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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVO NORDISK INC. and NOVO NORDISK A/S,	:	Honorable Esther Salas, U.S.D.J.
	:	Civil Action No. 23 CV 4027 (ES)(JSA)
Plaintiffs,	:	
v.	:	**DEFENDANT LUPIN LTD.'S ANSWER TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS FOR DECLARATORY JUDGMENT**
LUPIN LTD.,	:	
Defendant.	:	

Defendant Lupin Ltd. ("Lupin") by and through its undersigned attorneys, hereby submit its Answer and Affirmative Defenses to the Complaint for Patent Infringement filed by Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Plaintiffs").

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 Lupin's submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA"), by which Lupin seeks approval to market a generic version of Novo Nordisk's pharmaceutical product

* For ease of review, Lupin has used the same headings that Plaintiffs used in their Complaint. Lupin denies any and all allegations or characterizations presented by the headings.

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: The allegations in paragraph 1 are legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the Complaint purports to state an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code and that Lupin submitted an Abbreviated New Drug Application ("ANDA") No. 215421 to the United States Food and Drug Administration ("FDA") seeking FDA approval of the liraglutide injection solution, 18 mg/3 ml (6 mg/ml), as described therein. Lupin further denies any remaining allegations and characterizations in 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: Lupin lacks knowledge or information sufficient to form a belief as to the truth of the 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 Allé, 2880 Bagsværd, Denmark. NNI is an indirect, wholly owned subsidiary of NNAS.

ANSWER: Lupin lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3 and therefore denies the same.

4. On information and belief, Defendant Lupin Ltd. ("Lupin") is a corporation organized and existing under the laws of India, having its principal place of business at Kulpataru Inspire, 3rd Floor, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India. On information and belief, Lupin is in the business of making and selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States, alone and/or through its wholly owned subsidiaries and agents.

ANSWER: Lupin admits that Lupin Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Kulpataru Inspire, 3rd Floor, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India. Lupin admits that Lupin

develops and manufactures pharmaceutical products for sale and distribution in the United States, including in the State of New Jersey. Lupin denies the 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 conclusions of law for which no response is required. To the extent an answer is required, Lupin does not contest that the Court has subject matter jurisdiction over this action.

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

ANSWER: Paragraph 6 contains conclusions of law for which no response is required. To the extent an answer is required, Lupin does not contest that the Court has subject matter jurisdiction over this action.

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

ANSWER: Paragraph 7 contains conclusions of law for which no response is required. To the extent an answer is required, Lupin does not contest venue for the purposes of this action only.

8. This Court has personal jurisdiction over Defendant Lupin because, upon information and belief, it has a 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 conclusions of law for which no response is required. To the extent an answer is required, Lupin does not contest personal jurisdiction for purposes of this action only. Lupin denies the remaining allegations of paragraph 8.

9. Moreover, Lupin has previously litigated patent infringement disputes in this Judicial District and has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this Judicial District. *See, e.g.*, Senju Pharm. Co., Ltd. v. Lupin Ltd., C.A. No. 1:15-CV-00335, Dkt. 9 (D.N.J. Mar. 24, 2015); Janssen Prods., L.P. v. Lupin Ltd., C.A. No. 2:10-

CV-05954, Dkt. 191 (D.N.J. Jul. 23, 2012); Elan Pharma Int'l Ltd. v. Lupin Ltd., C.A. No. 2:09-CV-1008, Dkt. 12 (D.N.J. May 8, 2009).

ANSWER: Paragraph 9 contains conclusions of law for which no response is required. To the extent an answer is required, Lupin does not contest personal jurisdiction for purposes of this action only. Lupin denies the remaining allegations of paragraph 9.

10. On information and belief, Lupin 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) ("Lupin's Product"), directly or indirectly, throughout the United States and in this District. Lupin's filing of ANDA No. 215421 ("Lupin's ANDA") confirms this intention and further subjects Lupin to the specific personal jurisdiction of this Court.

ANSWER: Lupin admits that Lupin submitted Lupin's ANDA to the FDA seeking approval of the liraglutide injection solution, 18 mg/3 ml (6 mg/ml), as described therein. Lupin does not contest personal jurisdiction for purposes of this action only. Lupin denies the remaining allegations of paragraph 10.

11. Venue is proper in this Judicial District for Lupin because it is a foreign corporation, and thus venue is proper in any judicial district that has personal jurisdiction, including the District of New Jersey. Lupin has previously consented to venue in this Judicial District. *See, e.g.*, *Senju Pharm. Co., Ltd. v. Lupin Ltd.*, C.A. No. 1:15-CV-00335, Dkt. 9 (D.N.J. Mar. 24, 2015); *Janssen Prods., L.P. v. Lupin Ltd.*, C.A. No. 2:10-CV-05954, Dkt. 191 (D.N.J. Jul. 23, 2012); *Elan Pharma Int'l Ltd. v. Lupin Ltd.*, C.A. No. 2:09-CV-1008, Dkt. 12 (D.N.J. May 8, 2009).

ANSWER: Paragraph 11 contains conclusions of law for which no response is required. To the extent an answer is required, Lupin does not contest venue for the purposes of this action only.

THE PATENTS-IN-SUIT

12. 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: Lupin admits that the '833 patent states on its face that its title is "Propylene Glycol-Containing Peptide Formulations Which are Optimal for Production and for Use in

Injection Devices" with an issue date of February 14, 2012. Lupin further admits that the Complaint Exhibit A purports to be a copy of the '833 patent. Lupin lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 12 and therefore denies them.

13. 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: Lupin admits that the '893 patent states on its face that its title is "Injection Button" with an issue date of February 23, 2016. Lupin further admits that the Complaint Exhibit B purports to be a copy of the '893 patent. Lupin lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 13 and therefore denies them.

VICTOZA®

14. 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: Lupin admits that according to the FDA publication entitled *Approved Drug Products and Therapeutic Equivalence Evaluations* (the "Orange Book"), Novo Nordisk Inc. holds approved New Drug Application ("NDA") No. 022341 for Liraglutide Recombinant Solution (subcutaneous), 18 mg/3 ml (6 mg/ml) with the proprietary name Victoza®. To the extent there are remaining allegations in paragraph 14, Lupin denies the same.

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

ANSWER: Lupin lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 15 and therefore denies them.

16. 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: Lupin admits that the '833 and '893 patents appear to be listed in the Orange Book for Victoza®. Lupin lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 16 and therefore denies them.

LUPIN'S ANDA

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

ANSWER: Lupin admits that Lupin submitted Lupin's ANDA to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of liraglutide injection solution, 18 mg/3 ml (6 mg/ml) as described therein. To the extent there are remaining allegations in paragraph 17, Lupin denies the same.

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

ANSWER: Lupin admits that the reference listed drug identified in Lupin's ANDA is Victoza® (liraglutide) subcutaneous solution, injection, 18 mg/3 ml (6 mg/ml), approved under NDA 022341. Lupin denies the remaining allegations of paragraph 18.

19. By letter to NNI and NNAS, dated June 12, 2023 (the "Notice Letter"), Lupin stated that Lupin'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 Lupin's Product (the "Paragraph IV Certification"). Lupin 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: Lupin admits that it sent Plaintiffs a letter, dated June 12, 2023 (the "Notice Letter"), stating that Lupin's ANDA includes certifications 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 the product described in Lupin's ANDA. Lupin further admits that it attached a memorandum to the Notice Letter that detailed the factual

and legal bases for its Paragraph IV Certification. Lupin does not contest that this action is being brought within forty-five days of the receipt of the Notice Letter by one or more Plaintiffs. Lupin denies the remaining allegations of paragraph 19.

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

20. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1–19 of this Complaint.

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-19 of this Complaint.

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

ANSWER: Paragraph 21 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

22. 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. Lupin's manufacture, use, offer for sale or sale of Lupin's Product within the United States, or importation of Lupin's Product into the United States, during the term of the '833 patent would infringe claims 1–31 of the '833 patent.

ANSWER: Paragraph 22 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 23 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

24. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

25. Lupin 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: Lupin admits that Lupin's ANDA includes a Paragraph IV certification that the '833 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Lupin's ANDA Product, as stated in Lupin's Notice Letter. Lupin denies the remaining allegations of paragraph 25.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 9,265,893

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

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-25 of the Complaint.

27. Lupin has infringed the '893 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Lupin's ANDA, by which Lupin seeks approval from the FDA to manufacture, use, offer to sell, and sell Lupin's Product prior to the expiration of the '893 patent.

ANSWER: Paragraph 27 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 28 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 29 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

30. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

31. Lupin 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: Lupin admits that Lupin's ANDA includes a Paragraph IV certification that the '893 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Lupin's ANDA Product, as stated in Lupin's Notice Letter. Lupin denies the remaining allegations of paragraph 31.

PLAINTIFFS' PRAYER FOR RELIEF

Lupin denies that Plaintiffs are entitled to the general or specific relief requested against Lupin, or to any relief whatsoever, and pray for judgment in favor of Lupin dismissing this action with prejudice, and awarding Lupin its reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs and expenses in this action; and such other and further relief as the Court deems just and proper.

LUPIN'S AFFIRMATIVE DEFENSES

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

FIRST AFFIRMATIVE DEFENSE
(Invalidity)

The Patents-in-Suit and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND AFFIRMATIVE DEFENSE
(No Direct Infringement)

Lupin does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the Patents-in-Suit. If the product that is the subject of ANDA No. 215421 was marketed, Lupin would not infringe any valid and enforceable claim of the Patents-in-Suit. Lupin incorporates by reference the detailed statement of the factual and legal basis that Lupin does not infringe the Patents-in-Suit as if fully set forth herein.

THIRD AFFIRMATIVE DEFENSE
(No Indirect Infringement)

Lupin has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-in-Suit. If the product that is the subject of ANDA No. 215421 was marketed, Lupin would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-in-Suit.

FOURTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim for relief against Lupin.

FIFTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim for relief against Lupin for an exceptional case under 35 U.S.C. § 285.

SIXTH AFFIRMATIVE DEFENSE

Lupin has not willfully infringed any claim of the Patents-in-Suit.

SEVENTH AFFIRMATIVE DEFENSE

Any additional defenses that discovery may reveal.

WHEREFORE, Lupin respectfully requests that Plaintiffs take nothing by way of their Complaint, that judgment be entered in favor of Lupin, that Lupin be awarded its attorneys' fees and costs, and all other just and proper relief.

LUPIN LTD.'S COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Defendant/Counterclaim Plaintiff Lupin Ltd. ("Lupin" or "Counterclaim Plaintiff") brings the following Counterclaims against Plaintiffs/Counterclaim Defendants Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo" or "Counterclaim Defendants") for a declaratory judgment that U.S. Patent Nos. 8,114,833 (the "'833 patent") and 9,265,893 (the "'893 patent") (collectively, "Patents-in-Suit") are invalid and/or not infringed by the manufacture, use, sale, offer for sale, or importation of the liraglutide injection solution 18 mg/3 ml (6 mg/mL) ("Lupin's ANDA Product") that is the subject of Abbreviated New Drug Application ("ANDA") No. 215421 ("Lupin's ANDA").

THE PARTIES

1. Lupin Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Kalpataru Inspire, 3rd Floor, Off Western Express Highway, Santacruz (East), Mumbai 400 055, India.

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

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

JURISDICTION AND VENUE

4. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. Defendants seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202; and 35 U.S.C. § 271(e)(2).

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

6. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b), and by Counterclaim Defendants' choice of forum as stated in the Complaint.

BACKGROUND

7. This is an action based upon an actual controversy between the parties concerning the invalidity and/or non-infringement of the '833 and '893 patents and Lupin's right to continue to seek approval of Lupin's ANDA for Lupin's ANDA Product.

8. Counterclaim Defendants have alleged that the submission of Lupin's ANDA infringes, will infringe, will induce infringement, or will contribute to infringement of one or more claims of the '833 and '893 patents.

9. On July 27, 2023, Counterclaim Defendants filed in this Court an infringement action to enforce the '833 and '893 patents against Lupin.

10. On information and belief, and according to Counterclaim Defendants' allegations, Counterclaim Defendants are the assignees of the '833 and '893 patents. Upon information and belief, NNI holds approved New Drug Application ("NDA") No. 022341 for liraglutide recombinant solution (subcutaneous), 18 mg/3 mL (6 mg/mL), and markets the drug approved with this NDA as VICTOZA®.

11. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

12. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA") publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

13. Upon information and belief, Counterclaim Defendants caused the Patents-in-Suit to be listed in the Orange Book as patents that claim a pharmaceutical composition and device comprising and/or a method of using such a drug encompassed NDA No. 022341, which is held by NNI.

14. Lupin's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Lupin's ANDA Product.

15. In view of the foregoing, a conflict of asserted rights has arisen between Lupin and Counterclaim Defendants with respect to the non-infringement and invalidity of the relevant claims of the '833 and '893 patents, and as to Lupin's right to obtain FDA approval of Lupin's ANDA Product.

COUNT I
(Declaratory Judgment of Noninfringement of the '833 Patent)

16. Lupin realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

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

18. The manufacture, use, or sale of Lupin'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 Lupin'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.

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

20. Lupin 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.

21. Lupin is entitled to a declaration that the manufacture, use, or sale of Lupin'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)

22. Lupin realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

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

24. 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.

25. 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.

26. 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.

27. 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.

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

29. Lupin 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 Noninfringement of the '893 Patent)

30. Lupin realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

31. Counterclaim Defendants allege ownership of the '893 patent, and have brought claims against Lupin alleging infringement of the '893 patent.

32. The manufacture, use, or sale of Lupin'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 '893 patent, and the submission of Lupin'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 '893 patent.

33. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '893 patent.

34. Lupin has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '893 patent and is not liable for such infringement.

35. Lupin is entitled to a declaration that the manufacture, use, or sale of Lupin's ANDA Product would not infringe any valid or enforceable claim of the '893 patent.

COUNT IV

(Declaratory Judgment of Invalidity and/or Unenforceability of the '893 Patent)

36. Lupin realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

37. Counterclaim Defendants allege ownership of the '893 patent, and have brought claims against Lupin alleging infringement of the '893 patent.

38. One or more claims of the '893 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.

39. The '893 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.

40. The alleged invention of the '893 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 '893 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 '893 Patent and would have had a reasonable expectation of success in doing so.

41. The subject matter claimed in the '893 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.

42.

43. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '893 patent.

44. Lupin is entitled to a declaration that all claims of the '893 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Lupin requests judgment in its favor and against Counterclaim Defendants as follows:

a. Declaring that the Court order the Complaint dismissed with prejudice and judgment be entered in favor of Lupin;

b. Declaring that all claims of the Patents-in-Suit are invalid;

b. Declaring that the filing of Lupin's ANDA No. 215421 has not infringed, 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 enforceable claim of the Patents-in-Suit.

c. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the Patents-in-Suit.

d. Declaring this an exceptional case in favor of Lupin and awarding its attorneys' fees pursuant to 35 U.S.C. § 285.

e. Awarding costs and expenses; and

f. Awarding any and all such other relief as the Court determines to be just and proper.

MIDLIGE RICHTER LLC
Attorneys for Defendant, Lupin Ltd.

By: s/ James S. Richter
James S. Richter
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Dated: October 2, 2023

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify, to the best of my knowledge, that this action is related to the following action currently pending in this District: *Novo Nordisk Inc., et al. v. Lupin Ltd,* Civil Action No. 23 CV 4031 (ES)(JSA), concerning infringement of patents that include one of the same patents asserted herein, United States Patent Nos. 8,114,833, and Abbreviated New Drug Application submissions referencing the same Reference Listed Drug.

Lupin is not aware of any other action pending in any court or any pending arbitration or administrative proceeding related to this matter.

s/ James S. Richter
James S. Richter

Dated: October 2, 2023

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

s/ James S. Richter
James S. Richter

Dated: May 2, 2022

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Lupin's foregoing Answer, Affirmative Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on October 2, 2023.

s/ James S. Richter
James S. Richter

Dated: October 2, 2023