

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

NOVO NORDISK INC.,

Plaintiff,

v.

ELI LILLY AND COMPANY, *et al.*,

Defendants.

Civil Action No. 26-9027 (ZNQ) (RLS)

OPINION

QURAISHI, District Judge

THIS MATTER comes before the Court upon Plaintiff Novo Nordisk Inc.’s (“Novo”) Motion for a Preliminary Injunction (“Motion,” ECF No. 8) seeking to enjoin certain advertising by Defendants Eli Lilly and Company and Lilly USA, LLC (collectively, “Lilly”). Lilly filed an opposition (“Opp’n Br.,” ECF No. 26), to which Novo replied (“Reply Br.,” ECF No. 42). Pursuant to Federal Rule of Civil Procedure 65, the Court conducted an evidentiary hearing (the “Hearing”) on the record on August 27 and 28, 2026. (“Tr.”)

The Court has carefully considered the parties’ submissions as well as the evidence and arguments presented at the Hearing. For the reasons that follow, Novo’s Motion will be **DENIED**.

I. FACTUAL BACKGROUND

A. GLP-1s

Glucagon-like peptide-1 receptor agonists, more commonly known as “GLP-1s,” are prescription medicines used to treat serious chronic conditions, including obesity and type 2

diabetes. (Compl. ¶ 20.) GLP-1s have become one of the most important ways to treat type 2 diabetes and obesity. (*Id.* ¶ 21.)

Approximately 600 million people worldwide currently live with diabetes. (*Id.*) For patients with type 2 diabetes, GLP-1 medications can reduce A1c and improve glycemic control. (*Id.*) A1c is a measurement of a patient's average blood sugar levels over the prior three months and is expressed as a percentage. (*Id.*) This is important, as sustained high blood sugar is associated with serious complications, including cardiovascular disease, kidney disease, nerve damage, and vision loss. (*Id.*) For those living with type 2 diabetes, it is critical to reduce A1c. (*Id.*)

Approximately 100 million people in the United States and 900 million people worldwide meet the clinical criteria for obesity. (*Id.* ¶ 22.) Obesity is a chronic disease associated with serious health risks, including cardiovascular disease, type 2 diabetes, sleep apnea, and other weight-related complications. (*Id.*) GLP-1s, when paired with diet, exercise, and medical supervision, offer an important treatment option for patients with obesity. (*Id.*)

GLP-1s have quickly become some of the most widely known and discussed prescriptions in the United States. (*Id.* ¶ 23.) In 2025, Novo reported approximately \$12.5 billion in sales of obesity care medicines. (*Id.*) It is estimated that more than 30 million Americans may be using a GLP-1 treatment by 2030 and that the global sales for GLP-1s could reach \$190 billion by 2035. (*Id.*)

B. NOVO NORDISK'S WEGOVY AND OZEMPIC

Novo promotes, offers, and sells Wegovy and Ozempic branded medicines throughout the United States. (*Id.* ¶ 14.) These medications are not Novo's first foray into the GLP-1 space. (*Id.* ¶ 24.) In 2010, liraglutide, sold by Novo under the brand name Victoza, became the first GLP-1

approved by the Food and Drug Administration (“FDA”) to treat type 2 diabetes. (*Id.*) Four years later, liraglutide, sold by Novo under the brand name Saxenda, was the first GLP-1 approved by the FDA to treat weight reduction and management in adults. (*Id.*)

Since 2014, Novo has shifted toward semaglutide medicines: specifically, Ozempic and Wegovy. (*Id.* ¶ 25.) Ozempic was approved by the FDA in 2017 to treat type 2 diabetes. (*Id.*) Wegovy was approved by the FDA for weight loss: first, in injectable form in 2021, then in oral tablet form in 2025. (*Id.*) Semaglutide is the only GLP-1 with FDA indications spanning obesity, type 2 diabetes, chronic kidney disease, cardiovascular risk reduction, and metabolic dysfunction-associated steatohepatitis (“MASH”). (*Id.*) Novo is the only pharmaceutical company with FDA-approved medicines containing semaglutide. (*Id.*)

Wegovy, when combined with a reduced-calorie diet and increased physical activity, is indicated to reduce excess body weight and maintain weight reduction long term in adults and pediatric patients aged 12 years and older with obesity and overweight adults presenting with at least one weight-related comorbid condition. (*Id.* ¶ 26.) Wegovy, again in combination with diet and exercise, is also indicated to reduce the risk of major adverse cardiovascular events in overweight or obese adults with established cardiovascular disease. (*Id.*) Wegovy is also indicated to treat noncirrhotic MASH with moderate to advanced liver fibrosis in adults. (*Id.*) Wegovy is administered as a once-weekly subcutaneous injection in doses of 0.25 mg, 0.5 mg, 1 mg, 1.7 mg, and 2.4 mg. (*Id.* ¶ 27.) Patients start treatment at the lowest dose, then increase the dose over time. (*Id.*) Dosing escalation happens in stages in order to minimize gastrointestinal adverse reactions. (*Id.*) Once a patient has reached the maximum dosage he or she can tolerate, the patient continues this “maintenance dose” for ongoing, long-term treatment. (*Id.*) Prior to March 2026, the 2.4 mg dose of Wegovy was the highest recommended maintenance dose. (*Id.*)

In March 2026, the FDA approved Wegovy as a once-weekly 7.2 mg injection. (*Id.* ¶ 28.) Wegovy 7.2 mg is intended for patients who have tolerated Wegovy 2.4 mg and are clinically indicated for additional weight reduction. (*Id.*) The FDA's approval of Wegovy 7.2 mg was based on Novo's STEP UP clinical trial, which evaluated Wegovy 7.2 mg's safety and efficacy as compared to Wegovy 2.4 mg and placebo. (*Id.* ¶ 29.) The trial showed that Wegovy 7.2 prompted greater weight loss than Wegovy 2.4 mg. (*Id.*) In the trial, participants with obesity experienced average weight loss of 18.8% (an average of 47 pounds), and one in three participants achieved a 25% average weight loss (about 62 pounds from baseline body weight). (*Id.*) The STEP UP trial was a double-blind, randomized, placebo-controlled trial. (*Id.* ¶ 30.) In a double-blind trial, neither the participants nor those administering or monitoring treatment know which medicine each participant has been assigned to receive. (*Id.*)

Ozempic is a once-weekly injectable GLP-1 indicated to improve glycemic control in adults with type 2 diabetes. (*Id.* ¶ 31.) In 2022, the FDA approved Ozempic 2 mg, a higher maintenance dose than the already-approved lower Ozempic doses. (*Id.*) Ozempic 2 mg is indicated for adults with type 2 diabetes who may need additional glycemic control. (*Id.*) The FDA's approval was based in part on Novo's SUSTAIN FORTE trial, a double-blind, parallel-group, placebo-controlled trial that found that participants taking Ozempic 2 mg achieved an average A1c reduction of 2.1%, an improvement from Ozempic 1 mg. (*Id.*) In addition to lowering A1c, Ozempic has been shown to significantly lower the risk of major adverse cardiovascular events, such as heart attacks and strokes, in adults with type 2 diabetes mellitus and established cardiovascular disease, as well as reduce the risk of sustained eGFR decline (measure of the rate at which the kidneys filter blood), end stage kidney disease, and cardiovascular death in adults with type 2 diabetes and chronic kidney disease. (*Id.* ¶ 32.)

In the four years following the launch of Wegovy in 2021, Novo's total net sales of GLP-1s indicated to treat obesity increased from approximately \$1.3 billion annually to approximately \$12.6 billion annually. (*Id.* ¶ 34.) In 2025, sales of Ozempic reached approximately \$19.4 billion. (*Id.* ¶ 35.) In 2024, Novo held 55% of the value market share for the GLP-1 segment for type 2 diabetes. (*Id.*)

Novo's STEP UP trial supported the FDA's March 2026 approval of Wegovy 7.2 mg. (*Id.* ¶ 49.) STEP UP tested the efficacy of the highest and most effective dose of Wegovy and evaluated adults with obesity without diabetes who took Wegovy 7.2 mg against Wegovy 2.4 mg and a placebo over 72 weeks. (*Id.*) It showed that participants receiving Wegovy 7.2 mg achieved average weight reduction of 18.8%, or approximately 47 pounds. (*Id.*)

C. LILLY'S ZEPBOUND AND MOUNJARO

Lilly is one of Novo's principal competitors in the market for GLP-1 medicines indicated for type 2 diabetes and weight reduction and management. (*Id.* ¶ 36.) Lilly developed the medication tirzepatide, which is sold under the brand names Zepbound and Mounjaro. (*Id.* ¶ 15.) Tirzepatide is a dual glucose-dependent insulinitropic polypeptide and GLP-1 receptor agonist. (*Id.* ¶ 37.) Much like semaglutide, tirzepatide helps improve blood sugar control, reduce appetite, and support weight reduction. (*Id.*)

In 2022, the FDA approved Mounjaro for adults with type 2 diabetes. (*Id.* ¶ 38.) Mounjaro is a once-weekly subcutaneous injection offered in several doses: 2.5, 5, 7.5, 10, 12.5, and 15 mg. (*Id.*) It is recommended to begin treatment at 2.5 mg, and then increase the dose over time. (*Id.*) The recommended maintenance doses for glycemic control are 5, 10, and 15 mg. (*Id.*) When paired with diet and exercise, Mounjaro is indicated to improve glycemic control in adults with type 2 diabetes. (*Id.* ¶ 40.)

In 2023, the FDA approved Zepbound for weight reduction and management. (*Id.* ¶ 39.) Like Mounjaro, Zepbound is a once-weekly subcutaneous injection offered in the same dose strengths as Mounjaro. (*Id.* ¶ 39.) The range of approved doses for Zepbound has not changed since its introduction in 2023. (*Id.*) Again, like Mounjaro, patients begin treatment at 2.5 mg and increase the dose over time. (*Id.*) The recommended maintenance doses for weight reduction are 5, 10, and 15 mg. (*Id.*) In combination with a reduced-calorie diet and increased physical activity, Zepbound is indicated to reduce excess body weight and maintain weight reduction in obese adults and in overweight adults with at least one weight-related comorbidity. (*Id.* ¶ 40.) Zepbound is also indicated to treat moderate to severe obstructive sleep apnea in obese adults. (*Id.*)

In 2023 and 2024, Lilly sponsored SURMOUNT-5, a clinical trial to evaluate the safety and efficacy of Zepbound as compared to Wegovy in adults living with obesity or overweight adults with at least one weight-related complication but without diabetes. (*Id.* ¶ 42.) SURMOUNT-5 was an open-label trial, which means that participants and trial investigators knew which medication each participant received. (*Id.* ¶ 44.) The FDA has criticized the use of open-label trials to support comparative superiority claims, noting that the “open-label nature” of a comparative trial “introduces bias and reduces the internal validity of the trial results.” (*Id.* ¶ 44.) SURMOUNT-5 evaluated Zepbound 10 mg and 15 mg against Wegovy 1.7 mg and 2.4 mg. (*Id.* ¶ 45.) At the time the trial was conducted, those were the highest recommended maintenance doses of the medicines. (*Id.*) Participants treated with Zepbound 10 mg or 15 mg achieved an average weight reduction of 20.2%, compared to 13.7% for Wegovy 1.7 mg or 2.4 mg. (*Id.* ¶ 46.) In absolute weight terms, Zepbound patients lost on average 50.3 pounds compared to Wegovy patients who lost 33.1 pounds. (*Id.*) Critically, SURMOUNT-5 did not test Wegovy 7.2 mg because that dose had not yet been approved at the time the trial was conducted. (*Id.* ¶ 47.)

In 2022, Lilly sponsored SURMOUNT-1, a double-blind, randomized, placebo-controlled trial that evaluated tirzepatide, the active ingredient in Zepbound, for the treatment of obesity. (*Id.* ¶ 48.) SURMOUNT-1 examined obese adults or overweight adults with a weight-related comorbidity but without diabetes who took tirzepatide at doses of 5 mg, 10 mg, and 15 mg, or placebo, over 72 weeks. (*Id.* ¶ 48.) Participants receiving the 5 mg dose achieved average weight reduction of 15%, while participants receiving the 10 mg and 15 mg doses achieved average weight reduction of 19.5% and 20.9%, respectively. (*Id.* ¶ 48.)

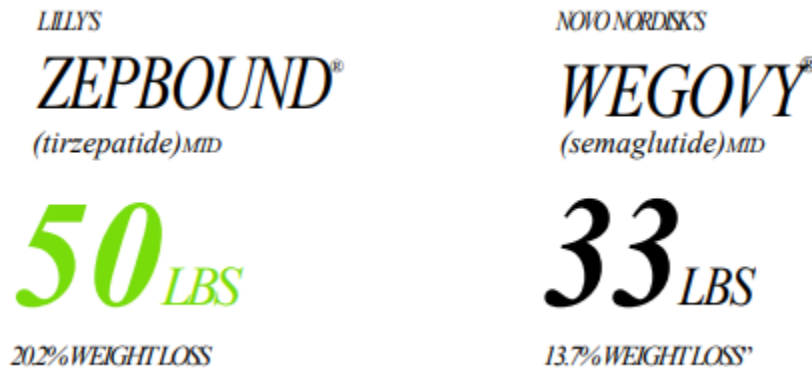
In 2021, Lilly published the results of SURPASS-2, a clinical trial designed to evaluate the safety and efficacy of tirzepatide, the active ingredient in Mounjaro, as compared to injectable semaglutide, the active ingredient in Ozempic, in adults with type 2 diabetes whose blood sugar was inadequately controlled with metformin¹ alone. (*Id.* ¶ 51.) SURPASS-2 was a 40-week, randomized, Phase 3 trial and examined 5, 10, and 15 mg of tirzepatide against 1 mg of semaglutide. (*Id.* ¶ 52.) SURPASS-2 was an open-label trial. (*Id.*) The trial reported greater reductions in A1c for participants treated with tirzepatide than for patients treated with semaglutide. (*Id.* ¶ 53.) Note that SURPASS-2 did not compare tirzepatide to semaglutide 2 mg. (*Id.* ¶ 54.)

D. LILLY’S COMPARATIVE ADVERTISING FOR ZEPBOUND

Lilly has launched a national comparative advertising campaign that cites the results of SURMOUNT-5 and makes comparative claims about the efficacy of Zepbound and Wegovy. (*Id.* ¶ 55.) This campaign includes commercials aired on television. (*Id.* ¶ 56.) Prior to the approval of Wegovy 7.2 mg, Lilly’s commercial included the following voiceover claim: “In a study, people

¹ Metformin is another medication indicated for the treatment of type 2 diabetes. (Compl. ¶ 51.)

using Zepbound lost an average of 50 pounds compared to an average of 33 pounds with the Wegovy injection.” (*Id.*) It also included the following written claim, reproduced below:



(*Id.*) Additionally, the commercial included a written disclaimer: “Data collected in a less-rigorous study. Findings less certain. Factors beyond medications may have contributed to weight loss. In a study of adults without diabetes with diet & exercise, average weight loss: Zepbound MTD (maximum tolerated dose, 10 mg or 15 mg); 20.2% (50 lbs). Wegovy injection MTD (1.7 mg or 2.4 mg) 13.7% (33 lbs). Avg baseline weight: 248.4 lbs (Zepbound MTD). 250 lbs (Wegovy MTD).” (*Id.*) A screenshot of the commercial is below:



(*Id.*)

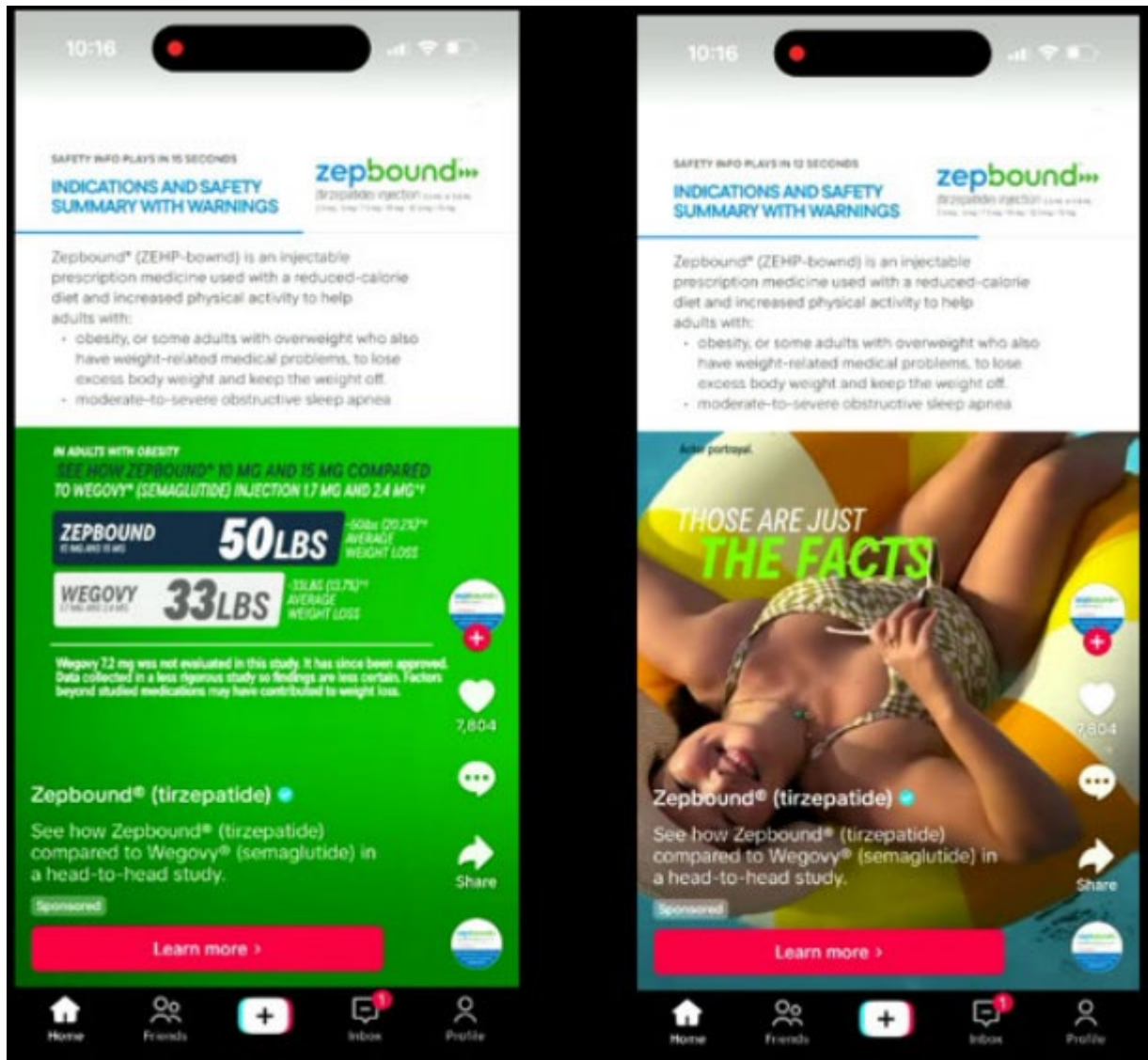
On April 22, 2026, Novo wrote to Lilly and objected to Lilly’s continued use of the above commercial following the FDA’s approval of Wegovy 7.2 mg in March 2026. (*Id.* ¶¶ 57–58.) Novo explained that, in the STEP UP trial, Wegovy had been shown to provide greater weight loss than Wegovy 2.4 mg and that Lilly’s continued reliance on the SURMOUNT-5 trial misleads consumers about the comparative efficacy of Wegovy and Zepbound. (*Id.* ¶ 58.) Novo requested that Lilly suspend the commercial and refrain from making future consumer-directed comparative claims based on SURMOUNT-5. (*Id.* ¶ 59.) Lilly did not respond to Novo’s letter. (*Id.*)

Shortly after Novo sent its April 22, 2026 letter, Lilly modified the commercial to include additional language in the voiceover, written claim, and disclaimer. (*Id.* ¶ 60.) The updated voiceover claim stated: “In a study, people using **Lilly’s** Zepbound lost an average of 50 pounds compared to an average of 33 pounds with ***up to a 2.4 mg dose of*** the Wegovy injection.” (*Id.* (emphasis in original).) The updated written disclaimer stated that “***Wegovy 7.2 mg was not evaluated in this study. It has since been approved.*** Data collected in a less-rigorous study. Findings less certain. Factors beyond medications may have contributed to weight loss. In a study of adults without diabetes with diet & exercise, average baseline weight: 248.4 lbs (Zepbound. 250 lbs (Wegovy).” (*Id.* (emphasis in original).) A screenshot of the updated commercial is below:



(*Id.*) Lilly also made revisions to the comparative claims on its consumer-facing Zepbound website. (*Id.* ¶ 61.)

Lilly also utilized social media marketing in its advertising campaign. (*Id.* ¶ 63.) The ad that launched on TikTok and Facebook in June 2026 repeats the same central comparison challenged in the above commercial. (*Id.* ¶ 63.) The social media advertising describes the comparison as a “head-to-head study” and, after presenting the comparison, states: “Those are just the facts.” (*Id.*) The TikTok advertisement includes a small-print disclosure stating that Wegovy 7.2 was not evaluated in the study and has since been approved. (*Id.*) A screenshot of the TikTok advertisement is reproduced below:

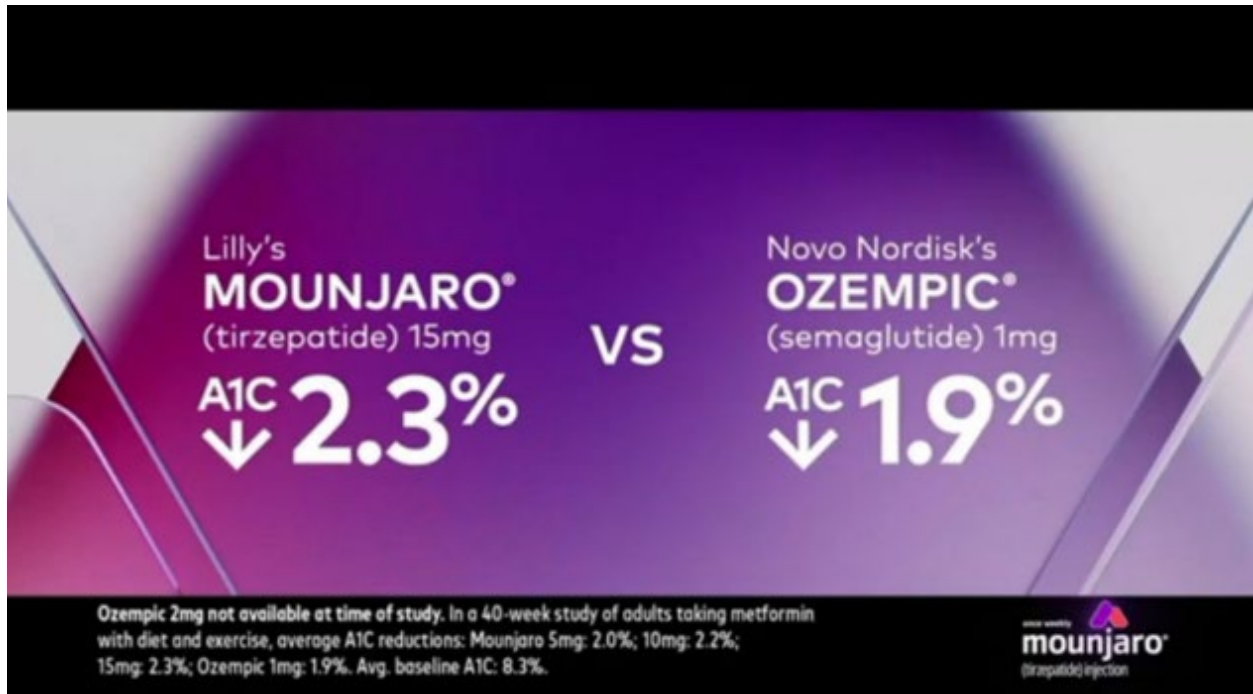


(Id.)

E. LILLY'S COMPARATIVE ADVERTISING FOR MOUNJARO

Lilly also disseminated a national television commercial making comparative claims for Mounjaro, Lilly's tirzepatide medicine indicated for type 2 diabetes. (*Id.* ¶ 67.) In this commercial, Lilly compares Mounjaro to Novo's Ozempic and presents a side-by-side efficacy claim stating that Lilly's Mounjaro 15 mg reduced A1c by 2.3%, compared to a 1.9% A1c reduction for Novo's Ozempic 1 mg. (*Id.*) This commercial includes a small-print disclaimer

stating: “Ozempic 2mg not available at the time of study.” (*Id.*) A screenshot of the commercial is reproduced below:



(*Id.*) The same comparison is made on Lilly’s consumer-facing Mounjaro website. (*Id.* ¶ 69.)

II. PROCEDURAL HISTORY

On July 21, 2026, Novo filed this suit based on Lilly’s Mounjaro and Zepbound advertisements. (*See generally id.*) Novo alleges false advertising and unfair competition under the Lanham Act and unfair competition under New Jersey law. (*Id.*) Three days later, Novo moved for a preliminary injunction, seeking to enjoin the advertisements and compel Lilly to run “corrective advertising” telling consumers that Lilly’s advertising was “deceptive.” (ECF No. 8.)

On July 24, 2026, the Court set a case management teleconference with counsel for the parties to be held on July 28, 2026. (ECF No. 10.) During the call, the Court set August 27 and 28, 2026 as the dates for a two-day hearing and ordered a briefing schedule for the opposition and reply to the Motion. (ECF No. 13.) The Court emphasized that it sought an *evidentiary* hearing (the “Hearing”) rather than mere oral argument from counsel. The primary purpose of the Hearing

was to provide Lilly with an opportunity to challenge Novo's proofs that were previously provided to the Court as well as an opportunity for Lilly to introduce its own evidence. The Court instructed counsel to meet and confer and submit a proposed agenda for the two-day hearing that included identification of witnesses and a proposed schedule. The parties timely submitted a proposed schedule—which although it presented some disputes, was largely agreed upon. (ECF No. 49.)

III. THE TWO-DAY HEARING

On August 27 and 28, the Court conducted the Hearing. Counsel were organized and well prepared. The Hearing proceeded efficiently, with ample time to call and cross-examine the parties' twelve witnesses, who all appeared in person. For the benefit of the parties and appellate review, the Court will describe the topics of the witnesses' testimony, together with its assessment of each witness's credibility.

Novo presented testimony from the following witnesses:

- Andrea Traina;
- Dr. Michael Radin;
- Derrick Gastineau;
- Hal Poret;
- Dr. Bruce Isaacson; and
- Edward Cinca.

IV. WITNESS TESTIMONY: ANDREA TRAINA (DAY 1 TR. 93:20)

Andrea Traina is the Medical Director Lead for the obesity and liver health therapeutic areas at Novo. (Declaration of Andrea Traina ("Traina Decl."), ECF No. 8-2 ¶ 1.) She has been in this role since December 2025 and has nearly two decades of experience specializing in endocrinology. (*Id.* ¶¶ 1–2.) Traina testified consistent with the topics covered in her Declaration (*Id.*) and Reply Declaration (ECF No. 43). Mainly, she discussed Wegovy and Ozempic's efficacy and the STEP UP and SURMOUNT trials. She also testified as to the importance of comparative efficacy to patients. On the whole, assessing Traina's demeanor, manner in which she testified,

and the substance of her testimony together with other corroborative evidence, the Court found Traina's testimony credible.

A. WITNESS TESTIMONY: DR. MICHAEL RADIN (TR. 129:1–164:17)

Dr. Michael Radin is the Medical Director Lead, Diabetes & Renal, Medical Affairs at Novo. (Declaration of Dr. Michael Radin ("Radin Decl."), ECF No. 18-8 ¶ 1.) He has served in that role for five years. (*Id.*) He has over two decades of research experience in endocrinology, diabetes, and metabolism and has been an investigator in over 30 clinical research trials and have authored 11 peer-reviewed publications in these areas. (*Id.* ¶ 6.) Dr. Radin testified consistent with the topics covered in his Declaration (*Id.*), including concerning Lilly's advertisements, the harm Lilly's advertisements are causing to Novo, and to respond to defenses Lilly raised in its opposition papers. On the whole, assessing Dr. Radin's demeanor, manner in which he testified, and the substance of his testimony together with other corroborative evidence, the Court found Dr. Radin's testimony credible.

B. WITNESS TESTIMONY: DERRICK GASTINEAU (DAY 1 TR. 165:5)

Derrick Gastineau serves as VP, US Therapeutic Area – Obesity and US Brand Leader of the Wegovy and CagriSema brands at Novo. (Declaration of Derrick Gastineau ("Gastineau Decl.") ECF No. 8-29 ¶ 1.) In this role, Gastineau leads Wegovy marketing and is responsible for developing, reviewing, and incorporating insights from consumer and market research into marketing strategies. (*Id.* ¶ 2.) Gastineau testified consistent with the topics covered in his Declaration (*Id.*), including the success of Novo's GLP-1 medications, Lilly's challenged advertising campaigns, and Novo's challenge to Lilly's advertising. He initially asserted that there was no change that Lilly could make to the challenged advertisements to prevent them from being misleading. (Day 1 Tr. 180:1–181:8.) He later testified that Lilly needed to provide additional information regarding the efficacy of Novo's 7.2 mg product, but that it would be improper for

Lilly to compare Lilly's SURMOUNT-5 clinical study to Novo's STEP UP clinical study. (*Id.* 182:5–189:10). His testimony was also evasive. On more than one occasion, he needed to be reminded to answer counsel's questions. (*Id.* 187:22 (examining counsel); 189:9–11, 22–25 (Court).) On the whole, assessing Gastineau's demeanor, manner in which he testified, and his conflicting, contradictory, and evasive testimony, the Court found his testimony was of low credibility.

C. WITNESS TESTIMONY: HAL PORET (DAY 1 TR. 204:19)

Dr. Hal Poret is the President of Hal Poret LLC, a survey research firm located in New York. (Declaration of Hal Poret ("Poret Decl."), ECF No. 18-48 ¶ 1.) Poret was retained by Novo to design and conduct a scientific survey to test whether a television commercial for Lilly's Mounjaro misleadingly communicates that Mounjaro is generally superior to Ozempic without adequately disclosing that the clinical study underlying that claim did not test Mounjaro against the highest and most effective dose of Ozempic currently available. (*Id.* ¶ 2.) Poret testified consistent with the topics covered in his Declaration (*Id.*) and Reply Declaration and Report (ECF Nos. 46 and 46-1), including the survey he conducted, as well as to respond to criticisms of Lilly's expert witnesses. On the whole, assessing Poret's demeanor, manner in which he testified, and the substance of his testimony together with other corroborative evidence, the Court found Poret's testimony credible.

D. WITNESS TESTIMONY: DR. BRUCE ISAACSON (DAY 1 TR. 271:3)

Dr. Bruce Isaacson is the Senior Managing Director and head of the Advisory Group business unit at IMS Legal Strategies. (Declaration of Dr. Bruce Isaacson ("Isaacson Decl."), ECF No. 8-43 ¶ 1.) This group provides expert witness and consulting services to law firms and corporations. (*Id.*) Dr. Isaacson was retained by Novo to design and conduct a scientific survey

to test whether a direct-to-consumer television commercial for Lilly's Zepbound medication communicates three messages to consumers: (1) that Zepbound helps patients lose significantly more weight than Wegovy; (2) that patients can lose 33 pounds with Wegovy; and (3) that the SURMOUNT-5 study tested the highest dose of Wegovy that is currently available to patients. (*Id.* ¶ 2.) Dr. Isaacson testified consistent with the topics covered in his Declaration (*Id.*) and Report (ECF No. 8-44) and to respond to criticisms of Lilly's expert witnesses. On the whole, assessing Dr. Isaacson's demeanor, manner in which he testified, and the substance of his testimony together with other corroborative evidence, the Court found Dr. Isaacson's testimony credible.

E. WITNESS TESTIMONY: EDWARD CINCA (DAY 1 TR. 354:3)

Edward Cinca is Novo's Senior Vice President for Marketing. (Tr. 23:19.) He is responsible for Novo's marketing strategies as well as insights and analytics that inform the strategies in which Novo communicates to patients and health care providers. (*Id.* at 354:21–24.)² On the whole, assessing Cinca's demeanor, manner in which he testified, and the substance of his testimony together with other corroborative evidence, the Court found Cinca's testimony credible.

Lilly presented testimony from:

- Dr. David Hyman;
- Janet Potts;
- Fernando Campo;
- Mark Stempel;
- Dr. David Neal; and
- Dr. Ran Kivetz.

² Lilly objected to Cinca's testimony because Novo introduced a declaration on his behalf for the first time on Reply. (*See id.* at 349:15–352:24.) Novo asserted at the hearing that Cinca would respond to Dr. David Hyman and Mark Stempel's declarations. The Court allowed Cinca to testify at the Hearing but reserved as to the scope of his testimony that it would consider. Having reviewed the record, the Court notes that it does have some concerns about the way Novo inserted Mr. Cinca as a declarant/witness. Nevertheless, the Court has considered in full Mr. Cinca's testimony from the Hearing. The Court's consideration of Cinca's testimony, however, is limited to the purposes of this motion only. Accordingly, the Court overrules Lilly's objection.

F. WITNESS TESTIMONY: DR. DAVID HYMAN (DAY 2 TR. 8:22)

Dr. David Hyman is Lilly's Chief Medical Officer. (Declaration of Dr. David Hyman ("Hyman Decl."), ECF No. 34 ¶ 1.) In this role, Dr. Hyman oversees all clinical development, patient safety, statistics, and regulatory work across Lilly's portfolio of products. (*Id.*) Dr. Hyman testified about the importance of head-to-head clinical trials, Lilly's SURPASS-2 and SURMOUNT-5 clinical trials, the continued validity of Lilly's clinical trials and SURPASS-2 and SURMOUNT-5 advertising, Novo's reliance on inappropriate cross-trial comparisons, and Novo's studies and advertising practices. On the whole, assessing Dr. Hyman's demeanor, manner in which he testified, and the substance of his testimony together with other corroborative evidence, the Court found Dr. Hyman's testimony credible.

G. WITNESS TESTIMONY: MARK STEMPEL (DAY 2 TR. 42:19)

Mark Stempel is Lilly's Senior Vice President and Chief Financial Officer. Stempel testified as to weekly prescription data showing the prevalence of the advertised doses of Mounjaro, Zepbound, Ozempic, and Wegovy and the continued validity of Lilly's SURPASS-2 and SURMOUNT-5 advertising. On the whole, assessing Stempel's demeanor, manner in which he testified, and the substance of his testimony together with other corroborative evidence, the Court found Stempel's testimony credible.

H. WITNESS TESTIMONY: JANET POTTS (DAY 2 TR. 50:17)

Janet Potts is the Vice President of Immunology Strategy at Lilly. (Declaration of Janet Potts ("Potts Decl."), ECF No. 27 ¶ 1.) Potts testified as to the development, timing, content, and continued validity of Lilly's SURPASS-2 advertising. On the whole, assessing Potts's demeanor, manner in which she testified, and the substance of her testimony together with other corroborative evidence, the Court found Potts's testimony credible.

I. WITNESS TESTIMONY: FERNANDO CAMPO (DAY 2 TR. 76:19)

Fernando Campo is the Vice President and Head of United States Obesity and Obstructive Sleep Apnea Marketing at Lilly. (Declaration of Fernando Campo (“Campo Decl.”), ECF No. 28 ¶ 1.) Campo oversees brand marketing for Zepbound and provided marketing or brand input into the development of the SURMOUNT-5 claim. (*Id.* ¶ 2.) Campo testified as to the development, timing, content, and continued validity of Lilly’s SURPASS-5 advertising. On the whole, assessing Campo’s demeanor, manner in which he testified, and the substance of his testimony together with other corroborative evidence, the Court found Campo’s testimony credible.

J. WITNESS TESTIMONY: DR. DAVID NEAL (DAY 2 TR. 103:15)

Dr. David Neal is the Managing Partner of Catalyst Behavioral Sciences LLC and publishes extensively in the areas of consumer behavior and decision-making. (Declaration of Dr. David T. Neal, PH.D. (“Neal Decl.”), ECF No. 31 ¶¶ 1–2.) Dr. Neal testified as to the topics covered in his report (ECF No. 31), which included his own surveys, which showed no actionable deception for Lilly’s SURPASS-2 advertisements and Lilly’s SURMOUNT-5 advertisements. Dr. Neal also discussed flaws in Novo’s experts’ surveys. On the whole, assessing Dr. Neal’s demeanor, manner in which he testified, and the substance of his testimony together with other corroborative evidence, the Court found Dr. Neal’s testimony credible.

K. WITNESS TESTIMONY: DR. RAN KIVETZ (DAY 2 TR. 130:16)

Dr. Ran Kivetz is the Philip H. Geier, Jr., chaired Professor of Marketing at Columbia University Business School. (Declaration of Dr. Ran Kivetz (“Kivetz Decl.”), ECF No. 31 ¶ 2.) Dr. Kivetz testified as to the topics covered in his report (ECF No. 30), including flaws in Novo’s experts’ surveys. On the whole, assessing Dr. Kivetz’s demeanor, manner in which he testified,

and the substance of his testimony together with other corroborative evidence, the Court found Dr. Kivetz's testimony credible.

V. SUBJECT MATTER JURISDICTION

The Court has original jurisdiction over the subject matter of this action pursuant to 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331, 1338 based on the Complaint's claims under federal law. The Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367(a).

VI. LEGAL STANDARD

A. PRELIMINARY INJUNCTIVE RELIEF

Federal Rule of Civil Procedure 65 governs motions for temporary and preliminary injunctive relief. Fed. R. Civ. P. 65. "A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. NRDC, Inc.*, 555 U.S. 7, 24 (2008); *Greater Phila. Chamber of Commerce v. City of Phila.*, 949 F.3d 116, 133 (3d Cir. 2020) (courts should grant preliminary injunctions only in "limited circumstances"). To obtain a preliminary injunction under the Rule, a movant must show:

- (1) a reasonable probability of eventual success in the litigation, and
 - (2) that it will be irreparably injured . . . if relief is not granted . . .
- [In addition,] the district court, in considering whether to grant a preliminary injunction, should take into account, when they are relevant, (3) the possibility of harm to other interested persons from the grant or denial of the injunction, and (4) the public interest.

Reilly v. City of Harrisburg, 858 F.3d 173, 176 (3d Cir. 2017) (quoting *Del. River Port Auth. v. Transam. Trailer Transp., Inc.*, 501 F.2d 917, 919–20 (3d Cir. 1974)). Of these factors, the first two are "most critical," and a movant's failure to establish either at the "gateway" requires the denial of the requested relief. *Reilly*, 858 F.3d at 179 (quoting *Nken v. Holder*, 556 U.S. 418, 434 (2009)).

B. THE LANHAM ACT: FALSE ADVERTISING

The Lanham Act prohibits false advertising. *See* 15 U.S.C. § 1125. “[A]nyone who, in connection with goods or services in commerce uses any false description or representation may be liable for damages or subject to an injunction barring such activities.” *CareDx, Inc. v. Natera, Inc.*, App. Nos. 23-2427/23-2428, 2025 WL 2480117, at *4 (3d Cir. Aug. 28, 2025) (interior quotation marks and citation omitted). To prevail on a Lanham Act false advertising claim, a plaintiff must prove: 1) that the defendant has made false or misleading statements as to his own product [or another’s]; 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods traveled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc. *Id.* (alterations in original), *cert. denied*, 146 S. Ct. 2693 (2026); *Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 198 (3d Cir. 2014) (citation omitted).

The Lanham Act includes an unusual feature with respect to motions for preliminary injunction. It was implemented in 2020 when Congress passed the Trademark Modernization Act (“TMA”). Under the TMA, a Lanham Act plaintiff seeking injunctive relief is “entitled to a rebuttal presumption of irreparable harm . . . upon a finding of likelihood of success on the merits.” 15 U.S.C. § 1116(a); *see Nichino Am., Inc. v. Valent U.S.A. LLC*, 44 F.4th 180, 185 (3d Cir. 2022). After the presumption has been established, “the burden of production shifts to the defendant to introduce evidence sufficient for a reasonably factfinder to conclude that the consumer confusion is unlikely to cause irreparable harm.” *Nichino*, 44 F.4th at 186. “If a defendant successfully rebuts the TMA’s presumption by making this slight evidentiary showing, the presumption has no further effect.” *Id.* “It has done its work and simply disappears like a bursting bubble.” *Id.* (citation

omitted). “So the burden of production returns to the plaintiff to point to evidence that irreparable harm is likely absent an injunction.” *Id.* (citations omitted).

VII. DISCUSSION

A. IRREPARABLE HARM

The parties agreed at oral argument that the Court need only consider irreparable harm if it concludes that Novo’s showing in that regard has been insufficient.³ (Day 2 Tr. 192:22–195:17, ECF No. 63). For the reasons set forth below, the Court finds that Novo’s showing in this regard is inadequate to warrant the extraordinary relief it seeks.

Demonstrating irreparable harm is “perhaps the single most important prerequisite for issuing a preliminary injunction.” *Donlow v. Garfield Park Acad.*, Civ. No. 09-6248, 2010 WL 1381010, at *1 (D.N.J. Apr. 1, 2010) (citation omitted). A movant “must demonstrate an injury that is neither remote nor speculative, but actual and imminent.” *In re Revel AC, Inc.*, 802 F.3d 558, 571 (3d Cir. 2015). Before a court may issue preliminary injunctive relief, it must be convinced that the injunction is “the only way of protecting the plaintiff from [the] harm” in

³ Assuming, for the sake of argument, that Novo may have been entitled to a rebuttable presumption of irreparable harm by virtue of its showing of a likelihood of success on the merits, the Court finds that Lilly has presented sufficient evidence to overcome that presumption. As affirmative evidence, Lilly offered the testimony of its CFO, Mark Stempel, who summarized data he obtained from a healthcare data and analytics provider showing volumes of prescriptions for Ozempic and Wegovy at their various dose strengths and formulation type. (Stempel Decl. ¶¶ 13–18, 20–26³.) The data reflects that prescriptions for Novo’s products remained stable during the April–July 2026 period the challenged ads ran. (*Id.*) Lilly also offered Novo’s delay in bringing the current suit, which is generally understood to militate against irreparable harm. Finally, Lilly introduced Novo’s own 2025 annual report (DX-26) and Novo’s own estimation of the value of its goodwill therein as evidence to rebut Novo’s claim that the injury to its goodwill caused by the challenged ads was irreparable partly because it is so difficult to quantify. (Day 1 Tr. 196:8–198:4, ECF No. 62.) This evidence is more than sufficient to meet the “slight evidentiary showing” to dispel any presumption afforded by the TMA.

At oral argument, Novo’s counsel also requested that the Court give some minimal, preliminary assessment of its case with respect to its likelihood of success on the merits. For the benefit of counsel (and any potential appellate review), without delving into a fulsome analysis, the undersigned notes that it found Novo’s case, at least on this very preliminary record, less than persuasive for a number of reasons. First, Novo concedes, as it must, that Lilly makes no actual misrepresentations in the challenged ads. Lilly’s advertisements disclose that 7.2 mg Wegovy is available on the market and was not studied. Second, Lilly’s challenges to the design of Novo’s studies as to consumer confusion left doubts as to their value. Third, Novo’s theory of this case appears to pointedly ignore the extent to which a prescribing doctor influences a would-be patient with regard to choosing a GLP-1.

question. *See Ace Am. Ins. Co. v. Wachovia Ins. Agency Inc.*, 306 F. App'x 727, 731 (3d Cir. 2009). “The dramatic and drastic power of injunctive force may be unleashed only against conditions generating a presently existing actual threat” of irreparable harm. *See Adams v. Freedom Forge Corp.*, 204 F.3d 475, 487 (3d Cir. 2000). “Establishing a risk of irreparable harm is not enough. [Rather,] a clear showing of immediate irreparable injury is required.” *Naccarati v. Wilkins Twp.*, 846 F. Supp. 405, 408 (W.D. Pa. 1993) (citing *ECRI v. McGraw-Hill, Inc.*, 809 F.2d 223, 226 (3d Cir. 1987)). In other words, the risk of irreparable harm cannot be speculative. *Acierno*, 40 F.3d at 655. A court cannot find irreparable harm where a breach can be adequately remedied by monetary damages. *Peterson v. HVM L.L.C.*, Civ. No. 14-1137, 2015 WL 3648839, at *6 (D.N.J. June 11, 2015).

Here, Novo asserts that Lilly’s advertising is causing lasting damage to Novo’s clinical reputation. (Moving Br. at 35.) But Novo offers only speculative claims of harm on this topic. In its briefing and its testimony, Novo baldly asserts, without citing or submitting any supporting evidence, that the challenged ads threaten future sales of Novo’s products and have harmed the goodwill Novo has cultivated over the years.⁴ (Moving Br. 34–36; Reply at 12; Gastineau Decl. ¶¶ 24–29.)

At the evidentiary hearing, Novo’s Gastineau testified that “[i]t’s nearly impossible to quantify the damage” to the goodwill of Novo and its brands. (Day 1 Tr. 176:3–12.) He stated that he had not attempted to determine its purported Novo’s harm. (Day 1 Tr. 196:13–16.) When confronted with a copy of Novo’s Annual Report during cross-examination that included a valuation of the company’s goodwill, he acknowledged that Novo does quantify its goodwill on a yearly basis. (*Id.*)

⁴ Novo also argued — again, without support — that prescribers are switching patients from Novo’s products to Lilly’s.

In fact, even though Novo “conduct[s] ongoing primary market research studies” (Day 1 Tr. 173:10–19), Gastineau confirmed that he did not attach any consumer insights to his declaration (Tr. 184:15–23). This is especially problematic considering that in his declaration, Gastineau baldly claims that “Lilly’s advertising necessarily will divert patient demand and prescriptions from Novo to Lilly’s medicines.” (Gastineau Decl. ¶ 25.) Gastineau’s failure to include any supporting documentation or evidence is fatal, because “bald assertion[s] of irreparable harm” do not establish an injury that is actual and imminent. *Johnson & Johnson*, 173 F.4th at 464–65.

On the other hand, Lilly introduced direct evidence that the market effect of the challenged ads in the three months between August and July has been negligible, if any. Its CFO, Mark Stempel, summarized data he obtained from a healthcare data and analytics provider that showed volumes of prescriptions for Ozempic and Wegovy at their various dose strengths and formulation type. (Stempel Decl. ¶¶ 13–18, 20–26.) The data reflects that prescriptions for Novo’s products remained stable between April and July. (*Id.*)

Finally, to the extent Novo might nevertheless suffer nontrivial harm without a preliminary injunction, it has not shown that its injury would be irreparable insofar as it could not be remedied by money damages.

For these reasons, the Court finds that Novo has not met its burden of showing irreparable harm. Insofar as it has not demonstrated this gateway factor, the Court finds its motion for a preliminary injunction must be denied on that basis.

B. UNCLEAN HANDS

As a separate matter, Lilly argues that Novo’s own advertising precludes it from obtaining injunctive relief. Specifically, Lilly asserts that Novo itself has engaged in the same behavior, and

thus Novo's motion should also be denied based on the doctrine of unclean hands. Lilly's position is persuasive.

"The equitable doctrine of unclean hands applies when a party seeking relief has committed an unconscionable act immediately related to the equity the party seeks in respect to the litigation." *Pharmacia v. GlaxoSmithKline Consumer Healthcare*, 292 F. Supp. 2d 594, 610 (D.N.J. 2003) (citing *Highmark v. UPMC Health Plan*, 276 F.3d 160, 174 (3d Cir. 2001)). The doctrine applies to Lanham Act cases. *Id.* (citation omitted). Still, courts do not apply the unclean hands doctrine automatically to plaintiffs who may have engaged in *some* inequitable conduct. The inequitable conduct identified by the defendant must "evinced a very close nexus" to the defendant's own misconduct that initially gave rise to the suit. *Id.* (citation omitted). The defendant must do more than merely allege misconduct; there must also be a claim that the defendant was injured "as a result of the misconduct." *Id.* (citing *Jiffy Lube Int'l, Inc. v. Jiffy Lube of Pa., Inc.*, Civ. No. 91-6818, 1992 WL 13682, *11 (E.D. Pa. Jan. 27, 1992), *aff'd*, 980 F.2d 723 (3d Cir. 1992)).

Novo contends that Lilly's advertisements are false and misleading because they rely on "outdated trials that did not test the highest and most effective approved doses of Novo's medicines currently available to patients." (Compl. ¶ 97.) In making this assertion, Novo turns a blind eye to its own advertising history. After Lilly received FDA approval for higher doses of Trulicity, Novo continued to make superiority claims based on Novo's SUSTAIN-7 clinical trial. (*See* Opp'n Br. at 35-36.) Novo's advertisements lacked any acknowledgement or disclaimer that higher doses of Trulicity were available or that those doses were not tested in the studies on which Novo's claims were based. (*Id.* at 36.) And, tellingly, Novo concedes that it ceased these

advertisements mere days before filing this lawsuit. (Day 1 Tr. 363:4–364:21 (Cinca); Day 2 Tr. 165:11–20 (Bernstein, closing)).

Novo’s attempts to distinguish its past advertising tactics on the basis that the GLP-1 market has since changed and the venues for its advertising were not the same are unavailing. At bottom, Novo engaged in a nearly identical advertising strategy and now complains because it is being subjected to similar conduct. That Lilly’s actions here might arguably be somewhat less palatable is not dispositive. *See Haagen-Dazs, Inc. v. Frusen Gladje Ltd.*, 493 F. Supp. 73, 76 (S.D.N.Y. 1980) (“[S]ince plaintiff’s hands are similarly unclean, they may not secure equitable relief simply because defendants’ hands may be a shade or two less clean.”). On this basis, the Court would also exercise its discretion to deny Novo the preliminary injunctive relief that it seeks.

VIII. CONCLUSION

For the reasons stated above, the Court will **DENY** Novo’s Motion for a Preliminary Injunction. An appropriate Order will follow.

Date: October 26, 2026

s/ Zahid N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE