IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

NOVO NORDISK INC. and NOVO NORDISK A/S,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

C.A. No. **1:22-cv-23 (Keeley)**

COMPLAINT

Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), by their undersigned attorneys, for their Complaint against Defendant Mylan Pharmaceuticals Inc. ("Mylan"), allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Mylan's submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA"), by which Mylan seeks approval to market a generic version of Novo Nordisk's pharmaceutical product Ozempic® prior to the expiration of United States Patent Nos. 8,114,833 (the "'833 patent"), 8,129,343 (the "'343 patent"), 8,536,122 (the "'122 patent"), 8,684,969 (the "'969 patent"), 8,920,383 (the "'383 patent"), 9,108,002 (the "'002 patent"), 9,132,239 (the "'239 patent"), 9,457,154 (the "'154 patent"), 9,616,180 (the "'180 patent"), 9,687,611 (the "'611 patent"), 9,775,953 (the "'953 patent"), 9,861,757 (the "'757 patent"), 10,220,155 (the "'155 patent"), 10,335,462 (the "'462 patent"), 10,357,616 (the "'616 patent"), 10,376,652 (the "'652 patent"),

11,097,063 (the "'063 patent"), and RE46,363 (the "'363 patent") which cover *inter alia*, Ozempic® and/or its use.

THE PARTIES

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

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

4. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. On information and belief, Mylan Pharmaceuticals Inc. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of West Virginia and throughout the United States.

JURISDICTION AND VENUE

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

6. This Court has personal jurisdiction over Defendant Mylan Pharmaceuticals Inc. by virtue of, *inter alia*, its presence in West Virginia, being a West Virginia corporation; and having engaged in systematic and continuous contacts with the State of West Virginia; 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.*, *Merck Sharp & Dohme BV v. Mylan Pharmaceuticals Inc.*, C.A. No. 20-00061 (N.D. W.

Va. Apr. 2, 2020); *Celgene Corp. v. Mylan Pharmaceuticals Inc.*, C.A. No. 20-00003 (N.D. W. Va. Jan. 3, 2020)).

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

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

9. On February 14, 2012, the United States Patent and Trademark Office issued the '833 patent, entitled "Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and for Use in Injection Devices," a copy of which is attached to this Complaint as Exhibit A. NNAS is the owner of all right, title, and interest in the '833 patent.

10. On March 6, 2012, the United States Patent and Trademark Office issued the '343 patent, entitled "Acylated GLP-1 Compounds," a copy of which is attached to this Complaint as Exhibit B. NNAS is the owner of all right, title, and interest in the '343 patent.

11. On September 17, 2013, the United States Patent and Trademark Office issued the '122 patent, entitled "Acylated GLP-1 Compounds," a copy of which is attached to this Complaint as Exhibit C. NNAS is the owner of all right, title, and interest in the '122 patent.

12. On April 1, 2014, the United States Patent and Trademark Office issued the '969 patent, entitled "Injection Device with Torsion Spring and Rotatable Display," a copy of which is attached to this Complaint as Exhibit D. NNAS is the owner of all right, title, and interest in the '969 patent.

13. On December 30, 2014, the United States Patent and Trademark Office issued the '383 patent, entitled "Dose Mechanism for an Injection Device for Limiting a Dose Setting Corresponding to the Amount of Medicament Left," a copy of which is attached to this Complaint as Exhibit E. NNAS is the owner of all right, title, and interest in the '383 patent.

14. On August 18, 2015, the United States Patent and Trademark Office issued the '002 patent, entitled "Automatic Injection Device with a Top Release Mechanism," a copy of which is attached to this Complaint as Exhibit F. NNAS is the owner of all right, title, and interest in the '002 patent.

15. On September 15, 2015, the United States Patent and Trademark Office issued the '239 patent, entitled "Dial-Down Mechanism for Wind-Up Pen," a copy of which is attached to this Complaint as Exhibit G. NNAS is the owner of all right, title, and interest in the '239 patent.

16. On October 4, 2016, the United States Patent and Trademark Office issued the '154 patent, entitled "Injection Device with an End of Dose Feedback Mechanism," a copy of which is attached to this Complaint as Exhibit H. NNAS is the owner of all right, title, and interest in the '154 patent.

17. On April 11, 2017, the United States Patent and Trademark Office issued the '180 patent, entitled "Automatic Injection Device with a Top Release Mechanism," a copy of which is attached to this Complaint as Exhibit I. NNAS is the owner of all right, title, and interest in the '180 patent.

18. On June 27, 2017, the United States Patent and Trademark Office issued the '611 patent, entitled "Injection Device with Torsion Spring and Rotatable Display," a copy of which is attached to this Complaint as Exhibit J. NNAS is the owner of all right, title, and interest in the '611 patent.

19. On October 3, 2017, the United States Patent and Trademark Office issued the '953 patent, entitled "Dose Mechanism for an Injection Device for Limiting a Dose Setting Corresponding to the Amount of Medicament Left," a copy of which is attached to this Complaint as Exhibit K. NNAS is the owner of all right, title, and interest in the '953 patent.

20. On January 9, 2018, the United States Patent and Trademark Office issued the '757 patent, entitled "Injection Device with an End of Dose Feedback Mechanism," a copy of which is attached to this Complaint as Exhibit L. NNAS is the owner of all right, title, and interest in the '757 patent.

21. On March 5, 2019, the United States Patent and Trademark Office issued the '155 patent, entitled "Syringe Device with a Dose Limiting Mechanism and an Additional Safety Mechanism," a copy of which is attached to this Complaint as Exhibit M. NNAS is the owner of all right, title, and interest in the '155 patent.

22. On July 2, 2019, the United States Patent and Trademark Office issued the '462 patent, entitled "Use of Long-Acting GLP-1 Peptides," a copy of which is attached to this Complaint as Exhibit N. NNAS is the owner of all right, title, and interest in the '462 patent.

23. On July 23, 2019, the United States Patent and Trademark Office issued the '616 patent, entitled "Injection Device with an End of Dose Feedback Mechanism," a copy of which is attached to this Complaint as Exhibit O. NNAS is the owner of all right, title, and interest in the '616 patent.

24. On August 13, 2019, the United States Patent and Trademark Office issued the '652 patent, entitled "Automatic Injection Device with a Top Release Mechanism," a copy of which is attached to this Complaint as Exhibit P. NNAS is the owner of all right, title, and interest in the '652 patent.

25. On August 24, 2021, the United States Patent and Trademark Office issued the '063 patent, entitled "Syringe Device with a Dose Limiting Mechanism and an Additional Safety Mechanism," a copy of which is attached to this Complaint as Exhibit Q. NNAS is the owner of all right, title, and interest in the '063 patent.

26. On April 11, 2017, the United States Patent and Trademark Office issued the '363 patent, entitled "Dial-Down Mechanism for Wind-Up Pen," a copy of which is attached to this Complaint as Exhibit R. NNAS is the owner of all right, title, and interest in the '363 patent.

OZEMPIC®

27. NNI holds approved New Drug Application No. 209637 (the "Ozempic® NDA") for Ozempic® (semaglutide) subcutaneous solution, 2 mg/1.5 ml (1.34 mg/ml) and 4 mg/3 ml (1.34 mg/ml), which NNI sells under the trade name Ozempic®.

28. The claims of the patents-in-suit cover, *inter alia*, Ozempic® and/or its use.

29. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '833, '343, '122, '969, '383, '002, '239, '154, '180, '611, '953, '757, '155, '462, '616, '652, '063, and '363 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Ozempic®.

MYLAN'S ANDA

30. On information and belief, Mylan submitted ANDA No. 216991 ("Mylan's ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market a generic version of semaglutide injection, 2 mg/1.5 ml (1.34 mg/ml) and 4 mg/3 ml (1.34 mg/ml) ("Mylan's Product").

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

32. By letter to NNI and NNAS, dated February 4, 2022 (the "Notice Letter"), Mylan stated that Mylan's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '833, '343, '122, '969, '383, '002, '239, '154, '180, '611, '953, '757, '155, '462, '616, '652, '063, and '363 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Mylan's Product (the "Paragraph IV Certification"). Mylan attached a memorandum to the Notice Letter in which it purported to allege factual and legal bases for its Paragraph IV Certification. NNI and NNAS file this suit within 45 days of receipt of the Notice Letter.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,114,833

33. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-32 of this Complaint.

34. Mylan has infringed the '833 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '833 patent.

35. Claims 1-15 of the '833 patent are directed to GLP-1 formulations. Claims 16-31 are directed to methods for preparing such formulations or methods of reducing deposits or reducing clogging by replacing the isotonicity agent in a formulation with propylene glycol. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '833 patent would infringe claims 1-31 of the '833 patent.

36. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '833 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '833 patent expires.

37. Novo Nordisk has no adequate remedy at law.

38. Mylan was aware of the '833 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorney's fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,129,343

39. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-38 of this Complaint.

40. Mylan has infringed the '343 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '343 patent.

41. Claims 1-2 and 4-5 of the '343 patent encompass semaglutide and pharmaceutical compositions comprising semaglutide. Claims 3 and 6 encompass methods of treating type 2 diabetes comprising administering to a patient an effective amount of semaglutide. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '343 patent would infringe claims 1-6 of the '343 patent.

42. Upon information and belief, Mylan's sale or offer for sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, or commercial marketing of Mylan's Product in the United States, during the term of and with knowledge of the

'343 patent, would intentionally induce others to use Mylan's Product in the United States, thus inducing infringement of claims 3 and 6 of the '343 patent.

43. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '343 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '343 patent expires.

44. Novo Nordisk has no adequate remedy at law.

45. Mylan was aware of the '343 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorney's fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,536,122

46. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-45 of this Complaint.

47. Mylan has infringed the '122 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '122 patent.

48. Claims 1-14 of the '122 patent encompass GLP-1 compounds and pharmaceutical compositions comprising GLP-1 compounds. Claims 15 and 16 encompass methods of treating type 2 diabetes comprising administering to a subject in need an effective amount of a claimed GLP-1 compound. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '122 patent would infringe claims 1-16 of the '122 patent.

49. Upon information and belief, Mylan's sale or offer for sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, or commercial

marketing of Mylan's Product in the United States, during the term of and with knowledge of the '122 patent, would intentionally induce others to use Mylan's Product in the United States, thus inducing infringement of claims 15 and 16 of the '122 patent.

50. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '122 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '122 patent expires.

51. Novo Nordisk has no adequate remedy at law.

52. Mylan was aware of the '122 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorney's fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,684,969

53. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-52 of this Complaint.

54. Mylan has infringed the '969 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '969 patent.

55. Claims 1-26 of the '969 patent are directed to an injection device comprising a torsion spring operatively connected to a dose setting member and a rotatably mounted display member. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '969 patent would infringe claims 1-26 of the '969 patent.

56. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '969 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '969 patent expires.

57. Novo Nordisk has no adequate remedy at law.

58. Mylan was aware of the '969 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,920,383

59. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-58 of this Complaint.

60. Mylan has infringed the '383 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '383 patent.

61. Claims 1-12 of the '383 patent are directed to a mechanism for preventing setting of a dose which exceeds the amount of a medicament left in a reservoir in an injection device. Claim 13 of the '383 patent is directed to a syringe device employing such a mechanism. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '383 patent would infringe claims 1-13 of the '383 patent.

62. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '383 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '383 patent expires.

63. Novo Nordisk has no adequate remedy at law.

64. Mylan was aware of the ’383 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,108,002

65. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-64 of this Complaint.

66. Mylan has infringed the ’002 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan’s ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan’s Product prior to the expiration of the ’002 patent.

67. Claims 1-2 of the ’002 patent are directed to an injection device with a release member opposite the end of the device where a needle may be mounted. Mylan’s manufacture, use, offer for sale or sale of Mylan’s Product within the United States, or importation of Mylan’s Product into the United States, during the term of the ’002 patent would infringe claims 1-2 of the ’002 patent.

68. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the ’002 patent and/or if the FDA is not enjoined from approving Mylan’s ANDA before the ’002 patent expires.

69. Novo Nordisk has no adequate remedy at law.

70. Mylan was aware of the ’002 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,132,239

71. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-70 of this Complaint.

72. Mylan has infringed the '239 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '239 patent.

73. Claims 1-3 of the '239 patent are directed to a dial-down mechanism for an injection device. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '239 patent would infringe claims 1-3 of the '239 patent.

74. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '239 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '239 patent expires.

75. Novo Nordisk has no adequate remedy at law.

76. Mylan was aware of the '239 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,457,154

77. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-76 of this Complaint.

78. Mylan has infringed the '154 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '154 patent.

79. Claims 1-17 of the '154 patent are directed to an injection device comprising a dose delivering mechanism which provides an audible feedback signal to a user at the end of injection of a set dose. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '154 patent would infringe claims 1-17 of the '154 patent.

80. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '154 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '154 patent expires.

81. Novo Nordisk has no adequate remedy at law.

82. Mylan was aware of the '154 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,616,180

83. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-82 of this Complaint.

84. Mylan has infringed the '180 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '180 patent.

85. Claims 1-14 of the '180 patent are directed to an injection device with a push button like release member opposite the end of the device where a needle may be mounted. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '180 patent would infringe claims 1-14 of the '180 patent.

86. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '180 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '180 patent expires.

87. Novo Nordisk has no adequate remedy at law.

88. Mylan was aware of the '180 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,687,611

89. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-88 of this Complaint.

90. Mylan has infringed the '611 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '611 patent.

91. Claims 1-13 and 15 of the '611 patent are directed to an injection device with a torsion spring operatively connected to a dose setting member and a rotatably mounted display member. Claim 14 of the '611 patent is directed to an injection pen comprising a torsion spring and a dose indicator barrel having a helical scale. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '611 patent would infringe claims 1-15 of the '611 patent.

92. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '611 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '611 patent expires.

93. Novo Nordisk has no adequate remedy at law.

94. Mylan was aware of the '611 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,775,953

95. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-94 of this Complaint.

96. Mylan has infringed the '953 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '953 patent.

97. Claims 1-10 and 12-25 of the '953 patent are directed to a mechanism for preventing setting of a dose which exceeds the amount of medicament left in a reservoir in an injection device. Claim 11 of the '953 patent is directed to a syringe device employing such a mechanism. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '953 patent would infringe claims 1-25 of the '953 patent.

98. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '953 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '953 patent expires.

99. Novo Nordisk has no adequate remedy at law.

100. Mylan was aware of the '953 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,861,757

101. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-100 of this Complaint.

102. Mylan has infringed the '757 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '757 patent.

103. Claims 1-12 of the '757 patent are directed to an injection device comprising a mechanism which provides a tactile feedback signal to a user at the end of injection of a set dose. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '757 patent would infringe claims 1-12 of the '757 patent.

104. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '757 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '757 patent expires.

105. Novo Nordisk has no adequate remedy at law.

106. Mylan was aware of the '757 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 10,220,155

107. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-106 of this Complaint.

108. Mylan has infringed the '155 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '155 patent.

109. Claims 1-8 of the '155 patent are directed to a syringe device with a dose limiting mechanism and a safety mechanism structure which prevent injection of a dose exceeding a set dose. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '155 patent would infringe claims 1-8 of the '155 patent.

110. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '155 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '155 patent expires.

111. Novo Nordisk has no adequate remedy at law.

112. Mylan was aware of the '155 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 10,335,462

113. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-112 of this Complaint.

114. Mylan has infringed the '462 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '462 patent.

115. Claims 1-10 of the '462 patent are directed to a method of treating type 2 diabetes comprising administering semaglutide to a subject in need thereof. Mylan's manufacture, use,

offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '462 patent would infringe claims 1-10 of the '462 patent.

116. Upon information and belief, Mylan's sale or offer for sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, or commercial marketing of Mylan's Product in the United States, during the term of and with knowledge of the '462 patent, would intentionally induce others to use Mylan's Product in the United States, thus inducing infringement of claims 1-10 of the '462 patent.

117. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '462 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '462 patent expires.

118. Novo Nordisk has no adequate remedy at law.

119. Mylan was aware of the '462 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 10,357,616

120. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-119 of this Complaint.

121. Mylan has infringed the '616 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '616 patent.

122. Claims 1-9 of the '616 patent are directed to an injection device comprising a mechanism which provides an audible feedback signal to a user at the end of injection of a set

dose. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '616 patent would infringe claims 1-9 of the '616 patent.

123. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '616 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '616 patent expires.

124. Novo Nordisk has no adequate remedy at law.

125. Mylan was aware of the '616 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 10,376,652

126. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-125 of this Complaint.

127. Mylan has infringed the '652 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '652 patent.

128. Claims 1-15 of the '652 patent are directed to an injection device with a release member opposite the end of the device where a needle may be mounted, and a display member. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '652 patent would infringe claims 1-15 of the '652 patent.

129. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '652 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '652 patent expires.

130. Novo Nordisk has no adequate remedy at law.

131. Mylan was aware of the '652 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 11,097,063

132. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-131 of this Complaint.

133. Mylan has infringed the '063 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '063 patent.

134. Claims 1-7 of the '063 patent are directed to a syringe device with a dose limiting mechanism and a safety mechanism structure which prevent ejection of a dose exceeding a set dose. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '063 patent would infringe claims 1-7 of the '063 patent.

135. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '063 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '063 patent expires.

136. Novo Nordisk has no adequate remedy at law.

137. Mylan was aware of the '063 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. RE46,363

138. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-137 of this Complaint.

139. Mylan has infringed the '363 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '363 patent.

140. Claims 1-8 of the '363 patent are directed to dial-down mechanism for an injection device. Claims 9 and 10 of the '363 patent are directed to a medication delivery device comprising such a dial-down mechanism. Claim 11 of the '363 patent is directed to a method for using a wind up injection pen. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '363 patent would infringe claims 1-11 of the '363 patent.

141. Upon information and belief, Mylan's sale or offer for sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, or commercial marketing of Mylan's Product in the United States, during the term of and with knowledge of the '363 patent, would intentionally induce others to use Mylan's Product in the United States, thus inducing infringement of claim 11 of the '363 patent.

142. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '363 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '363 patent expires.

143. Novo Nordisk has no adequate remedy at law.

144. Mylan was aware of the '363 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Novo Nordisk prays for a judgment in its favor and against Mylan and respectfully requests the following relief:

A. A judgment that Mylan has infringed the '833 patent;

B. A judgment that Mylan has infringed the '343 patent;

C. A judgment that Mylan has infringed the '122 patent;

D. A judgment that Mylan has infringed the '969 patent;

E. A judgment that Mylan has infringed the '383 patent;

F. A judgment that Mylan has infringed the '002 patent;

G. A judgment that Mylan has infringed the '239 patent;

H. A judgment that Mylan has infringed the '154 patent;

I. A judgment that Mylan has infringed the '180 patent;

J. A judgment that Mylan has infringed the '611 patent;

K. A judgment that Mylan has infringed the '953 patent;

L. A judgment that Mylan has infringed the '757 patent;

M. A judgment that Mylan has infringed the '155 patent;

N. A judgment that Mylan has infringed the '462 patent;

O. A judgment that Mylan has infringed the '616 patent;

P. A judgment that Mylan has infringed the '652 patent;

Q. A judgment that Mylan has infringed the ’063 patent;

R. A judgment that Mylan has infringed the ’363 patent;

S. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Mylan’s ANDA, under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the ’833, ’343, ’122, ’969, ’383, ’002, ’239, ’154, ’180, ’611, ’953, ’757, ’155, ’462, ’616, ’652, ’063, and ’363 patents, including any extensions, adjustments, and exclusivities;

T. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Mylan, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling Mylan’s Product within the United States, or importing Mylan’s Product into the United States, prior to the expiration of the ’833, ’343, ’122, ’969, ’383, ’002, ’239, ’154, ’180, ’611, ’953, ’757, ’155, ’462, ’616, ’652, ’063, and ’363 patents, including any extensions, adjustments, and exclusivities;

U. If Mylan commercially manufactures, uses, offers to sell, or sells Mylan’s Product within the United States, or imports Mylan’s Product into the United States, prior to the expiration of the ’833, ’343, ’122, ’969, ’383, ’002, ’239, ’154, ’180, ’611, ’953, ’757, ’155, ’462, ’616, ’652, ’063, and ’363 patents, including any extensions, adjustments, and exclusivities, a judgment awarding Novo Nordisk monetary relief, together with interest;

V. An award of attorneys’ fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

W. An award of costs and expenses in this action; and

X. Such other relief as the Court deems just and proper.

SCHRADER COMPANION DUFF & LAW, PLLC

/s/ James F. Companion
James F. Companion, Esq. (#790)
Sandra K. Law, Esq. (#6071)
401 Main Street
Wheeling, WV 26003
(304) 233-3390
jfc@schraderlaw.com

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

OF COUNSEL:

Jeffrey J. Oelke
Ryan P. Johnson
Robert E. Counihan
Laura T. Moran
FENWICK & WEST LLP
902 Broadway, Suite 14
New York, NY 10010-6035
(212) 430-2600

March 18, 2022