOUND[®].

102. Defendant's unauthorized use of the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs and related goods and services is likely to cause confusion, or to cause mistake, or to deceive as to the origin, sponsorship, or approval of the products and services and commercial activities of Defendant.

103. Consumers who encounter Defendant's unauthorized use of the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs and related goods and services are likely to think that they are provided, licensed, sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly.

104. Defendant's actions thereby unfairly and wrongfully exploit and infringe Lilly's trademark, goodwill, and reputation.

105. As a direct and proximate result of Defendant's unfair methods of competition, Lilly has suffered and will continue to suffer significant monetary damages and discernible competitive injury by the direct diversion of sales from Lilly to Defendant and by a loss of goodwill associated with Lilly's MOUNJARO[®] and ZEPBOUND[®] medicines and the Lilly Marks.

106. By reason of Defendant's acts, Lilly's remedy at law is not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Lilly is entitled to entry of preliminary and permanent injunctive relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Lilly prays that this Court enter judgment in its favor on each and every claim for relief set forth above and award it relief including, but not limited to, the following:

1. An Order declaring that Defendant:
 - a. Infringed the federally registered Lilly Marks, in violation of 15 U.S.C. § 1114(1);
 - b. Infringed the Lilly Marks and engaged in trademark infringement, false designation of origin, and unfair competition, in violation of 15 U.S.C. § 1125(a)(1)(A);
 - c. Engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a)(1)(B);
 - d. Engaged in unfair competition in violation of the common law of Texas;
 - e. That each of the above acts was willful and knowing.

2. An injunction preliminarily and then permanently enjoining and restraining Defendant and its officers, agents, servants, employees, and attorneys and all persons acting in concert or participation with any of them, from:

- a. Using the Lilly Marks or any mark confusingly similar to them, in connection with the advertising, promoting, marketing, selling or offering for sale of any goods or services (including, but not limited to, Unapproved Compounded Drugs) or otherwise engaging in any activity that is likely to cause confusion, cause mistake, or deceive or otherwise infringe any rights of Plaintiff Lilly in the Lilly Marks or any similar mark;
- b. Falsely stating or suggesting that Defendant's Unapproved Compounded Drugs are genuine or generic versions of MOUNJARO[®] or ZEPBOUND[®], that Defendant is associated or connected in any way with Plaintiff or its products, or that Defendant's Unapproved Compounded Drugs are approved by the FDA, have been the subject of clinical studies, or achieve certain therapeutic outcomes;
- c. Engaging in any unfair competition with Plaintiff Lilly; and
- d. Engaging in any deceptive or unfair acts.

3. An Order Requiring Defendant and its officers, agents, servants, employees, and attorneys and all persons acting in concert or participation with any of them, to engage in corrective advertising by informing consumers that Defendant is not and never has been authorized by, affiliated with, sponsored by, approved by, or related to Plaintiff Lilly or MOUNJARO[®] and ZEPBOUND[®], that Defendant's Unapproved Compounded Drugs are not

MOUNJARO[®] or ZEPBOUND[®], that Defendant's Unapproved Compounded Drugs are not generic MOUNJARO[®] or generic ZEPBOUND[®], that Defendant's Unapproved Compounded Drugs have never been genuine or generic versions of MOUNJARO[®] and ZEPBOUND[®], and that Defendant's Unapproved Compounded Drugs are not and have never been approved or reviewed by the FDA or tested for safety, quality, or effectiveness in clinical trials.

4. An Order directing Defendant to file with this Court and serve on Lilly's attorneys, thirty (30) days after the date of entry of any injunction, a report in writing and under oath setting forth in detail the manner and form in which they have complied with the Court's injunction.

5. An Order requiring Defendant to account for and pay to Lilly any and all profits arising from the foregoing acts of infringement, false designation of origin, false advertising, and unfair competition.

6. An Order requiring Defendant to pay Lilly compensatory damages in an amount as yet undetermined caused by the foregoing acts of infringement, false designation of origin, false advertising, and unfair competition, and trebling such compensatory damages for payment to Lilly in accordance with 15 U.S.C. § 1117 and other applicable laws.

7. An Order for pre-judgment and post-judgment interest on all damages.

8. An Order requiring Defendant to pay Lilly all types of monetary remedies available under Texas state law in amounts as of yet undetermined caused by the foregoing acts of unfair competition.

9. An Order requiring Defendant to pay Lilly's costs and attorney's fees in this action pursuant to 15 U.S.C. § 1117, Texas state law, and any other applicable provision of law.

10. Other relief as the Court may deem appropriate.

Dated: June 20, 2024

Respectfully submitted,

/s/ James John Lomeo

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JURY DEMAND

Lilly hereby demands a jury trial for all issues so triable.

/s/ James John Lomeo

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