IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: OZEMPIC (SEMAGLUTIDE) PATENT LITIGATION	)	MDL No. 22-MD-3038 (CFC) **ANDA CASE**
NOVO NORDISK INC. and NOVO NORDISK A/S,	)	
Plaintiffs,	)	
v.	)	C.A. No. 22-1040 (CFC) **ANDA CASE**
MYLAN PHARMACEUTICALS, INC.,	)	
Defendant.	)	

FIRST AMENDED COMPLAINT

Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), by their undersigned attorneys, for their First Amended 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 two Abbreviated New Drug Applications ("ANDA") to the United States Food

and Drug Administration ("FDA"), by which Mylan seeks approval to market generic versions 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"), 11,311,679 (the "'679 patent"), 11,446,443 (the "'443 patent"), and RE46,363 (the "'363 patent") which cover *inter alia*, Ozempic® and/or its use.

2. This is an amendment to a complaint that Novo Nordisk originally filed against Mylan Pharmaceuticals Inc. on March 18, 2022 in the Northern District of West Virginia in C.A. No. 1:22-cv-00023-JPB (the "West Virginia Complaint"). By order dated August 5, 2022 in MDL No. 3038, the West Virginia Complaint was transferred under 28 U.S.C. § 1407 to the District of Delaware as D. Del. C.A. No. 22-1040-CFC. The West Virginia Complaint appears in its original form at D. Del. C.A. No. 22-1040-CFC, D.I. 2. The allegations concerning personal jurisdiction and venue in this First Amended Complaint remain substantively unchanged and directed to West Virginia. *See In re Auto. Refinishing Paint Antitrust Litig.*, 358

F.3d 288, 297 n.11 (3d Cir. 2004) (when a litigation is transferred pursuant to 28 U.S.C. § 1407, "the transferee court can exercise personal jurisdiction to the same extent that the transferor court could"). Novo Nordisk makes those allegations without prejudice to Novo Nordisk's ability to litigate this dispute against Mylan Pharmaceuticals Inc. in the District of Delaware to the full extent permitted under 28 U.S.C. § 1407.

THE PARTIES

3. 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.

4. 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.

5. 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 3711 Collins Ferry 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

6. The Northern District of West Virginia has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. The Northern District of West Virginia 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 the Northern District of West Virginia; and having taken advantage of the rights and protections provided by the Northern District of West Virginia, including having asserted counterclaims in the Northern District of West Virginia (*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)).

8. On information and belief, Mylan intends to sell, offer to sell, use, and/or engage in the commercial manufacture of generic versions of Novo Nordisk's pharmaceutical product Ozempic®, directly or indirectly, throughout the United States and in the Northern District of West Virginia. Mylan's filing of two ANDAs for generic versions of Novo Nordisk's pharmaceutical product Ozempic® confirms this intention and further subjects Mylan to the specific personal jurisdiction of the Northern District of West Virginia.

9. Venue is proper in the Northern District of West Virginia pursuant to 28 U.S.C. §§ 1391 and 1400(b).

10. Venue is also proper in the District of Delaware for all pretrial purposes pursuant to 28 U.S.C. § 1407 and the August 5, 2022 order in MDL No. 3038.

THE PATENTS-IN-SUIT

11. 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 First Amended Complaint as Exhibit A. NNAS is the owner of all right, title, and interest in the ’833 patent.

12. 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 First Amended Complaint as Exhibit B. NNAS is the owner of all right, title, and interest in the ’343 patent.

13. 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 First Amended Complaint as Exhibit C. NNAS is the owner of all right, title, and interest in the ’122 patent.

14. 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 First Amended Complaint as Exhibit D. NNAS is the owner of all right, title, and interest in the '969 patent.

15. 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 First Amended Complaint as Exhibit E. NNAS is the owner of all right, title, and interest in the '383 patent.

16. 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 First Amended Complaint as Exhibit F. NNAS is the owner of all right, title, and interest in the '002 patent.

17. 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 First Amended Complaint as Exhibit G. NNAS is the owner of all right, title, and interest in the '239 patent.

18. 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 First Amended Complaint as Exhibit H. NNAS is the owner of all right, title, and interest in the '154 patent.

19. 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 First Amended Complaint as Exhibit I. NNAS is the owner of all right, title, and interest in the ’180 patent.

20. 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 First Amended Complaint as Exhibit J. NNAS is the owner of all right, title, and interest in the ’611 patent.

21. 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 First Amended Complaint as Exhibit K. NNAS is the owner of all right, title, and interest in the ’953 patent.

22. 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 First Amended Complaint as Exhibit L. NNAS is the owner of all right, title, and interest in the ’757 patent.

23. 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 First

Amended Complaint as Exhibit M. NNAS is the owner of all right, title, and interest in the '155 patent.

24. 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 First Amended Complaint as Exhibit N. NNAS is the owner of all right, title, and interest in the '462 patent.

25. 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 First Amended Complaint as Exhibit O. NNAS is the owner of all right, title, and interest in the '616 patent.

26. 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 First Amended Complaint as Exhibit P. NNAS is the owner of all right, title, and interest in the '652 patent.

27. 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 First Amended Complaint as Exhibit Q. NNAS is the owner of all right, title, and interest in the '063 patent.

28. 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 First Amended Complaint as Exhibit R. NNAS is the owner of all right, title, and interest in the '363 patent.

29. On April 26, 2022, the United States Patent and Trademark Office issued the '679 patent, entitled "Automatic Injection Device with a Top Release Mechanism," a copy of which is attached to this First Amended Complaint as Exhibit S. NNAS is the owner of all right, title, and interest in the '679 patent.

30. On September 20, 2022, the United States Patent and Trademark Office issued the '443 patent, entitled "Injection Device with Torsion Spring and Rotatable Display," a copy of which is attached to this First Amended Complaint as Exhibit T. NNAS is the owner of all right, title, and interest in the '443 patent.

OZEMPIC®

31. NNI holds approved New Drug Application No. 209637 (the "Ozempic® NDA") for Ozempic® (semaglutide) subcutaneous solution, 2 mg/3 ml (0.68 mg/ml), 2 mg/1.5 ml (1.34 mg/ml), 4 mg/3 ml (1.34 mg/ml), and 8 mg/3 ml (2.68 mg/ml) which NNI sells under the trade name Ozempic®.

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

33. 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, '679, '443, 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 FIRST ANDA

34. On information and belief, Mylan submitted ANDA No. 216991 ("Mylan's First 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 First ANDA Product").

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

36. By letter to NNI and NNAS, dated February 4, 2022 (the "First Notice Letter"), Mylan stated that Mylan's First 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 First ANDA Product (the "First Paragraph IV

Certification").[1] Mylan attached a memorandum to the First Notice Letter in which it purported to allege factual and legal bases for its First Paragraph IV Certification. NNI and NNAS filed this suit within 45 days of receipt of the First Notice Letter.

MYLAN'S SECOND ANDA

37. On information and belief, Mylan submitted ANDA No. 217706 ("Mylan's Second ANDA") (collectively with Mylan's First ANDA, "Mylan's ANDAs") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market a generic version of semaglutide injection, 8 mg/3 ml (2.68 mg/ml) ("Mylan's Second ANDA Product").

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

[1] Pursuant to Paragraphs 5 and 11 of the Scheduling Order governing this Action (*see* D.I. 53, adopting the Scheduling Order entered in C.A. No. 22-294-CFC, D.I. 22), Plaintiffs have previously disclosed that they are not asserting infringement of the originally asserted United States Patent Nos. 8,684,969 (the "'969 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"), 9,861,757 (the "'757 patent"), 10,220,155 (the "'155 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") (collectively, the "Non-Asserted Patents") as to Mylan's First ANDA Product. Accordingly, the Non-Asserted Patents are omitted from this First Amended Complaint as to Mylan's First ANDA Product. Plaintiffs' First Supplemental Disclosure of Asserted Patents and Claims dated February 9, 2023 regarding Mylan's First ANDA Product remains in effect.

39. By letter to NNI and NNAS, dated February 10, 2023 (the "Second Notice Letter"), Mylan stated that Mylan's Second 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, '616, '652, '063, '679, '443, and '363 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Mylan's Second ANDA Product (the "Second Paragraph IV Certification"). Mylan attached a memorandum to the Second Notice Letter in which it purported to allege factual and legal bases for its Second Paragraph IV Certification. NNI and NNAS file this First Amended Complaint within 45 days of receipt of the Second Notice Letter.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,114,833 BY MYLAN'S FIRST ANDA

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

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

42. 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 First ANDA Product within the United States, or importation of Mylan's First ANDA Product into the United States, during the term of the '833 patent would infringe claims 1-31 of the '833 patent.

43. 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 First ANDA before the '833 patent expires.

44. Novo Nordisk has no adequate remedy at law.

45. Mylan was aware of the '833 patent when it submitted its First 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. 8,114,833 BY MYLAN'S SECOND ANDA

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

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

48. 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 Second ANDA Product within the United States, or importation of Mylan's Second ANDA Product into the United States, during the term of the '833 patent would infringe claims 1-31 of the '833 patent.

49. 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 Second ANDA before the '833 patent expires.

50. Novo Nordisk has no adequate remedy at law.

51. Mylan was aware of the '833 patent when it submitted its Second 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 BY MYLAN'S FIRST ANDA

52. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-51 of this First Amended Complaint.

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

54. Claims 1-2 and 4-5 of the ’343 patent encompass semaglutide and pharmaceutical compositions comprising semaglutide. Mylan’s manufacture, use, offer for sale or sale of Mylan’s First ANDA Product within the United States, or importation of Mylan’s First ANDA Product into the United States, during the term of the ’343 patent would infringe claims 1-2 and 4-5 of the ’343 patent.

55. 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 First ANDA before the ’343 patent expires.

56. Novo Nordisk has no adequate remedy at law.

57. Mylan was aware of the ’343 patent when it submitted its First 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 BY MYLAN’S SECOND ANDA

58. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-57 of this First Amended Complaint.

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

60. Claims 1-2 and 4-5 of the ’343 patent encompass semaglutide and pharmaceutical compositions comprising semaglutide. Mylan’s manufacture, use, offer for sale or sale of Mylan’s Second ANDA Product within the United States, or importation of Mylan’s Second ANDA Product into the United States, during the term of the ’343 patent would infringe claims 1-2 and 4-5 of the ’343 patent.

61. 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 Second ANDA before the ’343 patent expires.

62. Novo Nordisk has no adequate remedy at law.

63. Mylan was aware of the ’343 patent when it submitted its Second 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 BY MYLAN’S FIRST ANDA

64. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-63 of this First Amended Complaint.

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

66. Claims 10 and 11 of the ’122 patent encompass GLP-1 compounds. Mylan’s manufacture, use, offer for sale or sale of Mylan’s First ANDA Product within the United States, or importation of Mylan’s First ANDA Product into the United States, during the term of the ’122 patent would infringe claims 10 and 11 of the ’122 patent.

67. 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 First ANDA before the ’122 patent expires.

68. Novo Nordisk has no adequate remedy at law.

69. Mylan was aware of the ’122 patent when it submitted its First 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 BY MYLAN’S SECOND ANDA

70. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-69 of this First Amended Complaint.

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

72. Claims 10 and 11 of the ’122 patent encompass GLP-1 compounds. Mylan’s manufacture, use, offer for sale or sale of Mylan’s Second ANDA Product within the United States, or importation of Mylan’s Second ANDA Product into the United States, during the term of the ’122 patent would infringe claims 10 and 11 of the ’122 patent.

73. 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 Second ANDA before the ’122 patent expires.

74. Novo Nordisk has no adequate remedy at law.

75. Mylan was aware of the ’122 patent when it submitted its Second 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 BY MYLAN’S SECOND ANDA

76. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-75 of this First Amended Complaint.

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

78. 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 Second ANDA Product within the United States, or importation of Mylan’s Second ANDA Product into the United States, during the term of the ’969 patent would infringe claims 1-26 of the ’969 patent.

79. 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 Second ANDA before the ’969 patent expires.

80. Novo Nordisk has no adequate remedy at law.

81. Mylan was aware of the ’969 patent when it submitted its Second 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 BY MYLAN’S FIRST ANDA

82. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-81 of this First Amended Complaint.

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

84. 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 First ANDA Product within the United States, or importation of Mylan’s First ANDA Product into the United States, during the term of the ’383 patent would infringe claims 1-13 of the ’383 patent.

85. 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 First ANDA before the ’383 patent expires.

86. Novo Nordisk has no adequate remedy at law.

87. Mylan was aware of the ’383 patent when it submitted its First 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 BY MYLAN’S SECOND ANDA

88. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-87 of this First Amended Complaint.

89. Mylan has infringed the ’383 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan’s Second ANDA, by which Mylan seeks

approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Second ANDA Product prior to the expiration of the '383 patent.

90. 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 Second ANDA Product within the United States, or importation of Mylan's Second ANDA Product into the United States, during the term of the '383 patent would infringe claims 1-13 of the '383 patent.

91. 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 Second ANDA before the '383 patent expires.

92. Novo Nordisk has no adequate remedy at law.

93. Mylan was aware of the '383 patent when it submitted its Second 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 BY MYLAN'S SECOND ANDA

94. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-93 of this First Amended Complaint.

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

96. 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 Second ANDA Product within the United States, or importation of Mylan's Second ANDA Product into the United States, during the term of the '002 patent would infringe claims 1-2 of the '002 patent.

97. 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 Second ANDA before the '002 patent expires.

98. Novo Nordisk has no adequate remedy at law.

99. Mylan was aware of the '002 patent when it submitted its Second 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 BY MYLAN'S SECOND ANDA

100. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-99 of this First Amended Complaint.

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

102. 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 Second ANDA Product within the United States, or importation of Mylan's Second ANDA Product into the United States, during the term of the '239 patent would infringe claims 1-3 of the '239 patent.

103. 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 Second ANDA before the '239 patent expires.

104. Novo Nordisk has no adequate remedy at law.

105. Mylan was aware of the '239 patent when it submitted its Second 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 BY MYLAN'S SECOND ANDA

106. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-105 of this First Amended Complaint.

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

108. 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 Second ANDA Product within the United States, or importation of Mylan's Second ANDA Product into the United States, during the term of the '154 patent would infringe claims 1-17 of the '154 patent.

109. 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 Second ANDA before the '154 patent expires.

110. Novo Nordisk has no adequate remedy at law.

111. Mylan was aware of the '154 patent when it submitted its Second 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 BY MYLAN'S SECOND ANDA

112. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-111 of this First Amended Complaint.

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

114. 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 Second ANDA Product within the United States, or importation of Mylan's Second ANDA Product into the United States, during the term of the '180 patent would infringe claims 1-14 of the '180 patent.

115. 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 Second ANDA before the '180 patent expires.

116. Novo Nordisk has no adequate remedy at law.

117. Mylan was aware of the '180 patent when it submitted its Second 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 BY MYLAN'S SECOND ANDA

118. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-117 of this First Amended Complaint.

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

120. 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 Second ANDA Product within the United States, or importation of Mylan's Second ANDA Product into the United States, during the term of the '611 patent would infringe claims 1-15 of the '611 patent.

121. 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 Second ANDA before the '611 patent expires.

122. Novo Nordisk has no adequate remedy at law.

123. Mylan was aware of the '611 patent when it submitted its Second 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 BY

MYLAN'S FIRST ANDA

124. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-123 of this First Amended Complaint.

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

126. 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 First ANDA Product within the United States, or importation of Mylan's First ANDA Product into the United States, during the term of the '953 patent would infringe claims 1-25 of the '953 patent.

127. 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 First ANDA before the '953 patent expires.

128. Novo Nordisk has no adequate remedy at law.

129. Mylan was aware of the ’953 patent when it submitted its First 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 BY MYLAN’S SECOND ANDA

130. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-129 of this First Amended Complaint.

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

132. 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 Second ANDA Product within the United States, or importation of Mylan’s Second ANDA Product into the United States, during the term of the ’953 patent would infringe claims 1-25 of the ’953 patent.

133. 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 Second ANDA before the ’953 patent expires.

134. Novo Nordisk has no adequate remedy at law.

135. Mylan was aware of the '953 patent when it submitted its Second 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 BY MYLAN'S SECOND ANDA

136. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-135 of this First Amended Complaint.

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

138. 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 Second ANDA Product within the United States, or importation of Mylan's Second ANDA Product into the United States, during the term of the '757 patent would infringe claims 1-12 of the '757 patent.

139. 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 Second ANDA before the '757 patent expires.

140. Novo Nordisk has no adequate remedy at law.

141. Mylan was aware of the '757 patent when it submitted its Second 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 BY MYLAN'S SECOND ANDA

142. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-141 of this First Amended Complaint.

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

144. 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 Second ANDA Product within the United States, or importation of Mylan's Second ANDA Product into the United States, during the term of the '155 patent would infringe claims 1-8 of the '155 patent.

145. 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 Second ANDA before the '155 patent expires.

146. Novo Nordisk has no adequate remedy at law.

147. Mylan was aware of the ’155 patent when it submitted its Second 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 BY MYLAN’S FIRST ANDA

148. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-147 of this First Amended Complaint.

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

150. 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 First ANDA Product within the United States, or importation of Mylan’s First ANDA Product into the United States, during the term of the ’462 patent would infringe claims 1-10 of the ’462 patent.

151. Upon information and belief, Mylan’s sale or offer for sale of Mylan’s First ANDA Product within the United States, or importation of Mylan’s First ANDA Product into the United States, or commercial marketing of Mylan’s First

ANDA Product in the United States, during the term of and with knowledge of the '462 patent, would intentionally induce others to use Mylan's First ANDA Product in the United States, thus inducing infringement of claims 1-10 of the '462 patent.

152. 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 First ANDA before the '462 patent expires.

153. Novo Nordisk has no adequate remedy at law.

154. Mylan was aware of the '462 patent when it submitted its First 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 BY MYLAN'S SECOND ANDA

155. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-154 of this First Amended Complaint.

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

157. 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 Second ANDA Product within the United States, or importation of Mylan's Second ANDA Product into the United States, during the term of the '616 patent would infringe claims 1-9 of the '616 patent.

158. 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 Second ANDA before the '616 patent expires.

159. Novo Nordisk has no adequate remedy at law.

160. Mylan was aware of the '616 patent when it submitted its Second 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 BY MYLAN'S SECOND ANDA

161. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-160 of this First Amended Complaint.

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

163. 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

Second ANDA Product within the United States, or importation of Mylan's Second ANDA Product into the United States, during the term of the '652 patent would infringe claims 1-15 of the '652 patent.

164. 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 Second ANDA before the '652 patent expires.

165. Novo Nordisk has no adequate remedy at law.

166. Mylan was aware of the '652 patent when it submitted its Second 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 BY MYLAN'S SECOND ANDA

167. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-166 of this First Amended Complaint.

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

169. 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 Second ANDA Product within the United States, or importation of Mylan's Second ANDA Product into the United States, during the term of the '063 patent would infringe claims 1-7 of the '063 patent.

170. 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 Second ANDA before the '063 patent expires.

171. Novo Nordisk has no adequate remedy at law.

172. Mylan was aware of the '063 patent when it submitted its Second 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 BY MYLAN'S SECOND ANDA

173. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-172 of this First Amended Complaint.

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

175. 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 Second ANDA Product within the United States, or importation of Mylan's Second ANDA Product into the United States, during the term of the '363 patent would infringe claims 1-11 of the '363 patent.

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

177. 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 Second ANDA before the '363 patent expires.

178. Novo Nordisk has no adequate remedy at law.

179. Mylan was aware of the '363 patent when it submitted its Second 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. 11,311,679 BY

MYLAN'S SECOND ANDA

180. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-179 of this First Amended Complaint.

181. Mylan has infringed the '679 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's Second ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Second ANDA Product prior to the expiration of the '679 patent.

182. Claims 1-6 of the '679 patent are directed to an injection device with 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 Second ANDA Product within the United States, or importation of Mylan's Second ANDA Product into the United States, during the term of the '679 patent would infringe claims 1-6 of the '679 patent.

183. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '679 patent and/or if the FDA is not enjoined from approving Mylan's Second ANDA before the '679 patent expires.

184. Novo Nordisk has no adequate remedy at law.

185. Mylan was aware of the '679 patent when it submitted its Second 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. 11,446,443 BY MYLAN'S SECOND ANDA

186. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-185 of this First Amended Complaint.

187. Mylan has infringed the '443 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's Second ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Second ANDA Product prior to the expiration of the '443 patent.

188. Claims 1-19 of the '443 patent are directed to an injection device with 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 Second ANDA Product within the United States, or importation of Mylan's Second ANDA Product into the United States, during the term of the '443 patent would infringe claims 1-19 of the '443 patent.

189. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '443 patent and/or if the FDA is not enjoined from approving Mylan's Second ANDA before the '443 patent expires.

190. Novo Nordisk has no adequate remedy at law.

191. Mylan was aware of the '443 patent when it submitted its Second 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 by Mylan’s First ANDA Product and Mylan’s Second ANDA Product;

B. A judgment that Mylan has infringed the ’343 patent by Mylan’s First ANDA Product and Mylan’s Second ANDA Product;

C. A judgment that Mylan has infringed the ’122 patent by Mylan’s First ANDA Product and Mylan’s Second ANDA Product;

D. A judgment that Mylan has infringed the ’969 patent by Mylan’s Second ANDA Product;

E. A judgment that Mylan has infringed the ’383 patent by Mylan’s First ANDA Product and Mylan’s Second ANDA Product;

F. A judgment that Mylan has infringed the ’002 patent by Mylan’s Second ANDA Product;

G. A judgment that Mylan has infringed the ’239 patent by Mylan’s Second ANDA Product;

H. A judgment that Mylan has infringed the ’154 patent by Mylan’s Second ANDA Product;

I. A judgment that Mylan has infringed the ’180 patent by Mylan’s Second ANDA Product;

J. A judgment that Mylan has infringed the ’611 patent by Mylan’s Second ANDA Product;

K. A judgment that Mylan has infringed the ’953 patent by Mylan’s First ANDA Product and Mylan’s Second ANDA Product;

L. A judgment that Mylan has infringed the ’757 patent by Mylan’s Second ANDA Product;

M. A judgment that Mylan has infringed the ’155 patent by Mylan’s Second ANDA Product;

N. A judgment that Mylan has infringed the ’462 patent by Mylan’s First ANDA Product;

O. A judgment that Mylan has infringed the ’616 patent by Mylan’s Second ANDA Product;

P. A judgment that Mylan has infringed the ’652 patent by Mylan’s Second ANDA Product;

Q. A judgment that Mylan has infringed the ’063 patent by Mylan’s Second ANDA Product;

R. A judgment that Mylan has infringed the ’363 patent by Mylan’s Second ANDA Product;

S. A judgment that Mylan has infringed the ’679 patent by Mylan’s Second ANDA Product;

T. A judgment that Mylan has infringed the ’443 patent by Mylan’s Second ANDA Product;

U. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Mylan’s First 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, ’383, ’953, and ’462 patents, including any extensions, adjustments, and exclusivities;

V. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Mylan’s Second 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, ’616, ’652, ’063, ’363, ’679, and ’443 patents, including any extensions, adjustments, and exclusivities;

W. 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 First ANDA Product within the United States, or importing Mylan’s First ANDA Product into the United States,

prior to the expiration of the ’833, ’343, ’122, ’383, ’953, and ’462 patents, including any extensions, adjustments, and exclusivities;

X. 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 Second ANDA Product within the United States, or importing Mylan’s Second ANDA Product into the United States, prior to the expiration of the ’833, ’343, ’122, ’969, ’383, ’002, ’239, ’154, ’180, ’611, ’953, ’757, ’155, ’616, ’652, ’063, ’363, ’679, and ’443 patents, including any extensions, adjustments, and exclusivities;

Y. If Mylan commercially manufactures, uses, offers to sell, or sells Mylan’s First ANDA Product within the United States, or imports Mylan’s First ANDA Product into the United States, prior to the expiration of the ’833, ’343, ’122, ’383, ’953, and ’462 patents, including any extensions, adjustments, and exclusivities, a judgment awarding Novo Nordisk monetary relief, together with interest;

Z. If Mylan commercially manufactures, uses, offers to sell, or sells Mylan’s Second ANDA Product within the United States, or imports Mylan’s Second ANDA Product into the United States, prior to the expiration of the ’833, ’343, ’122, ’969, ’383, ’002, ’239, ’154, ’180, ’611, ’953, ’757, ’155, ’616, ’652,

’063, ’363, ’679, and ’443 patents, including any extensions, adjustments, and exclusivities, a judgment awarding Novo Nordisk monetary relief, together with interest;

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

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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