

Arnold B. Calmann
Katherine A. Escanlar
SAIBER LLC
18 Columbia Turnpike
Suite 200
Florham Park, NJ 07932
T: (973) 622-3333
abc@saiber.com
kescanlar@saiber.com

*Attorneys for Defendant/Counterclaim Plaintiff,
Rio Biopharmaceuticals, Inc.*

Stephen R. Auten
Philip Y. Kouyoumdjian
Jaimin H. Shah
TAFT, STETTINIUS & HOLLISTER LLP
111 East Wacker Drive
Suite 2600
Chicago, IL 60601
312-527-4000
sauten@taftlaw.com
pkouyoumdjian@taftlaw.com
jshah@taftlaw.com

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

NOVO NORDISK INC. and)	
NOVO NORDISK A/S,)	
)	
Plaintiffs,)	Civil Action No. 1:24-cv-00688
)	
v.)	
)	<i>Document Filed Electronically</i>
RIO BIOPHARMACEUTICALS, INC.,)	
)	
Defendant.)	

**RIO BIOPHARMACEUTICALS, INC.'S ANSWER, SEPARATE DEFENSES, AND
COUNTERCLAIMS TO COMPLAINT FOR PATENT INFRINGEMENT**

Defendant, Rio Biopharmaceuticals, Inc., (“Rio”), by its undersigned attorneys, for its Answer to the Complaint for Patent Infringement filed by Plaintiffs, Novo Nordisk Inc. and Novo Nordisk A/S, (“Novo Nordisk”), states as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Rio denies all allegations in Novo Nordisk’s Complaint except those expressly admitted below.

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 Saxenda® prior to the expiration of United States Patent Nos. 8,114,833 (the “‘833 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”), 10,357,616 (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*, Saxenda® and/or its use.

ANSWER: Rio admits that Novo Nordisk purports to bring this action for infringement of United States Patent Nos. 8,114,833 (the “‘833 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”), 10,357,616 (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”) under the patent laws of the United States, Title 35 of the United States Code. Rio denies all remaining allegations of Paragraph 1.

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.

ANSWER: Upon information and belief, Rio admits that Novo Nordisk Inc. purports to be a Delaware corporation with a principal place of business in Plainsboro, New Jersey. Rio is without sufficient information to admit or deny the remaining allegations of Paragraph 2 and therefore denies the same.

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 Alle, 2880 Bagsværd, Denmark. NNI is an indirect, wholly-owned subsidiary of NNAS.

ANSWER: Upon information and belief, Rio admits that Novo Nordisk A/S purports to be an entity organized and existing under the laws of the Kingdom of Denmark with a principal place

of business in Bagsværd, Denmark, and that Novo Nordisk Inc. purports to be an indirect, wholly-owned subsidiary of Novo Nordisk A/S. Rio is without sufficient information to admit or deny the remaining allegations of Paragraph 3 and therefore denies the same.

4. On information and belief, Rio is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 116 Village Blvd, Suite 200, Princeton, NJ 08540. On information and belief, Rio is in the business of making and selling generic pharmaceutical products, for distribution in the State of New Jersey and throughout the United States.

ANSWER: Admitted that Rio has its principal place of business at 116 Village Blvd, Suite 200, Princeton, NJ 08540. Rio further admits that it sells generic drug products in the United States. Rio denies any and all remaining allegations of Paragraph 4.

JURISDICTION AND VENUE

5. This action for patent infringement arises under 35 U. S.C. § 1 *et seq.* generally and 35 U.S.C. § 271 specifically.

ANSWER: Paragraph 5 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rio admits that the Complaint filed by Plaintiffs purports to arise under 35 U. S.C. § 1 *et seq.* and 35 U.S.C. § 271. Rio denies any and all remaining allegations of Paragraph 5.

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

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rio does not contest that subject matter jurisdiction is proper for any properly listed patents asserted under 35 U.S.C. § 271(e)(2)(A). Rio denies any and all remaining allegations of Paragraph 6.

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

ANSWER: Paragraph 7 contains legal conclusions to which no response is required. To the extent an answer is required, denied. Rio further answers that Rio does not contest venue in this

judicial district solely for the limited purposes of this action only for any claims properly before this Court. Rio denies any and all remaining allegations of Paragraph 7.

8. This Court has personal jurisdiction over Rio because, upon information and belief, it has a physical presence in New Jersey; it conducts business in New Jersey; it derives revenue from conducting business in New Jersey; and it has engaged in systematic and continuous contacts with the State of New Jersey, either directly or through its affiliates and/or agents, including by marketing and/or selling pharmaceutical products in New Jersey, including in this Judicial District.

ANSWER: Paragraph 8 contains legal and factual conclusions to which no answer is required. To the extent an answer is required, Rio states that it does not contest personal jurisdiction in this judicial district solely for the limited purposes of this action only for any claims properly before this Court and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Rio otherwise denies the remaining allegations of paragraph 8.

9. On information and belief, Rio intends to sell, offer to sell, use, and/or engage in the commercial manufacture of a generic version of liraglutide injection solution, 18 mg/3 ml (6 mg/ml) (“Rio’s Product”), directly or indirectly, throughout the United States and in this Judicial District. Rio’s filing of Rio’s ANDA No. 218240 (“Rio’s ANDA”) confirms this intention and further subjects Rio to the specific personal jurisdiction of this Court.

ANSWER: Paragraph 9 contains legal and factual conclusions to which no answer is required. To the extent an answer is required, Rio states that it does not contest specific personal jurisdiction in this judicial district solely for the limited purposes of this action only for any claims properly before this Court and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Rio otherwise denies the remaining allegations of paragraph 9.

PATENTS-IN-SUIT

10. 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.

ANSWER: Rio admits that what purports to be a copy of the '833 patent is attached as Exhibit A to the Complaint; that the '833 patent states on its face that it is titled "Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and For Use in Injection Devices;" and that the '833 patent issued on February 14, 2012. Rio denies the remaining allegations in Paragraph 10.

11. 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 B. NNAS is the owner of all right, title, and interest in the '969 patent.

ANSWER: Rio admits that what purports to be a copy of the '969 patent is attached as Exhibit B to the Complaint; that the '969 patent states on its face that it is titled "Injection Device with Torsion Spring and Rotatable Display;" and that the '969 patent issued on April 1, 2014. Rio denies the remaining allegations in Paragraph 11.

12. 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 C. NNAS is the owner of all right, title, and interest in the '383 patent.

ANSWER: Rio admits that what purports to be a copy of the '383 patent is attached as Exhibit C to the Complaint; that the '383 patent states on its face that it is titled "Dose Mechanism for an Injection Device for Limiting a Dose Setting Corresponding to the Amount of Medicament Left;" and that the '383 patent issued on December 30, 2014. Rio denies the remaining allegations in Paragraph 12.

13. 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 D. NNAS is the owner of all right, title, and interest in the '002 patent.

ANSWER: Rio admits that what purports to be a copy of the '002 patent is attached as Exhibit D to the Complaint; that the '002 patent states on its face that it is titled "Automatic Injection

Device with a Top Release Mechanism;” and that the ’002 patent issued on August 18, 2015. Rio denies the remaining allegations in Paragraph 13.

14. 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 E. NNAS is the owner of all right, title, and interest in the ’239 patent.

ANSWER: Rio admits that what purports to be a copy of the ’239 patent is attached as Exhibit E to the Complaint; that the ’239 patent states on its face that it is titled “Dial-Down Mechanism for Wind-Up Pen;” and that the ’239 patent issued on September 15, 2015. Rio denies the remaining allegations in Paragraph 14.

15. 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 F. NNAS is the owner of all right, title, and interest in the ’154 patent.

ANSWER: Rio admits that what purports to be a copy of the ’154 patent is attached as Exhibit F to the Complaint; that the ’154 patent states on its face that it is titled “Injection Device with an End of Dose Feedback Mechanism;” and that the ’154 patent issued on October 4, 2016. Rio denies the remaining allegations in Paragraph 15.

16. 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 G. NNAS is the owner of all right, title, and interest in the ’180 patent.

ANSWER: Rio admits that what purports to be a copy of the ’180 patent is attached as Exhibit G to the Complaint; that the ’180 patent states on its face that it is titled “Automatic Injection Device with a Top Release Mechanism;” and that the ’180 patent issued on April 11, 2017. Rio denies the remaining allegations in Paragraph 16.

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

ANSWER: Rio admits that what purports to be a copy of the '611 patent is attached as Exhibit H to the Complaint; that the '611 patent states on its face that it is titled "Injection Device with Torsion Spring and Rotatable Display;" and that the '611 patent issued on June 27, 2017. Rio denies the remaining allegations in Paragraph 17.

18. 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 I. NNAS is the owner of all right, title, and interest in the '953 patent.

ANSWER: Rio admits that what purports to be a copy of the '953 patent is attached as Exhibit I to the Complaint; that the '953 patent states on its face that it is titled "Dose Mechanism for an Injection Device for Limiting a Dose Setting Corresponding to the Amount of Medicament Left;" and that the '953 patent issued on October 3, 2017. Rio denies the remaining allegations in Paragraph 18.

19. 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 J. NNAS is the owner of all right, title, and interest in the '757 patent.

ANSWER: Rio admits that what purports to be a copy of the '757 patent is attached as Exhibit J to the Complaint; that the '757 patent states on its face that it is titled "Injection Device with an End of Dose Feedback Mechanism;" and that the '757 patent issued on January 9, 2018. Rio denies the remaining allegations in Paragraph 19.

20. 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 K. NNAS is the owner of all right, title, and interest in the '155 patent.

ANSWER: Rio admits that what purports to be a copy of the '155 patent is attached as Exhibit K to the Complaint; that the '155 patent states on its face that it is titled "Syringe Device with a Dose Limiting Mechanism and an Additional Safety Mechanism;" and that the '155 patent issued on March 5, 2019. Rio denies the remaining allegations in Paragraph 20.

21. 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 L. NNAS is the owner of all right, title, and interest in the '616 patent.

ANSWER: Rio admits that what purports to be a copy of the '616 patent is attached as Exhibit L to the Complaint; that the '616 patent states on its face that it is titled "Injection Device with an End of Dose Feedback Mechanism;" and that the '616 patent issued on July 23, 2019. Rio denies the remaining allegations in Paragraph 21.

22. 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 M. NNAS is owner of all right, title, and interest in the '652 patent.

ANSWER: Rio admits that what purports to be a copy of the '652 patent is attached as Exhibit M to the Complaint; that the '652 patent states on its face that it is titled "Automatic Injection Device with a Top Release Mechanism;" and that the '652 patent issued on August 13, 2019. Rio denies the remaining allegations in Paragraph 22.

23. 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 N. NNAS is the owner of all right, title, and interest in the '063 patent.

ANSWER: Rio admits that what purports to be a copy of the '063 patent is attached as Exhibit N to the Complaint; that the '063 patent states on its face that it is titled "Syringe Device with a Dose Limiting Mechanism and an Additional Safety Mechanism;" and that the '063 patent issued on August 24, 2021. Rio denies the remaining allegations in Paragraph 23.

24. 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 Complaint as Exhibit O. NNAS is the owner of all right, title, and interest in the '679 patent.

ANSWER: Rio admits that what purports to be a copy of the '679 patent is attached as Exhibit O to the Complaint; that the '679 patent states on its face that it is titled "Automatic Injection Device with a Top Release Mechanism;" and that the '679 patent issued on April 26, 2022. Rio denies the remaining allegations in Paragraph 24.

25. 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 P. NNAS is the owner of all right, title, and interest in the '443 patent.

ANSWER: Rio admits that what purports to be a copy of the '443 patent is attached as Exhibit P to the Complaint; that the '443 patent states on its face that it is titled "Injection Device with Torsion Spring and Rotatable Display;" and that the '443 patent issued on September 20, 2022. Rio denies the remaining allegations in Paragraph 25.

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 Q. NNAS is the owner of all right, title, and interest in the '363 patent.

ANSWER: Rio admits that what purports to be a copy of the '363 patent is attached as Exhibit Q to the Complaint; that the '363 patent states on its face that it is titled "Dial-Down Mechanism for Wind-Up Pen;" and that the '363 patent issued on April 11, 2017. Rio denies the remaining allegations in Paragraph 26.

SAXENDA®

27. NNI holds approved New Drug Application No. 206321 (the "Saxenda® NDA") for Saxenda® (liraglutide recombinant) Solution Injection, 18 mg/3 ml (6 mg/ml), which NNI sells under the trade name Saxenda®.

ANSWER: Rio is without sufficient information to admit or deny the allegations of Paragraph 27 and therefore denies the same.

28. The claims of the '833 patent, the '969 patent, the '383 patent, the '002 patent, the '239 patent, the '154 patent, the '180 patent, the '611 patent, the '953 patent, the '757 patent, the '155 patent, the '616 patent, the '652 patent, the '063 patent, the '679 patent, the '443 patent, and the '363 patent cover, *inter alia*, Saxenda® and/or its use.

ANSWER: Paragraph 28 contains legal allegations and conclusions to which no answer is required. To the extent an answer is required, Rio denies the allegations of Paragraph 28.

29. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '833 patent, '969 patent, '383 patent, '002 patent, '239 patent, '154 patent, '180 patent, '611 patent, '953 patent, '757 patent, '155 patent, '616 patent, '652 patent, '063 patent, '679 patent, '443 patent, and '363 patent are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Saxenda®.

ANSWER: Rio does not contest that the electronic version of the United States Food and Drug Administration's (FDA) publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book"), identifies the '833 patent, '969 patent, '383 patent, '002 patent, '239 patent, '154 patent, '180 patent, '611 patent, '953 patent, '757 patent, '155 patent, '616 patent, '652 patent, '063 patent, '679 patent, '443 patent, and '363 patents with respect to Saxenda®. The remaining allegations in Paragraph 29 contain legal conclusions to which no answer is required. To the extent an answer is required, Rio denies the remaining allegations of Paragraph 29.

RIO'S ANDA

30. On information and belief, Rio submitted Rio's ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market Rio's Product, which is a generic version of liraglutide injection solution, 18 mg/3 ml (6 mg/ml).

ANSWER: Admitted that Rio filed ANDA No. 218240 seeking FDA approval to market a liraglutide injection solution, 18 mg/3 ml (6 mg/ml) ("Rio's Product"). The remaining allegations

in Paragraph 30 contain legal conclusions to which no answer is required. To the extent an answer is required, Rio denies the remaining allegations of Paragraph 30.

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

ANSWER: Admitted that Rio's ANDA contains data that supports the bioequivalence of the Rio Product. The remaining allegations in Paragraph 31 contain legal conclusions to which no answer is required. To the extent an answer is required, Rio denies the remaining allegations of Paragraph 31.

32. By letter to NNI and NNAS, dated December 22, 2023 (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 '833 patent, '969 patent, '383 patent, '002 patent, '239 patent, '154 patent, '180 patent, '611 patent, '953 patent, '757 patent, '155 patent, '616 patent, '652 patent, '063 patent, '679 patent, '443 patent, and '363 patent 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.

ANSWER: Admitted that Rio sent Plaintiffs a letter, dated December 22, 2023, via FedEx Priority Overnight Service stating that the '833 patent, '969 patent, '383 patent, '002 patent, '239 patent, '154 patent, '180 patent, '611 patent, '953 patent, '757 patent, '155 patent, '616 patent, '652 patent, '063 patent, '679 patent, '443 patent, and '363 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug products described in Rio's ANDA. Further admitted that Rio provided factual and legal bases for its statements regarding invalidity, unenforceability, and non-infringement. Rio further states that the documents speak for themselves. Rio is without sufficient information to admit or deny the remaining allegations of Paragraph 32 and therefore denies the same.

COUNT I: 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.

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1-

32 as if fully set forth herein.

34. Rio has infringed the '833 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 '833 patent.

ANSWER: The allegations in Paragraph 34 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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. 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 '833 patent would infringe claims 1–31 of the '833 patent.

ANSWER: The allegations in Paragraph 35 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Denied.

37. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

38. Rio 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 attorneys' fees under 35 U.S.C. § 285.

ANSWER: The allegations in Paragraph 38 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

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

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1-

38 as if fully set forth herein.

40. Rio has infringed the '969 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 '969 patent.

ANSWER: The allegations in Paragraph 40 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

41. 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. 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 '969 patent would infringe claims 1–26 of the '969 patent.

ANSWER: The allegations in Paragraph 41 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Denied.

43. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

44. Rio 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.

ANSWER: The allegations in Paragraph 44 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

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

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1–

44 as if fully set forth herein

46. Rio has infringed the '383 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 '383 patent.

ANSWER: The allegations in Paragraph 46 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

47. 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. 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 '383 patent would infringe claims 1–13 of the '383 patent.

ANSWER: The allegations in Paragraph 47 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Denied.

49. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

50. Rio 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.

ANSWER: The allegations in Paragraph 50 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

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

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1–

50 as if fully set forth herein.

52. Rio has infringed the '002 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 '002 patent.

ANSWER: The allegations in Paragraph 52 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

53. 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. 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 '002 patent would infringe claims 1–2 of the '002 patent.

ANSWER: The allegations in Paragraph 53 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Denied.

55. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied

56. Rio 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.

ANSWER: The allegations in Paragraph 56 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

57. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1–56 of this Complaint.

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1–

56 as if fully set forth herein.

58. 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.

ANSWER: The allegations in Paragraph 58 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

59. 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.

ANSWER: The allegations in Paragraph 59 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

60. 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.

ANSWER: Denied.

61. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

62. 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.

ANSWER: The allegations in Paragraph 62 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

63. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1–62 of this Complaint.

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1–

62 as if fully set forth herein.

64. 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.

ANSWER: The allegations in Paragraph 64 contain legal conclusions to which no answer is required. To the extent an answer is required, denied

65. 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.

ANSWER: The allegations in Paragraph 65 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

66. 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.

ANSWER: Denied.

67. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

68. 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.

ANSWER: The allegations in Paragraph 68 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

69. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1–68 of this Complaint.

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1–

68 as if fully set forth herein.

70. Rio has infringed the '180 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 '180 patent.

ANSWER: The allegations in Paragraph 70 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

71. 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. 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 '180 patent would infringe claims 1–14 of the '180 patent.

ANSWER: The allegations in Paragraph 71 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Denied.

73. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

74. Rio 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.

ANSWER: The allegations in Paragraph 74 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

75. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1–74 of this Complaint.

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1–74 as if fully set forth herein.

76. 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.

ANSWER: The allegations in Paragraph 76 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

77. 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.

ANSWER: The allegations in Paragraph 77 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

78. 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.

ANSWER: Denied.

79. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

80. 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.

ANSWER: The allegations in Paragraph 80 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

81. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1–80 of this Complaint.

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1–

80 as if fully set forth herein.

82. Rio has infringed the '953 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 '953 patent.

ANSWER: The allegations in Paragraph 82 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

83. 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 a 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. 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 '953 patent would infringe claims 1–25 of the '953 patent.

ANSWER: The allegations in Paragraph 83 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Denied.

85. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

86. Rio 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.

ANSWER: The allegations in Paragraph 86 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

87. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1–86 of this Complaint.

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1–86 as if fully set forth herein.

88. Rio has infringed the '757 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 '757 patent.

ANSWER: The allegations in Paragraph 88 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

89. 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. 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 '757 patent would infringe claims 1–12 of the '757 patent.

ANSWER: The allegations in Paragraph 89 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Denied.

91. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

92. Rio 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.

ANSWER: The allegations in Paragraph 92 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

93. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1–92 of this Complaint.

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1–92 as if fully set forth herein.

94. Rio has infringed the '155 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 '155 patent.

ANSWER: The allegations in Paragraph 94 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

95. Claims 1–8 of the '155 patent are directed to a syringe device with a dose limiting mechanism and a safety mechanism structure which prevents injection of a dose exceeding 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 '155 patent would infringe claims 1–8 of the '155 patent.

ANSWER: The allegations in Paragraph 95 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Denied.

97. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

98. Rio 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.

ANSWER: The allegations in Paragraph 98 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

99. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1–98 of this Complaint.

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1–98 as if fully set forth herein.

100. Rio has infringed the '616 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 '616 patent.

ANSWER: The allegations in Paragraph 100 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

101. 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. 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 '616 patent would infringe claims 1–9 of the '616 patent.

ANSWER: The allegations in Paragraph 101 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Denied.

103. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

104. Rio 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.

ANSWER: The allegations in Paragraph 104 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

105. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1–104 of this Complaint.

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1–104 as if fully set forth herein.

106. Rio has infringed the '652 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 '652 patent.

ANSWER: The allegations in Paragraph 106 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

107. 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. 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 '652 patent would infringe claims 1–15 of the '652 patent.

ANSWER: The allegations in Paragraph 107 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Denied.

109. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

110. Rio 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.

ANSWER: The allegations in Paragraph 110 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

111. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1–110 of this Complaint.

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1–

110 as if fully set forth herein.

112. Rio has infringed the '063 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 '063 patent.

ANSWER: The allegations in Paragraph 112 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

113. 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. 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 '063 patent would infringe claims 1–7 of the '063 patent.

ANSWER: The allegations in Paragraph 113 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Denied.

115. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

116. Rio 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.

ANSWER: The allegations in Paragraph 116 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

COUNT XV: INFRINGEMENT OF U.S. PATENT NO. 11,311,679

117. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1–116 of this Complaint.

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1–116 as if fully set forth herein.

118. Rio has infringed the '679 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 '679 patent.

ANSWER: The allegations in Paragraph 118 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

119. Claims 1–6 of the '679 patent are directed to an injection device with a release member on the end of the device opposite the injection needle. 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 '679 patent would infringe claims 1–6 of the '679 patent.

ANSWER: The allegations in Paragraph 119 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Denied.

121. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

122. Rio was aware of the '679 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.

ANSWER: The allegations in Paragraph 122 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

COUNT XVI: FOR INFRINGEMENT OF U.S. PATENT NO. 11,446,443

123. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-122 of this Complaint.

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1-122 as if fully set forth herein.

124. Rio has infringed the '443 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 '443 patent.

ANSWER: The allegations in Paragraph 124 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

125. 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. 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 '443 patent would infringe claims 1-19 of the '443 patent.

ANSWER: The allegations in Paragraph 125 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Denied.

127. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

128. Rio was aware of the '443 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.

ANSWER: The allegations in Paragraph 128 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

COUNT XVII: INFRINGEMENT OF U.S. PATENT NO. RE46,363

129. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1–128 of this Complaint.

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1–128 as if fully set forth herein.

130. Rio has infringed the '363 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 '363 patent.

ANSWER: The allegations in Paragraph 130 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

131. Claims 1–8 of the '363 patent are directed to a 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. 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 '363 patent would infringe claims 1–11 of the '363 patent.

ANSWER: The allegations in Paragraph 131 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

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

ANSWER: Denied.

133. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

134. Rio 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.

ANSWER: The allegations in Paragraph 134 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

PRAYER FOR RELIEF

No response is required from Rio to any Prayer for Relief against any entity other than Rio. Rio further answers that any allegations in the Complaint requiring a response from Rio that are not specifically admitted are denied, and that no response is required from Rio to the extent that the allegations in the Complaint are directed to an entity other than Rio. Rio also denies that Plaintiffs are entitled to the judgment and relief requested in Paragraphs A through W of Plaintiffs' Prayer for Relief.

SEPARATE DEFENSES

Rio asserts the following defenses undertaking the burden of proof only as to those defenses required by law, regardless of how such defenses are denominated below. Rio reserves the right to amend this Answer with additional defenses as further information is obtained in discovery. Rio asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted.

**First Separate Defense
(Non-Infringement)**

The manufacture, use, sale, offer for sale, or importation into the United States of the drug product described in ANDA No. 218240 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '833 patent, '969 patent, '383 patent, '002 patent, '239 patent, '154 patent, '180 patent, '611 patent, '953 patent, '757 patent, '155 patent, '616 patent, '652 patent, '063 patent, '679 patent, '443 patent, and '363 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

**Second Separate Defense
(Invalidity)**

The claims of the '833 patent, '969 patent, '383 patent, '002 patent, '239 patent, '154 patent, '180 patent, '611 patent, '953 patent, '757 patent, '155 patent, '616 patent, '652 patent,

'063 patent, '679 patent, '443 patent, and '363 patent are invalid for failure to comply with the requirements of at least 35 U. S.C. §§ 101, 102, 103, and/or 112, for obviousness-type double patenting, and/or for any other judicially created and/or non-statutory bases for invalidity or unenforceability.

**Third Separate Defense
(Failure to State a Claim)**

Plaintiffs' Complaint fails to state a claim against Rio upon which relief can be granted.

**Fourth Separate Defense
(Lack of Subject Matter Jurisdiction)**

The Court does not have subject matter jurisdiction for an action brought pursuant to 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

**Fifth Separate Defense
(Prosecution History Estoppel)**

Plaintiffs' claims of patent infringement under the doctrine of equivalents, if any, are barred in whole or in part by the doctrine of prosecution history estoppel and/or prosecution disclaimer.

**Sixth Separate Defense
(Ensnarement)**

Plaintiffs' claims of patent infringement under the doctrine of equivalents, if any, are barred under the doctrine of ensnarement.

**Seventh Separate Defense
(Safe Harbor Provision of 35 U.S.C. § 271(e)(1))**

The activities Rio performed in relation to Rio's ANDA Product have been solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

**Eighth Separate Defense
(No Injunctive Relief)**

Plaintiffs may not seek injunctive relief against Rio because Plaintiffs' alleged damages are not immediate or irreparable, and Plaintiffs therefore have an adequate remedy at law.

**Ninth Separate Defense
(No Exceptional Case)**

Plaintiffs cannot prove that this is an exceptional case justifying an award of attorney fees against Rio pursuant to 35 U.S.C. § 285.

RESERVATION OF ALL SEPARATE DEFENSES

Rio reserves the right to offer any other and additional defense that is now or may become available or appear during, or as a result of, discovery proceedings in this action.

WHEREFORE, Rio requests that the Complaint be dismissed with prejudice and that Rio be awarded the costs of this action, their attorney' fees, and all other relief that this Court deems just and proper.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Rio Biopharmaceuticals, Inc. (“Counterclaim Plaintiff” or “Rio”), by way of its attorneys, hereby states for its Counterclaims against Novo Nordisk Inc. and Novo Nordisk A/S (“Novo Nordisk A/S” or “Counterclaim Defendants”), the following, without prejudice to the denials in this Answer, without admitting any allegations of the Complaint not otherwise admitted, and without assuming the burden when such burden would otherwise be on Plaintiff/Counterclaim-Defendant:

THE PARTIES

1. 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 116 Village Blvd, Suite 200, Princeton, NJ 08540.
2. On information and belief, Counterclaim-Defendant Novo Nordisk Inc. avers it 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. On information and belief, Counterclaim-Defendant Novo Nordisk A/S avers it is an entity organized and existing under the laws of the Kingdom of Denmark, and has its principal place of business at Novo Alle, 2880 Bagsværd, Denmark.
4. Upon information and belief, Counterclaim-Defendant Novo Nordisk Inc. avers it is an indirect, wholly-owned subsidiary of Novo Nordisk A/S.

FACTUAL BACKGROUND

5. Upon information and belief, Counterclaim-Defendant Novo Nordisk Inc. is the holder of New Drug Application (“NDA”) No. 206321 for Saxenda®, Liraglutide Recombinant Solution Injection, 18 mg/3 mL (6 mg/mL), approved on December 23, 2014.

6. Upon information and belief, Saxenda® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kg/m² or greater (obese) or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g. hypertension, type 2 diabetes mellitus, or dyslipidemia).

7. A company seeking FDA approval to market a drug subject to an NDA may submit to the FDA for listing in the Orange Book the “patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug.” 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists these patents in the Orange Book, which is formally referred to as *Approved Drug Products with Therapeutic Equivalence Evaluations*.

8. The Orange Book for Saxenda® lists in relevant part U.S. Patent Nos. 8,114,833 (the “‘833 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”), 10,357,616 (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”) (collectively, “the Asserted Patents”).

9. Novo Nordisk requested that FDA list the Asserted Patents in the Orange Book, causing FDA to do so.

10. By causing the Asserted Patents to be listed in the Orange Book, Novo Nordisk created an opportunity for a First Applicant, as defined by 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb), to file an ANDA with a Paragraph IV Certification to the Asserted Patents and thereby become eligible for one hundred eighty (180) days of marketing exclusivity as to later-filed NDAs also having a Paragraph IV Certification to the Asserted Patents.

11. To date, such First Applicant remains eligible for the 180-day exclusivity period, as FDA has not determined any forfeiture of such eligibility.

12. The '833 patent is entitled "Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and for Use in Injection Devices" with an issue date of February 14, 2012.

13. The '969 patent is entitled "Injection Device with Torsion Spring and Rotatable Display," with an issue date of April 1, 2014.

14. The '383 patent is entitled "Dose Mechanism for an Injection Device for Limiting a Dose Setting Corresponding to the Amount of Medicament Left," with an issue date of December 30, 2014.

15. The '002 patent is entitled "Automatic Injection Device with a Top Release Mechanism," with an issue date of August 18, 2015.

16. The '239 patent is entitled "Dial-Down Mechanism for Wind-Up Pen," with an issue date of September 15, 2015.

17. The '154 patent is entitled "Injection Device with an End of Dose Feedback Mechanism," with an issue date of October 4, 2016.

18. The '180 patent is entitled "Automatic Injection Device with a Top Release Mechanism," with an issue date of April 11, 2017.

19. The '611 patent is entitled "Injection Device with Torsion Spring and Rotatable Display," with an issue date of June 27, 2017.

20. The '953 patent is entitled "Dose Mechanism for an Injection Device for Limiting a Dose Setting Corresponding to the Amount of Medicament Left," with an issue date of October 3, 2017.

21. The '757 patent is entitled "Injection Device with an End of Dose Feedback Mechanism," with an issue date of January 9, 2018.

22. The '155 patent is entitled "Syringe Device with a Dose Limiting Mechanism and an Additional Safety Mechanism," with an issue date of March 5, 2019.

23. The '616 patent is entitled "Injection Device with an End of Dose Feedback Mechanism," with an issue date of July 23, 2019.

24. The '652 patent is entitled "Automatic Injection Device with a Top Release Mechanism," with an issue date of August 13, 2019.

25. The '063 patent is entitled "Syringe Device with a Dose Limiting Mechanism and an Additional Safety Mechanism," with an issue date of August 24, 2021.

26. The '679 patent is entitled "Automatic Injection Device with a Top Release Mechanism," with an issue date of April 26, 2022.

27. The '443 patent is entitled "Injection Device with Torsion Spring and Rotatable Display," with an issue date of September 20, 2022.

28. The '363 patent is entitled "Dial-Down Mechanism for Wind-Up Pen," with an issue date of April 11, 2017.

29. Counterclaim-Defendant Novo Nordisk A/S claims to be the owner of all rights, title, and interest in the Asserted Patents.

30. Rio filed its Abbreviated New Drug Application ("Rio ANDA") No. 218240 under 21 U.S.C. § 355(j) seeking FDA approval for the commercial manufacture, use, or sale in the United States of Liraglutide Injection 18 mg/3 ml (6 mg/ml) prefilled pens ("the Rio Product"). Rio's ANDA contained certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (Paragraph IV Certifications) of the Federal, Food, Drug and Cosmetic Act ("FDCA") that the Asserted Patents are unenforceable, invalid, and/or will not be infringed by the Rio ANDA or the marketing, use or sale of the Rio Product.

31. Rio sent notice of these certifications to Counterclaim-Defendants on or about December 22, 2023. On information and belief, and as Counterclaim-Defendants allege in their Complaint, Counterclaim-Defendants received this letter.

32. On February 5, 2024, Counterclaim-Defendants filed suit in this Judicial District against Rio in connection with Rio's efforts to gain approval from the FDA to market the Rio Product. D.I. 1.

33. Rio is not the First Applicant and final FDA approval of the Rio ANDA remains blocked in part by the First Applicant's eligibility for the 180-days of market exclusivity.

34. On information and belief, delaying judicial consideration of Rio's Counterclaims could result in depriving Rio of the ability to trigger forfeiture of the First ANDA Applicant's potential 180-day market exclusivity pursuant to 21 U.S.C. § 355(j)(5)(D), thus blocking Rio from receiving final approval and prevent Rio from actually entering the market.

35. Upon information and belief, the delay in judicial consideration of Rio's counterclaims would contravene the purpose of the Generic Drug Use Fee Amendments, and the Hatch-Waxman Amendments to the FDCA, which is to ensure patients have access to safe, high-quality, and affordable generic drugs, and enable FDA to assess industry user fees to bring greater predictability and timeliness to the review of generic drug applications.

36. An actual and justiciable controversy exists as to infringement of the Asserted Patents and the validity of the Asserted Patents because Counterclaim-Defendants brought an action alleging that the importation, manufacture, use, offer for sale, or sale of the products that are the subject of the Rio ANDA would infringe those patents, and Rio has denied the alleged infringement and further alleges that the claims of the Asserted Patents are invalid. These controversies are of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

JURISDICTION AND VENUE

37. These Counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 and pursuant to 21 U.S.C. § 355(j)(5)(C).

38. The dispute as to noninfringement, unenforceability, and/or invalidity of the Asserted Patents presents a justiciable Article III controversy where a judgment in favor of Rio will trigger forfeiture of the First Applicant's eligibility for the 180-day period of generic marketing exclusivity.

39. Rio has standing to pursue these Counterclaims due to the concrete injury that is fairly traceable to Counterclaim Defendants' conduct which is likely to be redressed should the Court grant Rio's requested relief. Counterclaim Defendants' listing of the Asserted Patents in the Orange Book effectively denies Rio an economic opportunity to enter the marketplace unless Rio can obtain a

judgment that the Asserted Patents are invalid, unenforceable, and/or not infringed by Rio's ANDA Product.

40. Rio's Counterclaims are ripe for judicial review. Because Rio has submitted its ANDA for FDA approval, additional factual development would not help this Court determine whether Rio's ANDA Product does not infringe the Asserted Patents or whether the Asserted Patents are invalid or unenforceable.

41. Rio's Counterclaims have not been rendered moot. A finding that the Asserted Patents are invalid, unenforceable, and/or not infringed may cause forfeiture of the First Applicant's eligibility for the 180-day period of generic marketing exclusivity, as provided by 21 U.S.C. § 355(j)(5)(D)(i)(I).

42. This Court has personal jurisdiction over Counterclaim Defendants on the basis of, *inter alia*, their contacts with New Jersey relating to the subject matter of this action, including having filed the instant suit.

43. The Court has personal jurisdiction over Novo Nordisk Inc. because, *inter alia*, Novo Nordisk A/S subjected itself to the jurisdiction of this Court by filing this action, and because, on information and belief, Novo Nordisk A/S manufactures and markets branded drug products, and continuously and systematically conducts business throughout the United States, including in New Jersey and because, either directly or through agents, it transacts business in, and derives substantial revenue from, New Jersey.

44. Venue is proper in this Judicial District under 28 U. S.C. §§ 1391 and 1400 and by virtue of the Counterclaim Defendants' filing of this action in this Court.

COUNT I:

(Declaratory Judgment of Noninfringement of the '833 Patent)

45. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

46. Counterclaim Defendants allege ownership of the '833 patent, and have brought claims against Rio alleging infringement of the '833 patent.

47. The manufacture, use, or sale of Rio's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '833 patent, and the submission of Rio's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '833 patent.

48. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '833 patent.

49. Rio has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '833 patent and is not liable for such infringement.

50. Rio is entitled to a declaration that the manufacture, use, or sale of Rio's ANDA Product would not infringe any valid or enforceable claim of the '833 patent.

COUNT II:

(Declaratory Judgment of Invalidity and/or Unenforceability of the '833 Patent)

51. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

52. Counterclaim Defendants allege ownership of the '833 patent, and have brought claims against Rio alleging infringement of the '833 patent.

53. One or more claims of the '833 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

54. The '833 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

55. The alleged invention of the '833 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '833 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '833 patent and would have had a reasonable expectation of success in doing so.

56. The subject matter claimed in the '833 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

57. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '833 patent.

58. Rio is entitled to a declaration that all claims of the '833 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT III:

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,684,969)

59. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

60. Counterclaim Defendants allege ownership of the '969 patent, and have brought claims against Rio alleging infringement of the '969 patent.

61. The manufacture, use, or sale of Rio's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '969 patent, and the submission of Rio's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '969 patent.

62. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '969 patent.

63. Rio has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '969 patent and is not liable for such infringement.

64. Rio is entitled to a declaration that the manufacture, use, or sale of Rio's ANDA Product would not infringe any valid or enforceable claim of the '969 patent.

COUNT IV:

(Declaratory Judgment of Invalidity and/or Unenforceability of United States Patent No. 8,684,969)

65. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

66. Counterclaim Defendants allege ownership of the '969 patent, and have brought claims against Rio alleging infringement of the '969 patent.

67. One or more claims of the '969 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

68. The '969 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

69. The alleged invention of the '969 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '969 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings

of the prior art to achieve the alleged invention of the '969 patent and would have had a reasonable expectation of success in doing so.

70. The subject matter claimed in the '969 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

71. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '969 patent.

72. Rio is entitled to a declaration that all claims of the '969 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT V:

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,920,383)

73. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

74. Counterclaim Defendants allege ownership of the '383 patent, and have brought claims against Rio alleging infringement of the '383 patent.

75. The manufacture, use, or sale of Rio's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '383 patent, and the submission of Rio's ANDA

does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '383 patent.

76. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '383 patent.

77. Rio has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '383 patent and is not liable for such infringement.

78. Rio is entitled to a declaration that the manufacture, use, or sale of Rio's ANDA Product would not infringe any valid or enforceable claim of the '383 patent.

COUNT VI:

(Declaratory Judgment of Invalidity and/or Unenforceability of the '383 Patent)

79. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

80. Counterclaim Defendants allege ownership of the '383 patent, and have brought claims against Rio alleging infringement of the '383 patent.

81. One or more claims of the '383 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

82. The '383 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

83. The alleged invention of the '383 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '383 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '383 patent and would have had a reasonable expectation of success in doing so.

84. The subject matter claimed in the '383 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

85. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '383 patent.

86. Rio is entitled to a declaration that all claims of the '383 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT VII:

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,108,002)

87. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

88. Counterclaim Defendants allege ownership of the '002 patent, and have brought claims against Rio alleging infringement of the '002 patent.

89. The manufacture, use, or sale of Rio's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '002 patent, and the submission of Rio's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '002 patent.

90. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '002 patent.

91. Rio has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '002 patent and is not liable for such infringement.

92. Rio is entitled to a declaration that the manufacture, use, or sale of Rio's ANDA Product would not infringe any valid or enforceable claim of the '002 patent.

COUNT VIII:

(Declaratory Judgment of Invalidity and/or Unenforceability of United States Patent No. 9,108,002)

93. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

94. Counterclaim Defendants allege ownership of the '002 patent, and have brought claims against Rio alleging infringement of the '002 patent.

95. One or more claims of the '002 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

96. The '002 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

97. The alleged invention of the '002 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '002 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '002 patent and would have had a reasonable expectation of success in doing so.

98. The subject matter claimed in the '002 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a

person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

99. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '002 patent.

100. Rio is entitled to a declaration that all claims of the '002 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT IX:

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,132,239)

101. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

102. Counterclaim Defendants allege ownership of the '239 patent, and have brought claims against Rio alleging infringement of the '239 patent.

103. The manufacture, use, or sale of Rio's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '239 patent, and the submission of Rio's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '239 patent.

104. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale,

and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '239 patent.

105. Rio has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '239 patent and is not liable for such infringement.

106. Rio is entitled to a declaration that the manufacture, use, or sale of Rio's ANDA Product would not infringe any valid or enforceable claim of the '239 patent.

COUNT X:

(Declaratory Judgment of Invalidity and/or Unenforceability of United States Patent No. 9,132,239)

107. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

108. Counterclaim Defendants allege ownership of the '239 patent, and have brought claims against Rio alleging infringement of the '239 patent.

109. One or more claims of the '239 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

110. The '239 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

111. The alleged invention of the '239 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '239 patent is not more than the predictable use of prior art elements according to their

established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '239 patent and would have had a reasonable expectation of success in doing so.

112. The subject matter claimed in the '239 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

113. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '239 patent.

114. Rio is entitled to a declaration that all claims of the '239 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT XI:

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,457,154)

115. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

116. Counterclaim Defendants allege ownership of the '154 patent, and have brought claims against Rio alleging infringement of the '154 patent.

117. The manufacture, use, or sale of Rio's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or

contributorily), any valid or enforceable claim of the '154 patent, and the submission of Rio's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '154 patent.

118. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '154 patent.

119. Rio has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '154 patent and is not liable for such infringement.

120. Rio is entitled to a declaration that the manufacture, use, or sale of Rio's ANDA Product would not infringe any valid or enforceable claim of the '154 patent.

COUNT XII:

(Declaratory Judgment of Invalidity and/or Unenforceability of United States Patent No. 9,457,154)

121. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

122. Counterclaim Defendants allege ownership of the '154 patent, and have brought claims against Rio alleging infringement of the '154 patent.

123. One or more claims of the '154 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

124. The '154 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

125. The alleged invention of the '154 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '154 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '154 patent and would have had a reasonable expectation of success in doing so.

126. The subject matter claimed in the '154 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

127. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '154 patent.

128. Rio is entitled to a declaration that all claims of the '154 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT XIII:

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,616,180)

129. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

130. Counterclaim Defendants allege ownership of the '180 patent, and have brought claims against Rio alleging infringement of the '180 patent.

131. The manufacture, use, or sale of Rio's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '180 patent, and the submission of Rio's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '180 patent.

132. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '180 patent.

133. Rio has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '180 patent and is not liable for such infringement.

134. Rio is entitled to a declaration that the manufacture, use, or sale of Rio's ANDA Product would not infringe any valid or enforceable claim of the '180 patent.

COUNT XIV:

(Declaratory Judgment of Invalidity and/or Unenforceability of United States Patent No. 9,616,180)

135. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

136. Counterclaim Defendants allege ownership of the '180 patent, and have brought claims against Rio alleging infringement of the '180 patent.

137. One or more claims of the '180 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

138. The '180 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

139. The alleged invention of the '180 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '180 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '180 patent and would have had a reasonable expectation of success in doing so.

140. The subject matter claimed in the '180 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a

person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

141. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '180 patent.

142. Rio is entitled to a declaration that all claims of the '180 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT XV:

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,687,611)

143. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

144. Counterclaim Defendants allege ownership of the '611 patent, and have brought claims against Rio alleging infringement of the '611 patent.

145. The manufacture, use, or sale of Rio's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '611 patent, and the submission of Rio's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '611 patent.

146. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale,

and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '611 patent.

147. Rio has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '611 patent and is not liable for such infringement.

148. Rio is entitled to a declaration that the manufacture, use, or sale of Rio's ANDA Product would not infringe any valid or enforceable claim of the '611 patent.

COUNT XVI:

(Declaratory Judgment of Invalidity and/or Unenforceability of United States Patent No. 9,687,611)

149. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

150. Counterclaim Defendants allege ownership of the '611 patent, and have brought claims against Rio alleging infringement of the '611 patent.

151. One or more claims of the '611 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

152. The '611 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

153. The alleged invention of the '611 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '611 patent is not more than the predictable use of prior art elements according to their

established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '611 patent and would have had a reasonable expectation of success in doing so.

154. The subject matter claimed in the '611 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

155. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '611 patent.

156. Rio is entitled to a declaration that all claims of the '611 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT XVII:

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,775,953)

157. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

158. Counterclaim Defendants allege ownership of the '953 patent, and have brought claims against Rio alleging infringement of the '953 patent.

159. The manufacture, use, or sale of Rio's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or

contributorily), any valid or enforceable claim of the '953 patent, and the submission of Rio's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '953 patent.

160. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '953 patent.

161. Rio has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '953 patent and is not liable for such infringement.

162. Rio is entitled to a declaration that the manufacture, use, or sale of Rio's ANDA Product would not infringe any valid or enforceable claim of the '953 patent.

COUNT XVIII:

(Declaratory Judgment of Invalidity and/or Unenforceability of United States Patent No. 9,775,953)

163. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

164. Counterclaim Defendants allege ownership of the '953 patent, and have brought claims against Rio alleging infringement of the '953 patent.

165. One or more claims of the '953 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

166. The '953 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

167. The alleged invention of the '953 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '953 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '953 patent and would have had a reasonable expectation of success in doing so.

168. The subject matter claimed in the '953 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

169. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '953 patent.

170. Rio is entitled to a declaration that all claims of the '953 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT XIX:

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,861,757)

171. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

172. Counterclaim Defendants allege ownership of the '757 patent, and have brought claims against Rio alleging infringement of the '757 patent.

173. The manufacture, use, or sale of Rio's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '757 patent, and the submission of Rio's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '757 patent.

174. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '757 patent.

175. Rio has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '757 patent and is not liable for such infringement.

176. Rio is entitled to a declaration that the manufacture, use, or sale of Rio's ANDA Product would not infringe any valid or enforceable claim of the '757 patent.

COUNT XX:

(Declaratory Judgment of Invalidity and/or Unenforceability of United States Patent No. 9,861,757)

177. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

178. Counterclaim Defendants allege ownership of the '757 patent, and have brought claims against Rio alleging infringement of the '757 patent.

179. One or more claims of the '757 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

180. The '757 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

181. The alleged invention of the '757 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '757 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '757 patent and would have had a reasonable expectation of success in doing so.

182. The subject matter claimed in the '757 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a

person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

183. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '757 patent.

184. Rio is entitled to a declaration that all claims of the '757 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT XXI:

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,220,155)

185. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

186. Counterclaim Defendants allege ownership of the '155 patent, and have brought claims against Rio alleging infringement of the '155 patent.

187. The manufacture, use, or sale of Rio's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '155 patent, and the submission of Rio's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '155 patent.

188. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale,

and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '155 patent.

189. Rio has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '155 patent and is not liable for such infringement.

190. Rio is entitled to a declaration that the manufacture, use, or sale of Rio's ANDA Product would not infringe any valid or enforceable claim of the '155 patent.

COUNT XXII:

(Declaratory Judgment of Invalidity and/or Unenforceability of United States Patent No. 10,220,155)

191. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

192. Counterclaim Defendants allege ownership of the '155 patent, and have brought claims against Rio alleging infringement of the '155 patent.

193. One or more claims of the '155 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

194. The '155 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

195. The alleged invention of the '155 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '155 patent is not more than the predictable use of prior art elements according to their

established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '155 patent and would have had a reasonable expectation of success in doing so.

196. The subject matter claimed in the '155 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

197. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '155 patent.

198. Rio is entitled to a declaration that all claims of the '155 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT XXIII:

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,357,616)

199. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

200. Counterclaim Defendants allege ownership of the '616 patent, and have brought claims against Rio alleging infringement of the '616 patent.

201. The manufacture, use, or sale of Rio's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or

contributorily), any valid or enforceable claim of the '616 patent, and the submission of Rio's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '616 patent.

202. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '616 patent.

203. Rio has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '616 patent and is not liable for such infringement.

204. Rio is entitled to a declaration that the manufacture, use, or sale of Rio's ANDA Product would not infringe any valid or enforceable claim of the '616 patent.

COUNT XXIV:

(Declaratory Judgment of Invalidity and/or Unenforceability of United States Patent No. 10,357,616)

205. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

206. Counterclaim Defendants allege ownership of the '616 patent, and have brought claims against Rio alleging infringement of the '616 patent.

207. One or more claims of the '616 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

208. The '616 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

209. The alleged invention of the '616 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '616 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '616 patent and would have had a reasonable expectation of success in doing so.

210. The subject matter claimed in the '616 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

211. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '616 patent.

212. Rio is entitled to a declaration that all claims of the '616 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT XXV:

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,376,652)

213. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

214. Counterclaim Defendants allege ownership of the '652 patent, and have brought claims against Rio alleging infringement of the '652 patent.

215. The manufacture, use, or sale of Rio's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '652 patent, and the submission of Rio's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '652 patent.

216. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '652 patent.

217. Rio has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '652 patent and is not liable for such infringement.

218. Rio is entitled to a declaration that the manufacture, use, or sale of Rio's ANDA Product would not infringe any valid or enforceable claim of the '652 patent.

COUNT XXVI:

(Declaratory Judgment of Invalidity and/or Unenforceability of United States Patent No. 10,376,652)

219. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

220. Counterclaim Defendants allege ownership of the '652 patent, and have brought claims against Rio alleging infringement of the '652 patent.

221. One or more claims of the '652 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

222. The '652 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

223. The alleged invention of the '652 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '652 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '652 patent and would have had a reasonable expectation of success in doing so.

224. The subject matter claimed in the '652 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a

person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

225. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '652 patent.

226. Rio is entitled to a declaration that all claims of the '652 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT XXVII:

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 11,097,063)

227. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

228. Counterclaim Defendants allege ownership of the '063 patent, and have brought claims against Rio alleging infringement of the '063 patent.

229. The manufacture, use, or sale of Rio's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '063 patent, and the submission of Rio's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '063 patent.

230. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale,

and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '063 patent.

231. Rio has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '063 patent and is not liable for such infringement.

232. Rio is entitled to a declaration that the manufacture, use, or sale of Rio's ANDA Product would not infringe any valid or enforceable claim of the '063 patent.

COUNT XXVIII:

(Declaratory Judgment of Invalidity and/or Unenforceability of United States Patent No. 11,097,063)

233. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

234. Counterclaim Defendants allege ownership of the '063 patent, and have brought claims against Rio alleging infringement of the '063 patent.

235. One or more claims of the '063 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

236. The '063 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

237. The alleged invention of the '063 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '063 patent is not more than the predictable use of prior art elements according to their

established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '063 patent and would have had a reasonable expectation of success in doing so.

238. The subject matter claimed in the '063 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

239. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '063 patent.

240. Rio is entitled to a declaration that all claims of the '063 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT XXIX:

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 11,311,679)

241. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

242. Counterclaim Defendants allege ownership of the '679 patent, and have brought claims against Rio alleging infringement of the '679 patent.

243. The manufacture, use, or sale of Rio's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or

contributorily), any valid or enforceable claim of the '679 patent, and the submission of Rio's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '679 patent.

244. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '679 patent.

245. Rio has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '679 patent and is not liable for such infringement.

246. Rio is entitled to a declaration that the manufacture, use, or sale of Rio's ANDA Product would not infringe any valid or enforceable claim of the '679 patent.

COUNT XXX:

(Declaratory Judgment of Invalidity and/or Unenforceability of United States Patent No. 11,311,679)

247. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

248. Counterclaim Defendants allege ownership of the '679 patent, and have brought claims against Rio alleging infringement of the '679 patent.

249. One or more claims of the '679 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

250. The '679 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

251. The alleged invention of the '679 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '679 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '679 patent and would have had a reasonable expectation of success in doing so.

252. The subject matter claimed in the '679 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

253. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '679 patent.

254. Rio is entitled to a declaration that all claims of the '679 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT XXXI:

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 11,446,443)

255. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

256. Counterclaim Defendants allege ownership of the '443 patent, and have brought claims against Rio alleging infringement of the '443 patent.

257. The manufacture, use, or sale of Rio's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '443 patent, and the submission of Rio's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '443 patent.

258. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '443 patent.

259. Rio has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '443 patent and is not liable for such infringement.

260. Rio is entitled to a declaration that the manufacture, use, or sale of Rio's ANDA Product would not infringe any valid or enforceable claim of the '443 patent.

COUNT XXXII:

(Declaratory Judgment of Invalidity and/or Unenforceability of United States Patent No. 11,446,443)

261. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

262. Counterclaim Defendants allege ownership of the '443 patent, and have brought claims against Rio alleging infringement of the '443 patent.

263. One or more claims of the '443 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

264. The '443 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

265. The alleged invention of the '443 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '443 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '443 patent and would have had a reasonable expectation of success in doing so.

266. The subject matter claimed in the '443 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a

person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

267. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '443 patent.

268. Rio is entitled to a declaration that all claims of the '443 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT XXXIII:

(Declaratory Judgment of Non-Infringement of U.S. Patent No. RE46,363)

269. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

270. Counterclaim Defendants allege ownership of the '363 patent, and have brought claims against Rio alleging infringement of the '363 patent.

271. The manufacture, use, or sale of Rio's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '363 patent, and the submission of Rio's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '363 patent.

272. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale,

and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '363 patent.

273. Rio has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '363 patent and is not liable for such infringement.

274. Rio is entitled to a declaration that the manufacture, use, or sale of Rio's ANDA Product would not infringe any valid or enforceable claim of the '363 patent.

COUNT XXXIV:

(Declaratory Judgment of Invalidity and/or Unenforceability of United States Patent No. RE46,363)

275. Rio realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

276. Counterclaim Defendants allege ownership of the '363 patent, and have brought claims against Rio alleging infringement of the '363 patent.

277. One or more claims of the '363 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

278. The '363 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

279. The alleged invention of the '363 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '363 patent is not more than the predictable use of prior art elements according to their

established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '363 patent and would have had a reasonable expectation of success in doing so.

280. The subject matter claimed in the '363 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

281. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Rio's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Rio's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '363 patent.

282. Rio is entitled to a declaration that all claims of the '363 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Rio respectfully prays for judgment in its favor and against Counterclaim Defendants:

A. Declaring that the filing of Rio's ANDA did not infringe one or more valid and enforceable claims of the '833 patent, '969 patent, '383 patent, '002 patent, '239 patent, '154 patent, '180 patent, '611 patent, '953 patent, '757 patent, '155 patent, '616 patent, '652 patent, '063 patent, '679 patent, '443 patent, and '363 patent;

B. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of Rio's ANDA Product described in Rio's ANDA has not infringed, does not infringe, and would not — if made, used, sold, offered for sale, imported, or marketed — infringe, either directly or indirectly, any valid and/or enforceable claim of the '833 patent, '969 patent, '383 patent, '002 patent, '239 patent, '154 patent, '180 patent, '611 patent, '953 patent, '757 patent, '155 patent, '616 patent, '652 patent, '063 patent, '679 patent, '443 patent, and '363 patent, either literally or under the doctrine of equivalents;

C. Declaring that the claims of the '833 patent, '969 patent, '383 patent, '002 patent, '239 patent, '154 patent, '180 patent, '611 patent, '953 patent, '757 patent, '155 patent, '616 patent, '652 patent, '063 patent, '679 patent, '443 patent, and '363 patent are invalid;

D. Ordering that Counterclaim Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Rio;

E. Denying Counterclaim Defendants any of the relief requested in the Complaint;

F. Declaring this case exceptional and awarding Rio its reasonable attorneys' fees and costs of these Counterclaims under 35 U.S.C. § 285; and

G. Awarding Rio such other and further relief as the Court may deem just and proper.

Dated: April 22, 2024

SAIBER LLC

Attorneys for Defendant/Counterclaim Plaintiffs
Rio Biopharmaceuticals, Inc

By: /s/ Arnold B. Calmann

Arnold B. Calmann

Katherine A. Escanlar

18 Columbia Turnpike

Suite 200

Florham Park, NJ 07932

T: (973) 622-3333

abc@saiber.com

kescanlar@saiber.com

Of Counsel:

Stephen R. Auten
Philip Y. Kouyoumdjian
Jaimin H. Shah
TAFT STETTINIUS & HOLLISTER LLP
111 East Wacker Drive
Suite 2800
Chicago, IL 60601
312-527-4000
sauten@taftlaw.com
pkouyoumdjian@taftlaw.com
jshah@taftlaw.com

*Attorneys for Defendant/Counterclaim Plaintiffs
Rio Biopharmaceuticals, Inc.*

LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Defendant hereby certifies that this matter is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding, except *Novo Nordisk Inc., et al. v. Rio Biopharmaceuticals, Inc.*, Civil Action No. 24-330 (RMB)(SAK) (D.N.J.) *Novo Nordisk Inc., et al. v. Lupin Ltd.*, Civil Action No. 23-4027 (RMB)(SAK) (D.N.J.); *Novo Nordisk Inc., et al. v. Lupin Ltd.*, Civil Action No. 23-4031 (RMB)(SAK) (D.N.J.); *Novo Nordisk Inc., et al. v. ScinoPharm Taiwan Ltd.*, Civil Action No. 23-20935 (RMB)(SAK) (D.N.J.); *Novo Nordisk Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 23-22112 (RMB)(SAK) (D.N.J.); *Novo Nordisk Inc., et al. v. Biocon Pharma Ltd., et al.*, C.A. No. 22-937 (CFC) (D. Del.); *Novo Nordisk Inc., et al. v. Orbicular Pharm. Technologies Pvt. Ltd.*, C.A. Nos. 22-856 (CFC) and 23-179 (CFC) (D. Del.); *Novo Nordisk Inc., et al. v. Mylan Pharm., Inc.*, C.A. No. 22-1040 (CFC) (D. Del.); *Novo Nordisk Inc., et al. v. Sun Pharm. Indus. Ltd., et al.*, C.A. No. 22-296 (CFC) (D. Del.); and *Novo Nordisk Inc., et al. v. Dr. Reddy's Lab'ys, Ltd., et al.*, C.A. No. 22-298 (CFC) (D. Del.).

Dated: April 22, 2024

s/ Arnold B. Calmann
Arnold B. Calmann

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Defendant hereby certifies that Defendant seeks declaratory relief and therefore, this action is not appropriate for compulsory arbitration.

Dated: April 22, 2024

s/ Arnold B. Calmann
Arnold B. Calmann