IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and NOVO NORDISK A/S,, Plaintiffs, v. MYLAN PHARMACEUTICALS INC., Defendant.	C.A. No. 25-cv-00276-CFC C.A. No. 23-101 (CFC) CONSOLIDATED (lead case) **ANDA CASE**

MYLAN PHARMACEUTICALS INC.'S
ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO COMPLAINT
ASSERTING U.S. PATENT NO. 12,214,017

Mylan Pharmaceuticals Inc. ("MPI"), by its undersigned attorneys, answers and responds to the complaint of Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo"), 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.

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations in ¶ 1 and therefore denies those allegations.

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 Bagsværd Denmark. NNI is an indirect, wholly-owned subsidiary of NNAS.

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations in ¶ 2 and therefore denies those allegations.

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.

ANSWER: MPI admits that it is a corporation organized and existing under West Virginia law. MPI admits that it develops and manufactures pharmaceutical products. MPI admits that it has a place of business at 3711 Collins Ferry Road, Morgantown, WV 26505. MPI denies the remaining allegations in ¶ 3.

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.

ANSWER: The allegations in this paragraph relate solely to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for purposes of this litigation only, and therefore no answer is required. To the extent an answer is required, MPI denies the allegations in ¶ 4.

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.

ANSWER: Paragraph 5 states a legal conclusion to which no answer is required. To the extent an answer is required, MPI admits that Novo's complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq. To the extent any further answer is required, MPI admits it submitted an Abbreviated New Drug Application ("ANDA") seeking approval by the United States Food and Drug Administration ("FDA") for 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 single-dose prefilled pens. MPI admits its ANDA was amended to include a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the U.S. Patent No. 12,214,017 ("the

'017 Patent"). MPI is without knowledge or information sufficient to form a belief as to any remaining allegations in ¶ 5 and therefore denies those allegations.

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

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations in ¶ 6 and therefore denies those allegations.

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.

ANSWER: MPI admits that the Orange Book maintained by the FDA lists Novo Nordisk Inc. as the holder of NDA 215256 for Wegovy® (semaglutide) injection, for subcutaneous use, 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. MPI admits that the Full Prescribing Information for Wegovy® (semaglutide) injection, for subcutaneous use, revised 11/2024 (the version of the label operative at the time of Novo's complaint), states in § 3 (Dosage Forms and Strengths) that the WEGOVY® (semaglutide) dosage form is: "Injection: clear, colorless solution available in 5 prefilled, disposable, single-dose pens." MPI is without knowledge or information sufficient to form a belief as to the remaining allegations in ¶ 7 and therefore denies those allegations.

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.

ANSWER: MPI admits that the Orange Book maintained by the FDA currently lists the '017 Patent in conjunction with NDA 215256 for Wegovy® (semaglutide) injection, for subcutaneous use, 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. MPI is without knowledge or information sufficient to form a belief as to the remaining allegations in ¶ 8 and therefore denies those allegations.

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."

ANSWER: MPI admits that the following text appears in the Full Prescribing Information for Wegovy® (semaglutide) injection, for subcutaneous use, revised 11/2024 (the version of the label operative at the time of Novo's complaint), under § 1 (Indications and Usage):

"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.

Limitations of Use

- WEGOVY® contains semaglutide. Coadministration with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended."

MPI denies the remaining allegations in ¶ 9.

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

ANSWER: MPI admits that the following text appears in the Highlights of Prescribing Information for Wegovy®:

- Administer WEGOVY® once weekly as an adjunct to diet and increased physical activity, on the same day each week, at any time of day, with or without meals (2.1).

- Inject subcutaneously in the abdomen, thigh, or upper arm (2.1).

MPI denies the remaining allegations in ¶ 10.

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)]*."

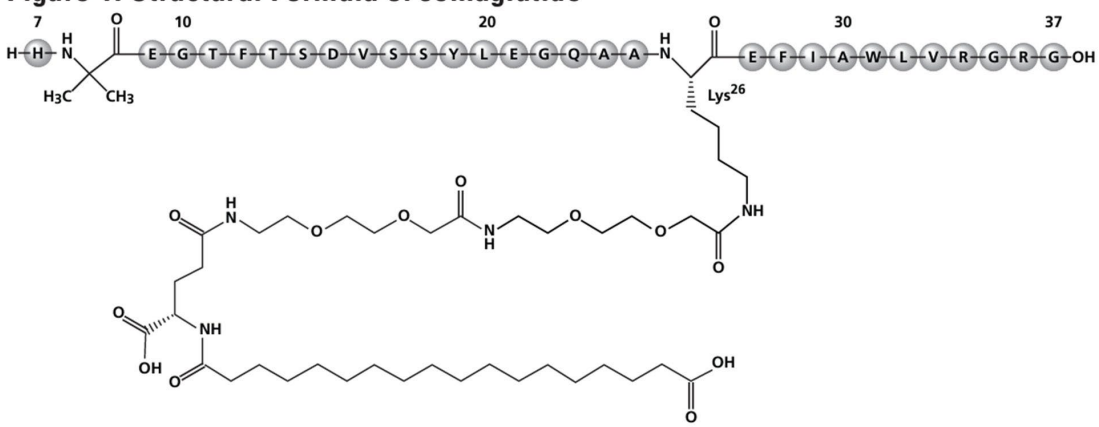
ANSWER: MPI admits that the Full Prescribing Information for Wegovy® (semaglutide) injection, under § 2.2 (Recommended Dosage in Adults and Pediatric Patients Aged 12 Years and Older), states "Initiate WEGOVY® with a dosage of 0.25 mg injected subcutaneously once weekly. Follow the dosage initiation and escalation in Table 1 to reduce the risk of gastrointestinal adverse reactions." MPI also admits that the Full Prescribing Information for Wegovy® states "[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 Adverse Reactions (6.1), Clinical Studies (14.2, 14.3)]*." MPI denies the remaining allegations in ¶ 11.

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."

ANSWER: MPI admits that the Full Prescribing Information for Wegovy® (semaglutide) injection, for subcutaneous use, revised 11/2024, includes "Table 1: Recommended Dosage Escalation in Adults and Pediatric Patients Aged 12 Years and Older" in § 2.2 "Recommended Dosage in Adults and Pediatric Patients Aged 12 Years and Older," which recites that the 0.25 mg, 0.5 mg, and 1 mg doses are not maintenance dosages. MPI denies the remaining allegations in ¶ 12.

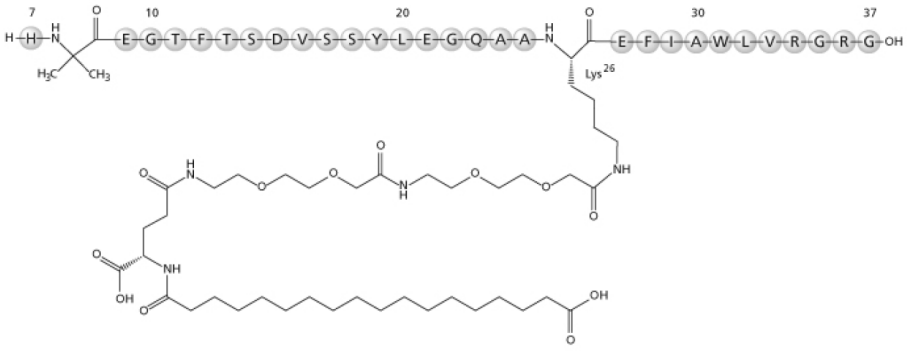
13. The active ingredient in WEGOVY® is semaglutide and its structure is:

Figure 1. Structural Formula of semaglutide



ANSWER: MPI admits that the Full Prescribing Information for Wegovy® (semaglutide) injection, for subcutaneous use, revised 11/2024, states in § 11 (Description) that "WEGOVY® (semaglutide) injection, for subcutaneous use, contains semaglutide, a human GLP-1 receptor agonist (or GLP-1 analog)." MPI further admits that the following image appears in the Full Prescribing Information for Wegovy® (semaglutide) injection, for subcutaneous use, revised 11/2024, § 11 (Description):

Figure 1. Structural Formula of semaglutide



MPI denies the remaining allegations in ¶ 13.

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®

containing1.7 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.

ANSWER: MPI admits that the Full Prescribing Information for Wegovy® (semaglutide) injection, for subcutaneous use, revised 11/2024, includes the following in § 11 (Description): "WEGOVY® is a sterile, aqueous, clear, colorless solution. Each 0.5 mL single-dose pen 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 of semaglutide." MPI denies the remaining allegations in ¶ 14.

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.

ANSWER: MPI admits that the Full Prescribing Information for Wegovy® (semaglutide) injection, for subcutaneous use, revised 11/2024, includes the following in § 11 (Description): "Each 1 mL of WEGOVY® contains the following inactive ingredients: disodium phosphate dihydrate, 1.42 mg; sodium chloride, 8.25 mg; and water for injection. WEGOVY® has a pH of approximately 7.4. Hydrochloric acid or sodium hydroxide may be added to adjust pH." MPI denies the remaining allegations in ¶ 15.

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").

ANSWER: MPI admits that it submitted ANDA No. 217705 to the FDA under 21 U.S.C. § 355(j) seeking approval for 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 single-dose prefilled pens. MPI denies the remaining allegations in ¶ 16.

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.

ANSWER: The allegations in this paragraph relate solely to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for purposes of this litigation only, and therefore no answer is required. Furthermore, the allegations in this paragraph relate to future acts and call for speculation as to those future acts. MPI denies the remaining allegations of ¶ 17.

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®.

ANSWER: MPI admits that ANDA No. 217705 refers to Wegovy® as the reference listed drug. MPI further admits that ANDA No. 217705 states that it demonstrates bioequivalence to the reference listed drug. MPI denies the remaining allegations in ¶ 18.

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.

ANSWER: Paragraph 19 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations in ¶ 19.

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

ANSWER: Paragraph 20 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations in ¶ 20.

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.

ANSWER: Paragraph 21 states a legal conclusion to which no answer is required. To the extent an answer is required, MPI does not dispute the Court's subject-matter jurisdiction under 28 U.S.C. §§ 1131, 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.

ANSWER: The allegations in this paragraph relate solely to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for purposes of this litigation only, and therefore no answer is required. To the extent an answer is required, MPI denies the remaining allegations of ¶ 22.

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 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, *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.

ANSWER: The allegations in this paragraph relate solely to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for purposes of this litigation only, and therefore no answer is required. To the extent an answer is required, MPI denies the remaining allegations of ¶ 23.

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.

ANSWER: The allegations in this paragraph relate solely to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for purposes of this litigation only, and therefore no answer is required. To the extent an answer is required, MPI denies the remaining allegations of ¶ 24.

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.

ANSWER: The allegations in this paragraph relate solely to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for purposes of this litigation only, and therefore no answer is required. To the extent an answer is required, MPI denies the remaining allegations of ¶ 25.

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.

ANSWER: The allegations in this paragraph relate solely to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for purposes of this litigation only, and therefore no answer is required. To the extent an answer is required, MPI denies the remaining allegations of ¶ 26.

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.

ANSWER: The allegations in this paragraph relate solely to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for purposes of this litigation only, and therefore no answer is required. To the extent an answer is required, MPI denies the remaining allegations of ¶ 27.

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.

ANSWER: The allegations in this paragraph relate solely to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for purposes of this litigation only, and therefore no answer is required. To the extent an answer is required, MPI denies the remaining allegations of ¶ 28.

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.

ANSWER: The allegations in this paragraph relate solely to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for purposes of this litigation only, and therefore no answer is required. To the extent an answer is required, MPI denies the remaining allegations of ¶ 29.

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.

ANSWER: The allegations in this paragraph relate solely to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for purposes of this litigation only, and therefore no

answer is required. To the extent an answer is required, MPI denies the remaining allegations of ¶ 30.

THE PATENT IN SUIT

31. The allegations above are incorporated herein by reference.

ANSWER: MPI incorporates its responses above by reference.

32. Novo Nordisk A/S is the owner of all rights, title, and interest in the '017 Patent, entitled "Semaglutide in Medical Therapy." 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.

ANSWER: MPI admits that a purported copy of the '017 Patent is attached to the complaint as Exhibit 1. MPI denies that the '017 Patent is titled "Semaglutide in Medical Therapy." MPI admits that, on its face, the '017 Patent bears an issuance date of February 4, 2025, identifies Eva Horn Moeller, Michael Duelund Soerensen, and Joakim Lundqvist as inventors, and identifies NNAS as assignee. MPI is without knowledge or information sufficient to form a belief as to the remaining allegations of ¶ 32 and therefore denies those allegations.

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.

ANSWER: Paragraph 33 states a legal conclusion to which no answer is required. To the extent an answer is required, MPI states that claim 1 of the '017 Patent recites, "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." MPI is without knowledge or information sufficient to form a belief as to the remaining allegations of ¶ 33 and therefore denies those allegations.

COUNT 1
(INFRINGEMENT OF THE '017 PATENT)

34. The allegations above are incorporated herein by reference.

ANSWER: MPI incorporates by reference its answer to each allegation above.

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.

ANSWER: MPI admits that it submitted ANDA No. 217705 to the FDA under 21 U.S.C. § 355(j) seeking approval for 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 single-dose prefilled pens. MPI denies the remaining allegations in ¶ 35.

36. Novo Nordisk intends to list the '017 Patent is listed 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).

ANSWER: Paragraph 36 states a legal conclusion to which no answer is required. To the extent an answer is required, MPI admits that the Orange Book maintained by the FDA currently lists the '017 Patent in conjunction with NDA 215256 for Wegovy® (semaglutide) injection, for subcutaneous use, 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. MPI is without knowledge or information sufficient to form a belief as to any remaining allegations in ¶ 36 and therefore denies those allegations.

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

ANSWER: MPI admits that it has actual knowledge of the '017 Patent as of the date of this response. MPI denies the remaining allegations in ¶ 37.

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.

ANSWER: MPI admits that the Full Prescribing Information for Wegovy® (semaglutide) injection, for subcutaneous use, revised 11/2024, states in § 11 (Description) that "[e]ach 0.5 mL single-dose pen 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 of semaglutide." MPI denies the remaining allegations in ¶ 38.

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.

ANSWER: MPI admits that the Full Prescribing Information for Wegovy® (semaglutide) injection, for subcutaneous use, revised 11/2024, states in § 11 (Description) that "[e]ach 1 mL of WEGOVY® contains the following inactive ingredients: disodium phosphate dihydrate, 1.42 mg; sodium chloride, 8.25 mg; and water for injection. WEGOVY® has a pH of approximately 7.4. Hydrochloric acid or sodium hydroxide may be added to adjust pH." MPI denies the remaining allegations in ¶ 39.

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

ANSWER: MPI repeats and realleges the answer to ¶ 10 as if set forth here. MPI denies the remaining allegations in ¶ 40.

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

ANSWER: Paragraph 41 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations in ¶ 41.

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

ANSWER: Paragraph 42 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations in ¶ 42.

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®.

ANSWER: Paragraph 43 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations in ¶ 43.

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.

ANSWER: Paragraph 44 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations in ¶ 44.

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.

ANSWER: Paragraph 45 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations in ¶ 45.

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.

ANSWER: Paragraph 46 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations in ¶ 46.

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).

ANSWER: Paragraph 47 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations in ¶ 47.

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).

ANSWER: MPI denies that Novo is entitled to the order described in ¶ 48.

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).

ANSWER: MPI denies that Novo is entitled to the order described in ¶ 49.

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(b) and/or (c).

ANSWER: MPI denies that Novo is entitled to the order described in ¶ 50.

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.

ANSWER: MPI denies that Novo is entitled to the order described in ¶ 51.

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.

ANSWER: Paragraph 52 states legal conclusions and allegations to which no answer is required. To the extent an answer is required, MPI denies the allegations in ¶ 52 and denies that Novo is entitled to the remedy described in ¶ 52.

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

ANSWER: Paragraph 53 states legal conclusions and allegations to which no answer is required. To the extent an answer is required, MPI denies the allegations in ¶ 53 and denies that Novo is entitled to the remedy described in ¶ 53.

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).

ANSWER: Paragraph 54 states legal conclusions to which no answer is required. To the extent an answer is required, MPI denies the allegations in ¶ 54 and denies that Novo is entitled to the remedy described in ¶ 54.

NOVO'S PRAYER FOR RELIEF

The remainder of Novo's complaint recites a prayer for relief for which no answer is required. To the extent any response is required, MPI answers that Novo is not entitled to any remedy or relief sought in their prayer for relief.

SEPARATE DEFENSES

Without making any admissions as to the burden of proof, burden of persuasion, or the truth of any allegations in Novo's complaint, MPI states the following defenses:

FIRST SEPARATE DEFENSE: NONINFRINGEMENT OF U.S. PATENT NO. 12,214,017

MPI has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '017 Patent.

SECOND SEPARATE DEFENSE: INVALIDITY OF U.S. PATENT NO. 12,214,017

The claims of the '017 Patent are invalid for double patenting and/or failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code, particularly §§ 101, 102, 103, 112, 115, and/or 116.

THIRD SEPARATE DEFENSE: FAILURE TO STATE A CLAIM

The complaint fails to state a claim upon which relief can be granted.

FOURTH SEPARATE DEFENSE: THIS IS NOT AN EXCEPTIONAL CASE

Neither the filing of MPI's ANDA No. 217705 nor MPI's actions defending this case give rise to an exceptional case under 35 U.S.C. § 285.

FIFTH SEPARATE DEFENSE: ESTOPPEL

Novo is estopped from asserting infringement by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

SIXTH SEPARATE DEFENSE: SAFE HARBOR PROVISION OF 35 U.S.C. § 271(e)(1)

Defendant's activities, if any, related to MPI's ANDA No. 217705 have been solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs.

SEVENTH SEPARATE DEFENSE: LACK OF SUBJECT-MATTER JURISDICTION

The complaint fails to establish this Court's subject-matter jurisdiction over any claim brought under 35 U.S.C. §§ 271(a), (b), (c), (e), and/or (f).

EIGHTH SEPARATE DEFENSE: NO ENTITLEMENT TO INJUNCTIVE RELIEF

Novo is not entitled to any injunctive relief, preliminary, permanent, or otherwise, including at least because Novo cannot show irreparable harm.

NINTH SEPARATE DEFENSE: UNENFORCEABILITY

Novo's statements during prosecution render the '017 patent unenforceable.

TENTH SEPARATE DEFENSE: RESERVATION OF RIGHTS

MPI's asserted separate defenses are based on information available and accessible to MPI at this time. MPI's investigation of its defenses will continue throughout discovery in this matter and MPI reserves the right to supplement and/or amend these defenses.

COUNTERCLAIMS

For its counterclaims against Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Plaintiffs"), Mylan Pharmaceuticals Inc. ("MPI") states as follows:

PARTIES

1. MPI has a principal place of business at 3711 Collins Ferry Road, Morgantown, WV 26505.

2. MPI owns ANDA No. 217705. MPI submitted ANDA No. 217705 on October 20, 2022, to the FDA under 21 U.S.C. § 355(j) to obtain approval for 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 single-dose pre-filled pens ("MPI's Proposed ANDA Product").

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

4. Upon information and belief, Novo Nordisk A/S ("NNAS") is an entity organized and existing under the laws of the Kingdom of Denmark, and has its principal place of business at Novo Allé, 2880 Bagsværd, Denmark. NNI is an indirect, wholly-owned subsidiary of NNAS.

NATURE OF THE ACTION

5. MPI seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. § 2201 et seq., that United States Patent No. 12,214,017 ("'017 Patent" or "Patent in Suit") is invalid and/or not infringed.

JURISDICTION AND VENUE

6. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. This Court has personal jurisdiction over Plaintiffs because, among other reasons, they subjected themselves to the jurisdiction of this Court by filing their complaint here.

8. Venue is proper in this Court for purposes of these counterclaims because, among other reasons, Plaintiffs commenced and continue to prosecute this action in this Court.

9. There is an actual and justiciable controversy between the parties as to the noninfringement and invalidity of the Patent in Suit.

BACKGROUND

10. MPI submitted Abbreviated New Drug Application ("ANDA") No. 217705 ("MPI's ANDA") to obtain FDA approval for MPI's Proposed ANDA Product.

11. On information and belief, NNI holds approved New Drug Application ("NDA") No. 215256 for WEGOVY® (semaglutide) injection, for subcutaneous use, 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 pen under Section 505(b) of the Federal Food Drug and Cosmetic Act ("FFDCA").

12. On information and belief, NNI caused the Patent in Suit to be listed in the FDA's publication entitled "Orange Book: Approved Drug Products with Therapeutic Equivalence

Evaluations" as a patent that purportedly claims the drug listed in NDA No. 215256, or a method of using or a kit containing that drug.

13. The '017 Patent, titled "GLP-1 Compositions and Uses Thereof," issued on February 4, 2025.

14. On information and belief, NNAS is the sole assignee of the '017 Patent.

15. MPI's ANDA contains "Paragraph IV" certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the Patent in Suit is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of MPI's Proposed ANDA Product.

16. On March 20, 2025, MPI sent Plaintiffs written notice of MPI's Paragraph IV Certifications ("MPI's Notice Letter"), under 21 U.S.C. § 355(j)(2)(B). MPI's Notice Letter asserted that the claims of the Patent in Suit are invalid, unenforceable, and/or will not be infringed by MPI's ANDA or the products or activities described therein.

17. MPI's Notice Letter included a detailed statement of the legal and factual basis for the Paragraph IV certifications included in MPI's ANDA, under 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

18. On March 7, 2025, Plaintiffs filed the present lawsuit alleging infringement of the Patent in Suit. There has been, and now is, an actual and justiciable controversy between MPI and Plaintiffs as to whether MPI's Proposed ANDA Product would infringe, induce infringement, or contribute to the infringement of any valid and enforceable claim of the Patent in Suit.

FIRST COUNTERCLAIM: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF U.S. PATENT NO. 12,214,017

19. MPI incorporates by reference the allegations in the foregoing Paragraphs of its counterclaims.

20. MPI's Proposed ANDA Product has not infringed, will not infringe, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '017 Patent.

21. Unless Plaintiffs are enjoined, Plaintiffs will continue to assert that MPI's Proposed ANDA Product is infringing the claims of the '017 Patent and will continue to interfere with MPI's business with respect to MPI's Proposed ANDA Product and its manufacture, use, offer for sale, and sale.

22. MPI will be irreparably harmed if Plaintiffs are not enjoined from continuing to assert the '017 Patent and from interfering with MPI's business.

23. A definite and concrete, real and substantial, justiciable controversy exists between MPI and Plaintiffs concerning MPI's noninfringement of the '017 Patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

24. MPI incorporates by reference MPI's Notice Letter, which contains exemplary and nonlimiting explanations that MPI's Proposed ANDA Product does not infringe the claims of the '017 Patent.

25. MPI is entitled to a declaratory judgment that MPI's Proposed ANDA Product has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '017 Patent.

SECOND COUNTERCLAIM: DECLARATORY JUDGMENT OF INVALIDITY OF U.S. PATENT NO. 12,214,017

26. MPI incorporates by reference the allegations in the foregoing Paragraphs of its counterclaims.

27. The claims of the '017 Patent are invalid for double patenting and/or failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code.

28. Unless Plaintiffs are enjoined, Plaintiffs will continue to assert that MPI's Proposed ANDA Product is infringing the claims of the '017 Patent and will continue to interfere with MPI's business with respect to MPI's Proposed ANDA Product and its manufacture, use, offer for sale, and sale.

29. MPI will be irreparably harmed if Plaintiffs are not enjoined from continuing to assert the '017 Patent and from interfering with MPI's business.

30. A definite and concrete, real and substantial, justiciable controversy exists between MPI and Plaintiffs concerning the invalidity of the '017 Patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

31. MPI incorporates by reference MPI's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '017 Patent are invalid.

32. MPI is entitled to a declaratory judgment that the claims of the '017 Patent are invalid.

REQUEST FOR RELIEF

Wherefore, Defendant respectfully requests that this Court enter judgment:

a. Dismissing the Complaint with prejudice and denying each and every prayer for relief contained therein;

b. Declaring that the proposed products described in MPI's ANDA No. 217705 do not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the Patent in Suit;

c. Declaring that the claims of the Patent in Suit are invalid;

d. Enjoining Plaintiffs and their respective officers, employees, agents, representatives, attorneys, and others acting on their behalf, from representing to anyone, either directly or

indirectly, that the proposed products described in MPI's ANDA No. 217705 have infringed, are infringing, or would infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid enforceable claim of the Patent in Suit;

e. Awarding Defendant its costs;

f. Declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Defendant its attorneys' fees; and

g. Awarding to Defendant such further relief as this Court may deem necessary, just and proper.

Dated: April 25, 2025

/s/ Stamatios Stamoulis
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CERTIFICATE OF SERVICE

I hereby certify that on April 25, 2025, I electronically filed the foregoing **MYLAN PHARMACEUTICALS INC.'S ANSWER, SEPARATE DEFENSES, AND COUNTER-CLAIMS TO COMPLAINT ASSERTING U.S. PATENT NO. 12,214,017** with the Clerk of the Court using the CM/ECF system, which will send notice of the same to the following counsel of record:

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