IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and NOVO NORDISK A/S,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
RIO BIOPHARMACEUTICALS INC. and EMS S/A,	)	
Defendants.	)	

COMPLAINT

Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), by their undersigned attorneys, for their Complaint against Defendants Rio Biopharmaceuticals, Inc. and EMS S/A (collectively, "Rio"), 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 Rio's submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA"), by which Rio seeks approval to market a generic version of Novo Nordisk's pharmaceutical product Ozempic® prior to the expiration of United States Patent Nos. 8,129,343 (the "'343 patent"), 9,132,239 (the "'239 patent"), 9,457,154 (the "'154 patent"), 9,687,611 (the "'611 patent"), and 10,335,462 (the "'462 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 Rio Biopharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 55 Ivan Allen Jr. Boulevard NW, Suite 525, Atlanta, Georgia 30313. On information and belief, Rio Biopharmaceuticals, Inc. is in the business of making and selling generic pharmaceutical products, for distribution in the State of Delaware and throughout the United States.

5. On information and belief, Defendant EMS S/A is a corporation organized and existing under the laws of Brazil, having its principal place of business at Rod. Jornalista Francisco Aguirre Proenca S/N KM 08 Bloco I, II E V Hortolandia, Sao Paulo, 13186-901, Brazil. On information and belief, EMS S/A is in the business of making and selling generic pharmaceutical products, for distribution in the State of Delaware and throughout the United States.

6. On information and belief, Defendant Rio Biopharmaceuticals, Inc. is a wholly owned subsidiary of Defendant EMS S/A.

7. On information and belief, Defendants Rio Biopharmaceuticals, Inc. and EMS S/A acted in concert to prepare and submit ANDA No. 216305 ("Rio's ANDA") to the FDA.

8. On information and belief, following any FDA approval of Rio's ANDA, Defendants Rio Biopharmaceuticals, Inc. and EMS S/A will act in concert to distribute and sell a generic version of semaglutide solution, 2 mg/1.5 ml (1.34 mg/ml) and 4 mg/3 ml (1.34 mg/ml) ("Rio's Product") throughout the United States, including within Delaware.

JURISDICTION AND VENUE

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

10. This Court has personal jurisdiction over Defendant Rio Biopharmaceuticals, Inc. by virtue of, *inter alia*, its presence in Delaware, being a Delaware corporation; having conducted business in Delaware; having derived revenue from conducting business in Delaware; and having engaged in systematic and continuous contacts with the State of Delaware.

11. This Court has personal jurisdiction over Defendant EMS S/A by virtue of, *inter alia*, its presence in Delaware through that of its wholly owned subsidiary, Rio Biopharmaceuticals, Inc., which is a Delaware corporation, through which it conducts business in Delaware and will derive revenue from conducting business in Delaware, by marketing, selling, and/or distributing generic pharmaceutical drug products to residents of Delaware.

12. If Defendant EMS S/A's connections with Delaware are found to be insufficient to confer personal jurisdiction, then, on information and belief, Defendant EMS S/A is not subject to jurisdiction in any state's courts of general jurisdiction and exercising jurisdiction over EMS S/A in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

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

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

THE PATENTS-IN-SUIT

15. 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 A. NNAS is the owner of all right, title, and interest in the '343 patent.

16. 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 B. NNAS is the owner of all right, title, and interest in the '239 patent.

17. 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 C. NNAS is the owner of all right, title, and interest in the '154 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 D. NNAS is the owner of all right, title, and interest in the '611 patent.

19. 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 E. NNAS is the owner of all right, title, and interest in the '462 patent.

OZEMPIC®

20. 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®.

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

22. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '343, '239, '154, '611, and '462 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Ozempic®.

RIO'S ANDA

23. On information and belief, Rio submitted ANDA No. 216305 ("Rio's ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market a generic version of semaglutide solution, 2 mg/1.5 ml (1.34 mg/ml) and 4 mg/3 ml (1.34 mg/ml) ("Rio's Product").

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

25. By letter to NNI and NNAS, dated January 21, 2022 (the "Notice Letter"), Rio stated that Rio's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '343, '239, '154, '611, and '462 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Rio's Product (the "Paragraph IV Certification"). Rio 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. 8,129,343

26. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-25 of this Complaint.

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

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

29. Upon information and belief, Rio's sale or offer for sale of Rio's Product within the United States, or importation of Rio's Product into the United States, or commercial marketing of Rio's Product in the United States, during the term of and with knowledge of the '343 patent, would intentionally induce others to use Rio's Product in the United States, thus inducing infringement of claims 3 and 6 of the '343 patent.

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

31. Novo Nordisk has no adequate remedy at law.

32. Rio 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. 9,132,239

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

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

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

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

37. Novo Nordisk has no adequate remedy at law.

38. Rio 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

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

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

41. 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. Rio's manufacture, use, offer for sale or sale of Rio's Product within the United

States, or importation of Rio's Product into the United States, during the term of the '154 patent would infringe claims 1-17 of the '154 patent.

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

43. Novo Nordisk has no adequate remedy at law.

44. Rio 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. 9,687,611

45. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-44 of this Complaint.

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

47. 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. Rio's manufacture, use, offer for sale or sale of Rio's Product within the United States, or importation of Rio's Product into the United States, during the term of the '611 patent would infringe claims 1-15 of the '611 patent.

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

49. Novo Nordisk has no adequate remedy at law.

50. Rio 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. 10,335,462

51. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-50 of this Complaint.

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

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

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

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

56. Novo Nordisk has no adequate remedy at law.

57. Rio 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.

PRAYER FOR RELIEF

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

A. A judgment that Rio has infringed the '343 patent;

B. A judgment that Rio has infringed the '239 patent;

C. A judgment that Rio has infringed the '154 patent;

D. A judgment that Rio has infringed the '611 patent;

E. A judgment that Rio has infringed the '462 patent;

F. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Rio'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 '343, '239, '154, '611, and '462 patents, including any extensions, adjustments, and exclusivities;

G. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Rio, 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 Rio's Product within the United States, or importing Rio's Product into the United States, prior to the expiration

of the ’343, ’239, ’154, ’611, and ’462 patents, including any extensions, adjustments, and exclusivities;

H. If Rio commercially manufactures, uses, offers to sell, or sells Rio’s Product within the United States, or imports Rio’s Product into the United States, prior to the expiration of the ’343, ’239, ’154, ’611, and ’462 patents, including any extensions, adjustments, and exclusivities, a judgment awarding Novo Nordisk monetary relief, together with interest;

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

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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