UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

NOVO NORDISK INC. Plaintiff, v. BROOKSVILLE PHARMACEUTICALS INC., Defendant.	Case No. 8:23-cv-1503

COMPLAINT

Plaintiff Novo Nordisk Inc. ("Plaintiff" or "Novo Nordisk"), by and through its attorneys, King & Spalding LLP, brings this action against Defendant Brooksville Pharmaceuticals Inc. ("Defendant" or "Brooksville") and alleges the following:

I. NATURE OF THE ACTION

1. Novo Nordisk is a leading healthcare company, focused on driving change to defeat serious chronic diseases, built upon its heritage in diabetes.

2. The development of semaglutide is an example of this 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. The FDA has not approved any generic versions of semaglutide.

4. Wegovy® is indicated for chronic weight management in adults and children aged ≥12 years with obesity (BMI ≥30 for adults, BMI ≥ 95th percentile for age and sex for children), or some adults with excess weight (BMI ≥27) (overweight) with weight-related medical problems, along with a reduced calorie meal plan and increased physical activity.

5. Ozempic® and Rybelsus® are 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.

6. Each of Wegovy®, Ozempic®, and Rybelsus® has a unique safety and efficacy profile which is detailed in its respective product label.

7. Wegovy®, Ozempic®, and Rybelsus® are prescription-only medicines that should only be prescribed in direct consultation with, and under the supervision of, a licensed healthcare professional.

8. Wegovy®, Ozempic®, and Rybelsus® have been extensively studied in clinical trials and are FDA-approved for the treatment of patients with serious chronic diseases.

9. Defendant markets and sells to patients certain drug products that purport to contain "semaglutide" and are not FDA approved ("Unapproved New Drugs"). Novo Nordisk brings this action to stop Defendant from unlawfully manufacturing and selling its Unapproved New Drugs. Florida state laws require drug manufacturers to demonstrate their drugs are safe and effective in order to obtain regulatory approval to market them. Defendant violates these laws by marketing and selling its Unapproved New Drugs throughout Florida and other states.

A. Florida Laws Against Unlawful and Unfair Business and Trade Practices

8. Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA") "protect[s] the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Fla. Stat. § 501.202(2). FDUTPA further forbids Defendant from violating "[a]ny law, statute, rule, regulation, or ordinance which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices." Fla. Stat. § 501.203(3)(c).

B. Florida Laws Prohibiting the Sale of Unapproved Drugs

9. Florida regulates the manufacture and sale of prescription drugs under the Florida Drug and Cosmetic Act. As relevant here, the Florida Drug and Cosmetic Act specifies that no person may "sell, offer for sale, hold for sale, manufacture,

repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the [Federal Food, Drug, and Cosmetic Act] or otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce." Fla. Stat. § 499.023. Florida's drug-approval provision is designed to ensure that when Floridians are treated with prescription drugs, they can rest assured that the products are safe and effective for their intended uses

10. Defendant disregards these and other state laws respecting the distribution of unapproved drugs. Rather than invest the time and resources necessary to research, develop, and test its products in order to ensure that they are safe and effective and to obtain regulatory approval to market them, Defendant is simply creating, marketing, selling, and distributing Unapproved New Drugs throughout Florida and other states.

C. The Importance of Drug Approval and the Purpose of this Action

11. Defendant is engaged in unlawful and unfair business and trade practices because Defendant manufactures and dispenses its Unapproved New Drugs in violation of the Florida Drug and Cosmetic Act. This law prohibits the sale of new drugs unless the drugs are approved by FDA or their sale are otherwise permitted by FDA.

12. Testing new drugs and obtaining the legally required regulatory

approval to sell them are time-consuming and very costly. Ignoring drug-approval requirements provides Defendant an unfair competitive advantage over pharmaceutical manufacturers like Novo Nordisk. Worse, it puts patients at risk by exposing them to drugs that have not been shown to be safe or effective.

13. Federal and state law require approval for new drugs for good reason. Drug approval is evidence-based, and it is essential to ensure the quality, safety, and effectiveness of new drugs. When companies circumvent the drug-approval process, safety and efficacy are, at best, unknown. The danger is not merely theoretical, as manufacturing and distribution of unapproved new drugs of unknown quality has endangered or adversely impacted public health. For example, in 2012, nearly 800 patients in 20 states were diagnosed with a fungal infection after receiving injections of an unapproved preservative-free methylprednisolone acetate drug manufactured in Massachusetts. Of those 753 patients, the U.S. Centers for Disease Control and Prevention reported that 64 patients in nine states died, though other sources report the death toll as exceeding 100 victims. The State of Florida alone reported 25 cases of persons with fungal infections linked to steroid injections and 7 deaths.[1] Other adverse events related to the sale of unapproved drugs have occurred in the years following 2012.

[1] Multistate Outbreak of Fungal Meningitis and Other Infections – Case Count, https://www.cdc.gov/hai/outbreaks/meningitis-map-large.html.

14. Novo Nordisk brings this action under FDUTPA to stop Defendant from unlawfully manufacturing, marketing, selling, and distributing Unapproved New Drugs. Novo Nordisk seeks a declaration that Defendant's business practices violate FDUTPA by manufacturing, distributing, and selling Unapproved New Drugs and an injunction prohibiting Defendant from committing such violations. Fla. Stat. §§ 499.023, 501.211(1).

15. Novo Nordisk also seeks attorney's fees and court costs. *See* Fla. Stat. § 501.211(2).

II. THE PARTIES

16. Novo Nordisk is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business in New Jersey.

17. Novo Nordisk promotes, offers, and/or sells FDA-approved, semaglutide-based products—Wegovy®, Ozempic®, and Rybelsus®—throughout the United States. Novo Nordisk is the only company in the U.S. with FDA-approved products containing semaglutide. The FDA has not approved any generic versions of semaglutide.

18. Novo Nordisk and/or its parents and affiliates have invested significant time and resources to research, develop, manufacture, and test Wegovy®, Ozempic®, and Rybelsus® in order to obtain regulatory approval from FDA to market these drugs.

19. Defendant is a corporation organized and existing under the laws of Florida, with its principal place of business at 16140 Flight Path Drive, Brooksville, Florida 34604.

20. Defendant manufactures its Unapproved New Drugs in this judicial district and sells them in this judicial district, throughout Florida, and in several other states.

III. JURISDICTION AND VENUE

21. This Court has subject matter jurisdiction under 28 U.S.C. § 1332. The parties are citizens of different States (¶¶ 16-20, *supra*), and the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

22. This Court has personal jurisdiction over Defendant. Defendant's principal place of business is located in this District, Defendant manufactures its Unapproved New Drugs in this District and, upon information and belief, Defendant ships its unapproved drugs throughout Florida and into several other states from this District. Plaintiff's claims arise out of or relate to Defendant's activities in this District.

23. Venue in this District is proper under 28 U.S.C. § 1391(b).

IV. FACTUAL ALLEGATIONS

A. Novo Nordisk is the Only Company in the U.S. with FDA-Approved Products Containing Semaglutide

24. Novo Nordisk markets and sells Ozempic® pursuant to New Drug

Application #N209637, which FDA approved on December 5, 2017.

25. Novo Nordisk markets and sells Rybelsus® pursuant to New Drug Application #N213051, which FDA approved on September 20, 2019.

26. Novo Nordisk markets and sells Wegovy® pursuant to New Drug Application #N215256, which FDA approved on June 4, 2021.

27. Novo Nordisk is the only company in the United States with FDA-approved products containing semaglutide.

B. Defendant's Activities Violate State Laws Against Selling Unapproved New Drugs

28. Defendant's manufacturing, marketing, sale, and distribution of Unapproved New Drugs is unlawful.

29. Under the laws of Florida, a new drug may not be introduced or delivered for introduction into interstate commerce unless an application approved by FDA under section 505 of the FDCA is in effect for the drug or the sale is otherwise permitted by FDA. *See* Fla. Stat. § 499.023.

30. The Florida Drug and Cosmetic Act provides that no person may "sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the [Federal Food, Drug, and Cosmetic Act] or otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce." Fla. Stat. § 499.023.

31. There is no approved New Drug Application or Abbreviated New Drug Application for Defendant's Unapproved New Drugs.

32. Defendant is violating the Florida Drug and Cosmetic Act because (i) it is selling its Unapproved New Drugs to customers in Florida and other states; and (ii) there is no application for the Unapproved New Drugs sold by Defendant under section 505 of the Federal Food, Drug, and Cosmetic Act (or any other relevant regulatory authority), nor is Defendant otherwise permitted by the Secretary of the United States Department of Health and Human Services to sell its Unapproved New Drugs.

C. Defendant's Business and Trade Practices Jeopardize Public Health

33. Defendant's unfair competition jeopardizes public health. FDA has stated that unapproved drugs pose a higher risk to patients than FDA-approved drugs because they have not undergone FDA premarket review for safety, effectiveness, and quality. To avoid potential clinical harm from substandard drugs patients should be treated with FDA-approved medications when possible.

D. Plaintiff has been Injured by Defendant's Unlawful and Unfair Competition

34. Defendant's actions have injured Plaintiff. Novo Nordisk is the only company in the United States with FDA-approved products containing semaglutide.

35. Defendant sells its Unapproved New Drugs to customers in Florida and other states.

36. As a result of Defendant's unlawful and unfair competition, Plaintiff has suffered injury.

37. Moreover, as a result of Defendant's unlawful and unfair competition, Novo Nordisk has suffered harm to its goodwill and reputation.

V. CAUSE OF ACTION

(Violation of Florida Deceptive and Unfair Trade Practices Act ("FDUTPA")
(Fla. Stat. § 501.201, *et seq*)

38. Plaintiff realleges and incorporates by reference each and every allegation set forth in paragraphs 1-37, above, as if fully stated herein.

39. FDUTPA makes "unlawful" "unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." Fla. Stat. § 501.204.

40. FDUTPA also creates a cause of action for "anyone aggrieved" by a violation of FDUTPA to bring an action against "a person who has violated, is violating, or is otherwise likely to violate" the Act. Fla. Stat. § 501.211.

41. Plaintiff is "aggrieved" under FDUTPA.

42. Defendant is a "person" who has violated and is violating FDUTPA.

43. Defendant engages in unfair, unconscionable, and deceptive conduct in "trade" and "commerce" in violation of FDUTPA when it unlawfully manufactures and sells Unapproved New Drugs in Florida (and into other states).

44. Given that Defendant's Unapproved New Drugs pose potential harm to

consumers, Defendant's manufacture and sale of its drugs is a practice that is immoral, unethical, oppressive, unscrupulous, and/or substantially injurious to consumers and to Plaintiff.

45. The practices described herein also offend established public policy regarding the protection of consumers against companies, like Defendant, that engage in unfair methods of competition. Defendant's conduct has caused substantial injury to Novo Nordisk in the form of harm to Novo Nordisk's goodwill and reputation that is not outweighed by countervailing benefits to any consumers or competition.

46. The practices described herein have caused harm and injury to consumers and, if not enjoined, will continue to cause harm and injury to consumers and to Plaintiff.

47. Defendant's business acts and practices are also unfair because they have caused harm and injury-in-fact to Novo Nordisk for which Defendant has no justification other than to increase, beyond what Defendant would have otherwise realized, its revenue from the sale of Unapproved New Drugs.

48. Defendant has further violated FDUTPA by violating a "statute . . . which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices." Fla. Stat. § 501.203(3)(c). Here, Defendant violated Florida's Drug and Cosmetic Act which proscribes certain unconscionable

acts and practices.

49. As a result of Defendant's unlawful and unfair competition, Novo Nordisk has suffered harm to its goodwill and reputation.

50. Plaintiff is entitled to declaratory and injunctive relief, the value of which exceeds $75,000, as well as reasonable attorney's fees and costs pursuant to Fla. Stat. §§ 501.2105, 501.211.

VI. CONCLUSION AND PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in its favor:

1. A permanent injunction enjoining Defendant from continuing the unlawful and unfair business practices alleged in this complaint, which injunction has a value in excess of $75,000;

2. A judgment that Defendant violated the TCPA;

3. Declaratory relief;

4. Attorney's fees and costs incurred in this action; and

5. Any further relief the Court may deem just and proper.

Dated: July 6, 2023

Respectfully submitted,

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