IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and NOVO NORDISK A/S,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
MYLAN PHARMACEUTICALS INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), for their Complaint against Defendant Mylan Pharmaceuticals Inc. ("MPI"), 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, MPI is a corporation organized and existing under the laws of the State of West Virginia with a place of business at 3711 Collins Ferry Road, Morgantown, WV 26505. On information and belief, MPI is in the business of making and selling generic pharmaceutical products, which they distribute in the State of Delaware and throughout the United States.

4. On information and belief, MPI develops, manufactures, seeks 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

5. 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(a), (e), and (f) arising from Defendant's submission of an Abbreviated New Drug Application ("ANDA") No. 217705 (the "Defendant's ANDA") to the United States Food and Drug Administration ("FDA"), by which MPI seeks approval of a generic version of Novo Nordisk's pharmaceutical product WEGOVY® (semaglutide) injection prior to the expiration of United States Patent No. 12,214,017 ("the '017 Patent"), which covers, *inter alia*, WEGOVY® (semaglutide) injection.

6. NNAS is the owner of all rights, title, and interest in the '017 Patent.

7. 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.

8. Novo Nordisk intends to list the '017 Patent 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®

9. 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."

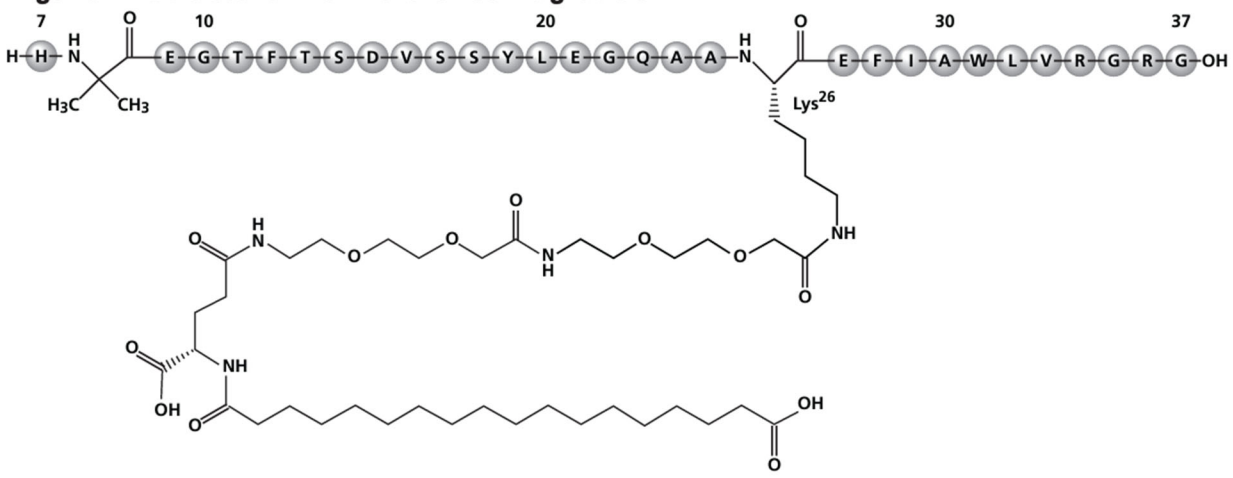
10. WEGOVY® is to be administered once weekly by subcutaneous injection.

11. 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)]*."

12. 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."

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

Figure 1. Structural Formula of semaglutide



14. 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.

15. 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.

DEFENDANT'S ANDA

16. On information and belief, MPI submitted Defendant'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 Defendant's ANDA ("Defendant's ANDA Product").

17. On information and belief, following any FDA approval of Defendant's ANDA, MPI will distribute and sell Defendant's ANDA Product throughout the United States, including within Delaware.

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

19. On information and belief, MPI has infringed or will infringe one or more claims of the '017 Patent under 35 U.S.C. § 271(e)(2)(A) by the submission of Defendant'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 Defendant's ANDA Product before the expiration of the '017 Patent or any extensions thereof.

20. MPI will infringe one or more claims of the '779 Patent under 35 U.S.C. § 271(a) and/or (f) should MPI engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Defendant's ANDA Product before the expiration of the '017 Patent or any extensions thereof.

JURISDICTION AND VENUE

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

22. This Court has personal jurisdiction over MPI because MPI has agreed not to contest and submitted itself to personal jurisdiction in this District.

23. Further, this Court has personal jurisdiction over MPI 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 co-pending actions involving assertions of patent infringement based on the same ANDA that is the subject of this Complaint (*see, e.g.*, Answer, Defenses, and Counterclaims, *Heron Therapeutics, Inc. v. Mylan Pharmaceuticals Inc.*, C.A. No. 23-1015 (D. Del. Dec. 4, 2023), D.I. 14; Answer, Defenses, and Counterclaims, *Novo Nordisk Inc., et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 22-1040 (D. Del. Aug. 2, 2023), D.I. 117; Answer, Affirmative Defenses and Counterclaims, *Novo Nordisk Inc., et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 23-101 (D. Del. Mar. 31, 2023), D.I. 11; 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, *Heron Therapeutics, Inc. v. Mylan Pharmaceuticals Inc.*, C.A. No. 23-1015 (D. Del. Dec. 4, 2023), D.I. 14; Answer, Defenses, and Counterclaims, *Novo Nordisk Inc., et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 22-1040 (D. Del. Aug. 2, 2023), D.I. 117; Answer, Affirmative Defenses, and Counterclaims, *Novo Nordisk Inc. et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 23-101 (D. Del. Mar. 31, 2023), D.I. 11; Answer, Affirmative Defenses, and Counterclaims, *Novo Nordisk Inc. et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 24-50 (D. Del. Jan. 12, 2024), D.I. 9; Answer, Affirmative Defenses, and Counterclaims, *Novo Nordisk Inc. et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 23-101 (D. Del. Jul. 31, 2024), D.I. 14.

24. This Court has personal jurisdiction over MPI because, on information and belief, MPI, upon approval of Defendant's ANDA, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under Defendant's ANDA that will be purposefully directed at Delaware, including the marketing of Defendant's ANDA Product in Delaware, prior to the expiration of the '017 Patent.

25. On information and belief, MPI prepared and submitted Defendant's ANDA, including amendments, and, if Defendant's ANDA is approved, will continue to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Defendant's ANDA Product in or into the United States, including Delaware, prior to the expiration of the '017 Patent.

26. On information and belief, MPI has taken the costly, significant step of applying to the FDA for approval, including submission of Defendant's ANDA and amendments thereto, to engage in future activities, including the marketing of Defendant's ANDA Product, that will be purposefully directed at Delaware and elsewhere.

27. On information and belief, MPI has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

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

29. Additionally, on information and belief, MPI is registered to do business in Delaware (File No. 4809319) and has appointed an agent in Delaware to receive service of process. This Court further has personal jurisdiction over MPI for other reasons that will be presented to the Court if jurisdiction is challenged.

30. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c), and 28 U.S.C. § 1400(b) because, among other reasons, MPI has agreed not to contest venue in this District. Venue is also proper in this District with respect to MPI for the same reasons that personal jurisdiction over MPI is proper in this District, as set forth above, including because MPI has committed acts of infringement in this District, and, upon information and belief, MPI will commit further acts of infringement in this District. Further, venue is proper with respect to MPI for other reasons that will be presented to the Court if venue is challenged.

THE PATENT-IN-SUIT

31. The allegations above are incorporated herein by reference.

32. Novo Nordisk A/S is the owner of all rights, title, and interest in the '017 Patent, entitled "GLP-1 Compositions and Uses Thereof." The USPTO duly and legally issued the '017 Patent on February 4, 2025. The '017 Patent names Eva Horn Moeller, Michael Duelund Soerensen, and Joakim Lundqvist as inventors. All named inventors assigned the '017 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '017 Patent and sue for infringement thereof. A true and correct copy of the '017 Patent is attached to this Complaint as Exhibit 1.

33. The '017 Patent claims a liquid pharmaceutical composition comprising semaglutide; wherein said composition (a) does not contain phenol; and (b) is administered parenterally; and (c)(i) is an aqueous solution comprising at least 60% (w/w) water or (ii) further comprises one or more pharmaceutically acceptable excipients selected from the group consisting of a buffer or an isotonic agent; and wherein the semaglutide is in the range of 0.01 mg/ml-10.0 mg/ml; and wherein the pH of the composition is in between 7.0 and 7.8.

COUNT I
(INFRINGEMENT OF THE '017 PATENT)

34. The allegations above are incorporated herein by reference.

35. MPI submitted Defendant's ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell Defendant's ANDA Product before the expiration of the '017 Patent, and any extensions thereof.

36. Novo Nordisk intends to list the '017 Patent in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), in connection with WEGOVY® (semaglutide) injection 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).

37. MPI has actual knowledge of the '017 Patent.

38. The WEGOVY® Label states that 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 or 2.4 mg semaglutide.

39. 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®. The WEGOVY® Label states that WEGOVY® has a pH of approximately 7.4 and that hydrochloric acid or sodium hydroxide may be added to adjust pH.

40. The WEGOVY® Label states WEGOVY® should be administered subcutaneously.

41. The WEGOVY® formulation is covered by at least claim 1 of the '017 Patent.

42. Thus, WEGOVY® and any corresponding generic semaglutide injection are covered by at least claim 1 of the ’017 Patent.

43. On information and belief, Defendant’s ANDA essentially copies the WEGOVY® Label and formulation as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(8)(iv), 314.94(a)(8)(iii), 314.127(a)(8)(ii)(B), and as such, the liquid pharmaceutical composition in Defendant’s ANDA Product is identical to that in WEGOVY®.

44. On information and belief, if Defendant’s ANDA is approved, MPI will make, offer for sale, sell, or import Defendant’s ANDA Product in a manner that would infringe at least claim 1 of the ’017 Patent.

45. 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 claim 1 of the ’017 Patent. On information and belief, Defendant’s ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claim 1 of the ’01 .

46. On information and belief, MPI has infringed or will infringe at least claim 1 of the ’017 Patent under 35 U.S.C. § 271(e)(2)(A) by their submission of Defendant’s ANDA to FDA seeking to obtain approval for Defendant’s ANDA Product, which is covered by at least claim 1 of the ’017 Patent, before the expiration of the ’017 Patent.

47. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Defendant’s ANDA would infringe directly at least claim 1 of the ’017 Patent under 35 U.S.C. §§ 271(a) and/or (f).

48. Novo Nordisk seeks an order declaring that MPI has infringed at least claim 1 of the ’017 Patent by submitting Defendant’s ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

49. Novo Nordisk seeks an order requiring that MPI amend any Paragraph IV Certification related to the '017 Patent in Defendant's ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(vii)(A).

50. Novo Nordisk seeks an order declaring that MPI will infringe at least claim 1 of the '017 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Defendant's ANDA Product before the expiration of the '017 Patent under 35 U.S.C. §§ 271(a) and/or (f).

51. 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 Defendant's ANDA be a date that is not earlier than the expiration of the '017 Patent or any later expiration of extensions, adjustments, and exclusivities for the '017 Patent to which Novo Nordisk becomes entitled.

52. Novo Nordisk will be irreparably harmed if MPI is not enjoined from infringing at least claim 1 of the '017 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.

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

54. To the extent MPI commercializes Defendant's ANDA Product prior to the expiration of the '017 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 MPI and grant the following relief:

A. An adjudication that MPI has infringed one or more claims of the '017 Patent under 35 U.S.C. § 271(e)(2)(A), by submitting to FDA Defendant'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 Defendant's ANDA Product before the expiration of the '017 Patent, or any later period of exclusivity to which Plaintiffs are or may become entitled;

B. A judgment declaring that MPI will infringe directly one or more claims of the '017 Patent under 35 U.S.C. §§ 271(a) and/or (f) if they market, manufacture, use, offer for sale, sell, distribute in, or import into the United States Defendant's ANDA Product before the expiration of the '017 Patent, or any later period of exclusivity to which Plaintiffs are or may become entitled;

C. An order requiring that MPI amend any Paragraph IV certification with respect to the '017 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 Defendant's ANDA for Defendant's ANDA Product be a date that is not earlier than the latest date of the expiration of the '017 Patent or any later period of exclusivity to which Plaintiffs are or may become entitled;

E. A permanent injunction enjoining MPI, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the '017 Patent, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in Defendant's ANDA;

F. An order enjoining MPI, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of

them from infringing the '017 Patent, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of Defendant's ANDA Product;

G. An assessment of pre-judgment and post-judgment interest and costs against MPI, 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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March 7, 2025