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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVO NORDISK INC. and NOVO NORDISK A/S, Plaintiffs, v. RIO BIOPHARMACEUTICALS, INC., Defendant.	Civil Action No. 1:24-cv-330-RMB-SAK *Document Filed Electronically*

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 Victoza® prior to the expiration of United States Patent Nos. 8,114,833 (the "'833 patent") and 9,265,893 (the "'893 patent"), which cover, *inter alia,* Victoza® 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") and 9,265,893 (the "'893 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 Bagsvxrd, 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 Bagsvxrd, 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. 218241 ("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 February 23, 2016, the United States Patent and Trademark Office issued the '893 patent, entitled, `Injection Button," a copy of which is attached to this Complaint as Exhibit B. NNAS is the owner of all right, title, and interest in the '893 patent.

ANSWER: Rio admits that what purports to be a copy of the '893 patent is attached as Exhibit B to the Complaint; that the '893 patent states on its face that it is titled "Injection Button;" and that the '893 patent issued on February 23, 2016. Rio denies the remaining allegations in Paragraph 11.

VICTOZA®

12. NNI holds approved New Drug Application No. 022341 (the "Victoza® NDA") for Liraglutide Recombinant Solution Injection, 18 mg/3 ml (6 mg/ml), which NNI sells under the trade name Victoza®.

ANSWER: Rio is without sufficient information to admit or deny the allegations of Paragraph 12 and therefore denies the same.

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

ANSWER: Paragraph 13 contains legal allegations and conclusions to which no answer is required. To the extent an answer is required, Rio denies the allegations of Paragraph 13.

14. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '833 and '893 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Victoza®.

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 and '893 patents with respect to Victoza®. The remaining allegations in Paragraph 14 contain legal conclusions to which no answer is required. To the extent an answer is required, Rio denies the remaining allegations of Paragraph 14.

RIO'S ANDA

15. 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. 218241 seeking FDA approval to market a liraglutide injection solution, 18 mg/3 ml (6 mg/ml) ("Rio's Product"). The remaining allegations in Paragraph 15 contain legal conclusions to which no answer is required. To the extent an answer is required, Rio denies the remaining allegations of Paragraph 15.

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

ANSWER: Admitted that Rio's ANDA contains data that supports the bioequivalence of the Rio Product. The remaining allegations in Paragraph 16 contain legal conclusions to which no answer is required. To the extent an answer is required, Rio denies the remaining allegations of Paragraph 16.

17. By letter to NNI and NNAS dated December 8, 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 and '893 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Rio's Product (the "Paragraph IV Certification"). Rio attached a memorandum to the Notice Letter in which it purported to allege factual and legal bases for its Paragraph IV Certification. NNI and NNAS file this suit within 45 days of receipt of the Notice Letter.

ANSWER: Admitted that Rio sent Plaintiffs a letter, dated December 8, 2023, via FedEx Priority Overnight Service stating that the '833 and '893 patents 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 17 and therefore denies the same.

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

18. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-17 of this Complaint.

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1-17 as if fully set forth herein.

19. 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 19 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

20. 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 to sell, or sale of Rio's Product within the United States, or importing 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 20 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

21. 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.

22. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

23. 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 23 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. 9,265,893

24. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-23 of this Complaint.

ANSWER: Rio incorporates by reference its answers to the allegations in Paragraphs 1-23 as if fully set forth herein.

25. Rio has infringed the '893 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 '893 patent.

ANSWER: The allegations in Paragraph 25 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

26. Claims 1-6 of the '893 patent are directed to a push button connection for an injection device. Rio's manufacture, use, offer for sale, or sale of Rio's Product within the United States, or importing of Rio's Product into the United States, during the term of the '893 patent would infringe claims 1-6 of the '893 patent.

ANSWER: The allegations in Paragraph 26 contain legal conclusions to which no answer is required. To the extent an answer is required, denied.

27. Novo Nordisk will be harmed substantially and irreparably if Rio is not enjoined from infringing the '893 patent and/or if the FDA is not enjoined from approving Rio's ANDA before the '893 patent expires.

ANSWER: Denied.

28. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

29. Rio was aware of the '893 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 29 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 H 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. 218241 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the'833 and '893 patents 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 and '893 patents 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" or "Counterclaim Defendant"), 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 Bagsvxrd, 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. 022341 for Victoza®, Liraglutide Recombinant Solution Injection, 18 mg/3 mL (6 mg/mL), approved on January 25, 2010.

6. Upon information and belief, Victoza® is indicated as an adjunct to diet and exercise to improve glycemic control in patients ten years and older with type 2 diabetes mellitus and to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.

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 Victoza® lists in relevant part U.S. Patent Nos. 8,114,833 (the "'833 patent") and 9,265,893 (the "'893 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 ANDAs 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 '893 patent is entitled "Injection Button" with an issue date of February 23, 2016.

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

15. Rio filed its Abbreviated New Drug Application ("Rio ANDA") No. 218241 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.

16. Rio sent notice of these certifications to Counterclaim-Defendants on or about December 8, 2023. On information and belief, and as Counterclaim-Defendants allege in their Complaint, Counterclaim-Defendants received this letter.

17. On January 19, 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.

18. 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.

19. 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.

20. 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.

21. 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

22. 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).

23. The dispute as to noninfringement, unenforceability, and/or invalidity of the Asserted Patents present 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.

24. 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.

25. 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.

26. 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).

27. 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.

28. 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 Delaware and because, either directly or through agents, it transacts business in, and derives substantial revenue from, Delaware.

29. 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 Non-Infringement of U.S. Patent No. 8,114,833

30. Rio restates and incorporates by reference the allegations in Paragraphs 1-29 above as if fully set forth herein.

31. Counterclaim-Defendants have alleged that Rio infringes claims 1-31 of the '833 patent, and has created a real, substantial, and justiciable controversy between the parties as to the infringement of the '833 patent.

32. Rio has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more of any valid claim of the '833 patent at least

for the representative and nonlimiting reasons set forth in the letter, dated December 8, 2023, sent by Rio to Counterclaim-Defendants via FedEx Priority Overnight Service stating that the '833 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug products described in Rio's ANDA and/or as apparent from Rio's ANDA.

33. Rio has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '833 patent.

34. Rio is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '833 patent.

COUNT II:

Declaratory Judgment of Invalidity of United States Patent No. 8,114,833

35. Rio restates and incorporates by reference the allegations in Paragraphs 1-29 above as if fully set forth herein.

36. The claims of the '833 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 *et seq.,* including but not limited to, §§ 101, 102, 103, and/or 112.

37. By way of non-limiting example, claims 1-31 of the '833 patent, which Counterclaim-Defendants have alleged that Rio infringes, are invalid pursuant to 35 U. S.C. § 103, as obvious in view of prior art disclosing the limitations of one or more claims of the '833 patent. Non-limiting examples of such art include International Patent Application Publication No. WO 2003/002136 A2, in addition to the knowledge of a POSA and the state of the art.

38. In addition, the claims of the '833 patent are invalid for obviousness-type double patenting in view of at least the '833 patent.

39. There is a real, substantial, and justiciable controversy between Rio and Counterclaim-Defendants concerning whether claims of the '833 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

40. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

41. Rio is entitled to a judicial declaration that claims 1-31 of the '833 patent are invalid.

COUNT III:

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,265,893

42. Rio restates and incorporates by reference the allegations in Paragraphs 1-29 above, as if fully set forth herein.

43. Counterclaim-Defendants have alleged that Rio infringes claims 1-6 of the '893 patent, and has created a real, substantial, and justiciable controversy between the parties as to the infringement of the '893 patent.

44. Rio has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more of any claim of the '893 patent, at least for the representative and nonlimiting reasons set forth in the letter, dated December 8, 2023, sent by Rio to Counterclaim-Defendants via FedEx Priority Overnight Service stating that the '893 patent is

invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug products described in Rio's ANDA and/or as apparent from Rio's ANDA.

45. Rio is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '893 patent.

COUNT IV:

Declaratory Judgment of Invalidity of United States Patent No. 9,265,893

46. Rio restates and incorporates by reference the allegations in Paragraphs 1-29 above as if fully set forth herein.

47. The claims of the '893 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 *et seq.,* including but not limited to, §§ 101, 102, 103, and/or 112.

48. By way of non-limiting example, claims 1-6 of the '893 patent, which Counterclaim-Defendants have alleged that Rio infringes, are invalid pursuant to 35 U.S.C. §§ 102 and 103 as anticipated and/or obvious in view of prior art disclosing the limitations of claims 1-6 of the '893 patent. Non-limiting examples of such art include International Patent Application Publication No. WO 2006/076921 and U.S. Patent No. 3,318,289, in addition to the knowledge of a POSA and the state of the art.

49. There is a real, substantial, and justiciable controversy between Rio and Counterclaim-Defendants concerning whether the claims of the '893 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

50. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

51. Rio is entitled to a judicial declaration that claims 1-6 of the ’893 patent are invalid.

PRAYER FOR RELIEF

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

(a) Declaring that the filing of Rio’s ANDA did not infringe one or more valid and enforceable claims of the ’833 and ’893 patents;

(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 and ’893 patents, either literally or under the doctrine of equivalents;

(c) Declaring that the claims of the ’833 and ’893 patents are invalid;

(d) Ordering that Plaintiffs' Complaint be dismissed with prejudice and judgment entered in favor of Rio;

(e) Denying Plaintiffs 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

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

Dated: April 15, 2024

By: /s/ Arnold B. Calmann
Arnold B. Calmann
Katherine A. Escanlar

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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. 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.); and *Novo Nordisk Inc., et al. v. Orbicular Pharm. Technologies Pvt. Ltd.*, C.A. Nos. 22-856 (CFC) and 23-179 (CFC) (D. Del.).

Dated: April 15, 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 15, 2024

s/ Arnold B. Calmann
Arnold B. Calmann