**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| NOVO NORDISK INC. and NOVO NORDISK A/S,<br><br>Plaintiffs,<br><br>v.<br><br>MYLAN PHARMACEUTICALS INC.,<br><br>Defendant. | C.A. No. 1:24-cv-1013-CFC<br><br>**ANDA CASE** |

**MYLAN PHARMACEUTICALS INC.'S ANSWER, SEPARATE DEFENSES AND COUNTERCLAIM TO COMPLAINT**

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"):

**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 Bagsvaerd 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 1000 Mylan Blvd., Canonsburg, Pennsylvania, 15317. 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 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 only to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for 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(b), (c), and (e) 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. 12,029,779 ("the '779 Patent"), which covers, *inter alia*, WEGOVY® (semaglutide) injection and/or its use.

**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 U.S., 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 denies that this action is properly brought under 35 U.S.C. § 271(b) or (c). MPI denies that this action is properly brought under 35 U.S.C. § 271(e) to the extent the action purports to relate to MPI's semaglutide injection, 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, or 1.7 mg/0.75 mL single-dose prefilled pens as the '779 patent is not listed in the Orange

Book for Product 001 (Wegovy 0.25 mg/0.5 mL prefilled single-dose pen), Product 002 (Wegovy 0.5 mg/0.5 mL prefilled single-dose pen), Product 003 (Wegovy 1 mg/0.5 mL prefilled single-dose pen), or Product 004 (Wegovy 1.7 mg/0.75 mL prefilled single-dose pen) for Novo's NDA 215256. 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 '779 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 states 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 in five separate strengths and approved as five separate products, 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 prefilled 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. 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.

**ANSWER:** MPI admits that the Orange Book maintained by the FDA currently lists the '779 patent in conjunction with NDA 215256 for Wegovy® (semaglutide) injection for subcutaneous use for NDA 215256 Product 005 (Wegovy 2.4 mg/0.75 mL prefilled single-dose pen). MPI denies that the '779 patent is listed in the Orange Book for NDA 215256 Products 001, 002, 003, or 004.

**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 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)]*."

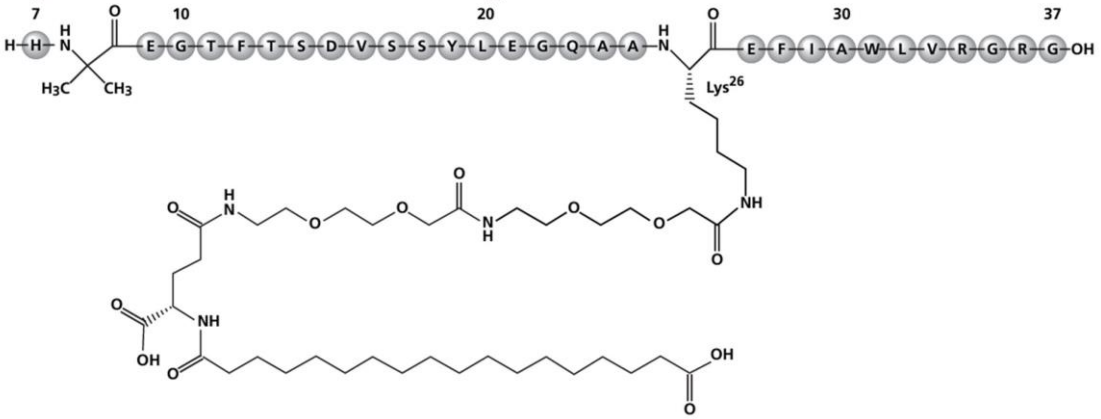
**ANSWER:** MPI admits that the Full Prescribing Information for Wegovy® (semaglutide) injection states "Initiate WEGOVY with a dosage of 0.25 mg injected subcutaneously once weekly. Then follow the dose escalation schedule presented in Table 1 to minimize gastrointestinal adverse reactions." MPI also admits that the Full Prescribing Information for Wegovy® states "[t]he maintenance dosage of WEGOVY in adults 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)]*." 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 includes "Table 2: Recommended Dosage Regimen for Pediatric Patients Aged 12 Years and Older" in § 2.3 "Recommended Dosage in Pediatric Patients Aged 12 Years and Older," which recites that the 0.25 mg, 0.5 mg, and 1 mg doses are "[n]ot approved as maintenance dosages." MPI denies the remaining allegations in ¶ 12.

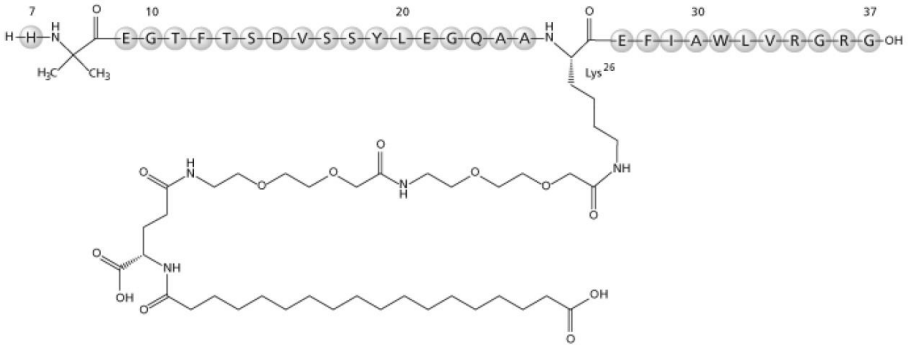
13. The active ingredient in WEGOVY® is semaglutide and its structure is:

**Figure 1. Structural Formula of semaglutide**



**ANSWER:** MPI admits that the Full Prescribing Information for Wegovy® (semaglutide) injection 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, § 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 Prescribing Information for Wegovy® describes five separate products. MPI admits that the Full Prescribing Information for Wegovy® (semaglutide) injection, 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 ¶ 13.

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 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 five separate products, 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 only to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for 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 shows bioequivalence to the reference listed drug for the five separate products described in ANDA No. 217705. MPI denies the remaining allegations in ¶ 18.

19. On information and belief, MPI 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 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 '779 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 '779 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 with respect to MPI's 2.4/0.75 mg/mL strength prefilled single-dose pens. MPI denies that subject matter is proper with respect to MPI's 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, and 1.7 mg/0.75 mL strength prefilled single-dose pens.

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 only to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for 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 only to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for 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 '779 Patent.

**ANSWER:** The allegations in this paragraph relate only to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for 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 '779 Patent.

**ANSWER:** The allegations in this paragraph relate only to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for 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 only to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for 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 only to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for 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 only to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for 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 only to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for 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 only to issues of venue and jurisdiction. MPI does not dispute venue and jurisdiction for 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 ’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.

**ANSWER:** MPI admits that a purported copy of the '779 patent is attached to the complaint as Exhibit 1. MPI admits that, on its face, the '779 patent is titled "Semaglutide in Medical Therapy," bears an issuance date of July 9, 2024, identifies Marianne Oelholm Larsen Groenning, Lars Endahl, Charlotte Giwercman Carson, Anders Bjerring Strathe, Maria Kabisch, and Thomas Hansen 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 '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.

**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 '779 patent recites, "A method for reducing body weight of a subject in need thereof, comprising administering semaglutide subcutaneously to the subject in an amount of about 2.4 mg weekly" and that claim 7 of the '779 patent recites, "A method for reducing body weight of a subject in need thereof, comprising administering semaglutide subcutaneously to the subject in an amount of 2.4 mg once weekly." 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 '779 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 '779 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 five separate semaglutide injection products, 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. 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).

**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 '779 patent in conjunction with NDA 215256 for Wegovy® (semaglutide) injection for subcutaneous use for NDA 215256 Product 005 (Wegovy 2.4 mg/0.75 mL strength prefilled single-dose pen). MPI denies that the '779 patent is listed in the Orange Book for NDA 215256 Products 001, 002, 003, or 004. 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 '779 Patent.

**ANSWER:** MPI admits that it has actual knowledge of the '779 patent as of the date of this response. MPI denies the remaining allegations in ¶ 37.

38. 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 repeats and realleges the answer to ¶ 9 as if set forth here. MPI denies the remaining allegations in ¶ 38.

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

**ANSWER:** MPI repeats and realleges the answer to ¶ 13 as if set forth here. MPI denies the remaining allegations in ¶ 39.

40. 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 repeats and realleges the answer to ¶ 11 as if set forth here. MPI denies the remaining allegations in ¶ 40.

41. 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 repeats and realleges the answer to ¶ 12 as if set forth here. MPI denies the remaining allegations in ¶ 41.

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

**ANSWER:** MPI repeats and realleges the answer to ¶ 10 as if set forth here. MPI denies the remaining allegations in ¶ 42.

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

Paragraph 43 contains a legal conclusion to which no answer is required. MPI states that the use of NDA 215256 Products 001, 002, 003, or 004 is not claimed in at least claims 2 and 7 of the '779

patent. MPI further states that using Wegovy in accordance with the Wegovy Label does not require administering a dose of 2.4 mg of semaglutide or about 2.4 mg of semaglutide at least because a 1.7 mg dose of Wegovy is approved as a maintenance dose. To the extent a further answer is required, MPI denies the allegations in ¶ 43.

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

**ANSWER:** Paragraph 44 contains a legal conclusion to which no answer is required. MPI states that the use of NDA 215256 Products 001, 002, 003, or 004 is not claimed in at least claims 2 and 7 of the '779 patent. MPI further states that using Wegovy in accordance with the Wegovy Label does not require administering a dose of 2.4 mg of semaglutide or about 2.4 mg of semaglutide at least because a 1.7 mg dose of Wegovy is approved as a maintenance dose. To the extent a further answer is required, MPI denies the allegations in ¶ 44.

45. 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, when used in accordance with the instructions of the proposed label for Defendant's ANDA Product, would infringe at least claims 2 and 7 of the '779 Patent.

**ANSWER:** Paragraph 45 contains a legal conclusion to which no answer is required. MPI denies that using the products described in ANDA No. 217705 would infringe claims 2 and 7 of the '779 patent, at least because MPI's semaglutide injection, 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, or 1.7 mg/0.75 mL single-dose prefilled pens are not capable of administering 2.4 mg of semaglutide or about 2.4 mg of semaglutide. To the extent a further answer is required, MPI denies the allegations in ¶ 45.

46. On information and belief, Defendant'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.

**ANSWER:** Paragraph 46 contains a legal conclusion to which no answer is required. MPI denies that using the products described in ANDA No. 217705 would infringe claims 2 and 7 of the '779 patent, at least because MPI's semaglutide injection, 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, or 1.7 mg/0.75 mL single-dose prefilled pens are not capable of administering 2.4 mg of semaglutide or about 2.4 mg of semaglutide. To the extent a further answer is required, MPI denies the allegations in ¶ 46.

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

**ANSWER:** Paragraph 47 contains a legal conclusion to which no answer is required. MPI denies that using the products described in ANDA No. 217705 would infringe claims 2 and 7 of the '779 patent, at least because MPI's semaglutide injection, 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, or 1.7 mg/0.75 mL single-dose prefilled pens are not capable of administering 2.4 mg of semaglutide or about 2.4 mg of semaglutide. To the extent a further answer is required, MPI denies the allegations in ¶ 47.

48. 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, Defendant'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.

**ANSWER:** Paragraph 48 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI states that the use of MPI's semaglutide injection, 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, or 1.7 mg/0.75 mL single-dose prefilled pens have substantial non-infringing uses with respect to claims 2 and 7 of the '779 patent. To the extent a further answer is required, MPI denies the allegations in ¶ 48.

49. On information and belief, MPI 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 Defendant's ANDA to

FDA seeking to obtain approval for Defendant's ANDA Product, which is covered by at least claims 2 and 7 of the '779 Patent, before the expiration of the '779 Patent.

**ANSWER:** Paragraph 49 contains a legal conclusion to which no answer is required. MPI denies that using the products described in ANDA No. 217705 would infringe claims 2 and 7 of the '779 patent, at least because MPI's semaglutide injection, 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, or 1.7 mg/0.75 mL single-dose prefilled pens are not capable of administering 2.4 mg of semaglutide or about 2.4 mg of semaglutide. To the extent a further answer is required, MPI denies the allegations in ¶ 49.

50. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Defendant'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).

**ANSWER:** Paragraph 50 contains a legal conclusion to which no answer is required. MPI denies that using the products described in ANDA No. 217705 would infringe claims 2 and 7 of the '779 patent, at least because MPI's semaglutide injection, 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, or 1.7 mg/0.75 mL single-dose prefilled pens are not capable of administering 2.4 mg of semaglutide or about 2.4 mg of semaglutide. MPI further states that claims under 35 U.S.C. §§ 271(a), (b), and/or (c) are improper, premature, and not ripe. To the extent a further answer is required, MPI denies the allegations in ¶ 50.

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

**ANSWER:** Paragraph 51 is a factual assertion to which no answer is required. To the extent an answer is required, MPI denies that Novo is entitled to the order described in ¶ 51.

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

**ANSWER:** Paragraph 52 is a factual assertion to which no answer is required. To the extent an answer is required, MPI denies that Novo is entitled to the order described in ¶ 52.

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

**ANSWER:** Paragraph 53 is a factual assertion to which no answer is required. To the extent an answer is required, MPI denies that Novo is entitled to the order described in ¶ 53.

54. 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 '779 Patent or any later expiration of extensions, adjustments, and exclusivities for the '779 Patent to which Novo Nordisk becomes entitled.

**ANSWER:** Paragraph 54 is a factual assertion to which no answer is required. MPI states that Novo is not entitled to any relief at least with respect to MPI's semaglutide injection, 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, or 1.7 mg/0.75 mL single-dose prefilled pens which are not capable of administering 2.4 mg of semaglutide or about 2.4 mg of semaglutide. To the extent a further answer is required, MPI denies that Novo is entitled to the order described in ¶ 54.

55. Novo Nordisk will be irreparably harmed if MPI 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.

**ANSWER:** Paragraph 55 states legal conclusions and allegations to which no answer is required. MPI states that Novo is not entitled to any relief at least with respect to MPI's semaglutide injection, 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, or 1.7 mg/0.75 mL single-dose prefilled pens which not capable of administering 2.4 mg of semaglutide or about 2.4 mg of semaglutide. To the extent an answer is required, MPI denies the allegations in ¶ 55 and denies that Novo is entitled to the remedy described in ¶ 55.

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

**ANSWER:** Paragraph 56 states legal conclusions and allegations to which no answer is required. To the extent an answer is required, MPI denies the allegations in ¶ 56 and denies that Novo is entitled to the remedy described in ¶ 56.

57. To the extent MPI commercializes Defendant'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).

**ANSWER:** Paragraph 57 states legal conclusions to which no answer is required. To the extent an answer is required, MPI denies the allegations in ¶ 57 and denies that Novo is entitled to the remedy described in ¶ 57.

## 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 its prayer for relief.

## MPI'S 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. 12,029,779

MPI has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid enforceable claim of the '779 patent.

### SECOND SEPARATE DEFENSE: INVALIDITY OF U.S. PATENT NO. 12,029,779

The claims of the '779 patent are invalid for double patenting and/or failure to meet one or more conditions for patentability specified in Title 35 of the U.S. 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)**

MPI'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).

**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: PATENT MISUSE**

Novo's attempt to seek remedies at least against MPI's semaglutide injection, 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, or 1.7 mg/0.75 mL single-dose prefilled pens which are not capable of administering 2.4 mg of semaglutide or about 2.4 mg of semaglutide constitutes patent misuse and renders the '779 Patent unenforceable.

**TENTH SEPARATE DEFENSE: LACK OF ENTITLEMENT TO AN ORDER PURSUANT TO 35 U.S.C. § 271(e)(4)(A)**

The '779 Patent is not listed in the Orange Book for NDA 215256 Products 001, 002, 003 and 004. Novo is not entitled to any relief under the Hatch Waxman Act for generic versions of those products, including an order pursuant to 35 U.S.C. § 271(e)(4)(A).

**ELEVENTH SEPARATE DEFENSE: LACK OF ENTITLEMENT TO AN ORDER PURSUANT TO 35 U.S.C. § 271(e)(4)(B)**

The '779 patent is not listed in the Orange Book for NDA 215256 Products 001, 002, 003 and 004. Novo is not entitled to any relief under the Hatch Waxman Act for generic versions of those products, including an order pursuant to 35 U.S.C. § 271(e)(4)(B).

**TWELFTH 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, "Novo"), Mylan Pharmaceuticals Inc. ("MPI") states:

**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 ("MPI's ANDA") 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 prefilled pens ("MPI's Proposed ANDA Products").

3. Upon information and belief, Novo Nordisk Inc. ("NNI") is a corporation organized and existing under Delaware law 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.

## 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 U.S. Patent No. 12,029,779 ("'779 patent") is 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 Novo because, among other reasons, it subjected itself to the jurisdiction of this Court by filing its complaint here.

8. Venue is proper in this Court for these counterclaims because, among other reasons, Novo commenced and continues 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 '779 patent.

## BACKGROUND

10. MPI submitted MPI's ANDA to obtain FDA approval for its 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 mg/mL single-dose prefilled pens.

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 prefilled single-dose pens under § 505(b) of the FFDCA.

12. On information and belief, NNI caused the '779 patent to be listed in the FDA's publication entitled "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations" in conjunction with NDA 215256 for Wegovy® (semaglutide) injection for the 2.4 mg/0.75 mL strength prefilled single-dose pen.

13. On information and belief, NNI *did not* cause the '779 patent to be listed in the FDA's publication entitled "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations" in conjunction with NDA 215256 for Wegovy® (semaglutide) injection for the 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, and 1.7 mg/0.75 mL strength prefilled single-dose pens.

14. The '779 patent, entitled "Semaglutide in Medical Therapy," issued on July 9, 2024.

15. The '779 patent includes two independent claims, claim 1 and claim 7.

16. Claim 1 of the '779 patent recites:

> 1. A method for reducing body weight of a subject in need thereof, comprising administering semaglutide subcutaneously to the subject in an amount of about 2.4 mg weekly.

17. Claim 7 of the '779 patent recites:

> 7. A method for reducing body weight of a subject in need thereof, comprising administering semaglutide subcutaneously to the subject in an amount of 2.4 mg weekly.

18. On information and belief, NNAS is the sole assignee of the '779 patent.

19. On September 5, 2024, Novo filed this lawsuit alleging infringement of the '779 patent. There has been, and now is, an actual and justiciable controversy between MPI and Novo as to whether MPI's Proposed ANDA Products, including MPI's 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, and 1.7 mg/0.75 mL strength prefilled single-dose pens, would infringe, induce

infringement, or contribute to the infringement of any valid and enforceable claim of the patent in suit.

**COUNTERCLAIM: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF U.S. PATENT NO. 12,029,779**

20. MPI incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

21. At least MPI's 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, and 1.7 mg/0.75 mL strength prefilled single-dose pens are not capable of "administering semaglutide subcutaneously to the subject in an amount of about 2.4 mg weekly" as required by claim 1 of the '779 patent. Accordingly, at least MPI's 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, and 1.7 mg/0.75 mL strength prefilled single-dose pens do not infringe claim 1 of the '779 patent.

22. At least MPI's 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, and 1.7 mg/0.75 mL strength prefilled single-dose pens are not capable of "administering semaglutide subcutaneously to the subject in an amount of 2.4 mg weekly" as required by claim 7 of the '779 patent. Accordingly, at least MPI's 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, and 1.7 mg/0.75 mL strength prefilled single-dose pens do not infringe claim 7 of the '779 patent.

23. Because dependent claims 2-6 and 8-14 depend, directly or indirectly from claims 1 or 7, at least MPI's 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, and 1.7 mg/0.75 mL strength prefilled single-dose pens do not infringe claims 2-6 and 8-14 of the '779 patent.

24. Accordingly, at least MPI's 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, and 1.7 mg/0.75 mL strength prefilled single-dose pens have not infringed, will not infringe, and are not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '779 patent under at least 35 U.S.C. §271(a), (b), (c) or (e).

25. Unless Novo is enjoined, Novo will continue to assert that at least MPI's 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, and 1.7 mg/0.75 mL strength prefilled single-dose pens are infringing the claims of the '779 patent and will continue to interfere with MPI's business with respect to at least MPI's 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, and 1.7 mg/0.75 mL strength prefilled single-dose pens and their manufacture, use, offer for sale, and sale.

26. MPI will be irreparably harmed if Novo is not enjoined from continuing to assert the '779 patent and from interfering with MPI's business.

27. A definite and concrete, real and substantial, justiciable controversy exists between MPI and Novo concerning MPI's noninfringement of the '779 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

28. MPI is entitled to a declaratory judgment that at least MPI's 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, and 1.7 mg/0.75 mL strength prefilled single-dose pens have not infringed, are not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '779 patent under at least 35 U.S.C. §271(a), (b), (c) or (e).

## REQUEST FOR RELIEF

**WHEREFORE,** MPI respectfully requests that this Court enter judgment:

a. Dismissing Novo's complaint with prejudice and denying every prayer for relief contained therein;

b. Declaring that at least MPI's 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, and 1.7 mg/0.75 mL strength prefilled single-dose pens do not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid enforceable claim of the '779 patent under at least 35 U.S.C. §271(a), (b), (c) or (e);

c. Enjoining Novo and its respective officers, employees, agents, representatives, attorneys, and others acting on its behalf, from representing to anyone, either directly or indirectly, that at least MPI's 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, and 1.7 mg/0.75 mL strength prefilled single-dose pens have infringed, are infringing, or would infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid enforceable claim of the '779 patent under at least 35 U.S.C. §271(a), (b), (c) or (e);

d. Awarding MPI its costs;

e. Declaring that this case is exceptional under 35 U.S.C. § 285 and awarding MPI its attorneys' fees; and

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

Dated: November 12, 2024

*/s/ Stamatios Stamoulis*
Stamatios Stamoulis (#4606)
Richard C. Weinblatt (#5080)
800 N. West Street, Third Floor
Wilmington, DE 19801
Telephone: (302) 999-1540
Facsimile: (302) 762-1688
stamoulis@swdelaw.com
weinblatt@swdelaw.com

OF COUNSEL (pro hac vice forthcoming):

Brandon M. White
Shannon M. Bloodworth
PERKINS COIE LLP
700 13th Street NW, Suite 800
Washington, DC 20005
BMWhite@perkinscoie.com
SBloodworth@perkinscoie.com

David L. Anstaett
PERKINS COIE LLP
33 East Main Street, Suite 201
Madison, WI 53703-3095
DAnstaett@perkinscoie.com

*Attorneys for Mylan Pharmaceuticals Inc.*

**CERTIFICATE OF SERVICE**

I certify that on November 12, 2024, I electronically filed the foregoing **MYLAN PHARMACEUTICALS INC.'S ANSWER, SEPARATE DEFENSES AND COUNTERCLAIM TO COMPLAINT** with the Clerk of the Court using the CM/ECF system, which will send notice of the same to the following counsel of record:

Jack B. Blumenfeld (#1014)
Brian P. Egan (#6227)
Travis J. Murray (#6882)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
began@morrisnichols.com
tmurray@morrisnichols.com

*Attorneys for Plaintiffs*
*Novo Nordisk Inc. and Novo Nordisk A/S*

OF COUNSEL:
Nicholas Groombridge
Josephine Young
Peter Sandel
Jenny Wu
Daniel Klein
Naz E. Wehrli
Joshua Reich
GROOMBRIDGE, WU, BAUGHMAN & STONE LLP
565 Fifth Avenue, Suite 2900
New York, NY 10017
(332) 269-0030

Philip S. May
GROOMBRIDGE, WU, BAUGHMAN & STONE LLP
801 17th Street NW, Suite 1050
Washington, DC 20006
(202) 505-5830

*/s/ Stamatios Stamoulis*
Stamatios Stamoulis (#4606)
Richard C. Weinblatt (#5080)
800 N. West Street, Third Floor
Wilmington, DE 19801
Telephone: (302) 999-1540
Facsimile: (302) 762-1688
stamoulis@swdelaw.com
weinblatt@swdelaw.com

*Attorneys for Mylan Pharmaceuticals Inc.*