UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

ELI LILLY AND COMPANY,

Plaintiff,

v.

AGV SASON INC. D/B/A LUCY'S LASER & MEDSPA,

Defendant.

Case No. 1:24-cv-1036

JURY TRIAL DEMANDED

COMPLAINT FOR TRADEMARK INFRINGEMENT, FALSE ADVERTISING, FALSE DESIGNATION OF ORIGIN, AND DECEPTIVE TRADE PRACTICES

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 AGV Sason Inc. d/b/a Lucy's Laser & Medspa ("Defendant") has designed its website 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 insulinotropic 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

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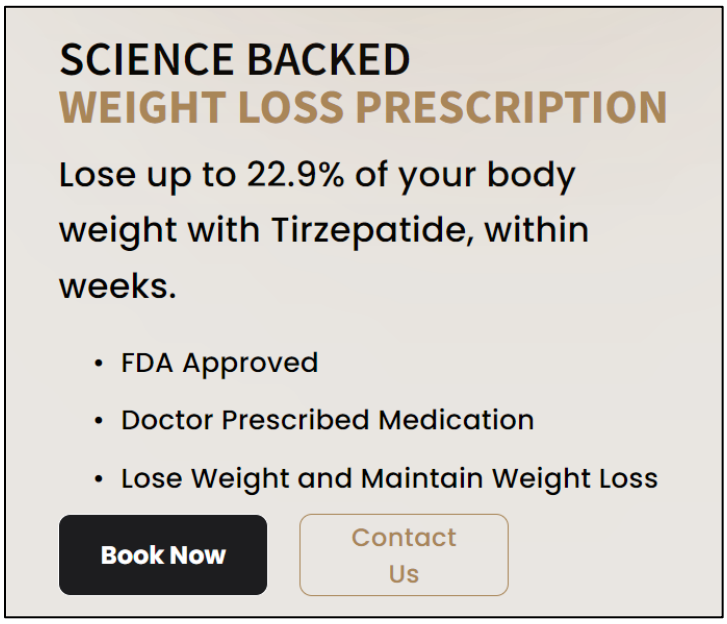
[1] In support of this Complaint, Lilly's allegations are upon actual knowledge with respect to itself and its own acts, and upon information and belief as to all other matters.

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 begins with its eye-catching product description, wherein Defendant claims to offer a "Science Backed Weight Loss Prescription" that is "FDA Approved," as shown below.



7. Despite this impossible-to-miss advertisement, Defendant's product is neither "science backed" nor "FDA approved." Rather, it is untested, unapproved, and unsafe.

8. Lilly therefore brings this action pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, and for violation of Ohio statutory and common law regarding deceptive and unfair trade practices. 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, deceptive trade practices, and unfair methods of 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 an Ohio corporation d/b/a Lucy's Laser & Medspa, with a principal place of business in Concord, Ohio, in this District. Defendant additionally does business at

8806 Mentor Avenue, Suite G, Mentor, Ohio 44060, also in this District. Its registered agent is Lucille Zappitelli Sason with a registered agent address 6726 Rosemarie Court, Concord, Ohio 44077.

11. Defendant also does business using the domain name "https://lucyslasermedspa.com."

JURISDICTION AND VENUE

12. 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).

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

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

14. 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.*

15. 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.

16. 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).

17. 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 ≥ 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.

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

19. 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.*

20. 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.

21. Lilly now promotes, offers, and sells MOUNJARO® and ZEPBOUND® medicines in Ohio and throughout the United States.

LILLY'S MOUNJARO® AND ZEPBOUND® TRADEMARKS

22. 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.

23. 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.

24. 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.

25. 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.

26. 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.

27. 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.

28. 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.

29. 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

30. 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").

31. 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.

32. 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).

33. 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).

34. 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).

35. 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).

36. 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.*

37. 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).

38. 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.

39. 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

40. 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.

41. 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).

42. 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).

43. 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.*

44. 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).

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

DEFENDANT'S FALSE ADVERTISING AND TRADEMARK INFRINGEMENT

46. 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.

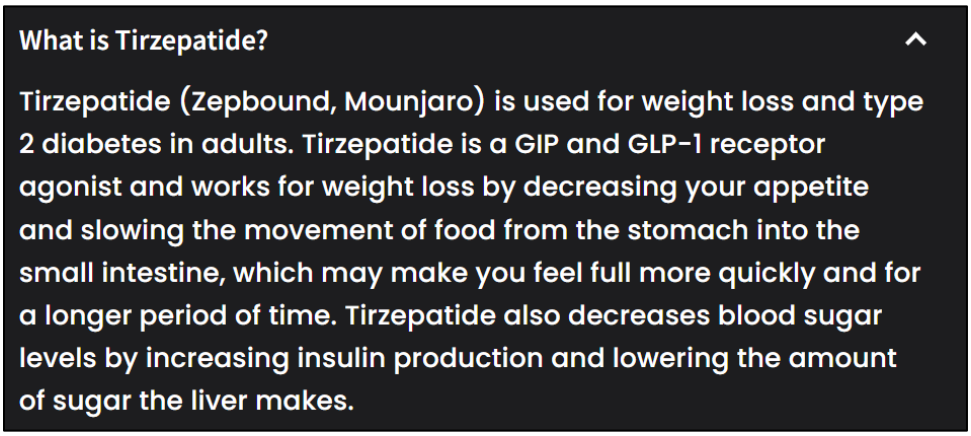
47. On information and belief, Defendant does not sell Lilly's MOUNJARO® and ZEPBOUND® and has no association with Lilly. Yet Defendant boldly and falsely appropriates the Lilly Marks to market and sell Unapproved Compounded Drugs purporting to contain tirzepatide. These drugs are ***not*** MOUNJARO® or ZEPBOUND®. Rather, Defendant passes off Unapproved Compounded Drugs as "Zepbound, Mounjaro." Defendant's unlawful use of the Lilly Marks can only be intended to deceptively lure in patients in pursuit of revenues and profits.

48. 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.

49. Defendant also passes off as "Mounjaro" its own Unapproved Compounded Drugs for a use for which it is not approved or indicated, namely "weight loss."

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 its Tirzepatide webpage (https://lucyslasermedspa.com/tirzepatide), is shown below.



52. As the image shows, Defendant promotes its Unapproved Compounded Drugs with the explanation that they are "Zepbound, Mounjaro."

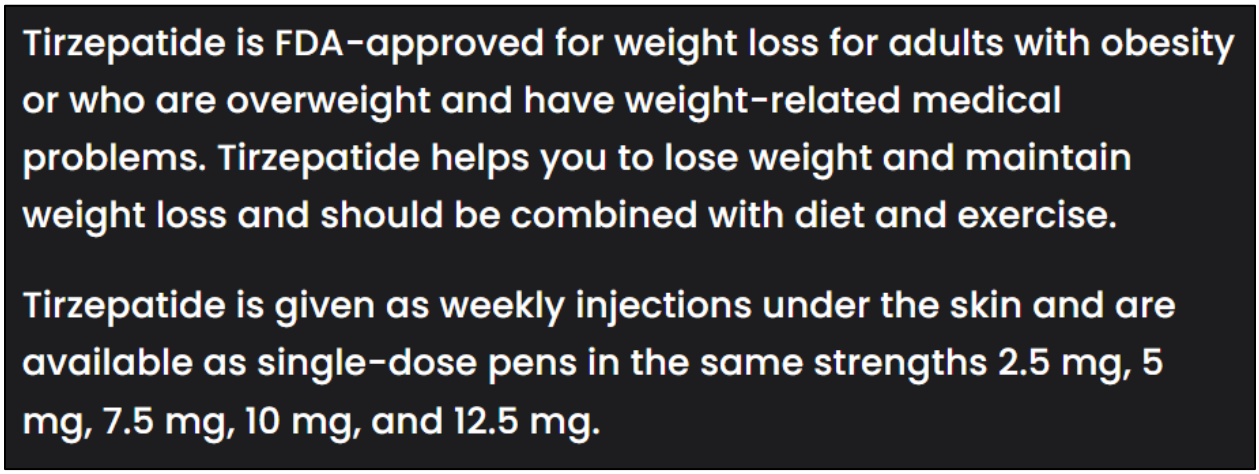
53. Defendant's website conveys the unmistakable impression that Defendant is offering for sale a product that either is, has the same source as, or is the same as, Lilly's MOUNJARO® and ZEPBOUND®. But Lilly is the only approved source of MOUNJARO® and ZEPBOUND® in the United States, and Lilly does not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

54. 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.

55. Defendant also falsely advertises its Unapproved Compounded Drugs on its website 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.

56. For example, as shown below, Defendant's "Tirzepatide" webpage advertises that: "Tirzepatide is FDA-approved for weight loss." "Tirzepatide," however, is ***not*** approved for weight loss or any other condition; Lilly's MOUNJARO® and ZEPBOUND®, medicines ***containing*** tirzepatide, are FDA approved for the indications described above.



57. Additionally, as shown above, Defendant claims to offer its Unapproved Compounded Drugs in "single-dose pens" in doses corresponding to FDA-approved dosages of MOUNJARO® and ZEPBOUND®, which can only be construed as a reference to Lilly's MOUNJARO® and ZEPBOUND® autoinjector pens. Defendant does not, however, offer Lilly's MOUNJARO® and ZEPBOUND®, in autoinjector pen or any other form.

58. In fact, Defendant stated in an October 26, 2023 Instagram post that Defendant gets its "tirzepatide from trusted United states Compounding pharmacies ***only***." https://www.instagram.com/p/Cy3On4mLgC7/ (emphasis added).

59. In another Instagram post, from December 13, 2023, Defendant referred to "studies" that allegedly proved the safety, quality, or effectiveness of Defendant's Unapproved Compounded Drugs. These "studies," however, were conducted on ***Lilly's*** medicines and do not prove anything about Defendant's Unapproved Compounded Drugs.

60. 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*** subjected to clinical trials, and therefore are ***not*** "clinically proven" to achieve any results.

61. Defendant continues to use the Lilly Marks, including in advertising and promotion on its website, 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.

62. 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.

63. 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.

64. 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 Lilly's reputation 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.

65. 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.

66. 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 OHIO AND LILLY

67. 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.

68. 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.

69. Defendant advertises itself as providing MOUNJARO® and ZEPBOUND® (or their supposed equivalents), 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.

70. Not only does this deceitful content expose the people of Ohio 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

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

72. 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.

73. 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.

74. 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.

75. 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.

76. 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.

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

78. 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

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

80. 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.

81. 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.

82. 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).

83. 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.

84. 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.

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

86. 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)

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

88. 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).

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

90. 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.

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

92. 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.

93. 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.

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

95. 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
Deceptive Trade Practices
in Violation of Ohio Rev. Code § 4165.01 *et seq*.

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

97. The above-described acts of Defendant constitute deceptive trade practices in violation of Ohio Rev. Code § 4165.01 et seq.

98. Among other things, Ohio Rev. Code § 4165.02 defines actions that constitute a "deceptive trade practice" as including, but not limited to, the following:

> (1) Passes off goods or services as those of another;
> (2) Causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
> (3) Causes likelihood of confusion or misunderstanding as to affiliation, connection, or association with, or certification by, another;
> * * *
> (7) Represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have;
> * * *
> (9) Represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;
> * * *
> (11) Advertises goods or services with intent not to sell them as advertised;

99. As set forth herein, Defendant's actions fit within the scope of Ohio Rev. Code § 4165.02.

100. 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.

101. Defendant's actions are likely to cause confusion, or to cause mistake, or to deceive the public and consumers as to the origin, sponsorship, or approval of the products and services and commercial activities of Defendant, and thus constitute deceptive trade practices with respect to the Lilly Marks, in violation of Ohio Rev. Code § 4165.01 *et seq*.

102. 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 with the intent to deceive.

103. Defendant's actions additionally include deceptively relying on Lilly's clinical trials for MOUNJARO® and ZEPBOUND® to advertise Defendant's Unapproved Compounded Drugs. These representations amount to false assurances of the safety, quality, and effectiveness of Defendant's Unapproved Compounded Drugs. Defendant's false and misleading misrepresentations and omissions were material because they involve information that would be important to consumers, and therefore, likely their use of, or conduct, regarding Defendant's Unapproved Compounded Drugs.

104. 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.

105. Members of the public are also likely to suffer injury from the above-described acts of Defendant by purchasing a drug that they believe to be genuine MOUNJARO® and ZEPBOUND®, not an Unapproved Compounded Drug.

106. Under the principles of equity, Lilly is entitled to entry of preliminary and permanent injunctive relief. In addition, Lilly is entitled to attorneys' fees and costs.

FIFTH CAUSE OF ACTION
Trademark Infringement and Unfair Competition in Violation of Ohio Common Law

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

108. The above-described acts of Defendant constitute trademark infringement and unfair competition in violation of Ohio common law.

109. 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®.

110. 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.

111. 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.

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

113. As a direct and proximate result of Defendant's trademark infringement and unfair methods of competition, Lilly has suffered and will continue to suffer significant monetary damages and a loss of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® medicines and the Lilly Marks. Defendant therefore has unfairly profited from the actions alleged.

114. 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 in addition to monetary damages.

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 deceptive trade practices, false advertising, unfair competition, and trademark infringement in violation of Ohio Rev. Code § 4165.01 *et seq.* and Ohio common law;

   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 deceptive trade practices.

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 Ohio state law in amounts as of yet undetermined caused by the foregoing acts of infringement, false designation of origin, false advertising, and 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, Ohio 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/ Matthew J. Cavanagh

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Attorneys for Plaintiff
ELI LILLY AND COMPANY

JURY DEMAND

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

/s/ Matthew J. Cavanagh

Matthew J. Cavanagh (OH 0079522)
Attorney for Plaintiff
ELI LILLY AND COMPANY

EXHIBIT A

United States of America
United States Patent and Trademark Office

MOUNJARO

Reg. No. 6,809,369

Registered Aug. 02, 2022

Int. Cl.: 5

Trademark

Principal Register

Eli Lilly and Company (INDIANA CORPORATION)
Lilly Corporate Center
Indianapolis, INDIANA 46285

CLASS 5: Pharmaceutical preparations, namely, pharmaceutical preparations for the treatment of diabetes

FIRST USE 6-3-2022; IN COMMERCE 6-3-2022

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT STYLE, SIZE OR COLOR

SER. NO. 88-680,946, FILED 11-05-2019

Katherine Kelly Vidal

Director of the United States
Patent and Trademark Office

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

- ***First Filing Deadline:*** You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. See 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

- ***Second Filing Deadline:*** You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between the 9th and 10th years after the registration date.* See 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

- You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the United States Patent and Trademark Office (USPTO). The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. See 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. See 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

NOTE: A courtesy e-mail reminder of USPTO maintenance filing deadlines will be sent to trademark owners/holders who authorize e-mail communication and maintain a current e-mail address with the USPTO. To ensure that e-mail is authorized and your address is current, please use the Trademark Electronic Application System (TEAS) Correspondence Address and Change of Owner Address Forms available at http://www.uspto.gov.

United States of America
United States Patent and Trademark Office

MOUNJARO

Reg. No. 7,068,463

Registered May 30, 2023

Int. Cl.: 44

Service Mark

Principal Register

Eli Lilly and Company (INDIANA CORPORATION)
Lilly Corporate Center
Indianapolis, INDIANA 46285

CLASS 44: Medical information services in the field of diabetes

FIRST USE 6-7-2022; IN COMMERCE 6-7-2022

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT STYLE, SIZE OR COLOR

SER. NO. 97-468,410, FILED 06-21-2022

Katherine Kelly Vidal

Director of the United States
Patent and Trademark Office

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

- ***First Filing Deadline:*** You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. See 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

- ***Second Filing Deadline:*** You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between the 9th and 10th years after the registration date.* See 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

- You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the United States Patent and Trademark Office (USPTO). The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. See 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. See 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

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United States of America
United States Patent and Trademark Office

ZEPBOUND

Reg. No. 7,288,373

Registered Jan. 23, 2024

Int. Cl.: 5

Trademark

Principal Register

Eli Lilly and Company (INDIANA CORPORATION)
Lilly Corporate Center
Indianapolis, INDIANA 46285

CLASS 5: Pharmaceutical preparations, namely, pharmaceutical preparations for the treatment of obesity

FIRST USE 11-30-2023; IN COMMERCE 11-30-2023

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT STYLE, SIZE OR COLOR

SER. NO. 97-362,818, FILED 04-14-2022

Katherine Kelly Vidal

Director of the United States
Patent and Trademark Office

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

- ***First Filing Deadline:*** You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. See 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

- ***Second Filing Deadline:*** You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between the 9th and 10th years after the registration date.* See 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

- You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the United States Patent and Trademark Office (USPTO). The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. See 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. See 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

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EXHIBIT B

WEIGHT LOSS SOLUTIONS

TIRZEPATIDE

Lose weight safely in the comfort of your own home with this medical weight loss solution.

Book Appointment | Contact

NOTE:
Service includes 4 FREE Vitamin B12 Energy Injections

SCIENCE BACKED
WEIGHT LOSS PRESCRIPTION

Lose up to 22.9% of your body weight with Tirzepatide, within weeks.

- FDA Approved
- Doctor Prescribed Medication
- Lose Weight and Maintain Weight Loss

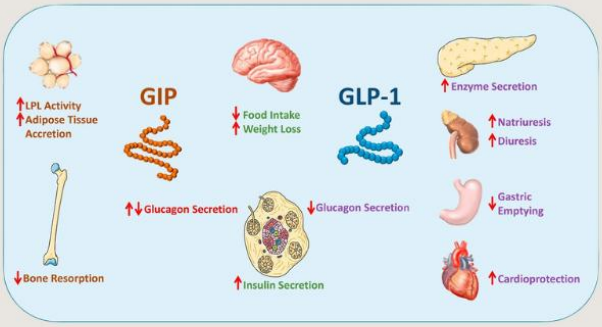
Book Now | Contact Us

HOW IT WORKS
MAINTAINING WEIGHT LOSS

Tirzepatide is a dual GIP and GLP-1 receptor agonist.

- Action on both receptors provides additional benefits
- GLP-1 works to support sustained weight loss
- You'll lose the weight, and keep it off

Book Now | Contact Us



FREQUENTLY ASKED QUESTIONS

How much does Tirzepatide cost

Prices below include 4 FREE Vitamin B12 energy injections!

- 2.5 mg 4 WEEK SUPPLY – $325
- 5.0 mg 4 WEEK SUPPLY – $350
- 7.5 mg 4 WEEK SUPPLY – $410

- 10 mg 4 WEEK SUPPLY - $470
- 12.5 mg 4 WEEK SUPPLY - $540
- 15 mg 4 WEEK SUPPLY - $610

What is Tirzepatide?

How should I use Tirzepatide?

What are the side effects of Tirzepatide?

Important information when using Tirzepatide

Before using Tirzepatide

LUCY'S
LASER + MEDSPA

Hours

Monday: 7:30 am - 5:30 pm
Tuesday: 7:30 am -7:30 pm
Wednesday: 7:30 am -4:00 pm
Thursday: 7:30 am - 5:30 pm
Friday: 7:30 am - 2:00 pm

Contact

(440) 600-0373
lucy@llmspa.com
8806 Mentor Ave, Unit G
Mentor, OH 44060

Privacy Policy

FREQUENTLY ASKED QUESTIONS

How much does Tirzepatide cost

What is Tirzepatide?

Tirzepatide (Zepbound, Mounjaro) is used for weight loss and type 2 diabetes in adults. Tirzepatide is a GIP and GLP-1 receptor agonist and works for weight loss by decreasing your appetite and slowing the movement of food from the stomach into the small intestine, which may make you feel full more quickly and for a longer period of time. Tirzepatide also decreases blood sugar levels by increasing insulin production and lowering the amount of sugar the liver makes.

Tirzepatide is FDA-approved for weight loss for adults with obesity or who are overweight and have weight-related medical problems. Tirzepatide helps you to lose weight and maintain weight loss and should be combined with diet and exercise.

Tirzepatide is given as weekly injections under the skin and are available as single-dose pens in the same strengths 2.5 mg, 5 mg, 7.5 mg, 10 mg, and 12.5 mg.

Tirzepatide is a GIP and GLP-1 receptor agonist, so it works (mechanism of action) by activating both GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide-1) hormone receptors. GLP-1 helps control appetite and calorie intake, and GIP is thought to contribute to regulating food intake as well.

How should I use Tirzepatide?

What are the side effects of Tirzepatide?

Important information when using Tirzepatide

Before using Tirzepatide

FREQUENTLY ASKED QUESTIONS

How much does Tirzepatide cost

What is Tirzepatide?

How should I use Tirzepatide?

It is important to use this medicine exactly as directed. Do not take more or less of it or take it more often than prescribed by your provider.

Tirzepatide is a once-weekly injection given under the skin (subcutaneous) using a pre-filled single-dose pen.

It is usually given:

- Once a week.
- Can be given with or without meals at any time of the day.
- May be injected into the thigh, abdomen, or upper arm.
- You should rotate injection sites with each dose.

What are the side effects of Tirzepatide?

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What are the side effects of Tirzepatide?

Common tirzepatide side effects

The most common tirzepatide side effects include abdominal pain, burping, constipation, diarrhea, dyspepsia, fatigue, gastroesophageal reflux disease, hair loss, hypersensitivity reactions, injection site reactions, nausea, and vomiting, which affects 5% or more patients.

Serious tirzepatide side effects

Stop using this medicine and get emergency medical help if you have:

• Signs of an allergic reaction: hives; difficulty breathing; feeling light-headed; swelling of your face, lips, tongue, or throat; or

• Pancreatitis with symptoms of severe pain in your upper stomach spreading to your back, nausea , and vomiting.

Tirzepatide side effects (more detail)

Call your provider at once if you have:

• Severe stomach problems;

• Eye side effects or vision changes, including blurry vision or blurred vision;

• Signs of a thyroid tumor symptoms may include swelling or a lump in your neck, trouble swallowing, a hoarse voice, or if you feel short of breath;

• Gallbladder problem with symptoms including chalky-colored stools, stomach pain after eating, nausea, heartburn, bloating, and severe upper stomach pain that may spread to your back;

• Low blood sugar symptoms may include headache, hunger, weakness, sweating, confusion, irritability, dizziness, fast heart rate, or feeling jittery or

• Kidney problems with little or no urination, swelling in your feet or ankles, feeling tired or short of breath.

Important information when using Tirzepatide

Before using Tirzepatide

FREQUENTLY ASKED QUESTIONS

- How much does Tirzepatide cost
- What is Tirzepatide?
- How should I use Tirzepatide?
- What are the side effects of Tirzepatide?
- Important information when using Tirzepatide

Tirzepatide may cause thyroid C-cell tumors. It is important to tell your provider if you have a personal or your family has a history of thyroid cancer or a condition called Multiple Endocrine Neoplasia (MEN) syndrome. This is a syndrome that causes tumors to develop on endocrine glands. If you experience any of these symptoms: lump or swelling in your neck, difficulty in swallowing, hoarseness, or shortness of breath, then you should call your provider immediately.

Keep all appointments with your provider, health professionals, and the laboratory. Your provider may order certain tests to check your body's response to this medicine.

- Before using Tirzepatide

FREQUENTLY ASKED QUESTIONS

- How much does Tirzepatide cost
- What is Tirzepatide?
- How should I use Tirzepatide?
- What are the side effects of Tirzepatide?
- Important information when using Tirzepatide
- Before using Tirzepatide

Tell your provider and pharmacist if you are allergic to tirzepatide, any other medications, or any of the ingredients in this medicine. There is a list of ingredients in this medicine, at the bottom of this page.

Tell your provider if you have or have ever had kidney or pancreas disease, a history of diabetic retinopathy or any stomach problems such as difficulty digesting food.

Tell your provider if you plan to become pregnant, are pregnant, or are breastfeeding. If you become pregnant while taking this medicine, you should tell your provider.

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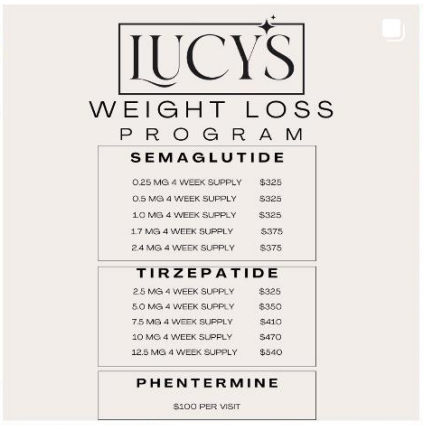

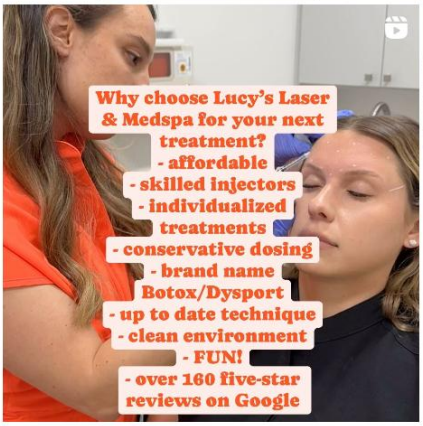

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FAQs : SEMAGLUTIDE / TIRZEPATIDE

Looking for some weight loss assistance but have no idea where to start? Look no further! Both semaglutide and tirzepatide are available at Lucy's Laser & Medspa!

We are taking new patients and eager to assist you in your weight loss journey!

☎4406000373

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Start the conversation.

11 likes
December 13, 2023

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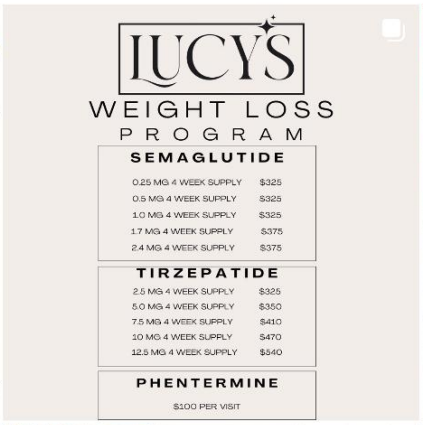
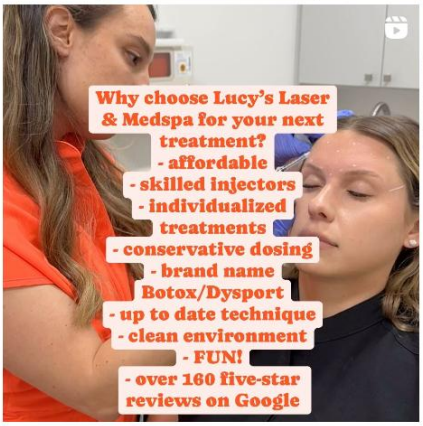
More posts from **lucyslasermedspa**





AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of Ohio

Eli Lilly and Company

Plaintiff(s)

v.

AGV Sason Inc. d/b/a Lucy's Laser & Medspa

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* AGV Sason Inc. d/b/a Lucy's Laser & Medspa
c/o Lucille Zappitelli Sason
6726 Rosemarie Court
Concord, Ohio 44077

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Matthew J. Cavanagh (OH 0079522)
MCDONALD HOPKINS LLC
600 Superior Avenue, East, Ste. 2100
Cleveland, Ohio 44114
Tel. (216) 348-5400

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

SANDY OPACICH, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print