IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

NOVO NORDISK A/S and NOVO NORDISK INC., Plaintiffs, v. HIMS & HERS HEALTH, INC. and HIMS, INC., Defendants.	Case No. _____ DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiffs Novo Nordisk A/S ("NNAS") and Novo Nordisk Inc. ("NNI") (collectively, "Plaintiffs" or "Novo Nordisk") file their complaint against Hims & Hers Health, Inc. and Hims, Inc. (together, "Hims" or "Defendants") for patent infringement, and state as follows:

INTRODUCTION

1. Building on decades of research and billions of dollars invested, Novo Nordisk has been a pioneer at the forefront of research studying a class of molecules known as glucagon-like peptide 1 receptor agonists ("GLP-1s").[1] These GLP-1s are designed to bind GLP-1 receptors, mimicking the function of naturally occurring GLP-1 hormones. This case concerns Novo Nordisk's discovery and development of a particular GLP-1 molecule called semaglutide.

2. Semaglutide is the active pharmaceutical ingredient in Ozempic®, Wegovy®, and Rybelsus®—medicines approved by the U.S. Food and Drug Administration ("FDA") based on its

[1] *GLP-1-Based Therapy for Obesity*, LASKER FOUND., https://laskerfoundation.org/winners/glp-1-based-therapy-for-obesity (last visited Feb. 7, 2026).

review of clinical trials and testing that demonstrated these drugs are safe and effective. To bring these innovative drugs to market, Novo Nordisk met the demanding requirements under the laws and regulations governing the approval of pharmaceutical drug products, which ensure the safety, effectiveness, and quality of medicines before they reach patients. This process gives the public confidence in the medicines that millions take every day.

3. Novo Nordisk's intellectual property, including U.S. Patent No. 8,129,343 (the "'343 Patent"), protects semaglutide and the pharmaceutical products containing it, which Novo Nordisk developed through intensive research and development. The '343 Patent is attached hereto as Exhibit 1. Pursuant to United States laws and regulations, Novo Nordisk listed the '343 Patent, among others, in FDA's Orange Book for Ozempic®, Wegovy®, and Rybelsus®. Other pharmaceutical companies that wish to develop and make generic semaglutide products have applied for FDA approval of their proposed generic products, and in doing so filed with FDA required certifications as to Novo Nordisk intellectual property.

4. Defendants, however, attempt to circumvent the regulatory process by marketing products it describes as "compounded GLP-1s" that have not been reviewed or approved by FDA. Defendants' compounded semaglutide products, which contain semaglutide, infringe the '343 Patent and are referred to herein as the Accused Products. On its websites, Hims states that its compounded GLP-1 products contain "the same active ingredient in the brand-name medication Wegovy® and Ozempic®," which the websites further describe as semaglutide. Novo Nordisk, however, does not directly or indirectly sell semaglutide API for use in compounding. Instead, Hims markets compounded semaglutide that it admits on its website is "not approved or evaluated

for safety, effectiveness, or quality by the FDA."[2] Novo Nordisk files this lawsuit to stop Hims' ongoing infringement.

THE PARTIES

5. Plaintiff NNAS is an entity organized and existing under the laws of the Kingdom of Denmark and has its principal place of business at Novo Allé, 2880 Bagsværd, Denmark.

6. NNAS developed the Ozempic®, Rybelsus®, and Wegovy® medicines.

7. Plaintiff NNI is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 800 Scudders Mill Rd., Plainsboro, New Jersey 08536. NNI is an indirect, wholly owned subsidiary of NNAS.

8. NNI promotes, offers, and sells Novo Nordisk's Ozempic®, Rybelsus®, and Wegovy® medicines throughout the United States, including in this District.

9. On information and belief, Defendant Hims & Hers Health, Inc. is a Delaware corporation with its principal place of business at 2269 Chestnut Street, #523, San Francisco, California 94123.

10. On information and belief, Defendant Hims, Inc. is a Delaware corporation and a fully owned subsidiary of Hims & Hers Health, Inc., with its principal place of business at 2269 Chestnut Street, #523, San Francisco, California 94123.

JURISDICTION AND VENUE

11. Novo Nordisk's claims for patent infringement against Defendants arise under the patent laws of the United States, including 35 U.S.C. §§ 271 and 281–85.

[2] *E.g.*, *Weight Loss*, HIMS, https://www.hims.com/weight-loss (last visited Feb. 7, 2026).

12. This Court has original subject matter jurisdiction over this suit pursuant to 28 U.S.C. §§ 1331 and 1338.

13. Defendants are subject to personal jurisdiction in Delaware because they are incorporated in Delaware.

14. On information and belief, Hims & Hers Health, Inc. is a Delaware corporation with a registered agent in the State of Delaware located at 108 Lakeland Ave., Dover, Delaware 19901. Thus, Hims & Hers Health, Inc. resides within, and has consented to personal jurisdiction within, this District.

15. On information and belief, Hims, Inc. is a Delaware corporation with a registered agent in the State of Delaware located at 108 Lakeland Ave., Dover, Delaware 19901. Thus, Hims, Inc. resides within, and has consented to personal jurisdiction within, this District.

16. In addition, Defendants, directly or through agents, subsidiaries, or intermediaries, have committed acts within Delaware giving rise to this action and/or have established minimum contacts with Delaware such that this Court's exercise of jurisdiction would not offend traditional notions of fair play and justice. On information and belief, Defendants have regularly and systematically transacted business in Delaware directly or through agents, subsidiaries, or intermediaries, and/or committed acts of patent infringement in Delaware, as alleged in this Complaint, that will lead to foreseeable harm and injury to Novo Nordisk. On information and belief, Defendants have placed, and continue to place, infringing products into the stream of commerce by offering infringing products for sale in Delaware, shipping those products into Delaware, or knowing that the products would be shipped into Delaware. On information and belief, Defendants have purposefully availed themselves of the privilege of doing business in Delaware, and they have maintained such continuous and systematic contacts so as to authorize

this Court's exercise of personal jurisdiction over them in this matter. For example, Hims's websites indicate that it markets "Compounded Semaglutide (GLP)-1 treatment" to patients in Delaware.[3]

17. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400, at least because Defendants reside in this district by virtue of their organization under the laws of the State of Delaware.

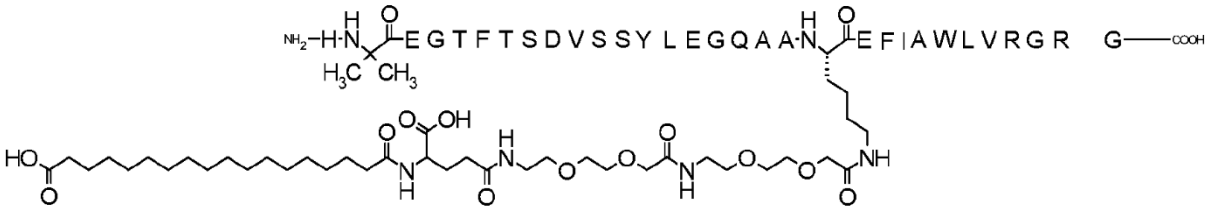
18. Defendants are jointly and severally liable for infringing one or more claims of the Asserted Patent. Defendants' liability stems from the same transactions or occurrences regarding the use, sale, offer for sale, and/or inducement of manufacture, sale, offer for sale, or use and/or the importation of semaglutide or compounded products containing semaglutide, including the Accused Products. Consequently, this action involves questions of law and fact common to all Defendants.

NOVO NORDISK'S FDA-APPROVED SEMAGLUTIDE MEDICINES

19. Semaglutide, also known as N6.26-{18-[N-(17-carboxyheptadecanoyl)-L-γ-glutamyl]-10-oxo-3,6,12,15-tetraoxa-9,18-diazaoctadecanoyl}-[8-(2-amino-2-propanoic acid),34-L-arginine]human glucagon-like peptide 1(7-37), is an acylated GLP-1, the structure of

[3] *Getting Started*, HIMS, INC. (Oct. 6, 2025) https://support.hims.com/hc/en-us/articles/25901088679707-Where-do-you-offer-your-Compounded-Semaglutide-GLP-1-treatment (last visited Feb. 7, 2026) (answering "Where do you offer your Compounded Semaglutide (GLP-1) treatment?" with "Right now, our Compounded Semaglutide is only available to medically eligible customers in the U.S. who reside in the states listed below. . . . Delaware (DE)").

which results in a longer duration of action *in vivo* as compared to other GLP-1 compounds. The structure of semaglutide is depicted below:



20. Medications containing semaglutide have proven effective in treating a number of crippling diseases, including type 2 diabetes, which affects 462 million people worldwide and results in one million deaths annually,[4] and obesity, which affects one in eight people worldwide.[5]

21. Semaglutide is the active pharmaceutical ingredient in the FDA-approved products Ozempic®, Rybelsus®, and Wegovy®.

22. Ozempic® was approved by FDA pursuant to New Drug Application ("NDA") No. 209637, issued to and held by NNI. FDA approved Ozempic® on December 5, 2017.[6] The Prescribing information for Ozempic® is attached hereto as Exhibit 2.

23. Ozempic® is a semaglutide solution for subcutaneous injection, approved in multi-injection pens for various doses—2 mg/3 mL pens for either eight injections of 0.25 mg or four injections of 0.5 mg, a 4 mg/3 mL pen for four injections of 1 mg, and an 8 mg/3 mL pen for four injections of 2 mg. Ozempic® is indicated as an adjunct to diet and exercise to improve glycemic

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[4] Moien Abdul Basith Khan et al., *Epidemiology of Type 2 Diabetes — Global Burden of Disease and Forecasted Trends*, 10(1) J. EPIDEMIOLOGY & GLOB. HEALTH 107, 108 (2020).

[5] *Obesity and Overweight*, WORLD HEALTH ORG. (Dec. 8, 2025), https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight (last visited Feb. 7, 2026).

[6] *Company Announcement*, NOVO NORDISK A/S (Dec. 5, 2017), https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=712 (last visited Feb. 7, 2026).

control in adults with type 2 diabetes mellitus, to reduce the risk of major cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease, and to reduce the risk of sustained eGFR decline, end-stage kidney disease and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease.

24. Rybelsus® was approved by FDA pursuant to NDA Nos. 213051 and 213182, issued to and held by NNI. FDA approved Rybelsus® on September 20, 2019,[7] and in January 2026, FDA approved a name change, renaming Rybelsus® as Ozempic® tablets. The Prescribing Information for Rybelsus® and Ozempic® tablets is attached hereto as Exhibit 3.

25. Rybelsus® and Ozempic® tablets are semaglutide tablets for oral administration approved in various doses—3 mg, 7 mg, and 14 mg (Rybelsus®) and 1.5 mg, 4 mg, and 9 mg (Ozempic® tablets). Rybelsus® and Ozempic® tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus who are at high risk for these events.

26. Wegovy® is semaglutide that is approved in two forms—a pill and a subcutaneous injection. Wegovy® injection was approved by FDA on June 4, 2021, pursuant to NDA No. 215256, issued to and held by NNI.[8] Wegovy® injection is a once-weekly subcutaneous injection approved in various doses—0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg /0.5 mL, 1.7 mg/0.75 mL, and 2.4 mg/0.75 mL. It is indicated, in combination with a reduced calorie diet and increased

[7] *Company Announcement*, NOVO NORDISK A/S (Sept. 20, 2019), https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=356 (last visited Feb. 7, 2026).

[8] *Company Announcement*, NOVO NORDISK A/S (June 4, 2021), https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=62112 (last visited Feb. 7, 2026).

physical activity, (1) to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight, and (2) to reduce excess body weight and maintain weight reduction long term in adults and pediatric patients aged 12 years and older with obesity and adults with overweight in the presence of at least one weight-related comorbid condition.

27. Novo Nordisk recognized the benefits to patients that could be provided by a more convenient dosage form, so its scientists worked tirelessly to develop a version of Wegovy® that could be administered orally. The Wegovy® pill was approved by FDA on December 22, 2025, pursuant to NDA No. 218316, issued to and held by NNI.[9] The Wegovy® pill is a once-daily tablet for oral administration approved in various doses—1.5 mg, 4 mg, 9 mg, and 25 mg. It is indicated, in combination with a reduced calorie diet and increased physical activity, (1) to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight, and (2) to reduce excess body weight and maintain weight reduction long term in adults with obesity, or in adults with overweight in the presence of at least one weight-related comorbid condition. The Prescribing Information for the Wegovy® (injection and tablet) is attached hereto as Exhibit 4.

28. The Wegovy® pill is the first FDA-approved GLP-1 pill for weight loss,[10] and its launch has been incredibly successful. In just the second week post-launch, outlets reported

[9] *Company Announcement*, NOVO NORDISK A/S (Dec. 22, 2025), https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=916472 (last visited Feb. 7, 2026).

[10] *Novo Nordisk Takes the Field at the Big Game, Putting Wegovy® Pill in Customers' Hands*, PR NEWSWIRE (Feb. 6, 2026), https://www.prnewswire.com/news-releases/novo-nordisk-takes-the-field-at-the-big-game-putting-wegovy-pill-in-consumers-hands-302680855.html (last visited Feb. 7, 2026).

between 18,000 and 20,000 prescriptions, which was "'numerically higher' than both injectable Wegovy (roughly 1,600 prescriptions) and its Lilly counterpart Zepbound (around 7,300 prescriptions) in the first two weeks of their respective launches."[11] The health-care investment bank Leerink Partners is quoted as recognizing the Wegovy® pill launch as the "the fastest drug launch ever."[12]

29. Only Novo Nordisk has FDA-approved medicines containing semaglutide. The FDA has not approved any generic versions of semaglutide medicines or any other drug products containing semaglutide. Novo Nordisk does not sell its semaglutide API to Defendants, compounding pharmacies, or outsourcing facilities for the purpose of compounding semaglutide products.

30. Novo Nordisk produces its semaglutide medicines in accordance with FDA requirements and under strict controls in its state-of-the-art facilities. Novo Nordisk employs thousands of professionals who have the expertise needed to adhere to these quality and safety standards.

31. Novo Nordisk follows Current Good Manufacturing Practices ("cGMP"), the industry standards that help to ensure quality and safety throughout the design, monitoring, and control of its products across manufacturing processes and facilities. Such practices mean that Novo Nordisk has processes in place to detect and investigate product quality issues and to ensure the quality of its source materials when procuring its products.

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[11] Novo's Wegovy Pill Launch Wows with Strong Early Uptake: Analysts, FIERCEPHARMA (Jan. 23, 2026), https://www.fiercepharma.com/pharma/novos-impressive-wegovy-pill-launch-headline-and-itself-evercore-says (last visited Feb. 7, 2026).

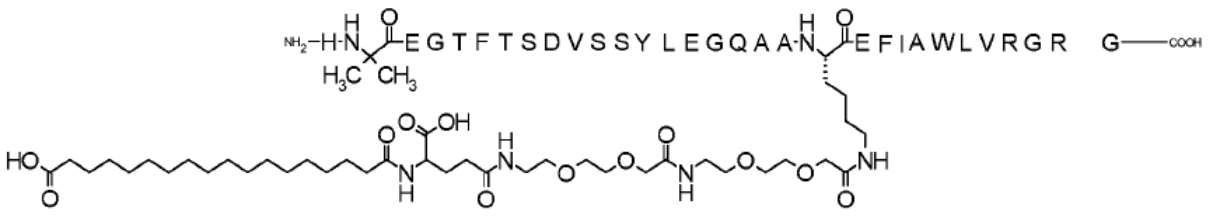
[12] *Wegovy pill is the nation's fastest drug launch: Report*, BECKER'S HOSPITAL REVIEW (Feb. 2, 2026) https://www.beckershospitalreview.com/glp-1s/wegovy-pill-is-the-nations-fastest-drug-launch-report/ (last visited Feb. 7, 2026).

32. Novo Nordisk follows all applicable laws under the Federal Food, Drug, and Cosmetic Act ("FDCA") and manufactures its medicines under strict FDA oversight. Novo Nordisk's medicines are subject to exacting pre-approval testing for safety and efficacy under specific conditions for use; its manufacturing facilities are subject to routine FDA inspections; and the company conducts post-market surveillance and studies. Novo Nordisk's medicines also must be and always are accompanied by labels, instructions, and warnings, which themselves are approved by FDA. Thus, Novo Nordisk's Ozempic®, Rybelsus®, and Wegovy® products meet the world's most rigorous quality and safety standards.

THE PATENT-IN-SUIT

33. NNAS is the owner of all rights, title, and interest in the '343 Patent, entitled "Acylated GLP-1 Compounds." The United States Patent and Trademark Office ("USPTO") duly and legally issued the '343 Patent on March 6, 2012. The '343 Patent names Jesper Lau, Paw Bloch, and Thomas Kruse Hansen as inventors. All named inventors assigned the '343 Patent to NNAS. NNI holds the exclusive right to sell, distribute, and market semaglutide products, including Ozempic®, Rybelsus®, and Wegovy®, in the United States.

34. The '343 Patent claims a compound of the following structure, which corresponds to semaglutide:



as well as a pharmaceutical composition comprising the above claimed compound and a pharmaceutically acceptable excipient.

35. The '343 Patent also claims a method of treatment by administering a pharmaceutical composition comprising the claimed compound and a pharmaceutically acceptable excipient.

36. The '343 Patent is listed in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for Ozempic®, Rybelsus®, and Wegovy®.

37. The Prescribing Information for Ozempic®, Rybelsus®, and Wegovy® identify patent information on Novo Nordisk's website. This website identifies the '343 Patent for Ozempic®, Rybelsus®, and Wegovy®.[13]

38. NNI markets, advertises, promotes, offers for sale, and sells Ozempic®, Rybelsus®, and Wegovy® in the United States. NNI holds the NDA for each of Ozempic®, Rybelsus®, and Wegovy®.

39. On information and belief, Defendants have had knowledge of the '343 Patent and of their infringement of that patent since Defendants began marketing compounded semaglutide products in 2024. Defendants are large and sophisticated companies in the healthcare space that would be aware that semaglutide—one of the most successful and revolutionary drugs in recent medical history—is subject to patent protection. On information and belief, Defendants in fact monitor patent coverage associated with GLP-1 drugs but actively disregard those patents. Responding to an analyst question about Defendants' "GLP-1 business" and "patent protection and where you sit" in light of the analyst's comment that "companies like Lilly and Novo are clearly going to go out of their way to protect the franchises they have," Hims's CEO Andrew Dudum in August 2024 stated that there were "very few, if any, examples where large pharma

[13] *Product Patents*, NOVO NORDISK, https://www.novonordisk-us.com/products/product-patents.html (last visited Feb. 7, 2026).

comes after legitimate, clinically necessary compounding," and noted that "liraglutide [is] now coming off patent," thereby indicating both generally that Hims knows whether drug products that it compounds are patented and specifically that semaglutide, as opposed to liraglutide, was not "off patent."[14] It has also been reported that Mr. Dudum "said Canada will be a road map for future countries as Ozempic goes off patent," again indicating Defendants' awareness and monitoring of Plaintiffs' patents covering semaglutide products.[15] The '343 Patent is listed in the publicly-available Orange Book for each of Ozempic®, Rybelsus®, and Wegovy®, and there is ongoing Hatch-Waxman litigation between Novo Nordisk and generic drug companies involving that patent. In addition, Novo Nordisk's Ozempic® and Wegovy® Prescribing Information—to which Defendants include links on their websites—identifies numerous Novo Nordisk's patents covering semaglutide products, including the '343 Patent.[16]

40. In addition, Defendants had knowledge of the '343 Patent and their infringement of that patent at least as of February 8, 2026, when Novo Nordisk sent a letter to Defendants reiterating that compounded semaglutide products being used, sold, and offered for sale by

[14] *Q2 2024 Earnings Call*, HIMS & HERS HEALTH, INC., at 17–18 (Aug. 5, 2024), https://s27.q4cdn.com/787306631/files/doc_financials/2024/q2/CORRECTED-TRANSCRIPT_-Hims-Hers-Health-Inc-HIMS-US-Q2-2024-Earnings-Call-5-August-2024-5_00-PM-ET.pdf (last visited Feb. 7, 2026); *see also id.* at 12 (referencing "off-patent GLP-1s like liraglutide").

[15] Exhibit 6, *Hims & Hers Acquires Livewell in Canada in Anticipation of Generic Ozempic*, THE GLOBE AND MAIL (Dec. 4, 2025), https://www.theglobeandmail.com/business/economy/article-hims-hers-launches-in-canada-in-anticipation-of-generic-ozempic/ (last visited Feb. 8, 2026).

[16] *E.g.*, *Semaglutide*, HIMS, https://www.hims.com/drugs/info/semaglutide (last visited Feb. 7, 2026) ("This information is from the label for brand name Wegovy®. See the Full Prescribing Information for more complete information.") (and linking Wegovy® Prescribing Information)); *Ozempic®*, HIMS, https://www.hims.com/drugs/info/ozempic (last visited Feb. 7, 2026) (similar and linking Ozempic® Prescribing Information).

Defendants infringe the '343 Patent. A true and correct copy of Novo Nordisk's email to Defendants is attached hereto as Exhibit 5.

THE ACCUSED PRODUCTS

41. The Accused Products, including Defendants' "Compounded GLP-1," "Compounded GLP-1 Microdose," and "Compounded GLP-1 Pill," are compounded semaglutide products made, used, sold, or offered for sale by Defendants, or whose making, use, sale, or offer for sale has been knowingly induced by Defendants.

42. On information and belief, Defendants offer for sale and sell compounded drug products, including the Accused Products, to consumers in the United States. Defendants state in their 2024 10-K SEC filing ("Form 10-K") that they "offer access to a range of health and wellness products and services available for customers to purchase through [their] websites and mobile applications," and that "[m]ost of the offerings on [their] websites and mobile applications are sold to customers on a subscription basis."[17]

43. On information and belief, Defendants earn revenue from the sale of prescription products, including the Accused Products, on their websites and set the prices that customers pay for those products. Defendants state in their 2024 Form 10-K that their "consolidated revenue primarily comprises online sales of health and wellness products and services through [their] websites and mobile applications, including prescription and non-prescription products" and that "[Defendants], in [their] sole discretion, sets all listed prices charged on its websites and mobile applications for products and services."[18]

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[17] *Form 10-K*, HIMS & HERS HEALTH, INC., at 2–3 (Feb. 24, 2025), https://www.sec.gov/ix?doc=/Archives/edgar/data/0001773751/000177375125000062/hims-20241231.htm (last visited Feb. 7, 2026).

[18] *Id.* at 81–82.

44. On information and belief, Defendants began marketing compounded semaglutide injection in or around May 2024. In a May 20, 2024 press release, Defendants announced that they would begin selling compounded semaglutide, and that "[t]hrough a partnership with a leading US manufacturer of generic and 503B compounded injectable medications, Hims & Hers can help millions of Americans who have obesity and are looking for help safely managing their weight."[19] The press release stated that "GLP-1 injections are fulfilled and shipped from Hims & Hers' affiliated pharmacies."[20] A separate May 20, 2024 press release attributed to Hims & Hers Health, Inc.'s CEO Andrew Dudum stated that "[s]tarting today, we are providing access to compounded GLP-1 treatments for eligible customers at prices starting at $199/monthly" and that Defendants were "now partnering with a leading US manufacturer of generic and 503B compounded injectable medications as our supplier for these drugs."[21]

45. On information and belief, Defendants began marketing compounded semaglutide tablets in or around February 2026. In a February 5, 2026 press release, Defendants announced "an expansion of [their] weight loss specialty by enabling providers to prescribe a Compounded Semaglutide Pill with the same active ingredient as Wegovy®," and "[s]tarting today, eligible customers can access treatment plans that include Compounded Semaglutide Pills at a special

[19] *Hims & Hers Announces Access to GLP-1 Injections, Passing Cost Savings onto Customers*, HIMS & HERS (May 20, 2024), https://investors.hims.com/news/news-details/2024/Hims--Hers-Announces-Access-to-GLP-1-Injections-Passing-Cost-Savings-Onto-Customers/default.aspx (last visited Feb. 7, 2026).

[20] *Id.*

[21] *Affordable and Safe Weight Loss Care: How Hims & Hers is Delivering a new GLP-1 Experience*, HIMS & HERS (Mar. 31, 2024), https://news.hims.com/newsroom/affordability-and-safety-how-hims-hers-is-delivering-a-new-glp-1-experience-through-the-scale-of-our-platform (last visited Feb. 7, 2026).

introductory offer starting at just $49 for the first month."[22] The next day, on February 6, 2026, FDA announced "its intent to take decisive steps to restrict GLP-1 active pharmaceutical ingredients (APIs) intended for use in non-FDA-approved compounded drugs that are being mass-marketed by companies—including Hims & Hers and other compounding pharmacies—as similar alternatives to FDA-approved drugs."[23] Also on February 6, 2026, the U.S. Department of Health and Human Services General Counsel stated that he had referred Hims "to the Department of Justice for investigation for potential violations by Hims of the Federal Food, Drug, and Cosmetic Act and applicable Title 18 provisions."[24] Two days after Hims had announced its compounded semaglutide tablets, Hims announced on February 7, 2026, that it had "decided to stop offering access to this treatment."[25] Subsequent to that announcement, Hims' "Compounded GLP-1 Pill" remained on its website.

46. On information and belief, Defendants, either alone or in concert with their affiliates, own and operate the websites located at www.hims.com and www.forhers.com.

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[22] *Hims & Hers Expands Personalized Weight Loss Portfolio with Access to Compounded Semaglutide Pills Starting at $49/Month*, HIMS & HERS (Feb. 5, 2026), https://investors.hims.com/news/news-details/2026/Hims--Hers-Expands-Personalized-Weight-Loss-Portfolio-with-Access-to-Compounded-Semaglutide-Pills-Starting-at-49Month/default.aspx (last visited Feb. 7, 2026).

[23] FDA Statement, *FDA Intends to Take Action Against Non-FDA-Approved GLP-1 Drugs*, U.S. FOOD & DRUG ADMINISTRATION (Feb. 6, 2026), https://www.fda.gov/news-events/press-announcements/fda-intends-take-action-against-non-fda-approved-glp-1-drugs (last visited Feb. 7, 2026).

[24] HHS General Counsel Mike Stuart, X (Feb. 6, 2026, 4:16 PM), https://x.com/HHSGCMikeStuart/status/2019882833041608990 (last visited Feb. 7, 2026).

[25] *Hims to Stop Offering GLP-1 Pill After FDA Warned of* Crackdown, REUTERS (Feb. 7, 2026), https://www.reuters.com/legal/litigation/hims-hers-stop-offering-compounded-semaglutide-pill-after-fda-crackdown-2026-02-07/ (last visited Feb. 7, 2026).

47. On information and belief, Defendants offer for sale and sell compounded semaglutide products to their customers via their websites and through other avenues, such as their mobile application.

48. On hims.com, Defendants offer for sale products called "Compounded GLP-1" and "Compound GLP-1 Microdose," which they describe as "weekly injectable[s]" with the "same active ingredient as Ozempic® and Wegovy®," as shown in Figure 1 below. The hims.com website also shows that Defendants offer for sale a product called "Compounded GLP-1 Pill," which they describe as a "once-daily pill with the same active ingredient as Wegovy®," as shown in Figure 2 below.

FIGURE 1[26]

[26] *Compounded GLP-1, Compounded GLP-1 Microdose*, HIMS, https://www.hims.com/weight-loss (last visited Feb. 7, 2026).

FIGURE 2[27]

49. The hims.com website also depicts a vial labeled "hims Compounded Semaglutide, 5 mg/2 mL (2.5 mg/mL), 2 mL Multiple Dose Vial, Rx Only," as shown in Figure 3 below.

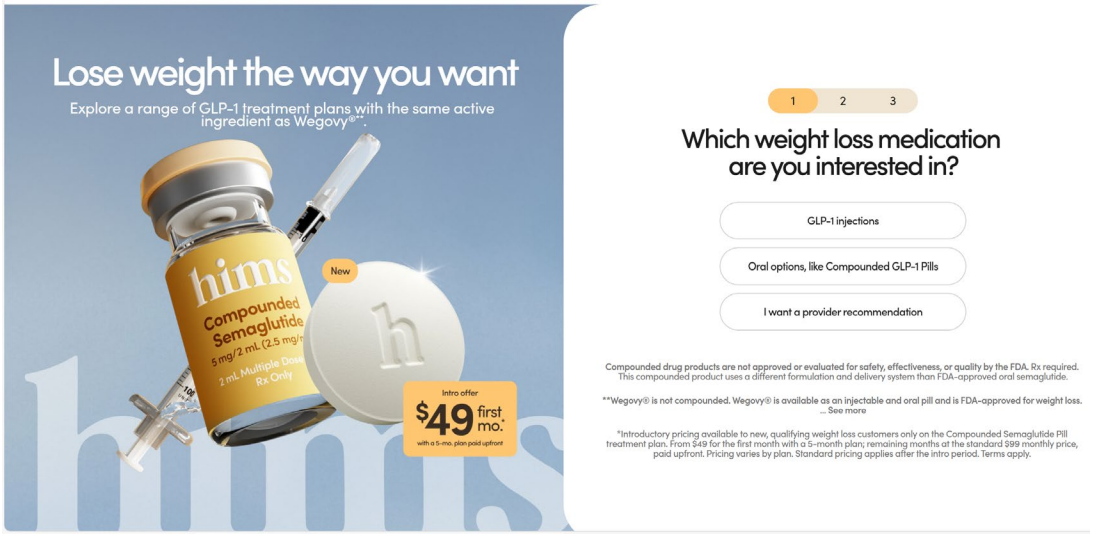

FIGURE 3[28]

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[27] *Compounded GLP-1 Pill*, HIMS, https://www.hims.com/weight-loss (last visited Feb. 7, 2026).

[28] *Lose Weight the Way You Want*, HIMS, https://www.hims.com/lp/wl-start-hims-glp1-injections-compounded-semalgutide?gclid=935a0a6f821c133a2cd763eabd2f5e70&gclsrc=3p.ds&&utm_source=bing&utm_medium=pla&utm_campaign=487079120&utm_term=1266639070175926--kwd-

(continued…)

50. Defendants' hims.com website states that the price for their "Compounded GLP-1 Pill" starts at $49 for the first month with a five-month plan, and the price for their "Compounded GLP-1" and "Compounded GLP-1 Microdose" start at $199 per month for a six-month plan, as shown in Figure 4 below.

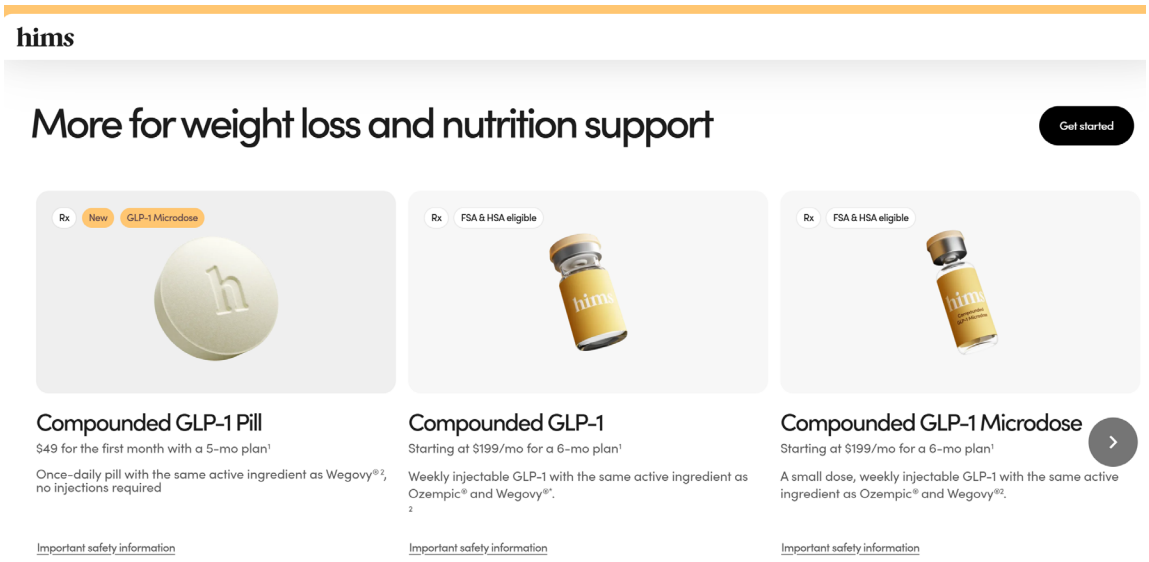


FIGURE 4[29]

51. Similarly, on forhers.com, Defendants offer for sale "Compounded GLP-1," and "Compounded GLP-1 Microdose," which they state has the "same active ingredient as Ozempic® and Wegovy®," and "Compounded GLP-1 Pill," which they state has the "same active ingredient

2330964651405430:loc-4087&utm_content=&mt=b&utm_platform=c&utm_product=nb_demeter&msclkid=935a0a6f821c133a2cd763eabd2f5e70 (last visited Feb. 7, 2026).

[29] *More for Weight Loss and Nutrition Support*, HIMS, https://www.hims.com/lp/wl-start-hims-glp1-injections-compounded-semalgutide?gclid=935a0a6f821c133a2cd763eabd2f5e70&gclsrc=3p.ds&&utm_source=bing&utm_medium=pla&utm_campaign=487079120&utm_term=1266639070175926--kwd-2330964651405430:loc-4087&utm_content=&mt=b&utm_platform=c&utm_product=nb_demeter&msclkid=935a0a6f821c133a2cd763eabd2f5e70 (last visited Feb. 7, 2026).

as Wegovy®" as shown in Figures 5, 6, and 7 below. The forhers.com website states that the price for Defendants' "Compounded GLP-1 Pill" starts at $49 for the first month with a five-month plan, and the price for their "Compounded GLP-1" and "Compounded GLP-1 Microdose" start at $199 per month for a six-month plan.

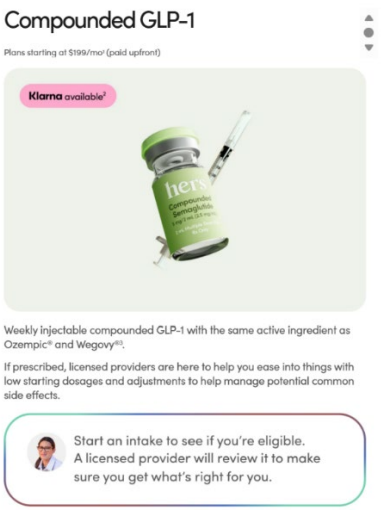


FIGURE 5[30]

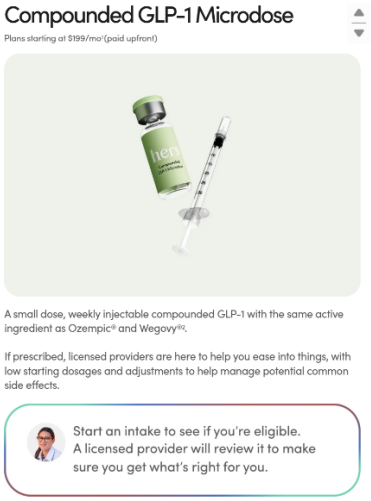


FIGURE 6[31]

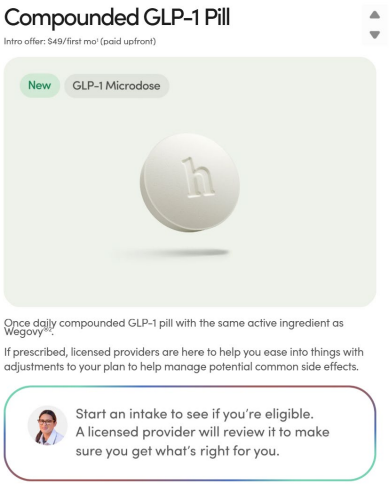


FIGURE 7[32]

[30] *Compounded GLP-1*, HERS, https://www.forhers.com/weight-loss?srsltid=AfmBOopiduY1Q5ZIfra2YIvKCd0JVHbKBYNrugt0aWirdLsRr8ImqNkT&page_product_category=weight_management&page_product_subcategory=WEIGHT_MANAGEMENT (last visited Feb. 7, 2026).

[31] *Compounded GLP-1 Microdose*, HERS, https://www.forhers.com/weight-loss?srsltid=AfmBOopiduY1Q5ZIfra2YIvKCd0JVHbKBYNrugt0aWirdLsRr8ImqNkT&page_product_category=weight_management&page_product_subcategory=WEIGHT_MANAGEMENT (last visited Feb. 7, 2026).

[32] *Compounded GLP-1 Pill*, HERS, https://www.forhers.com/weight-loss?srsltid=AfmBOopiduY1Q5ZIfra2YIvKCd0JVHbKBYNrugt0aWirdLsRr8ImqNkT&page_product_category=weight_management&page_product_subcategory=WEIGHT_MANAGEMENT (last visited Feb. 7, 2026).

52. On information and belief, Defendants administer health questionnaires to prospective GLP-1 weight-loss customers via hims.com and forhers.com.

53. On information and belief, upon completion of said questionnaire, Defendants direct these questionnaires to medical professionals belonging to Defendants' "Affiliated Medical Groups," contractors who "provide services to patients exclusively through the Hims & Hers platform."[33]

54. On information and belief, weight-loss customers purchase compounded GLP-1 products from Defendants and obtain prescriptions for these products from medical professionals from Affiliated Medical Groups.

55. On information and belief, GLP-1 customers who receive compounded semaglutide prescriptions pay Defendants for compounded semaglutide directly on Defendants' websites.

56. On information and belief, Defendants fulfill the compounded semaglutide prescriptions through their "Affiliated Pharmacies," which Defendants state "are licensed mail order pharmacies providing prescription fulfillment solely to our customers."[34]

57. On information and belief, Defendants directly control all relevant actions of their Affiliated Pharmacies, including their dispensing of prescriptions. Indeed, Defendants state in their Form 10-K that they "ha[ve] sole discretion in determining which pharmacy fills a customer's prescription," and the Affiliated Pharmacies, "fill the prescription based on fulfillment instructions

[33] *Form 10-K*, HIMS & HERS HEALTH, INC., at 5 (Feb. 24, 2025), https://www.sec.gov/ix?doc=/Archives/edgar/data/0001773751/000177375125000062/hims-20241231.htm (last visited Feb. 7, 2026).

[34] *Id.* at 60.

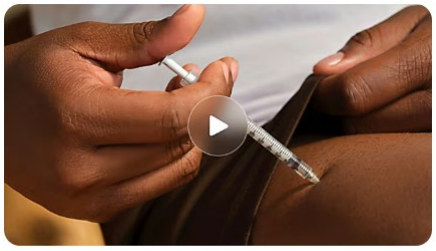
provided by [Defendants], including using [Defendants'] branded packaging for generic products."[35]

58. On information and belief, Defendants serve as the principal directly controlling the actions of their agents in sales of compounded semaglutide products to customers. Indeed, in their Form 10-K Defendants state that they "account[] for prescription product revenue as a principal in the arrangement with [their] customers" because "(i) [Defendants] ha[ve] sole discretion in determining which pharmacy fills a customer's prescription; (ii) the pharmacies fill the prescription based on fulfillment instructions provided by [Defendants], including using [Defendants'] branded packaging for generic products; (iii) [Defendants are] primarily responsible to the customer for the satisfactory fulfillment and acceptability of the order; (iv)[Defendants are] responsible for refunds of the prescription medication after transfer of control to the customer; and (v) [Defendants], in [their] sole discretion, sets all listed prices charged on [their] websites and mobile applications for products and services."[36]

59. The hims.com website provides a link to a YouTube video that demonstrates "[h]ow to [i]nject Hims [w]eight [l]oss [m]edications," as shown in Figures 8 and 9 below.

[35] *Id.* at 82.

[36] *Id.*



Video: How to Inject Hims Weight Loss Medications

FIGURE 8[37]

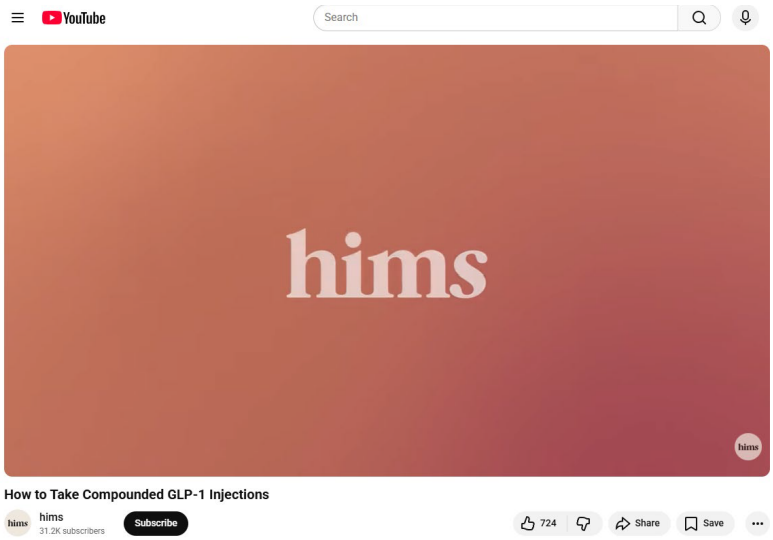


FIGURE 9[38]

60. The forhers.com website provides a "step-by-step guide" for patients to "learn exactly how to inject semaglutide safely and comfortably at home," as shown in Figure 10 below.

[37] *Video: How to Inject Hims Weight Loss Medications*, HIMS, https://www.hims.com/learn/weight-loss (last visited Feb. 7, 2026).

[38] *How to Take Compounded GLP-1 Injections*, HIMS (Aug. 26, 2024), https://www.youtube.com/watch?v=aqpHYUm_B5c (last visited Feb. 7, 2026).

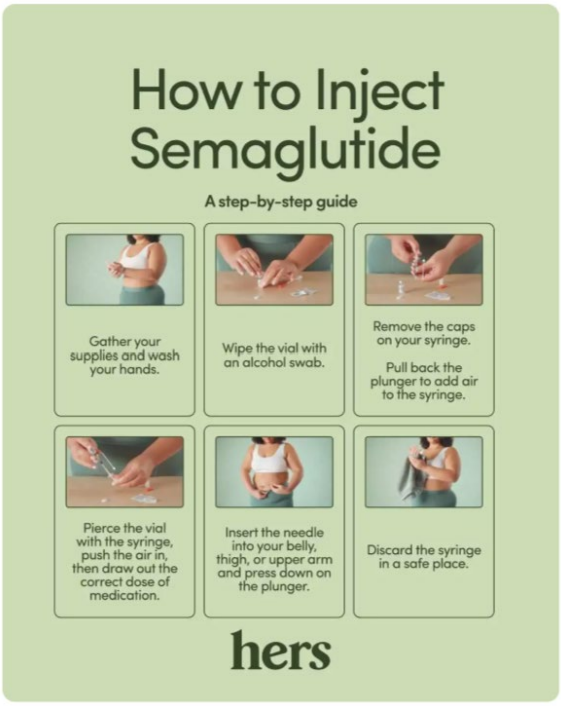


FIGURE 10[39]

61. On information and belief, Defendants have sold compounded semaglutide to individual customers. In 2025, Defendants published a white paper entitled "The 1-Year Journey of Hims & Hers Weight Loss Customers," which purportedly reported data concerning Defendants' customers' use of Defendants' compounded injectable GLP-1 products.[40]

COUNT 1 – INFRINGEMENT OF U.S. PATENT NO. 8,129,343

62. Plaintiffs reallege and incorporate by reference each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

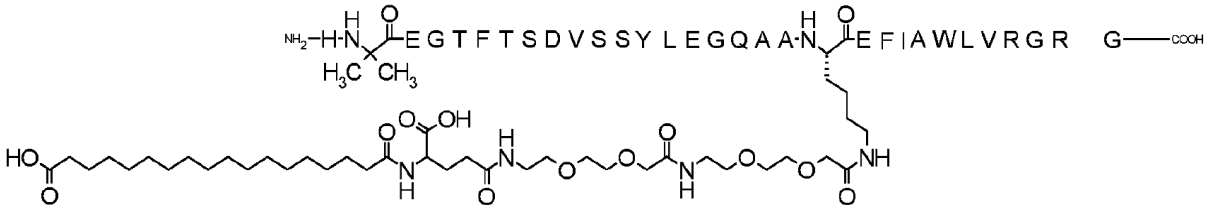
[39] *How to Inject Semaglutide: A Step-by-Step Guide*, HERS (Aug. 16, 2024), https://www.forhers.com/blog/how-to-inject-semaglutide (last visited Feb. 7, 2026).

[40] *The 1-Year Journey of Hims & Hers Weight Loss Customers*, HIMS & HERS, at 4 (July 2025), https://cloudinary.forhims.com/image/upload/v1753719124/cms/shared/newsroom/07-28-2025/Hims_Hers_Weight_Loss_Report_July_2025.pdf (last visited Feb. 7, 2026).

63. On information and belief, Defendants, individually and/or in concert with one another, have infringed and continue to directly infringe, knowingly and intentionally, the ’343 Patent under 35 U.S.C. § 271(a) by using, selling, and/or offering for sale in the United States compounded products containing semaglutide, including the Accused Products, without authority.

64. Independent claim 1 of the ’343 Patent recites the structure corresponding to semaglutide:

1. A compound of the structure



where the amino acid sequence is that of SEQ ID NO:7.

65. On information and belief, the Accused Products meet each of the limitations of at least claim 1 of the ’343 Patent because they contain semaglutide.

66. By using, selling, and/or offering for sale in the United States the Accused Products, Defendants directly infringe (literally and/or under the doctrine of equivalents) at least claim 1 of the ’343 Patent.

67. On information and belief, Defendants, individually and/or in concert with one another, have induced infringement of at least claim 1 of the ’343 Patent under 35 U.S.C. § 271(b) by knowingly and intentionally inducing others to directly infringe the ’343 Patent. Defendants’ inducement of infringement of the ’343 Patent is ongoing.

68. On information and belief, Defendants have had knowledge of the ’343 Patent and that their acts, and the acts of downstream third parties, constitute infringement at least since

Defendants began marketing compounded semaglutide products in 2024. In addition, on February 8, 2026, Defendants received Novo Nordisk's letter specifically raising their infringement of the '343 Patent and demanding that they immediately cease their unauthorized use of the patent.

69. Defendants have actively encouraged others to infringe the '343 Patent and intended that such infringement would occur. For example, on information and belief, Defendants have knowingly and intentionally induced third-party semaglutide suppliers, partner and/or affiliated pharmacies, affiliated medical groups, providers, and/or patients to directly infringe (literally or under the doctrine of equivalents) the '343 Patent by making, using, selling, and/or offering to sell in the United States, or importing into the United States, semaglutide or compounded semaglutide products, including the Accused Products.

70. Moreover, on information and belief, Defendants, individually and/or in concert with one another, take active steps, directly and/or through contractual relationships with others, with the specific intent to cause providers and/or patients to use compounded semaglutide or semaglutide-containing products, including the Accused Products, that infringe at least claim 1 of the '343 Patent. On information and belief, such steps include, among other things, making the Accused Products available to providers and/or patients in the United States and providing instructions to providers and/or patients for how to use them, and knowing that such infringing uses would occur.

71. Novo Nordisk has suffered damages as a result of the direct and indirect infringing activities of Defendants and will continue to suffer such damages as long as those infringing activities continue.

72. Pursuant to 35 U.S.C. § 284, Novo Nordisk is entitled to damages adequate to compensate it for Defendants' infringement, but in no event less than a reasonable royalty.

73. On information and belief, Defendants' infringement has been, and continues to be, willful. For example, Defendants have been on notice of the '343 Patent and their infringement of the '343 Patent at least since they began marketing compounded semaglutide products and on February 8, 2026 they received Novo Nordisk's letter specifically raising their infringement of the '343 Patent and demanding that they immediately cease their unauthorized use of the patent.

74. As a result of Defendants' deliberate and willful infringement, Novo Nordisk is entitled to enhanced damages under 35 U.S.C. § 284.

75. Defendants' direct and indirect infringement has caused and will continue to cause irreparable harm to Novo Nordisk, unless and until such infringement is enjoined by this Court.

76. Remedies at law are inadequate to compensate for the injury to Novo, with the balance of hardships between Novo Nordisk and Defendants, and the public interest, warranting an injunction.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests that this Court enter judgment against Defendants, granting the following relief:

A. Declaring that Defendants have directly infringed and/or induced infringement of, and are continuing to directly infringe and/or induce infringement of, one or more claims of the '343 Patent;

B. Declaring that Defendants' infringement of the '343 Patent has been, and continues to be, willful;

C. Permanently enjoining Defendants, together with their affiliates, subsidiaries, agents, officers, employees, directors, licensees, servants, successors, assigns, and those persons in active concert or participation with any of them, from directly or indirectly infringing one or more claims of the ’343 Patent;

D. Awarding Plaintiffs damages adequate to compensate for Defendants’ direct and indirect infringing activities;

E. Awarding supplemental damages for any post-verdict infringement up until entry of the final judgment with an accounting, as needed, together with pre-judgment and post-judgment interest on the damages awarded;

F. Awarding Plaintiffs enhanced damages under 35 U.S.C. § 284;

G. Finding that this is an exceptional case, and awarding Plaintiffs their attorneys’ fees in this action pursuant to 35 U.S.C. § 285; and

H. Awarding Plaintiffs such other and further relief as the Court may deem just and proper.

Respectfully submitted,

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

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February 9, 2026