IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and NOVO NORDISK A/S,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SUN PHARMACEUTICAL INDUSTRIES LTD. and SUN PHARMACEUTICAL INDUSTRIES, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), for their Complaint against Defendant Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, "Sun"), allege as follows:

THE PARTIES

1. Plaintiff Novo Nordisk Inc. ("NNI") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

2. Plaintiff Novo Nordisk A/S ("NNAS") is an entity organized and existing under the laws of the Kingdom of Denmark, having its principal place of business at Novo Allé, 2880 Bagsvaerd Denmark. NNI is an indirect, wholly-owned subsidiary of NNAS.

3. On information and belief, Defendant Sun Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra, India 400063. On information and belief, Sun Pharmaceutical Industries Ltd. is in

the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

4. On information and belief, Defendant Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2 Independence Way, Princeton, New Jersey, 08540. On information and belief, Sun Pharmaceutical Industries, Inc. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

5. On information and belief, Defendant Sun Pharmaceutical Industries, Inc. is a wholly owned subsidiary of Defendant Sun Pharmaceutical Industries Ltd.

6. On information and belief, Defendants Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc. collaborate to develop, manufacture, seek regulatory approval for, import, market, distribute, and sell generic pharmaceutical products in the State of Delaware and throughout the United States.

NATURE OF THE ACTION

7. This action arises under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271(b), (c), and (e) arising from Sun's submission of an Abbreviated New Drug Application ("ANDA") No. 217962 (the "Sun's ANDA") to the United States Food and Drug Administration ("FDA"), by which Sun seeks approval of a generic version of Novo Nordisk's pharmaceutical product WEGOVY® (semaglutide) injection prior to the expiration of United States Patent No. 12,029,779 ("the '779 Patent"), which covers, *inter alia*, WEGOVY® (semaglutide) injection and/or its use.

8. NNAS is the owner of all rights, title, and interest in the '779 Patent.

9. NNI is the holder of New Drug Application ("NDA") No. 215256 for WEGOVY® (semaglutide) injection, for subcutaneous use, administered with 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 Pre-filled Single-dose Pens, which NNI sells under the trade name WEGOVY®. NNI holds the exclusive right to sell, distribute, and market WEGOVY® (semaglutide) injection in the United States.

10. The '779 Patent is listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), in connection with WEGOVY® and the related NDA.

NOVO NORDISK'S WEGOVY®

11. The WEGOVY® Label states that "WEGOVY® is indicated in combination with a reduced calorie diet and increased physical activity:

- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight.
- to reduce excess body weight and maintain weight reduction long term in:
    - Adults and pediatric patients aged 12 years and older with obesity
    - Adults with overweight in the presence of at least one weight-related comorbid condition."

12. WEGOVY® is to be administered once weekly by subcutaneous injection.

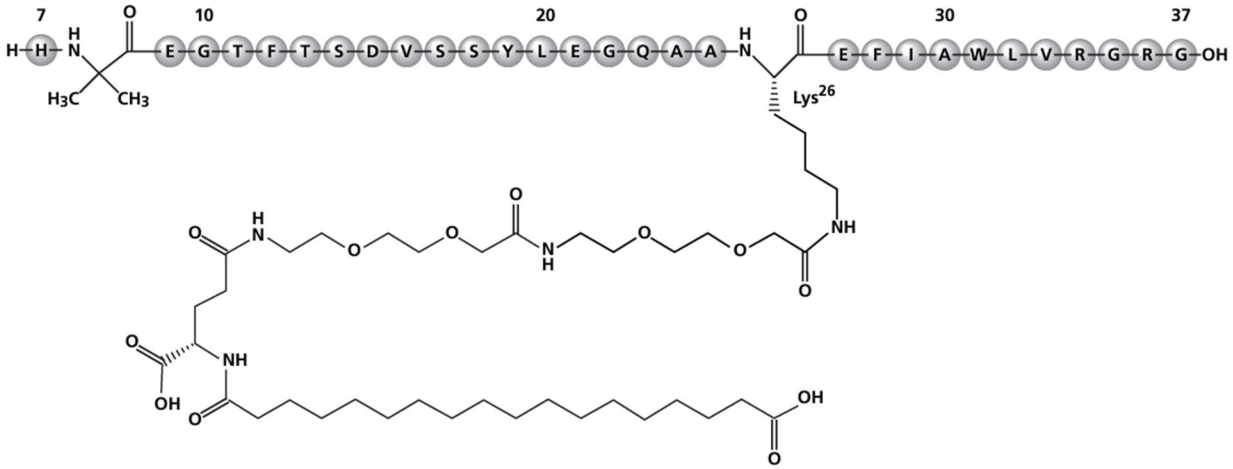
13. For adults, the WEGOVY® Label instructs to administer WEGOVY® once weekly according to a dose escalation schedule that includes an initiating dosage of semaglutide at 0.25 mg for four weeks, 0.5 mg for the next four weeks, 1 mg for the next four weeks, then 1.7 mg for the next four weeks after that. The WEGOVY® Label further instructs "[t]he maintenance dosage of WEGOVY is either 2.4 mg (recommended) or 1.7 mg once weekly" and to "[c]onsider treatment response and tolerability when selecting the maintenance dosage *[see Clinical Studies (14.2)]*."

14. For pediatric patients, the WEGOVY® Label instructs to administer WEGOVY® once weekly according to a dose escalation schedule that includes an initiating dosage of

semaglutide at 0.25 mg for four weeks, 0.5 mg for the next four weeks, 1 mg for the next four weeks, then 1.7 mg for the next four weeks after that. The WEGOVY® Label instructs that "the maintenance dosage of WEGOVY in pediatric patients aged 12 years or older is 2.4 mg once weekly" and that "if patients do not tolerate the 2.4 mg once-weekly maintenance dosage, the maintenance dosage may be reduced to 1.7 mg once weekly."

15. The active ingredient in WEGOVY® is semaglutide and its structure is:

Figure 1. Structural Formula of semaglutide



16. WEGOVY® is an aqueous solution. Each 0.5 mL single-dose pen (i.e., prefilled syringe with needle) contains a solution of WEGOVY® containing 0.25 mg, 0.5 mg, or 1 mg of semaglutide; and each 0.75 mL single-dose pen contains a solution of WEGOVY® containing 1.7 mg or 2.4 mg of semaglutide. Thus, each 1 mL of WEGOVY® contains 0.5 mg, 1 mg, 2 mg, 2.3 mg, or 3.2 mg of semaglutide depending on the dosage.

17. The WEGOVY® Label lists 1.42 mg disodium phosphate dihydrate (also known as disodium hydrogen phosphate dihydrate), 8.25 mg sodium chloride, and water for injection as inactive ingredients in each 1 mL of WEGOVY®. WEGOVY® has a pH of approximately 7.4. Hydrochloric acid or sodium hydroxide may be added to adjust pH.

SUN'S ANDA

18. On information and belief, Sun Pharmaceutical Industries Inc., acting as U.S. agent for Sun Pharmaceutical Industries Ltd., submitted Sun's ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), *i.e.*, 21 U.S.C. § 355(j), seeking approval to commercially manufacture, use, and/or sell a generic version of semaglutide injection, 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 for subcutaneous use pursuant to Sun's ANDA ("Sun's ANDA Product").

19. On information and belief, Defendant Sun Pharmaceutical Industries Inc. and Defendant Sun Pharmaceutical Industries Ltd. acted in concert to prepare and submit Sun's ANDA.

20. On information and belief, following any FDA approval of Sun's ANDA, Defendant Sun Pharmaceutical Industries Inc. and Defendant Sun Pharmaceutical Industries Ltd. will act in concert to distribute and sell Sun's ANDA Product throughout the United States, including within Delaware.

21. On information and belief, Sun's ANDA refers to and relies upon WEGOVY®'s NDA and contains data that, according to Sun, demonstrate the bioequivalence of Sun's ANDA Product and WEGOVY®.

22. On information and belief, Sun has infringed or will infringe one or more claims of the '779 Patent under 35 U.S.C. § 271(e)(2)(A) by the submission of Sun's ANDA, including any amendments or supplements thereof, seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States of Sun's ANDA Product before the expiration of the '779 Patent or any extensions thereof.

23. Sun will infringe one or more claims of the '779 Patent under 35 U.S.C. § 271(b) and/or (c) should Sun engage in, induce, or contribute to the commercial manufacture use, offer

for sale, sale, distribution in, or importation into the United States of Sun's ANDA Product before the expiration of the '779 Patent or any extensions thereof.

JURISDICTION AND VENUE

24. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331,1338(a), 2201, and 2202.

25. This Court has personal jurisdiction over Defendant Sun Pharmaceutical Industries Ltd. by virtue of, *inter alia*, its presence in Delaware, having conducted business in Delaware; having derived revenue from conducting business in Delaware; previously consenting to personal jurisdiction in this Court, including in a co-pending action involving assertions of patent infringement based on the same ANDA that is the subject of this Complaint (*see, e.g.*, Answer, Defenses, and Counterclaims, *Novo Nordisk Inc., et al. v. Sun Pharmaceutical Industries Ltd., et al.*, C.A. No. 22-296 (D. Del. May 9, 2022), D.I. 11; Answer, Affirmative Defenses and Counterclaims, *Boehringer Ingelheim Pharmaceuticals, et al. v. Sun Pharmaceutical Industries Ltd., et al.*, C.A. No. 21-356 (D. Del. Apr. 5, 2021), D.I. 9); and having taken advantage of the rights and protections provided by this Court, including having asserted counterclaims in this jurisdiction (*see, e.g.*, Answer, Defenses, and Counterclaims, *Novo Nordisk Inc., et al. v. Sun Pharmaceutical Industries Ltd., et al.*, C.A. No. 22-296 (D. Del. May 9, 2022), D.I. 11; Answer, Affirmative Defenses, and Counterclaims, *Allergan USA, Inc., et al. v. Sun Pharmaceutical Industries Ltd.*, C.A. No. 21-1065 (D. Del. Nov. 10, 2021), D.I. 266 in lead C.A. No. 19-1727; Answer, Affirmative Defenses, and Counterclaims, *Novo Nordisk Inc., et al. v. Sun Pharmaceutical Industries Ltd., et al.*, C.A. No. 23-1459 (D. Del. Dec. 21, 2023), D.I. 9; Answer, Affirmative Defenses, and Counterclaims, *Veloxis Pharmaceuticals, Inc. v. Sun Pharmaceutical Industries Ltd., et al.*, C.A. No. 24-726 (D. Del. Jun. 19, 2024), D.I. 12).

26. This Court has personal jurisdiction over Defendant Sun Pharmaceutical Industries, Inc. by virtue of, *inter alia*, its presence in Delaware, being a Delaware corporation and having conducted business in Delaware; having derived revenue from conducting business in Delaware; previously consenting to personal jurisdiction in this Court; and having taken advantage of the rights and protections provided by this Court, including having asserted counterclaims in this jurisdiction (*see, e.g.*, Answer, Defenses, and Counterclaims, *Novo Nordisk Inc., et al. v. Sun Pharmaceutical Industries Ltd., et al.*, C.A. No. 22-296 (D. Del. May 9, 2022), D.I. 11; Answer and Counterclaim, *Pfizer, Inc. et al. v. Sun Pharmaceutical Industries Ltd. et al.*, C.A. No. 19-758 (D. Del. July 10, 2019), D.I. 11; Answer, Affirmative Defenses and Counterclaims, *Boehringer Ingelheim Pharmaceuticals, et al. v. Sun Pharmaceutical Industries Ltd., et al.*, C.A. No. 21-356 (D. Del. Apr. 5, 2021), D.I. 9).

27. On information and belief, Sun intends to sell, offer to sell, use, and/or engage in the commercial manufacture of Sun's ANDA Product, directly or indirectly, throughout the United States and in this District. Sun's filing of Sun's ANDA confirms this intention and further subjects Sun to the specific personal jurisdiction of this Court.

28. Defendant Sun Pharmaceutical Industries, Inc. is incorporated in the State of Delaware and therefore resides in this judicial district. Defendant Sun Pharmaceutical Industries Ltd. is a foreign corporation not resident in the United States. Thus, venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c), and 28 U.S.C. § 1400(b).

THE PATENT-IN-SUIT

29. The allegations above are incorporated herein by reference.

30. Novo Nordisk A/S is the owner of all rights, title, and interest in the '779 Patent, entitled "Semaglutide in Medical Therapy." The USPTO duly and legally issued the '779 Patent on July 9, 2024. The '779 Patent names Marianne Oelholm Larsen Groenning, Lars Endahl,

Charlotte Giwercman Carson, Anders Bjerring Strathe, Maria Kabisch, and Thomas Hansen as inventors. All named inventors assigned the '779 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '779 Patent and sue for infringement thereof. A true and correct copy of the '779 Patent is attached to this Complaint as Exhibit 1.

31. The '779 Patent claims, among others, methods for reducing body weight of a subject in need thereof, comprising administering semaglutide subcutaneously to the subject in an amount of 2.4 mg, or about 2.4 mg, once weekly.

COUNT I
(INFRINGEMENT OF THE '779 PATENT)

32. The allegations above are incorporated herein by reference.

33. Sun submitted Sun's ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Sun's ANDA Product before the expiration of the '779 Patent, and any extensions thereof.

34. The '779 Patent is listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), in connection with WEGOVY® in its 2.4 mg dosage strength and the related NDA. ANDA applicants generally must amend or supplement ANDAs to submit an appropriate patent certification for patents that issue after submission of the ANDA and before approval of the ANDA pursuant to 21 U.S.C. § 355(j)(2)(B)(ii)(II) and 21 C.F.R. § 314.94(a)(12)(viii)(C)(1)(ii).

35. Sun has actual knowledge of the '779 Patent.

36. The WEGOVY® Label states that "WEGOVY® is indicated in combination with a reduced calorie diet and increased physical activity:

- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight.

- to reduce excess body weight and maintain weight reduction long term in:
    - Adults and pediatric patients aged 12 years and older with obesity
    - Adults with overweight in the presence of at least one weight-related comorbid condition."

37. The WEGOVY® Label states that the active ingredient in WEGOVY® is semaglutide.

38. For adults, the WEGOVY® Label instructs to administer WEGOVY® once weekly according to a dose escalation schedule that includes an initiating dosage of semaglutide at 0.25 mg for four weeks, 0.5 mg for the next four weeks, 1 mg for the next four weeks, then 1.7 mg for the next four weeks after that. The WEGOVY® Label further instructs "[t]he maintenance dosage of WEGOVY is either 2.4 mg (recommended) or 1.7 mg once weekly" and to "[c]onsider treatment response and tolerability when selecting the maintenance dosage *[see Clinical Studies (14.2)]*."

39. For pediatric patients, the WEGOVY® Label instructs to administer WEGOVY® once weekly according to a dose escalation schedule that includes an initiating dosage of semaglutide at 0.25 mg for four weeks, 0.5 mg for the next four weeks, 1 mg for the next four weeks, then 1.7 mg for the next four weeks after that. The WEGOVY® Label instructs that "the maintenance dosage of WEGOVY in pediatric patients aged 12 years or older is 2.4 mg once weekly" and that "if patients do not tolerate the 2.4 mg once-weekly maintenance dosage, the maintenance dosage may be reduced to 1.7 mg once weekly."

40. The WEGOVY® Label further instructs administering WEGOVY® by subcutaneous injection.

41. The use of WEGOVY® in accordance with the WEGOVY® Label is claimed in at least claims 2 and 7 of the '779 Patent.

42. Thus, the use of WEGOVY® and any corresponding generic semaglutide injection is covered by at least claims 2 and 7 of the '779 Patent.

43. On information and belief, if Sun's ANDA is approved, Sun will make, offer for sale, sell, or import Sun's ANDA Product in a manner that, when used in accordance with the instructions of the proposed label for Sun's ANDA Product, would infringe at least claims 2 and 7 of the '779 Patent.

44. On information and belief, Sun's ANDA essentially copies the WEGOVY® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(8)(iv), and therefore instructs, recommends, encourages, promotes, and/or suggests that physicians, prescribers, and/or patients infringe at least claims 2 and 7 of the '779 Patent.

45. On information and belief, if Sun's ANDA is approved, physicians, prescribers, and/or patients will follow the instructions in the proposed label for Sun's ANDA Product and thereby infringe at least claims 2 and 7 of the '779 Patent.

46. WEGOVY® and any corresponding generic semaglutide injection formulation is not a staple article of commerce and has no substantial approved uses that do not infringe at least claims 2 and 7 of the '779 Patent. On information and belief, Sun's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claims 2 and 7 of the '779 Patent.

47. On information and belief, Sun has infringed or will infringe at least claims 2 and 7 of the '779 Patent under 35 U.S.C. § 271(e)(2)(A) by their submission of Sun's ANDA to FDA seeking to obtain approval for Sun's ANDA Product, which is covered by at least claims 2 and 7 of the '779 Patent, before the expiration of the '779 Patent.

48. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Sun's ANDA would infringe directly or contribute to or induce infringement of at least claims 2 and 7 of the '779 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

49. Novo Nordisk seeks an order declaring that Sun has infringed at least claims 2 and 7 of the '779 Patent by submitting Sun's ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

50. Novo Nordisk seeks an order requiring that Sun amend any Paragraph IV Certification related to the '779 Patent in Sun's ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(vii)(A).

51. Novo Nordisk seeks an order declaring that Sun will infringe at least claims 2 and 7 of the '779 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Sun's ANDA Product before the expiration of the '779 Patent under 35 U.S.C. §§ 271(b) and/or (c).

52. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A), including an order that the effective date of any FDA approval of Sun's ANDA be a date that is not earlier than the expiration of the '779 Patent or any later expiration of extensions, adjustments, and exclusivities for the '779 Patent to which Novo Nordisk becomes entitled.

53. Novo Nordisk will be irreparably harmed if Sun is not enjoined from infringing, actively inducing, or contributing to the infringement of at least claims 2 and 7 of the '779 Patent. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Novo Nordisk is entitled to a permanent injunction against further infringement. Novo Nordisk does not have an adequate remedy at law.

54. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

55. To the extent Sun commercializes Sun's ANDA Product prior to the expiration of the '779 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C).

PRAYER FOR RELIEF

WHEREFORE, Novo Nordisk respectfully requests that this Court enter judgment in their favor against Sun and grant the following relief:

A. An adjudication that Sun has infringed one or more claims of the '779 Patent under 35 U.S.C. § 271(e)(2)(A), by submitting to FDA Sun's ANDA, including any amendments or supplements thereof, to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Sun's ANDA Product before the expiration of the '779 Patent, or any later period of exclusivity to which Plaintiffs are or may become entitled;

B. A judgment declaring that Sun will contribute to the direct infringement of and/or induce the direct infringement of one or more claims of the '779 Patent under 35 U.S.C. §§ 271(b) and/or (c) if they market, manufacture, use, offer for sale, sell, distribute in, or import into the United States Sun's ANDA Product before the expiration of the '779 Patent, or any later period of exclusivity to which Plaintiffs are or may become entitled;

C. An order requiring that Sun amend any Paragraph IV certification with respect to the '779 Patent to a Paragraph III certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

D. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Sun's ANDA for Sun's ANDA Product be a date that is not earlier than the latest date of the expiration of the '779 Patent or any later period of exclusivity to which Plaintiffs are or may become entitled;

E. A permanent injunction enjoining Sun, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '779 Patent or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in Sun's ANDA;

F. An order enjoining Sun, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '779 Patent, contributing to, or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of Sun's ANDA Product;

G. An assessment of pre-judgment and post-judgment interest and costs against Sun, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284;

H. An award to Plaintiffs of their attorneys' fees incurred in connection with this lawsuit pursuant to 35 U.S.C. § 285; and

I. Such other and further relief as this Court may deem just and proper.

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September 5, 2024