IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT

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

THE PARTIES

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

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

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

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

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

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

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

NATURE OF THE ACTION

7. This action arises under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271(a), (b), (c), (e), and (f), arising from Sun's submission of an Abbreviated New Drug Application ("ANDA") No. 217962 ("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 Nos. 8,129,343 ("the '343 Patent"); 9,764,003 ("the '003 Patent"); 10,888,605 ("the '605 Patent"); 11,318,191 ("the '191 Patent"); and 11,752,198 ("the '198 Patent") (collectively, the "Asserted Patents"), which cover, *inter alia*, WEGOVY® (semaglutide) injection and/or its use.

8. NNAS is the owner of all rights, title, and interest in the Asserted Patents.

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

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

NOVO NORDISK'S WEGOVY®

11. The WEGOVY® Label states that "WEGOVY® is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in [1] adults with an initial body mass index (BMI) of . . . 30 kg/m^2 or greater (obesity) or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) [and 2] pediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater standardized for age and sex (obesity)."

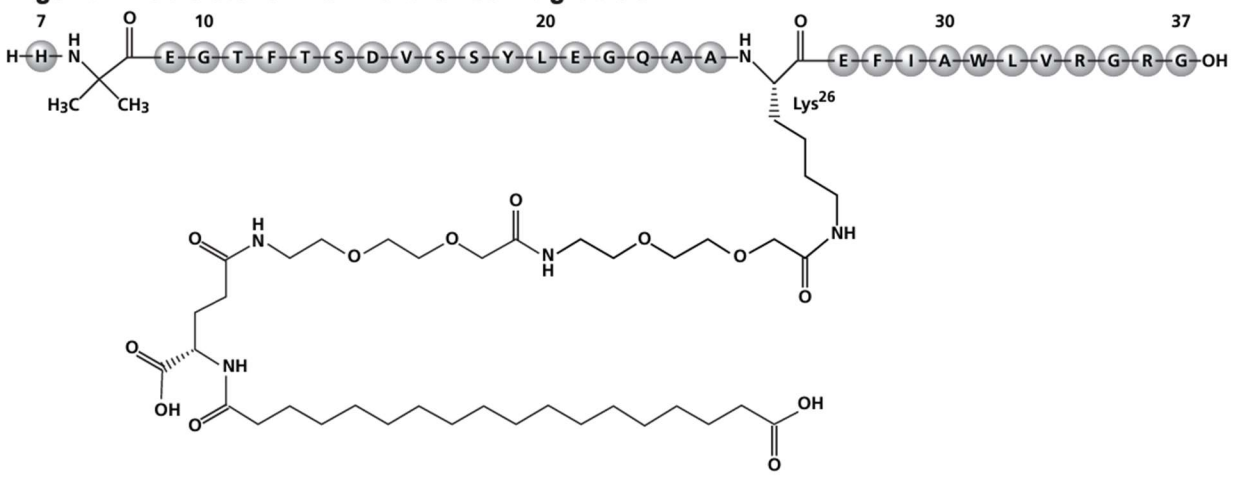
12. WEGOVY® is to be administered once weekly by subcutaneous injection.

13. The WEGOVY® Label provides limitations of use, including, but not limited to, instructing that WEGOVY® should not be used in combination with other semaglutide-containing products or any other GLP-1 receptor agonist, cautions that there may be certain side effects and/or unestablished safety and efficacy when coadministered with other therapeutics.

14. The WEGOVY® Label further instructs to administer WEGOVY® once weekly according to a dose escalation schedule that includes an initiating dosage at 0.25 mg of semaglutide for four weeks, 0.5 mg for the next four weeks, and 1 mg for the next four weeks after that.

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

Figure 1. Structural Formula of semaglutide



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

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

SUN'S ANDA AND PARAGRAPH IV CERTIFICATION

18. On information and belief, Sun Pharmaceutical Industries Inc., acting as U.S. agent for Sun Pharmaceutical Industries Ltd., submitted Sun's ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), *i.e.*, 21 U.S.C. § 355(j), seeking approval to commercially manufacture, use, and/or sell a generic version of semaglutide injection, 0.25 mg/0.5

mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, 1.7 mg/0.75 mL and 2.4 mg/0.75 mL for subcutaneous use pursuant to Sun's ANDA ("Sun's ANDA Product").

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

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

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

22. On information and belief, Sun made and included in Sun's ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that, in their opinion and to the best of their knowledge, the Asserted Patents are invalid and/or not infringed.

23. Novo Nordisk received written notice of Sun's ANDA and Paragraph IV Certification as to the Asserted Patents ("Notice Letter"), which was dated November 8, 2023, along with an enclosed statement that is required to state all the factual and legal bases for stating that the commercial manufacture, use, or sale of Sun's ANDA Product allegedly will not infringe any valid claim of the Asserted Patents and/or that the claims of the Asserted Patents allegedly are invalid and/or unenforceable (the "Detailed Statement"). The Notice Letter identified "Sun Pharmaceuticals, Inc." as the U.S. Agent for Defendant Sun Pharmaceuticals Industries Ltd.

24. Novo Nordisk received a corrected written notice of Sun's ANDA and Paragraph IV Certification as to the Asserted Patents ("Corrected Notice Letter"), which was dated November 10, 2023. The Corrected Notice Letter purported to correct the identification of "Sun Pharmaceuticals, Inc." to Defendant Sun Pharmaceuticals Industries, Inc. as the U.S. Agent for Defendant Sun Pharmaceutical Industries Ltd. The Corrected Notice Letter contained an enclosed statement that is required to state all the factual and legal bases for stating that the commercial manufacture, use, or sale of Sun's ANDA Product allegedly will not infringe any valid claim of the Asserted Patents and/or that the claims of the Asserted Patents allegedly are invalid and/or unenforceable (the "Corrected Detailed Statement").

25. Novo Nordisk received a third written notice of Sun's ANDA and Paragraph IV Certification as to the '198 Patent (the "Third Notice Letter"), which was dated December 13, 2023. The Third Notice Letter purported to correct an error related to the timing of Sun's Paragraph IV Certification as to the '198 Patent. The Third Notice Letter contained an enclosed statement that is required to state all the factual and legal bases for stating that the commercial manufacture, use, or sale of Sun's ANDA Product allegedly will not infringe any valid claim of the '198 Patent and/or that the claims of the '198 Patent allegedly are invalid and/or unenforceable (the "Third Detailed Statement").

26. Sun's Detailed Statement, Corrected Detailed Statement, and Third Detailed Statement do not allege or provide any separate factual bases to assert that the Asserted Patents are unenforceable.

27. Sun's Detailed Statement, Corrected Detailed Statement, and Third Detailed Statement do not allege or provide any separate factual bases for stating that the '343 and '198

Patents will not be infringed by Sun's ANDA Product apart from contending that the '343 and '198 Patents are invalid.

28. Sun's Detailed Statement, Corrected Detailed Statement, and Third Detailed Statement do not allege or provide any separate factual bases for stating that the '605 Patent is invalid.

29. This action is being commenced within 45 days of receipt of the Notice Letter, Corrected Notice Letter, and Third Notice Letter.

30. Sun has infringed one or more claims of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A) by filing Sun's ANDA with a Paragraph IV Certification and seeking FDA approval of Sun's ANDA before the expiration of the Asserted Patents or any extensions thereof.

31. Sun has infringed one or claims of the Asserted Patents 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 Asserted Patents or any extensions thereof.

32. Sun will infringe one or more claims of the Asserted Patents under 35 U.S.C. § 271(a), (b), (c), or (f) 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 Asserted Patents or any extensions thereof.

JURISDICTION AND VENUE

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

34. 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 (*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).

35. 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).

36. 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.

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

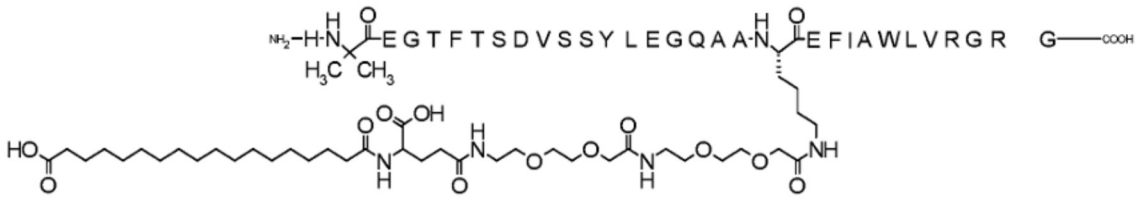
THE PATENTS-IN-SUIT

U.S. Patent No. 8,129,343

38. The allegations above are incorporated herein by reference.

39. Novo Nordisk A/S is the owner of all rights, title, and interest in the '343 Patent, entitled "Acylated GLP-1 Compounds." The United States Patent and Trademark Office ("USPTO") duly and legally issued the '343 Patent on March 6, 2012. The '343 Patent names Jesper Lau, Paw Bloch, and Thomas Kruse Hansen as inventors. All named inventors assigned the '343 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '343 Patent and sue for infringement thereof. A true and correct copy of the '343 Patent is attached to this Complaint as Exhibit 1.

40. The '343 Patent claims a compound of the following structure, as well as a pharmaceutical composition comprising the same compound with the following structure and a pharmaceutically acceptable excipient:



41. The ’343 Patent also claims a method of treatment by administering a pharmaceutical composition comprising the claimed compound and a pharmaceutically acceptable excipient.

U.S. Patent No. 9,764,003

42. The allegations above are incorporated herein by reference.

43. Novo Nordisk A/S is the owner of all rights, title, and interest in the ’003 Patent, entitled “Use of Long-Acting GLP-1 Peptides.” The USPTO duly and legally issued the ’003 Patent on September 19, 2017. The ’003 Patent names Christine B. Jensen as the sole inventor, who assigned the ’003 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the ’003 Patent and sue for infringement thereof. A true and correct copy of the ’003 Patent is attached to this Complaint as Exhibit 2.

44. The ’003 Patent claims a method for reducing body weight, comprising administering semaglutide once weekly in an amount of at least 0.7 mg and up to 1.6 mg to a subject in need thereof, wherein the said semaglutide is administered without another therapeutic agent.

U.S. Patent No. 10,888,605

45. The allegations above are incorporated herein by reference.

46. Novo Nordisk A/S is the owner of all rights, title, and interest in the ’605 Patent, entitled “GLP-1 Compositions and Uses Thereof.” The USPTO duly and legally issued the ’605 Patent on January 12, 2021. The ’605 Patent names Eva Horn Moeller, Michael Duelund

Soerensen, and Joakim Lundqvist as inventors. All named inventors assigned the '605 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '605 Patent and sue for infringement thereof. A true and correct copy of the '605 Patent is attached to this Complaint as Exhibit 3.

47. The '605 Patent claims a liquid pharmaceutical composition comprising semaglutide and phenol wherein said composition is for parenteral administration, is an aqueous solution comprising at least 60% (w/w) water, or further comprises one or more pharmaceutically acceptable excipients selected from the group consisting of a buffer or an isotonic agent, wherein the semaglutide is in the range of 0.5 mg/mL to 5.0 mg/mL, wherein the phenol is no more than 0.1 mg/mL, and wherein the pH of the composition is in between 7.0 and 7.8.

48. The '605 Patent also claims a method of treating obesity comprising administering to a subject in need thereof a therapeutically effective amount of a liquid pharmaceutical composition comprising semaglutide and phenol wherein said composition is for parenteral administration, is an aqueous solution comprising at least 60% (w/w) water, or further comprises one or more pharmaceutically acceptable excipients selected from the group consisting of a buffer or an isotonic agent, wherein the semaglutide is in the range of 0.5 mg/mL to 5.0 mg/mL, wherein the phenol is no more than 0.1 mg/mL, and wherein the pH of the composition is in between 7.0 and 7.8..

U.S. Patent No. 11,318,191

49. The allegations above are incorporated herein by reference.

50. Novo Nordisk A/S is the owner of all rights, title, and interest in the '191 Patent, entitled "GLP-1 Compositions and Uses Thereof." The USPTO duly and legally issued the '191 Patent on May 3, 2022. The '191 Patent names Dorthe Kot Engelund, Soeren Snitker, and Andrew Mark Louw as inventors. All named inventors assigned the '191 Patent to Novo Nordisk A/S.

Novo Nordisk has the right to enforce the '191 Patent and sue for infringement thereof. A true and correct copy of the '191 Patent is attached to this Complaint as Exhibit 4.

51. The '191 Patent claims a liquid pharmaceutical composition comprising 0.5 to 10 mg/mL semaglutide, 0.0% (w/w) to 0.1% (w/w) phenol, and 8.2 to 8.9 mg/mL sodium chloride.

52. The '191 Patent also claims a method of treatment comprising administering to a subject in need thereof a therapeutically effective amount of the liquid pharmaceutical composition comprising 0.5 to 10 mg/mL semaglutide, 0.0% (w/w) to 0.1% (w/w) phenol, and 8.2 to 8.9 mg/mL sodium chloride.

U.S. Patent No. 11,752,198

53. The allegations above are incorporated herein by reference.

54. Novo Nordisk A/S is the owner of all rights, title, and interest in the '198 Patent, entitled "GLP-1 Compositions and Uses Thereof." The USPTO duly and legally issued the '198 Patent on September 12, 2023. The '198 Patent names Eva Horn Moeller, Michael Duelund Soerensen, and Joakim Lundqvist as inventors. All named inventors assigned the '198 Patent to Novo Nordisk A/S. Novo Nordisk has the right to enforce the '198 Patent and sue for infringement thereof. A true and correct copy of the '198 Patent is attached to this Complaint as Exhibit 5.

55. The '198 Patent claims a liquid pharmaceutical composition comprising semaglutide; wherein said composition does not contain phenol; is for parenteral administration; is an aqueous solution comprising at least 60% (w/w) water; or further comprises one or more pharmaceutically acceptable excipients selected from the group consisting of a buffer or an isotonic agent; and wherein the semaglutide is in the range of 0.01 mg/mL to 10.0 mg/mL; and wherein the pH of the composition is in between 7.0 and 7.8; wherein the liquid pharmaceutical composition exhibits improved chemical and/or physical stability as compared to a liquid pharmaceutical composition that contains phenol.

56. The '198 Patent also claims a method of treating obesity comprising administering to a subject in need thereof a therapeutically effective amount of a liquid pharmaceutical composition comprising semaglutide; wherein said composition does not contain phenol; is for parenteral administration; is an aqueous solution comprising at least 60% (w/w) water; or further comprises one or more pharmaceutically acceptable excipients selected from the group consisting of a buffer or an isotonic agent; and wherein the semaglutide is in the range of 0.01 mg/mL to 10.0 mg/mL; and wherein the pH of the composition is in between 7.0 and 7.8; wherein the liquid pharmaceutical composition exhibits improved chemical and/or physical stability as compared to a liquid pharmaceutical composition that contains phenol.

COUNT I
(INFRINGEMENT OF THE '343 PATENT)

57. The allegations above are incorporated herein by reference.

58. 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 '343 Patent, and any extensions thereof.

59. The Notice Letter and Corrected Notice Letter state that Sun's ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Sun's ANDA Product before the expiration of the '343 Patent. The Notice Letter and Corrected Notice Letter represent that Sun's ANDA was submitted with a Paragraph IV Certification that the '343 Patent is "invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Sun's ANDA Product."

60. Sun has actual knowledge of the '343 Patent.

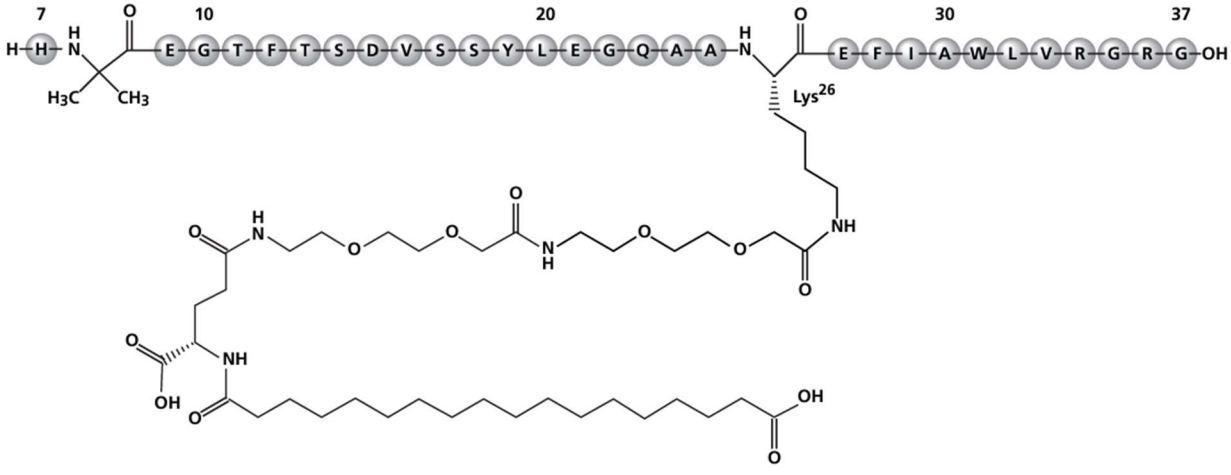
61. Sun was required to include in its Detailed Statement (and Corrected Detailed Statement) for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. *See* 21 CFR § 314.95(c)(7).

62. The Detailed Statement and Corrected Detailed Statement do not provide any separate factual bases for stating that the '343 Patent will not be infringed by Sun's ANDA Product apart from arguing that the '343 Patent is invalid. If Sun had any reasonable basis for asserting that Sun's ANDA Product is not covered by the claims of the '343 Patent, Sun was required to provide a full and detailed explanation as to why. Accordingly, on information and belief, Sun's ANDA Product is covered by at least claim 1 of the '343 Patent, and Sun has therefore infringed the '343 Patent. The Detailed Statement and Corrected Detailed Statement do not allege that the '343 Patent is unenforceable.

63. The WEGOVY® Label states that the active ingredient in WEGOVY® is semaglutide and that WEGOVY® contains inactive ingredients.

64. The WEGOVY® Label states that the structure of semaglutide is:

Figure 1. Structural Formula of semaglutide



65. WEGOVY® is covered by at least claim 1 of the '343 Patent.

66. The WEGOVY® Label instructs physicians that "WEGOVY® is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in [1] adults with an initial body mass index (BMI) of . . . 30 kg/m^2 or greater (obesity) or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) [and 2] pediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater standardized for age and sex (obesity)."

67. The use of WEGOVY® is covered by, among others, at least claim 3 of the '343 Patent.

68. Thus, WEGOVY® and any corresponding generic semaglutide injection are covered by at least claims 1 and 3 of the '343 Patent.

69. The '343 Patent is listed in the Orange Book for WEGOVY®.

70. On information and belief, Sun's ANDA essentially copies the WEGOVY® Label and formulation as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(8)(iv), 314.94(a)(9)(iii), 314.127(a)(8)(ii)(B), and as such, the liquid pharmaceutical composition in Sun's ANDA Product is identical to that in WEGOVY®.

71. On information and belief, if Sun's ANDA is approved, Sun will make, use, offer for sale, sell, or import Sun's ANDA Product in a manner that would infringe at least claims 1 and 3 of the '343 Patent.

72. 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 claim 3 of the '343 Patent.

73. 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 1 and 3 of the '343 Patent.

74. 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 1 and 3 of the '343 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 1 and 3 of the '343 Patent.

75. Sun has infringed at least claims 1 and 3 of the '343 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 1 and 3 of the '343 Patent, before the expiration of the '343 Patent.

76. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Sun's ANDA would directly infringe at least claim 1 of the '343 Patent under 35 U.S.C. §§ 271(a) and/or (f).

77. 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 1 and 3 of the '343 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

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

79. Novo Nordisk seeks an order declaring that Sun has infringed at least claims 1 and 3 of the '343 Patent by submitting Sun's ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

80. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4), 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 '343 Patent or any later expiration of extensions, adjustments, and exclusivities for the '343 Patent to which Novo Nordisk becomes entitled.

81. Novo Nordisk seeks an order declaring that Sun will infringe at least claims 1 and 3 of the '343 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Sun's ANDA Product before the expiration of the '343 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

82. Novo Nordisk will be irreparably harmed if Sun is not enjoined from infringing, actively inducing, or contributing to the infringement of at least claims 1 and 3 of the '343 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.

83. On information and belief, Sun's Detailed Statement and Corrected Detailed Statement setting forth the factual and legal bases for their opinion regarding infringement and validity of the '343 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

84. To the extent Sun commercializes Sun's ANDA Product prior to the expiration of the '343 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C).

COUNT II
(INFRINGEMENT OF THE '003 PATENT)

85. The allegations above are incorporated herein by reference.

86. 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 '003 Patent, and any extensions thereof.

87. The Notice Letter and Corrected Notice Letter state that Sun's ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Sun's ANDA Product before the expiration of the '003 Patent. The Notice Letter and Corrected Notice Letter represent that Sun's ANDA was submitted with a Paragraph IV Certification that the '003 Patent is "invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Sun's ANDA Product."

88. Sun has actual knowledge of the '003 Patent.

89. Sun was required to include in its Detailed Statement (and Corrected Detailed Statement) for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. *See* 21 CFR § 314.95(c)(7).

90. On information and belief, Sun's ANDA Product is covered by at least claim 1 of the '003 Patent, and Sun has therefore infringed the '003 Patent. The Detailed Statement and Corrected Detailed Statement do not allege that the '003 Patent is unenforceable.

91. The WEGOVY® Label instructs physicians that "WEGOVY® is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in [1] adults with an initial body mass index (BMI) of . . . 30 kg/m^2 or greater (obesity) or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) [and 2] pediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater standardized for age and sex (obesity)." The label further instructs to administer WEGOVY® once weekly.

92. The WEGOVY® Label provides limitations of use, including, but not limited to, instructing that WEGOVY® should not be used in combination with other semaglutide-containing products or any other GLP-1 receptor agonist, cautions that there may be certain side effects and/or unestablished safety and efficacy when coadministered with other therapeutics.

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

94. The WEGOVY® Label instructs to administer WEGOVY® once weekly according to a dose escalation schedule that includes an initiating dosage at 0.25 mg of semaglutide for four weeks, 0.5 mg for the next four weeks, and 1 mg for the next four weeks after that.

95. The use of WEGOVY® is claimed in at least claim 1 of the '003 Patent.

96. Thus, WEGOVY® and any corresponding generic semaglutide injection are covered by at least claim 1 of the '003 Patent.

97. The '003 Patent is listed in the Orange Book for WEGOVY®.

98. On information and belief, Sun's ANDA essentially copies the WEGOVY® Label and formulation as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(8)(iv), 314.94(a)(9)(iii), 314.127(a)(8)(ii)(B), and as such, the liquid pharmaceutical composition in Sun's ANDA Product is identical to that in WEGOVY®.

99. On information and belief, if Sun's ANDA is approved, Sun will make, use, offer for sale, sell, or import Sun's ANDA Product in a manner that would infringe at least claim 1 of the '003 Patent.

100. 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 claim 1 of the '003 Patent.

101. 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 claim 1 of the '003 Patent.

102. WEGOVY® and any corresponding generic semaglutide injection formulation is not a staple article of commerce and has no substantial approved uses that do not infringe at least claim 1 of the '003 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 claim 1 of the '003 Patent.

103. Sun has infringed at least claim 1 of the '003 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 claim 1 of the '003 Patent, before the expiration of the '003 Patent.

104. 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 claim 1 of the '003 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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

106. Novo Nordisk seeks an order declaring that Sun has infringed at least claim 1 of the '003 Patent by submitting Sun's ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

107. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4), 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 '003 Patent or any later expiration of extensions, adjustments, and exclusivities for the '003 Patent to which Novo Nordisk becomes entitled.

108. Novo Nordisk seeks an order declaring that Sun will infringe at least claim 1 of the '003 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Sun's ANDA Product before the expiration of the '003 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

109. Novo Nordisk will be irreparably harmed if Sun is not enjoined from infringing, actively inducing, or contributing to the infringement of at least claim 1 of the '003 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.

110. On information and belief, Sun's Detailed Statement and Corrected Detailed Statement setting forth the factual and legal bases for their opinion regarding infringement and validity of the '003 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

111. To the extent Sun commercializes Sun's ANDA Product prior to the expiration of the '003 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C).

COUNT III
(INFRINGEMENT OF THE '605 PATENT)

112. The allegations above are incorporated herein by reference.

113. 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 '605 Patent, and any extensions thereof.

114. The Notice Letter and Corrected Notice Letter state that Sun's ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Sun's ANDA Product before the expiration of the '605 Patent. The Notice Letter and Corrected Notice Letter represent that Sun's ANDA was submitted with a Paragraph IV Certification that the '605 Patent is "invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Sun's ANDA Product."

115. Sun has actual knowledge of the '605 Patent.

116. Sun was required to include in its Detailed Statement (and Corrected Detailed Statement) for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. *See* 21 CFR § 314.95(c)(7).

117. On information and belief, Sun's ANDA Product is covered by at least claim 1 of the '605 Patent, and Sun has therefore infringed the '605 Patent. The Detailed Statement and Corrected Detailed Statement do not allege that the '605 Patent is unenforceable.

118. The WEGOVY® Label states that each 0.5 mL single-dose pen (i.e., prefilled syringe with needle) contains a solution of WEGOVY® containing 0.25 mg, 0.5 mg or 1 mg of semaglutide; and each 0.75 mL single-dose pen contains a solution of WEGOVY® containing 1.7 or 2.4 mg semaglutide.

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

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

121. The WEGOVY® formulation is covered by at least claim 1 of the '605 Patent.

122. The WEGOVY® Label instructs physicians that "WEGOVY® is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in [1] adults with an initial body mass index (BMI) of . . . 30 kg/m^2 or greater (obesity) or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) [and 2] pediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater standardized for age and sex (obesity)."

123. The use of WEGOVY® is claimed, among others, in at least claim 14 of the '605 Patent.

124. Thus WEGOVY® and any corresponding generic semaglutide injection are covered by at least claims 1 and 14 of the '605 Patent.

125. The '605 Patent is listed in the Orange Book for WEGOVY®.

126. On information and belief, Sun's ANDA essentially copies the WEGOVY® Label and formulation as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(8)(iv), 314.94(a)(9)(iii), 314.127(a)(8)(ii)(B), and as such, the liquid pharmaceutical composition in Sun's ANDA Product is identical to that in WEGOVY®.

127. On information and belief, if Sun's ANDA is approved, Sun will make, use, offer for sale, sell, or import Sun's ANDA Product in a manner that would infringe at least claims 1 and 14 of the '605 Patent.

128. 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 1 and 14 of the '605 Patent.

129. 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 1 and 14 of the '605 Patent.

130. 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 1 and 14 of the '605 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 1 and 14 of the '605 Patent.

131. Sun has infringed at least claims 1 and 14 of the '605 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 1 and 14 of the '605 Patent, before the expiration of the '605 Patent.

132. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Sun's ANDA would directly infringe at least claim 1 of the '605 Patent under 35 U.S.C. §§ 271(a) and/or (f)

133. 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 1 and 14 of the '605 Patent under 35 U.S.C. §§ 271(a), (b), (c) and/or (f).

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

135. Novo Nordisk seeks an order declaring that Sun has infringed at least claims 1 and 14 of the '605 Patent by submitting Sun's ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

136. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4), 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 '605 Patent or any later expiration of extensions, adjustments, and exclusivities for the '605 Patent to which Novo Nordisk becomes entitled.

137. Novo Nordisk seeks an order declaring that Sun will infringe at least claims 1 and 14 of the '605 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Sun's ANDA Product before the expiration of the '605 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

138. Novo Nordisk will be irreparably harmed if Sun is not enjoined from infringing, actively inducing, or contributing to the infringement of at least claims 1 and 14 of the '605 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.

139. On information and belief, Sun's Detailed Statement and Corrected Detailed Statement setting forth the factual and legal bases for their opinion regarding infringement and validity of the '605 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

140. To the extent Sun commercializes Sun's ANDA Product prior to the expiration of the '605 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C).

COUNT IV
(INFRINGEMENT OF THE '191 PATENT)

141. The allegations above are incorporated herein by reference.

142. 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 '191 Patent, and any extensions thereof.

143. The Notice Letter and Corrected Notice Letter state that Sun's ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Sun's ANDA Product before the expiration of the '191 Patent. The Notice Letter and Corrected Notice Letter represent that Sun's ANDA was submitted with a Paragraph IV Certification that the '191 Patent is "invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Sun's ANDA Product."

144. Sun has actual knowledge of the '191 Patent.

145. Sun was required to include in its Detailed Statement (and Corrected Detailed Statement) for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. *See* 21 CFR § 314.95(c)(7).

146. On information and belief, Sun's ANDA Product is covered by at least claim 1 of the '191 Patent, and Sun has therefore infringed the '191 Patent. The Detailed Statement and Corrected Detailed Statement do not allege that the '191 Patent is unenforceable.

147. The WEGOVY® Label states that each 0.5 mL single-dose pen (i.e., prefilled syringe with needle) contains a solution of WEGOVY® containing 0.25 mg, 0.5 mg or 1 mg of semaglutide; and each 0.75 mL single-dose pen contains a solution of WEGOVY® containing 1.7 or 2.4 mg semaglutide.

148. The WEGOVY® Label lists 1.42 mg disodium phosphate dihydrate (also known as disodium hydrogen phosphate dihydrate), 8.25 mg sodium chloride, and water for injection as inactive ingredients in each 1 mL of WEGOVY®. The WEGOVY® Label states that WEGOVY®

has a pH of approximately 7.4 and that hydrochloric acid or sodium hydroxide may be added to adjust pH.

149. The WEGOVY® formulation is covered by at least claim 1 of the '191 Patent.

150. The WEGOVY® Label instructs physicians that "WEGOVY® is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in [1] adults with an initial body mass index (BMI) of . . . 30 kg/m^2 or greater (obesity) or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) [and 2] pediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater standardized for age and sex (obesity)."

151. The use of WEGOVY® is claimed, among others, in at least claim 15 of the '191 Patent.

152. Thus WEGOVY® and any corresponding generic semaglutide injection are covered by at least claims 1 and 15 of the '191 Patent.

153. The '191 Patent is listed in the Orange Book for WEGOVY®.

154. On information and belief, Sun's ANDA essentially copies the WEGOVY® Label and formulation as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(8)(iv), 314.94(a)(9)(iii), 314.127(a)(8)(ii)(B), and as such, the liquid pharmaceutical composition in Sun's ANDA Product is identical to that in WEGOVY®.

155. On information and belief, if Sun's ANDA is approved, Sun will make, use, offer for sale, sell, or import Sun's ANDA Product in a manner that would infringe at least claims 1 and 15 of the '191 Patent.

156. 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 1 and 15 of the '191 Patent.

157. 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 1 and 15 of the '191 Patent.

158. 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 1 and 15 of the '191 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 1 and 15 of the '191 Patent.

159. Sun has infringed at least claims 1 and 15 of the '191 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 1 and 15 of the '191 Patent, before the expiration of the '191 Patent.

160. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Sun's ANDA would directly infringe at least claim 1 of the '191 Patent under 35 U.S.C. §§ 271(a) and/or (f)

161. 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 1 and 15 of the '191 Patent under 35 U.S.C. §§ 271(a), (b), (c) and/or (f).

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

163. Novo Nordisk seeks an order declaring that Sun has infringed at least claims 1 and 15 of the '191 Patent by submitting Sun's ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

164. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4), 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 '191 Patent or any later expiration of extensions, adjustments, and exclusivities for the '191 Patent to which Novo Nordisk becomes entitled.

165. Novo Nordisk seeks an order declaring that Sun will infringe at least claims 1 and 15 of the '191 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Sun's ANDA Product before the expiration of the '191 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

166. Novo Nordisk will be irreparably harmed if Sun is not enjoined from infringing, actively inducing, or contributing to the infringement of at least claims 1 and 15 of the '191 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.

167. On information and belief, Sun's Detailed Statement and Corrected Detailed Statement setting forth the factual and legal bases for their opinion regarding infringement and validity of the '191 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

168. To the extent Sun commercializes Sun's ANDA Product prior to the expiration of the '191 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C).

COUNT V
(INFRINGEMENT OF THE '198 PATENT)

169. The allegations above are incorporated herein by reference.

170. 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 '198 Patent, and any extensions thereof.

171. The Notice Letter, Corrected Notice Letter, and Third Notice Letter state that Sun's ANDA was submitted to obtain approval to manufacture, use, offer to sell, and sell Sun's ANDA Product before the expiration of the '198 Patent. The Notice Letter, Corrected Notice Letter, and Third Notice Letter represent that Sun's ANDA was submitted with a Paragraph IV Certification that the '198 Patent is "invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Sun's ANDA Product."

172. Sun has actual knowledge of the '198 Patent.

173. Sun was required to include in its Detailed Statement (and Corrected Detailed Statement and Third Detailed Statement) for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. *See* 21 CFR § 314.95(c)(7).

174. The Detailed Statement, Corrected Detailed Statement, and Third Detailed Statement do not provide any separate factual bases for stating that the '198 Patent will not be infringed by Sun's ANDA Product apart from arguing that the '198 Patent is invalid. If Sun had any reasonable basis for asserting that Sun's ANDA Product is not covered by the claims of the '198 Patent, Sun was required to provide a full and detailed explanation as to why. Accordingly,

on information and belief, Sun's ANDA Product is covered by at least claim 1 of the '198 Patent, and Sun has therefore infringed the '198 Patent. The Detailed Statement, Corrected Detailed Statement, and Third Detailed Statement do not allege that the '198 Patent is unenforceable.

175. The WEGOVY® Label states that each 0.5 mL single-dose pen (i.e., prefilled syringe with needle) contains a solution of WEGOVY® containing 0.25 mg, 0.5 mg or 1 mg of semaglutide; and each 0.75 mL single-dose pen contains a solution of WEGOVY® containing 1.7 or 2.4 mg semaglutide.

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

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

178. The WEGOVY® formulation is covered by at least claim 1 of the '198 Patent.

179. The WEGOVY® Label instructs physicians that "WEGOVY® is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in [1] adults with an initial body mass index (BMI) of . . . 30 kg/m^2 or greater (obesity) or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) [and 2] pediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater standardized for age and sex (obesity)."

180. The use of WEGOVY® is claimed, among others, in at least claim 8 of the '198 Patent.

181. Thus WEGOVY® and any corresponding generic semaglutide injection are covered by at least claims 1 and 8 of the '198 Patent.

182. The '198 Patent is listed in the Orange Book for WEGOVY®.

183. On information and belief, Sun's ANDA essentially copies the WEGOVY® Label and formulation as required by FDA, *see* 21 C.F.R. §§ 314.94(a)(8)(iv), 314.94(a)(9)(iii), 314.127(a)(8)(ii)(B), and as such, the liquid pharmaceutical composition in Sun's ANDA Product is identical to that in WEGOVY®.

184. On information and belief, if Sun's ANDA is approved, Sun will make, use, offer for sale, sell, or import Sun's ANDA Product in a manner that would infringe at least claims 1 and 8 of the '198 Patent.

185. 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 1 and 8 of the '198 Patent.

186. 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 1 and 8 of the '198 Patent.

187. 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 1 and 8 of the '198 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 1 and 8 of the '198 Patent.

188. Sun has infringed at least claims 1 and 8 of the '198 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 1 and 8 of the '198 Patent, before the expiration of the '198 Patent.

189. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under Sun's ANDA would directly infringe at least claim 1 of the '198 Patent under 35 U.S.C. §§ 271(a) and/or (f)

190. 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 1 and 8 of the '198 Patent under 35 U.S.C. §§ 271(a), (b), (c) and/or (f).

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

192. Novo Nordisk seeks an order declaring that Sun has infringed at least claims 1 and 8 of the '198 Patent by submitting Sun's ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

193. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4), 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 '198 Patent or any later expiration of extensions, adjustments, and exclusivities for the '198 Patent to which Novo Nordisk becomes entitled.

194. Novo Nordisk seeks an order declaring that Sun will infringe at least claims 1 and 8 of the '198 Patent by commercially manufacturing, using, offering to sell, selling, distributing, or importing Sun's ANDA Product before the expiration of the '198 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (f).

195. Novo Nordisk will be irreparably harmed if Sun is not enjoined from infringing, actively inducing, or contributing to the infringement of at least claims 1 and 8 of the '198 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.

196. On information and belief, Sun's Detailed Statement, Corrected Detailed Statement, and Third Detailed Statement setting forth the factual and legal bases for their opinion regarding infringement and validity of the '198 Patent is devoid of an objective good faith basis in the facts or the law. This case is exceptional, and Novo Nordisk is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

197. To the extent Sun commercializes Sun's ANDA Product prior to the expiration of the '198 Patent, Novo Nordisk will also be entitled to damages under 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C).

PRAYER FOR RELIEF

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

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

B. A judgment declaring that Defendants will infringe directly, contribute to the direct infringement of, and/or induce the direct infringement of one or more claims of each of the Asserted Patents under 35 U.S.C. §§ 271(a), (b), (c) and/or (f) if they market, manufacture, use,

offer for sale, sell, distribute in, or import into the United States Sun's ANDA Product before the expiration of the Asserted Patents, or any later period of exclusivity to which Plaintiffs are or may become entitled;

C. An order requiring that Sun amend its Paragraph IV certification to a Paragraph III certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

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

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

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

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

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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