UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF FLORIDA TALLAHASSEE DIVISION

NOVO NORDISK A/S AND NOVO NORDISK INC.,

Plaintiffs,

Case No. 4:23-cv-265

v.

EFFINGER HEALTH, P.A. D/B/A NUVIDA RX WEIGHT LOSS – TALLAHASSEE CLINIC

Defendant.

<u>COMPLAINT FOR TRADEMARK INFRINGEMENT,</u> FALSE ADVERTISING, AND UNFAIR COMPETITION

Plaintiffs Novo Nordisk A/S ("NNAS") and Novo Nordisk Inc. ("NNI") (collectively, "Plaintiffs" or "Novo Nordisk"), by and through their attorneys, King & Spalding LLP, file their complaint against Effinger Health, P.A., doing business as Nuvida RX Weight Loss – Tallahassee Clinic ("Defendant") for injunctive and other relief. Plaintiffs allege as follows, upon actual knowledge with respect to themselves and their own acts, and upon information and belief as to all other matters.

INTRODUCTION

1. Novo Nordisk is a healthcare company with a 100-year history of innovation in developing medicines to treat serious chronic diseases like diabetes and obesity.

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2. The development of semaglutide is an example of Novo Nordisk's commitment to innovation for people living with chronic diseases. Semaglutide is the foundational molecule which serves as the primary ingredient for Novo Nordisk's three prescription-only medicines approved by the Food and Drug Administration ("FDA"): Wegovy[®] (semaglutide) injection 2.4 mg, for chronic weight management, and Ozempic[®] (semaglutide) injection 0.5 mg, 1 mg, or 2 mg and Rybelsus[®] (semaglutide) tablets 7 mg or 14 mg, both for adults with type 2 diabetes.

3. Novo Nordisk is the only company in the U.S. with FDA-approved products containing semaglutide. Novo Nordisk is also the only company authorized to identify its products containing semaglutide using the trademarks Wegovy[®], Ozempic[®], and Rybelsus[®]. The FDA has not approved any generic versions of semaglutide.

4. This is an action brought pursuant to the Lanham Act, 15 U.S.C. §§ 1051 et seq., related state laws and the common law, arising out of Defendant's infringement of Plaintiffs' rights in their Ozempic[®] mark and Defendant's acts of false advertising and unfair competition.

<u>Novo Nordisk's FDA-Approved Semaglutide Product,</u> <u>Ozempic[®], and Registered Trademark</u>

5. Plaintiffs use the trademark "Ozempic" to identify and promote the FDA-approved drug, Ozempic[®]. Ozempic[®] is sold and marketed in the United States by NNAS's, indirect, wholly owned subsidiary, NNI.

6. Ozempic[®] is indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise. Ozempic[®] also lowers the risk of major cardiovascular events such as stroke, heart attack or death in adults with type 2 diabetes and known heart disease.

7. Ozempic[®] has a unique safety and efficacy profile which is detailed in its product label.

8. Ozempic[®] is a prescription-only medicine that should only be prescribed in direct consultation with, and under the supervision of, a licensed healthcare professional.

9. Ozempic[®] has been extensively studied in clinical trials and is FDAapproved.

Novo Nordisk does not sell its FDA-approved semaglutide product,
 Ozempic[®], to Defendant, for resale or redistribution.

11. Novo Nordisk first adopted and used the Ozempic[®] mark at least as early as 2017, and has used it continuously since that time. Novo Nordisk has extensively promoted, advertised and marketed its prescription-only medicines

bearing the Ozempic[®] mark in many different channels, directed both to physicians and other health care professionals and to consumers.

12. As a result of its use of the Ozempic[®] mark, NNAS owns valuable common law rights in and to the Ozempic[®] mark.

<u>Defendant's Trademark Infringement and False Advertising</u> <u>in Connection With its Sale to Patients of Unapproved</u> Compounded Drugs

13. Defendant markets and sells to patients compounded drug products that purport to contain semaglutide and that are not approved by the FDA ("Unapproved Compounded Drugs").

14. On information and belief, the Unapproved Compounded Drugs sold by Defendant are made by compounding pharmacies, which deliver them to Defendant for administration or dispensing to patients.

15. The FDA defines compounding 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." See https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding.

16. 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."

17. The FDA has further stated 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."¹

18. On May 31, 2023, FDA issued guidance on "medications containing semaglutide marketed for Type 2 diabetes or weight loss," which provides that: (1) "compounded drugs are not FDA-approved, and the agency does not verify the safety or effectiveness of compounded drugs"; and (2) "FDA has received adverse event reports after patients used compounded semaglutide. Patients should not use a compounded drug if an approved drug is available to treat a patient. Patients and health care professionals should understand that the agency does not review compounded versions of these drugs for safety, effectiveness, or quality."

Defendant uses Novo Nordisk's Ozempic[®] trademark to market and sell
 Unapproved Compounded Drugs purporting to contain "semaglutide" that is not

¹ Compounding and the FDA: Questions and Answers, https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.

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Ozempic[®]. Defendant unlawfully uses Novo Nordisk's trademark to attract customers and generate revenues and profits, including by passing off as Ozempic[®] its own Unapproved Compounded Drugs purporting to contain "semaglutide."

20. Defendant first started using Novo Nordisk's Ozempic[®] mark to advertise its Unapproved Compounded Drugs well after NNAS's first use and registration of its Ozempic[®] mark.

21. Defendant also falsely advertises its Unapproved Compounded Drugs on its website by making statements that describe Ozempic[®], but are false or misleading as to Defendant's Unapproved Compounded Drugs.

22. Defendant has made misleading statements in advertising and promotion that claim or imply that its Unapproved Compounded Drugs have been approved by FDA and/or have been subjected to clinical studies and trials.

23. Defendant continues to use the Ozempic[®] mark, including in advertising and promotion on its website viewed by its customers who, upon information and belief, are seeking to buy but are in fact not buying genuine Ozempic[®] products.

24. Defendant's prominent and misleading use of the Ozempic[®] mark is likely to cause consumers to falsely believe that they are actually purchasing genuine Ozempic[®] products, that Defendant is a source for Novo Nordisk's FDA-approved

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products, and/or that Defendant's services are provided, licensed, sponsored, authorized, or approved by Novo Nordisk.

25. Defendant's use of the Ozempic[®] mark is without the permission, consent or authorization of Novo Nordisk. Defendant has no right to use, and Defendant knows that it has no right to use, the Ozempic[®] mark in connection with Defendant's Unapproved Compounded Drugs or otherwise.

26. Novo Nordisk has no control over the nature, quality or efficacy of the products sold by Defendant, including the Unapproved Compounded Drugs.

THE PARTIES

27. Plaintiff NNAS is a corporation organized and existing under the laws of the Kingdom of Denmark and has its principal place of business in Bagsværd, Denmark.

28. Plaintiff NNI is a Delaware corporation and has its principal place of business in Plainsboro, New Jersey.

29. NNI promotes, offers, and/or sells Novo Nordisk's Ozempic[®] products throughout the United States, including in this District. NNAS has granted to NNI exclusive rights to market, advertise, promote, offer for sale and sell Ozempic[®] products in the United States.

30. Nuvida RX Weight Loss – Tallahassee Clinic ("Nuvida RX") is a fictitious name entity registered in Florida with a registered business address at 1891

Capital Circle NE, Ste 9, Tallahassee, Florida 32308, in this judicial district. Nuvida RX sells and promotes Unapproved Compounded Drugs masquerading as Ozempic[®] and/or uses the Ozempic[®] mark in its advertising and promotion of Unapproved Compounded Drugs that are not Ozempic[®].

31. Defendant Effinger Health, P.A. is a Florida corporation with a business address at 1891 Capital Circle NE, Suite #9, Tallahassee, Florida 32308, in this judicial district. Defendant Effinger Health, P.A. is the fictitious name owner and principal of Nuvida RX. By and through Nuvida RX, Defendant Effinger Health, P.A. sells and promotes Unapproved Compounded Drugs masquerading as Ozempic[®] and/or uses the Ozempic[®] mark in its advertising and promotion of Unapproved Compounded Drugs that are not Ozempic[®].

JURISDICTION AND VENUE

32. The Court has subject matter jurisdiction over the Lanham Act causes of action pleaded herein pursuant to 35 U.S.C. § 1121 and 28 U.S.C. § 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).

33. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendant operates in this District, manufactures and/or sells its Unapproved Compounded Drugs in this District, and otherwise conducts business in this District. Defendant is subject to personal jurisdiction in this District.

NOVO NORDISK'S OZEMPIC[®] TRADEMARK

34. Plaintiff NNAS is the owner of U.S. trademark registration number 4,774,881, issued on July 21, 2015, for the mark OZEMPIC for pharmaceutical preparations, in International Class 5. A true and correct copy of Plaintiff NNAS's registration for the OZEMPIC[®] mark is attached hereto as <u>Exhibit A</u>.

35. The Ozempic[®] trademark is inherently distinctive.

36. Novo Nordisk promotes and advertises its Ozempic[®] products through various channels, including on the websites ozempic.com and/or novonordisk-us.com, and to physicians and licensed healthcare professionals, among others.

37. As a result of Novo Nordisk's long use, promotion, and advertising of the Ozempic[®] trademark and products, the Ozempic[®] mark is exclusively associated with Plaintiffs, serves to identify genuine Novo Nordisk products, and is a valuable asset of Novo Nordisk.

38. As a result of Novo Nordisk's long use, promotion, and advertising of the Ozempic[®] trademark and products, the Ozempic[®] trademark is a well-known, strong and famous mark, and became famous prior to any of the acts of Defendant complained of herein.

DEFENDANT'S INFRINGING USE OF THE OZEMPIC[®] MARK

39. Long after Novo Nordisk's first use of the Ozempic[®] mark at least as early as 2017, long after NNAS's priority date of 2014 for the Ozempic[®] mark, and

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long after NNAS secured federal registration for the Ozempic[®] mark in 2015, Defendant started using the Ozempic[®] mark in commercial advertising and promotion to promote its Unapproved Compounded Drugs in a false and misleading way. Examples of Defendant's trademark infringement and false advertising are attached hereto as <u>Exhibit B</u>.

40. Defendant promotes its Unapproved Compounded Drugs by advertising them using the Ozempic[®] mark on its website. The image below is a true and correct representation of information on Defendant's website https://www.nuvidarx.com/ as of the date of this Complaint.



41. Defendant's website has a popup on the homepage promoting its Unapproved Compounded Drugs by advertising it as, "Introducing Ozempic!" as

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part of a "Special" for "\$400 for 1-month supply of Ozempic." The image below is a true and correct representation of information on Defendant's website https://www.nuvidarx.com/ as of the date of this Complaint.



Defendant also promotes its Unapproved Compounded Drugs by 42. "Ozempic Special" advertising its its website the **URL** on at https://www.nuvidarx.com/services/ozempic, with an entire page dedicated to information on Plaintiffs' FDA-approved Ozempic® products, but with no reference to the fact that Defendant sells its Unapproved Compounded Drugs, not Plaintiffs' FDA-approved Ozempic[®] products. The image below is a true and correct representation of information Defendant's website on https://www.nuvidarx.com/services/ozempic as of the date of this Complaint.

Ozempic

What is Ozempic?

Ozempic is a synthetically created hormone that imitates the Glucagon-like peptide 1 (GLP-1) that naturally occurs in body. The GLP-1 hormone helps to regulate blood sugar levels, and also plays a part in controlling our hunger and fullness cues. This makes it a key player in managing our appetite and keeping our weight under control. Ozempic works in a similar way, helping patients to control their blood sugar, insulin levels, and rate of digestion.

43. Defendant's labels, advertising and promotional materials are false and misleading, suggesting and/or stating an association with Plaintiffs' FDA-approved Ozempic[®] products, when no such association exists.

44. There is no need for Defendant to use the Ozempic[®] trademark to advertise or promote its Unapproved Compounded Drugs purporting to contain "semaglutide," other than to trade upon the reputation of Plaintiffs and to create confusion in the marketplace and/or mislead the public regarding the origin, identity or source of Defendant's Unapproved Compounded Drugs.

45. Defendant's unauthorized use of the Ozempic[®] trademark is likely to cause confusion, to cause mistake, or to deceive, and infringes Plaintiffs' established exclusive rights in that trademark.

46. Upon information and belief, unless enjoined by this Court, Defendant will continue to use the Ozempic[®] mark and/or otherwise falsely advertise its products as associated with or being Ozempic[®], all in violation of Plaintiffs' rights.

FIRST CAUSE OF ACTION

(Trademark Infringement in Violation of 15 U.S.C. § 1114(1))

47. Plaintiff NNAS realleges and incorporates by reference each of the allegations contained in the paragraphs 1-46 of this Complaint as though fully set forth here.

48. Plaintiff NNAS's Ozempic[®] mark is an inherently distinctive, strong, valid, and protectable trademark owned by Plaintiff NNAS.

49. Plaintiff NNAS's registration for its Ozempic[®] mark is incontestable and therefore constitutes conclusive evidence of the validity of the mark, of Plaintiff NNAS's registration and ownership of the mark, and of Plaintiff NNAS's exclusive right to use the mark in commerce on or in connection with the goods identified in the registration.

50. By virtue of its prior use and registrations, Plaintiff NNAS has priority over Defendant with respect to the use of the Ozempic[®] mark for pharmaceutical preparations sold in the United States.

51. Defendant uses the Ozempic[®] mark in connection with the sale, advertising, and promotion of Unapproved Compounded Drugs purporting to contain semaglutide.

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52. Defendant's use in commerce of the Ozempic[®] mark is likely to cause confusion, to cause mistake, or to deceive with respect to Plaintiff NNAS's identical mark.

53. The above-described acts of Defendant constitute infringement of registered trademark in violation of Section 32(1) of the Lanham Act, 15 U.S.C. § 1114(1), entitling Plaintiff NNAS to relief.

54. Defendant has unfairly profited from its trademark infringement.

55. By reason of Defendant's acts of trademark infringement, Plaintiff NNAS has suffered damage to the goodwill associated with its mark.

56. Defendant's acts of trademark infringement have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiff NNAS, its federally registered trademark and the valuable goodwill associated with that trademark.

57. Defendant's acts of trademark infringement have irreparably harmed, and if not enjoined, will continue to irreparably harm the interests of the public in being free from confusion, mistake, and deception.

58. By reason of Defendant's acts, Plaintiff NNAS's remedies at law are not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Plaintiff NNAS is entitled to entry of preliminary and permanent injunctive relief pursuant to 15 U.S.C. § 1116.

59. By reason of Defendant's willful acts of trademark infringement, Plaintiff NNAS is entitled to treble damages under 15 U.S.C. § 1117.

60. This is an exceptional case, making Plaintiff NNAS eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

SECOND CAUSE OF ACTION

(Trademark Infringement, Use of False Designation of Origin and Unfair Competition in Violation of 15 U.S.C. § 1125(a)(1)(A))

61. Plaintiffs reallege and incorporate by reference each of the allegations contained in paragraphs 1-46 of this Complaint as though fully set forth here.

62. Defendant uses the Ozempic[®] mark in commerce in connection with Defendant's goods and services and in commercial advertising and promotion of its goods and services.

63. Defendant uses the Ozempic[®] mark in commerce in a manner that is likely to cause confusion, or to cause mistake, or to deceive the relevant public into believing that Defendant's goods or services are authorized, sponsored, approved by, or otherwise affiliated with Plaintiffs, with Plaintiffs' genuine Ozempic[®] products, and/or with the Ozempic[®] mark.

64. The above-described acts of Defendant constitute infringement of the Ozempic[®] mark and use of false designations of origin in violation of Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A), entitling Plaintiffs to relief.

65. Defendant has unfairly profited from the actions alleged.

66. By reason of the above-described acts of Defendant, Plaintiffs have suffered damage to the goodwill associated with the Ozempic[®] trademark.

67. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs, the Ozempic[®] trademark, and the valuable goodwill associated with the trademark.

68. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

69. By reason of Defendant's acts, Plaintiffs' remedies at law are not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Plaintiffs are entitled to entry of preliminary and permanent injunctive relief pursuant to 15 U.S.C. § 1116.

70. Because the above-described acts of Defendant are willful, Plaintiffs are entitled to treble damages under 15 U.S.C. § 1117.

71. This is an exceptional case, making Plaintiffs eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

THIRD CAUSE OF ACTION

(Defendant's False and Misleading Advertising and Promotion in Violation of 15 U.S.C. § 1125(a)(1)(B))

72. Plaintiffs reallege and incorporate by reference each of the allegations contained in paragraphs 1-46 of this Complaint as though fully set forth here.

73. Defendant's practices, as described in this Complaint, constitute unfair competition and false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

74. Defendant has violated the Lanham Act by using false or misleading descriptions of fact and false or misleading representations of fact in its commercial advertising or promotion that misrepresent the nature, characteristics, and/or qualities of Defendant's business practices and products, as set forth above.

75. Defendant has also engaged in other false or misleading advertising and promotion intended to assure consumers that Defendant's practices are lawful. Upon information and belief, Nuvida RX provides consumers who purchase Defendant's Unapproved Compounded Drugs (or whom Defendant is trying to persuade to purchase its drugs) information that makes several false or misleading statements, including:

76. Defendant advertises its "Ozempic Special" on its website, with an entire webpage discussing Ozempic[®], implying and misleading readers into believing that Defendant is selling Ozempic[®].

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77. Defendant has an entire section of its website dedicated to information pertaining to the benefits and functionality of Ozempic[®], implying and misleading readers into believing Defendant's Unapproved Compounded Drugs have been subjected to clinical trials and are FDA approved.

78. The above-described acts of Defendant, if not enjoined by this Court, are likely to deceive members of the general public.

79. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs.

80. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

81. By reason of Defendant's acts as alleged above, Plaintiffs have suffered and will continue to suffer injuries, including injury to Plaintiffs' business reputation. However, Plaintiffs' remedies at law are not adequate to compensate for all the injuries inflicted by Defendant. Accordingly, Plaintiffs are entitled to entry of preliminary and permanent injunctive relief requiring Defendant to cease its false and misleading advertising and promotion and unfair competitive practices.

FOURTH CAUSE OF ACTION

(Common Law Unfair Competition)

82. Plaintiffs reallege and incorporate by reference each of the allegations contained in paragraphs 1-46 of this Complaint as though fully set forth here.

83. The above-described acts of Defendant constitute common law unfair competition.

84. The above-described acts of Defendant unfairly and wrongfully exploit Plaintiffs' trademark, goodwill and reputation.

85. By reason of the above-described acts of Defendant, Plaintiffs have suffered damage to the goodwill associated with the Ozempic[®] trademark.

86. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs and the Ozempic[®] trademark.

87. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

88. By reason of Defendant's acts, Plaintiffs' remedies at law are not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Plaintiffs are entitled to entry of preliminary and permanent injunctive relief, in

addition to monetary relief in the form of disgorgement of Defendant's profits, and corrective advertising costs.

FIFTH CAUSE OF ACTION

(Violation of § 502.201, et seq., Florida Statutes)

89. Plaintiffs reallege and incorporate by reference each of the allegations contained in paragraphs 1-46 of this Complaint as though fully set forth here.

90. The above-described acts of Defendant constitute unfair methods of competition, and/or unconscionable, deceptive, or unfair acts or practices in violation of the laws of the State of Florida, including Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA"), section 502.201, et seq., Florida Statutes.

91. FDUTPA is designed "[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair trade practices in the conduct of any trade or commerce."

92. The above-described acts of Defendant are made in the conduct of Defendant's business, trade or commerce.

93. The above-described acts of Defendant wrongfully exploit Plaintiffs' trademark in a manner likely to deceive the public and mislead reasonable consumers.

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94. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs and the trademark.

95. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

96. Members of the public are also likely to suffer injury from the abovedescribed acts of Defendant by purchasing a drug that they believe to be Plaintiff's FDA-approved product, Ozempic[®], not an Unapproved Compounded Drug that does not have the same safety, quality, and effectiveness assurances as approved drugs.

97. By reason of the above-described acts of Defendant, Plaintiffs have suffered damage to the goodwill associated with its trademark.

98. Defendant has unfairly profited from the actions alleged.

99. By reason of Defendant's acts, Plaintiffs' remedy at law is not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Plaintiffs are entitled to entry of preliminary and permanent injunctive relief, in addition to monetary relief in the form of disgorgement of Defendant's profits, and corrective advertising costs.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request judgment against Defendant as follows:

1. That the Court enter a judgment against Defendant that Defendant has:

- a. Infringed the rights of Plaintiff NNAS in its federally registered Ozempic[®] mark, in violation of 15 U.S.C. § 1114(1);
- b. Infringed the rights of Plaintiffs in the Ozempic® mark and engaged in unfair competition, in violation of 15 U.S.C. § 1125(a);
- c. Engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a);
- d. Engaged in unfair competition under the common law of Florida and the Florida Deceptive and Unfair Trade Practices Act.
- 2. That each of the above acts was willful.

3. That the Court preliminarily and permanently enjoin and restrain Defendant and its agents, servants, employees, successors and assigns, and all other persons acting in concert with or in conspiracy with or affiliated with Defendant, from:

a. Using the trademark Ozempic[®], or any marks, names or designations confusingly similar to it, 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

infringes any rights of Plaintiffs in and to the Ozempic[®] mark or any similar marks;

- b. Falsely stating or suggesting that any Unapproved Compounded Drugs are genuine Ozempic[®] products, that Defendant is associated or connected in any way with Plaintiffs or Plaintiffs' products, or that Defendant's Unapproved Compounded Drugs are approved by the FDA;
- c. Falsely stating or suggesting that Defendant's Unapproved Compounded Drugs have been proven to achieve certain therapeutic results or effects;
- d. Engaging in any unfair competition with Plaintiffs; and/or
- e. Engaging in any deceptive acts or practices.

4. Requiring Defendant, its agents, servants, employees, successors and assigns, and all other persons acting in concert with or in conspiracy with or affiliated with Defendant, to engage in corrective advertising by informing consumers that Defendant is not and never has been authorized, affiliated, sponsored, approved, or related to Plaintiffs or genuine Ozempic[®] products and that Defendant's Unapproved Compounded Drugs are not and have never been genuine Ozempic[®] products or approved by the FDA.

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5. That Plaintiffs be awarded monetary relief in the form of disgorgement of Defendants' profits for Defendant's trademark infringement, false advertising and unfair competition and that this monetary relief be trebled due to Defendant's willfulness, in accordance with the provisions of 15 U.S.C. § 1117 and any applicable state laws.

6. That Plaintiffs be awarded all Defendants' profits resulting from Defendant's infringement of Plaintiffs' rights and by means of Defendant's unfair competition.

7. That Defendant be ordered to account for and disgorge to Plaintiffs all amounts by which Defendant has been unjustly enriched by reason of Defendant's unlawful actions.

8. That Plaintiffs be awarded punitive damages by reason of Defendant's willful unlawful actions.

9. For pre-judgment and post-judgment interest on all damages.

10. That the Court award Plaintiffs their reasonable attorneys' fees pursuant to 15 U.S.C. § 1117, the Florida Deceptive and Unfair Trade Practices Act, and any other applicable provision of law.

11. That the Court award Plaintiffs the costs of suit incurred herein.

12. For such other or further relief as the Court may deem just and proper.

DATED: June 20, 2023

Respectfully submitted,

By: <u>/s/ Samantha J. Kavanaugh</u> Samantha J. Kavanaugh Florida Bar No. 0194662 **King & Spalding LLP** Southeast Financial Center 200 S Biscayne Boulevard, Suite 4700 Miami, FL 33131 (305) 462-6000 skavanaugh@kslaw.com

> Aaron S. Craig (Pro hac vice application forthcoming) Joseph N. Akrotirianakis (Pro hac vice application forthcoming) 633 West Fifth Street, Suite 1600 Los Angeles, CA 90071 (213) 443-4355 acraig@kslaw.com jakro@kslaw.com

> Bruce W. Baber (*Pro hac vice application forthcoming*) 1180 Peachtree Street, NE, Suite 1600 Atlanta, GA 30309-3521 (404) 572-4600 bbaber@kslaw.com

Attorneys for Plaintiffs NOVO NORDISK A/S and NOVO NORDISK INC.

Exhibit A



Ozempic

| Reg. No. 4,774,881 Registered July 21, 2015 Int. Cl.: 5 TRADEMARK PRINCIPAL REGISTER | DENMARK FOR: PHARMACEUTICAL PREPARATIONS FOR THE TREATMENT OF DIABETES, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52). THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PAR- TICULAR FONT, STYLE, SIZE, OR COLOR. PRIORITY DATE OF 11-13-2014 IS CLAIMED. OWNER OF INTERNATIONAL REGISTRATION 1233427 DATED 12-3-2014, EXPIRES 12- |
|--|---|
| | 3-2024. SER. NO. 79-159,431, FILED 12-3-2014. |

ROBIN MITTLER, EXAMINING ATTORNEY



Michelle K. Len

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.

Exhibit B





About Services

NuvidaRx Weight Loss > Our Services

Services





"I have had a fantastic experience. Everybody is very professional and welcoming, and they have helped me to lose 15 pounds in a short period of

000

Pause

LOCATION

NuvidaRx Weight Loss 1891 Capital Circle NE, Suit 4 Tallahassee, FL 32308 Phone: 682-217-5757 Fax: 888-698-2714

OFFICE HOURS

Monday Tuesday Wednesday Thursday Friday Saturday Sunday 11:00 am - 7:00 pm Closed 11:00 am - 7:00 pm 11:00 am - 7:00 pm 11:00 am - 2:30 pm 9:00 am - 12:00 pm Closed

GET IN TOUCH

C 682-217-5757

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NuvidaRx Weight Loss, Tallahassee, FL Phone (appointments): 682-217-5757 | Phone (general inquiries): 682-217-5757 Address: 1891 Capital Circle NE, Suit 4, Tallahassee, FL 32308





| | Ozempic | |
|---|---|--------------|
| | | |
| NuvidaRx Weight Loss > Our Services > Ozempic | | Tweet 🔞 Save |
| R | Ozempic Special \$400 for 1- month supply of Ozempic 682-217-5757 | |
| NuvidaRx Weight Loss Weight Loss Clinic located in Tallahassee, FL | | |

Ozempic

What is Ozempic?

Ozempic is a synthetically created hormone that imitates the Glucagon-like peptide 1 (GLP-1) that naturally occurs in body. The GLP-1 hormone helps to regulate blood sugar levels, and also plays a part in controlling our hunger and fullness cues. This makes it a key player in managing our appetite and keeping our weight under control. Ozempic works in a similar way, helping patients to control their blood sugar, insulin levels, and rate of digestion.

The big difference between GLP-1 and Ozempic is that the molecular structure of Ozempic is modified just slightly to improve its longevity in the body and decrease the rate at which it's broken down. It is administered once weekly via injection which can either be done in a clinic or at home.

How do Ozempic injections work?

Glucagon-like peptide 1 (GLP-1) is a naturally occurring hormone produced by the body that helps to regulate blood sugar levels and plays a key role in controlling the level of satiety one feels after they eat.

Ozempic is nearly identical to the hormone GLP-1, but slight molecular differences make it more effective at aiding in sustainable weight loss. This synthetic hormone is specifically designed to delay the rate at which the stomach empties food into the intestine, leaving its users feeling fuller for longer and more satiated overall. In combination with healthy lifestyle choices, Ozempic offers an additional layer of aid for those struggling to shed their unwanted weight.

Ozempic can be administered at home, or at a clinical office, once a week via a small injection to the upper arm, thigh, or abdomen.

What are the benefits of Ozempic injections?

Ozempic can help those with diabetes to stabilize and control their blood sugar levels. It has also been proven to effectively help patients lose excess weight when used in combination with a healthy diet and exercise.

Ozempic aids wight loss by:

Case 4:23-cv-00265-WS-MJF Document 1-2 Filed 06/20/23 Page 7 of 7 • Delaying gastric emptying. This allows food to stay in the stomach for more time which leads patients to feeling fuller and more satiated over a longer period.

• Reducing hunger. Ozempic affects the hypothalamus region of the brain which is responsible for regulating hunger and appetite. By intervening in this area, they help delay the neural cues so that recipients (1) don't feel hungry as often and (2) feel satiated for longer when they do eat.

• Preventing overeating. This hormone injection affects your satiety levels, helping its takers to feel full earlier. This lessens the likelihood of eating past the point of fullness and/or comfort.

• Improving cardiovascular health. Ozempic has been shown to reduce waist circumference and improve cardiovascular function. Studies have shown reductions in both systolic and diastolic blood pressure. As a result, those patients with cardiovascular risk factors may prefer Ozempic over other weight loss medications.

Who qualifies for Ozempic injections for weight loss?

Ozempic may be an option for those individuals who are diabetic, have a body mass index (BMI) that is significantly over the healthy range (27 or above), who have a weight-related disease, or who have cardiovascular issues in addition to weight problems. It is also meant to be used alongside healthy lifestyle changes, including a balanced diet and exercise regime, for sustainable and long-term results.

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| provided | l by local rules of court | . This form, approved by th | he Judicial Conference of t | supplement the filing and service he United States in September 1 | | | |
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| | of initiating the civil de PLAINTIFFS | ocket sheet. (SEE INSTRUC | CTIONS ON NEXT PAGE OF T | THIS FORM.) DEFENDANTS | | | |
| | Novo Nordisk A/S and Novo Nordisk Inc. | | | | Effinger Health, P.A. D/B/A Nuvida RX Weight Loss – | | |
| (b) | (b) County of Residence of First Listed Plaintiff <u>Hovedstaden, Denma</u> (EXCEPT IN U.S. PLAINTIFF CASES) | | | County of Residence | County of Residence of First Listed Defendant <u>Tulsa County</u> (IN U.S. PLAINTIFF CASES ONLY) | | |
| | Samantha J. Ka Southeast Finan #4700_Miami_F | Address, and Telephone Numbe vanaugh, King & Sp icial Center, 200 S E L 33131. (305) 462- ICTION (Place an "X" in i | alding LLP, Biscayne Boulevard, 6027: see attachme | Attorneys (If Known) | | Place an "X" in One Box for Plaintiff | |
| _ | | | | (For Diversity Cases Only) | a | ind One Box for Defendant) | |
| 1 U. | S. Government Plaintiff | X 3 Federal Question (U.S. Government Not a Party) | | Citizen of This State | _ | | |
| 2 U. | U.S. Government 4 Diversity Defendant (Indicate Citizenship of Parties in Item III) | | ip of Parties in Item III) | Citizen of Another State | 2 2 Incorporated and F of Business In A | | |
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| | VII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: unspecified; injunction JURY DEMAND: Yes X No | | | | | | |
| | RELATED CASI IF ANY | E(S) (See instructions): | JUDGE | | DOCKET NUMBER | | |
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UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF FLORIDA TALLAHASSEE DIVISION

NOVO NORDISK A/S AND NOVO NORDISK INC.,

Plaintiffs,

Case No. 4:23-cv-265

v.

EFFINGER HEALTH, P.A. D/B/A NUVIDA RX WEIGHT LOSS – TALLAHASSEE CLINIC

Defendant.

ADDENDUM TO JS-44: ATTORNEYS OF RECORD FOR PLAINTIFFS NOVO NORDISK A/S AND NOVO NORDISK INC.

King & Spalding LLP

Southeast Financial Center 200 S Biscayne Boulevard, Suite 4700 Miami, FL 33131 (305) 462-6027

<u>Attorneys of record:</u> Samantha J. Kavanaugh Florida Bar No. 0194662 Southeast Financial Center 200 S Biscayne Boulevard, Suite 4700 Miami, FL 33131 (305) 462-6027 skavanaugh@kslaw.com Aaron S. Craig (Pro hac vice application forthcoming) Joseph N. Akrotirianakis (Pro hac vice application forthcoming) 633 West Fifth Street, Suite 1600 Los Angeles, CA 90071 (213) 443-4355 acraig@kslaw.com jakro@kslaw.com

Bruce W. Baber (*Pro hac vice application forthcoming*) 1180 Peachtree Street, NE, Suite 1600 Atlanta, GA 30309-3521 (404) 572-4600 <u>bbaber@kslaw.com</u>