IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and NOVO NORDISK A/S, *Plaintiffs*, v. SUN PHARMACEUTICAL INDUSTRIES LTD. and SUN PHARMACEUTICAL INDUSTRIES, INC., *Defendants*.	CA No. 24-1014-CFC **ANDA CASE**

DEFENDANTS' ANSWER,
DEFENSES, AND COUNTERCLAIMS TO COMPLAINT

Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Inc. (collectively, "Sun" or "Defendants") by their undersigned attorneys, answer and respond to the Complaint of Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk" or "Plaintiffs").

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: Sun lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 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: Sun lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 2, and, therefore, denies those allegations.

3. On information and belief, Defendant Sun Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra, India 400063. On information and belief, Sun Pharmaceutical Industries Ltd. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

ANSWER: Sun admits that Sun Pharmaceutical Industries Ltd. ("SPIL") is a corporation organized and existing under the laws of India, having its principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra, India 400063. Sun admits that SPIL, among other things, manufactures and sells pharmaceutical products. Sun denies any remaining allegations set forth in paragraph 3.

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

ANSWER: Sun admits that Sun Pharmaceutical Industries, Inc. ("SPI") is a corporation organized and existing under the laws of the State of Delaware, having

its principal place of business at 2 Independence Way, Princeton, New Jersey, 08540. Sun denies any remaining allegations set forth in paragraph 4.

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

ANSWER: Sun admits that Sun Pharmaceutical Industries, Inc. is indirectly wholly owned by Sun Pharmaceutical Industries Ltd. Sun denies any remaining allegations set forth in paragraph 5.

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

ANSWER: Denied.

NATURE OF THE ACTION

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

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sun admits that Plaintiffs purport to bring this action under the Patent Laws of the United States. Sun admits that SPIL is the owner of ANDA No. 217962 and seeks FDA approval of ANDA No. 217962. Sun denies any remaining allegations set forth in paragraph 7.

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

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the allegations in paragraph 8, and, therefore, denies those allegations.

9. NNI is the holder of New Drug Application ("NDA") No. 215256 for WEGOVY® (semaglutide) injection, for subcutaneous use, administered with 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, 1.7 mg/0.75 mL, and 2.4 mg/0.75 mL Pre-filled Single-dose Pens, which NNI sells under the trade name WEGOVY®. NNI holds the exclusive right to sell, distribute, and market WEGOVY® (semaglutide) injection in the United States.

ANSWER: Sun admits that the products that are the subject of NDA No. 215256 are marketed under the trade name WEGOVY®. Sun admits that Novo Nordisk Inc. is indicated in the records of the FDA as the holder of NDA No. 215256 for an injectable drug product containing, *inter alia*, 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 of the active pharmaceutical ingredient, semaglutide. Sun lacks sufficient knowledge of information to form a belief as to the truth of the remaining allegations in paragraph 9, and, therefore, denies those allegations.

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

ANSWER: Paragraph 10 states a legal conclusion to which no answer is required. To the extent an answer is required, Sun admits that the '779 Patent is listed in the Orange Book in connection with NDA No. 215256. Sun denies the remaining allegations in paragraph 10.

NOVO NORDISK'S WEGOVY®

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

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

ANSWER: Sun admits that the prescribing information provided with WEGOVY® includes a section entitled "Indications and Usage." Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 11, and, therefore, denies those allegations.

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

ANSWER: Sun admits that the prescribing information provided with WEGOVY® includes a section entitled "Dosage and Administration." Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 12, and, therefore, denies those allegations.

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

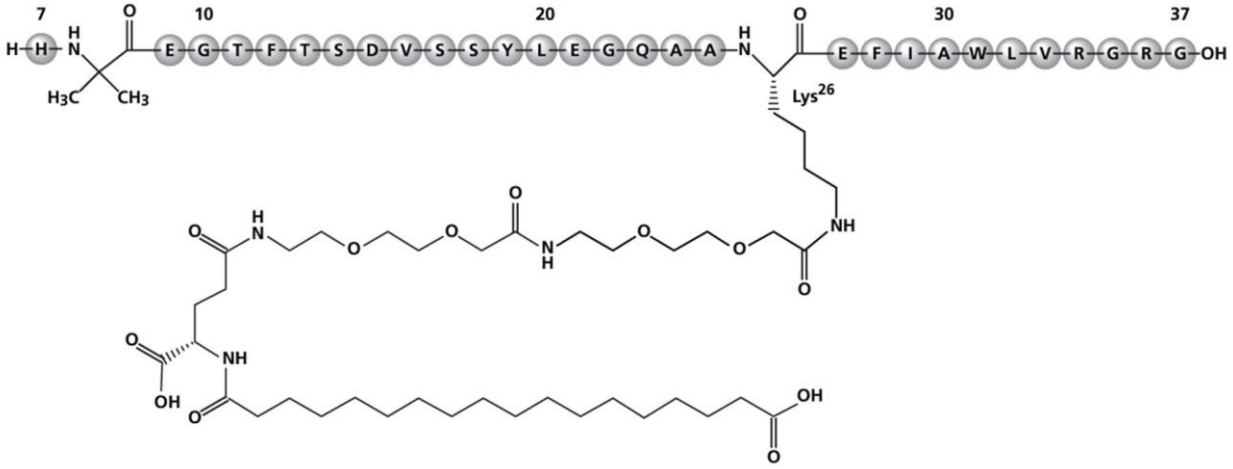
ANSWER: Sun admits that the prescribing information provided with WEGOVY® includes a section entitled "Dosage and Administration." Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 13, and, therefore, denies those allegations.

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

ANSWER: Sun admits that the prescribing information provided with WEGOVY® includes a section entitled "Dosage and Administration." Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 14, and, therefore, denies those allegations.

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

Figure 1. Structural Formula of semaglutide



ANSWER: Sun admits that the prescribing information provided with WEGOVY® includes a section entitled "Description" that purportedly identifies the contents of the products marketed under the name WEGOVY®. Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 15, and, therefore, denies those allegations.

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

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the allegations in paragraph 16, and, therefore, denies those allegations.

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

ANSWER: Sun admits that the prescribing information provided with WEGOVY® includes a section entitled "Description" that purportedly identifies the contents of the products marketed under the name WEGOVY®. Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 17, and, therefore, denies those allegations.

SUN'S ANDA

18. On information and belief, Sun Pharmaceutical Industries Inc., acting as U.S. agent for Sun Pharmaceutical Industries Ltd., submitted Sun's ANDA under

Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), *i.e.*, 21 U.S.C. § 355(j), seeking approval to commercially manufacture, use, and/or sell a generic version of semaglutide injection, 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, 1.7 mg/0.75 mL and 2.4 mg/0.75 mL for subcutaneous use pursuant to Sun's ANDA ("Sun's ANDA Product").

ANSWER: Sun admits that SPIL is the owner of ANDA No. 217962 and seeks FDA approval of ANDA No. 217962. Sun denies any remaining allegations set forth in paragraph 18.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

23. Sun will infringe one or more claims of the '779 Patent under 35 U.S.C. § 271(b) and/or (c) should Sun engage in, induce, or contribute to the commercial manufacture use, offer for sale, sale, distribution in, or importation into the United States of Sun's ANDA Product before the expiration of the '779 Patent or any extensions thereof.

ANSWER: Denied.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no answer is required.

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

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, SPIL does not contest personal jurisdiction in Delaware. Sun denies any remaining allegations set forth in paragraph 25.

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

ANSWER: Paragraph 26 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of this litigation, SPI does not contest personal jurisdiction in Delaware. Sun denies any remaining allegations set forth in paragraph 26.

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

ANSWER: Paragraph 27 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, for the sole purpose of

this litigation, SPIL and SPI do not contest personal jurisdiction in Delaware. Sun denies any remaining allegations set forth in paragraph 27.

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

ANSWER: Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sun admits SPIL is a foreign corporation and SPI is a corporation organized and existing under the laws of the State of Delaware. Sun denies any remaining allegations set forth in paragraph 28.

THE PATENT-IN-SUIT

29. The allegations above are incorporated herein by reference.

ANSWER: Sun hereby incorporates by reference its responses to paragraphs 1-28 as if fully set forth herein.

30. Novo Nordisk A/S is the owner of all rights, title, and interest in the '779 Patent, entitled "Semaglutide in Medical Therapy." The USPTO duly and legally issued the '779 Patent on July 9, 2024. The '779 Patent names Marianne Oelholm Larsen Groenning, Lars Endahl, Charlotte Giwercman Carson, Anders Bjerring Strathe, Maria Kabisch, and Thomas Hansen as inventors. All named inventors assigned the '779 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '779 Patent and sue for infringement thereof. A true and correct copy of the '779 Patent is attached to this Complaint as Exhibit 1.

ANSWER: Sun admits that Plaintiffs purport to attach a copy of the '779 patent to the Complaint as Exhibit 1. Sun admits that the '779 patent states on its

face that it was issued July 9, 2024, and is titled "Semaglutide in Medical Therapy." Sun admits the '779 patent lists Marianne Oelholm Larsen Groenning, Lars Endahl, Charlotte Giwercman Carson, Anders Bjerring Strathe, Maria Kabisch, and Thomas Hansen as inventors. Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 30 and, therefore, denies those allegations.

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

ANSWER: Paragraph 31 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sun lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 31, and, therefore, denies those allegations.

COUNT I
(INFRINGEMENT OF THE '779 PATENT)

32. The allegations above are incorporated herein by reference.

ANSWER: Sun hereby incorporates by reference its responses to paragraphs 1-31 as if fully set forth herein.

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

ANSWER: Sun admits that SPIL is the owner of ANDA No. 217962 and seeks FDA approval of ANDA No. 217962. Sun admits the '779 patent is listed in

the Orange Book with respect to WEGOVY®. Sun denies the remaining allegations set forth in paragraph 33.

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

ANSWER: Sun admits that in compliance with 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95, a letter was sent on September 16, 2024 to Novo Nordisk A/S and Novo Nordisk Inc. notifying in writing that ANDA No. 217962 had been filed containing a Paragraph IV Certification pursuant to 21 U.S.C. § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 with respect to the'779 patent. Sun denies any remaining allegations set forth in paragraph 34.

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

ANSWER: Paragraph 35 states a legal conclusion to which no answer is required. To the extent an answer is required, Sun admits the '779 patent is listed in the Orange Book with respect to WEGOVY®. Sun denies the remaining allegations set forth in paragraph 35.

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

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

ANSWER: Sun admits that the prescribing information provided with WEGOVY® includes a section entitled "Indications and Usage." Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 36, and, therefore, denies those allegations.

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

ANSWER: Sun admits that the prescribing information provided with WEGOVY® includes a section entitled "Description" that purportedly identifies the contents of the products marketed under the name WEGOVY®. Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 37, and, therefore, denies those allegations.

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

ANSWER: Sun admits that the prescribing information provided with WEGOVY® includes a section entitled "Indications and Usage." Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 38, and, therefore, denies those allegations.

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

ANSWER: Sun admits that the prescribing information provided with WEGOVY® includes a section entitled "Indications and Usage." Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 39, and, therefore, denies those allegations.

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

ANSWER: Sun admits that the prescribing information provided with WEGOVY® includes a section entitled "Dosage and Administration." Sun lacks sufficient knowledge or information to form a belief as to the remaining allegations in paragraph 40, and, therefore, denies those allegations.

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

ANSWER: Paragraph 41 states a legal conclusion to which no answer is required. To the extent an answer is required, Sun denies the allegations in paragraph 41.

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

ANSWER: Paragraph 42 states a legal conclusion to which no answer is required. To the extent an answer is required, Sun denies the allegations in paragraph 42.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 49, and, therefore, denies those allegations.

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

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 50, and, therefore, denies those allegations.

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

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 51, and, therefore, denies those allegations.

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

ANSWER: Sun lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 52, and, therefore, denies those allegations.

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

ANSWER: Denied.

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

ANSWER: Paragraph 54 states a legal conclusion to which no answer is required. To the extent an answer is required, Sun denies the allegations in paragraph 54.

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

ANSWER: Denied.

RESPONSE TO "PRAYER FOR RELIEF"

Sun denies that Plaintiffs are entitled to any judgment or relief against Sun and, therefore specifical denies paragraphs A through I of Plaintiffs' Prayer for Relief.

GENERAL DENIAL

Sun denies all remaining allegations not specifically admitted herein. Sun further denies that Plaintiffs are entitled to any judgment or relief requested in the Complaint, or to any relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the responses and denials set forth in Sun's Answer, without admitting any allegations of the Complaint not expressly admitted, and without assuming the burden of proof on any such defense that would otherwise rest with Plaintiffs, Sun asserts the following separate defenses to the Complaint:

FIRST DEFENSE

Each purported claim in the Complaint, in whole or in part, is barred for failure to state a claim upon which relief can be granted.

SECOND DEFENSE

The claims of United States Patent No. 12,029,779 ("the '779 Patent") are invalid and/or unenforceable for failure to comply with and/or satisfy one or more of the conditions and requirements of Title 35 of the United States Code, including,

but not limited to, one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b).

THIRD DEFENSE

Sun does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the Patent-in-Suit, either directly, indirectly, contributorily, by inducement, or in any other manner.

FOURTH DEFENSE

The Complaint fails to state a claim for an exceptional case and/or willful infringement under 25 U.S.C. § 285 and/or 35 U.S.C. § 271(e)(4). Moreover, Sun's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

FIFTH DEFENSE

Plaintiffs may not seek injunctive relief against Sun because Plaintiffs' alleged damages are not immediate or irreparable.

ADDITIONAL DEFENSES

Sun reserves the right to allege additional affirmative defenses as they become known through the course of discovery.

COUNTERCLAIMS

Counterclaim-Plaintiffs Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Inc. (collectively "Sun"), by and through the undersigned

attorneys, hereby assert the following counterclaims against Plaintiffs/Counterclaim-Defendants Novo Nordisk Inc. ("NNI") and Novo Nordisk A/S ("NNAS") (collectively "Novo Nordisk").

THE PARTIES

1. Counterclaim Plaintiff Sun Pharmaceutical Industries Ltd. ("SPIL") has a principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra, India 400063.

2. Counterclaim Plaintiff Sun Pharmaceutical Industries Inc. ("SPI") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2 Independence Way, Princeton, New Jersey, 08540.

3. SPIL is the owner of ANDA No. 217962 and seeks FDA approval of ANDA No. 217962.

4. According to Plaintiffs/Counterclaim-Defendants' allegations, NNI purports to be 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.

5. According to Plaintiffs/Counterclaim-Defendants' allegations, NNAS purports to be 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

6. Sun seeks a declaratory judgment that the claims of the '779 patents are invalid and/or will not be infringed by Sun.

JURISDICTION AND VENUE

7. These counterclaims arise 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 and 2202.

8. The Court has jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Without prejudice, venue is proper in this District for purposes of these counterclaims because Plaintiffs/Counterclaim-Defendants have commenced and continue to prosecute this action in this District.

10. Plaintiffs/Counterclaim-Defendants are subject to personal jurisdiction in this District because they commenced and continue to prosecute this action in this District.

BACKGROUND

11. Plaintiffs/Counterclaim-Defendants have alleged in the instant action that they are the owner of all legal rights, title, and interests in the '779 patent.

12. Upon information and belief, and according to Plaintiffs/Counterclaim-Defendants' allegations, Novo Nordisk is the holder of NDA No. 215256 for WEGOVY®.

13. The '779 patent is listed in the electronic version of the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for WEGOVY®.

14. SPIL owns ANDA No. 217962 and seeks FDA approval of ANDA No. 217962 to market in the United States the products described therein.

15. A letter was sent on September 16, 2024 (the "Notice Letter") to Novo Nordisk A/S and Novo Nordisk Inc. notifying in writing that ANDA No. 217962 had been filed containing a Paragraph IV Certification pursuant to 21 U.S.C. § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 with respect to the '779 patent.

16. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7), the Notice Letter was accompanied by a detailed statement of the factual and legal bases for the Paragraph IV Certifications with respect to the '779 patent.

COUNT 1

(Declaratory Judgment of Noninfringement of the ’779 Patent)

17. Paragraphs 1-16 of the Counterclaims are incorporated as if fully set forth herein.

18. Plaintiffs/Counterclaim-Defendants have accused Sun of infringing claims of the ’779 patent in connection with ANDA No. 217962.

19. Sun 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 ’779 patent.

20. Unless Plaintiffs/Counterclaim-Defendants are enjoined, Sun believes that Plaintiffs/Counterclaim-Defendants will continue to assert that Sun is infringing the claims of the ’779 patent and will continue to interfere with Sun’s business.

21. Sun will be irreparably harmed if Plaintiffs/Counterclaim-Defendants are not enjoined from continuing to assert the ’779 patent and from interfering with Sun’s business.

22. A definite and concrete, real and substantial, justiciable controversy exists between Sun and Plaintiffs/Counterclaim-Defendants concerning Sun’s noninfringement of the ’779 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

23. Sun is entitled to declaratory judgment that Sun's proposed semaglutide 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 '779 patent.

COUNT 2

(Declaratory Judgment of Invalidity of the '779 Patent)

24. Paragraphs 1-23 of the Counterclaims are incorporated as if fully set forth herein.

25. The claims of the '779 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code.

26. The alleged invention of the '779 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '779 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '779 patent and would have had a reasonable expectation of success in doing so.

27. The claims of the '779 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art. The differences between the subject matter claimed in the '779 patent and the prior art are such that the subject matter as a whole

was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

28. Unless Plaintiff/Counterclaim-Defendants are enjoined, Sun believes that Plaintiffs/Counterclaim-Defendants will continue to assert that Sun infringes the claims of the ’779 patent and will continue to interfere with Sun’s business.

29. Sun will be irreparably harmed if Plaintiffs/Counterclaim-Defendants are not enjoined from continuing to assert the ’779 patent and from interfering with Sun’s business.

30. A definite and concrete, real and substantial, justiciable controversy exists between Sun and Plaintiffs/Counterclaim-Defendants concerning the invalidity of the ’779 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

31. Sun is entitled to a declaratory judgment that the claims of the ’779 patent are invalid.

COUNT 3

(Declaratory Judgment of No Injunctive Remedy for the ’779 Patent)

32. Paragraphs 1-31 of the Counterclaims are incorporated as if fully set forth herein.

33. Plaintiffs/Counterclaim-Defendants cannot demonstrate any alleged harm that is irreparable or otherwise not compensable via monetary damages even if infringement of a valid and enforceable patent were presumed.

34. Plaintiffs/Counterclaim-Defendants are not entitled to any injunctive remedy of any kind.

35. A definite and concrete, real and substantial, justiciable controversy exists between Sun and Plaintiffs/Counterclaim-Defendants concerning the existence of no injunctive remedy for alleged infringement of the '779 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

36. Sun is entitled to a declaratory judgment that Plaintiffs/Counterclaim-Defendants are not entitled to any injunctive remedy of any kind regarding any alleged infringement of the claims of the '779 patent.

EXCEPTIONAL CASE

This case is an exceptional one, and Sun is entitled to an award of its reasonable attorneys' fees, costs, and expenses under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, Sun respectfully requests that this Court enter judgment:

a. Ordering that Plaintiffs/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment be entered in favor of Sun;

b. Declaring that Plaintiffs/Counterclaim-Defendants are not entitled to any declaratory or injunctive relief or any alleged damages for alleged patent infringement by Sun;

c. Declaring that Sun does not infringe, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’779 patent;

d. Declaring that the ’779 patent is invalid;

e. Enjoining Plaintiffs/Counterclaim-Defendants and their officers, employees, agents, representatives, attorneys, and others acting on their behalf from representing to anyone, either directly or indirectly, that Sun has infringed, is infringing, or will infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid or enforceable claim of the’779 patent;

f. Awarding Sun its costs;

g. Declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Sun its attorneys’ fees; and

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

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DATED: November 26, 2024

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