MIDLIGE RICHTER, LLC
645 Martinsville Road
Basking Ridge, New Jersey 07920
(908) 626-0622
James S. Richter

Attorneys for Defendants,
Lupin Ltd.

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 4031 (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 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"),

* 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.

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"), and RE46,363 (the "'363 patent"), which cover inter alia, Saxenda® 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. 218382 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. 218382 ("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 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: Lupin admits that the '969 patent states on its face that its title is "Injection Device with Torsion Spring and Rotatable Display" with an issue date of April 1, 2014. Lupin further admits that the Complaint Exhibit B purports to be a copy of the '969 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.

14. 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: Lupin admits that the '383 patent states on its face that its title is "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. Lupin further admits that the Complaint Exhibit C purports to be a copy of the '383 patent. Lupin lacks knowledge or

information sufficient to form a belief about the truth of the remaining allegations of paragraph 14 and therefore denies them.

15. 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: Lupin admits that the '002 patent states on its face that its title is "Automatic Injection Device with a Top Release Mechanism" with an issue date of August 18, 2015. Lupin further admits that the Complaint Exhibit D purports to be a copy of the '002 patent. Lupin lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 15 and therefore denies them.

16. On September 15, 2015, the United States Patent and Trademark Office issued the '239 patent, entitled "Dial-Down Mechanism for Wind-Up Pen," a copy of which is attached to this Complaint as Exhibit E. NNAS is the owner of all right, title, and interest in the '239 patent.

ANSWER: Lupin admits that the '239 patent states on its face that its title is "Dial-Down Mechanism for Wind-Up Pen" with an issue date of September 15, 2015. Lupin further admits that the Complaint Exhibit E purports to be a copy of the '239 patent. Lupin lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 16 and therefore denies them.

17. On October 4, 2016, the United States Patent and Trademark Office issued the '154 patent, entitled "Injection Device with an End of Dose Feedback Mechanism," a copy of which is attached to this Complaint as Exhibit F. NNAS is the owner of all right, title, and interest in the '154 patent.

ANSWER: Lupin admits that the '154 patent states on its face that its title is "Injection Device with an End of Dose Feedback Mechanism" with an issue date of October 4, 2016. Lupin further admits that the Complaint Exhibit F purports to be a copy of the '154 patent. Lupin lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 17 and therefore denies them.

18. 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: Lupin admits that the '180 patent states on its face that its title is "Automatic Injection Device with a Top Release Mechanism" with an issue date of April 11, 2017. Lupin further admits that the Complaint Exhibit G purports to be a copy of the '180 patent. Lupin lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 18 and therefore denies them.

19. 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: Lupin admits that the '611 patent states on its face that its title is "Injection Device with Torsion Spring and Rotatable Display" with an issue date of June 27, 2017. Teva further admits that the Complaint Exhibit H purports to be a copy of the '611 patent. Lupin lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 19 and therefore denies them.

20. 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: Lupin admits that the '953 patent states on its face that its title is "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. Lupin further admits that the Complaint Exhibit I purports to be a copy of the '953 patent. Lupin lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 20 and therefore denies them.

21. 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: Teva admits that the '757 patent states on its face that its title is "Injection Device with an End of Dose Feedback Mechanism" with an issue date of January 9, 2018. Lupin further admits that the Complaint Exhibit J purports to be a copy of the '757 patent. Lupin lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 21 and therefore denies them.

22. 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: Lupin admits that the '155 patent states on its face that its title is "Syringe Device with a Dose Limiting Mechanism and an Additional Safety Mechanism" with an issue date of March 5, 2019. Lupin further admits that the Complaint Exhibit K purports to be a copy of the '155 patent. Lupin lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 22 and therefore denies them.

23. 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: Lupin admits that the '616 patent states on its face that its title is "Injection Device with an End of Dose Feedback Mechanism" with an issue date of July 23, 2019. Lupin further admits that the Complaint Exhibit L purports to be a copy of the '616 patent. Lupin lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 23 and therefore denies them.

24. 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: Lupin admits that the '652 patent states on its face that its title is "Automatic Injection Device with a Top Release Mechanism" with an issue date of August 13, 2019. Lupin further admits that the Complaint Exhibit M purports to be a copy of the '652 patent. Lupin lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 24 and therefore denies them.

25. 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: Lupin admits that the '063 patent states on its face that its title is "Syringe Device with a Dose Limiting Mechanism and an Additional Safety Mechanism" with an issue date of August 24, 2021. Lupin further admits that the Complaint Exhibit N purports to be a copy of the '063 patent. Lupin lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 25 and therefore denies them.

26. 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: Lupin admits that the '679 patent states on its face that its title is "Automatic Injection Device with a Top Release Mechanism" with an issue date of April 26, 2022. Lupin further admits that the Complaint Exhibit O purports to be a copy of the '679 patent. Lupin lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 26 and therefore denies them.

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

ANSWER: Lupin admits that the '363 patent states on its face that its title is "Dial-Down Mechanism for Wind-Up Pen" with an issue date of April 11, 2017. Lupin further admits that the Complaint Exhibit P purports to be a copy of the '363 patent. Lupin lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 27 and therefore denies them.

SAXENDA®

28. 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: 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. 206321 for Liraglutide Recombinant Solution (subcutaneous), 18 mg/3 ml (6 mg/ml) with the proprietary name Saxenda®. To the extent there are remaining allegations in paragraph 28, Lupin denies the same.

29. 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, and the '363 patent cover, *inter alia*, Saxenda® and/or its use.

ANSWER: Lupin lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 29 and therefore denies them.

30. 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, and '363 patent are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Saxenda®.

ANSWER: Lupin admits that the '833, '969, '383, '002, '239, '154, '180, '611, '953, '757, '155, '616, '652, '063, '679, and '363 patents appear to be listed in the Orange Book for

Saxenda®. Lupin lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 30 and therefore denies them.

LUPIN'S ANDA

31. 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 31, Lupin denies the same.

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

ANSWER: Lupin admits that the reference listed drug identified in Lupin's ANDA is SAXENDA® (liraglutide) Injection, 18 mg/3 mL (6 mg/mL) under NDA No. 206321. Lupin denies the remaining allegations of paragraph 32.

33. 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 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, and '363 patent 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, '969, '383, '002, '239, '154, '180, '611,'953, '757, '155, '616, '652, '063, '679, and '363 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 33.

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

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

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-33 of this Complaint.

35. 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 35 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

36. 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 36 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

37. 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 37 contains conclusions of law for which no response is required. To the extent an answer is required, denied

38. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

39. 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 39.

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

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

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-39 of the Complaint.

41. Lupin has infringed the '969 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 '969 patent.

ANSWER: Paragraph 41 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

42. 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. 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 '969 patent would infringe claims 1–26 of the '969 patent.

ANSWER: Paragraph 42 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 43 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

44. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

45. Lupin 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: Lupin admits that Lupin's ANDA includes a Paragraph IV certification that the '969 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 45.

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

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

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-45 of this Complaint.

47. Lupin has infringed the '383 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 '383 patent.

ANSWER: Paragraph 47 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

48. 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. 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 '383 patent would infringe claims 1–13 of the '383 patent.

ANSWER: Paragraph 48 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 49 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

50. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

51. Lupin 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: Lupin admits that Lupin's ANDA includes a Paragraph IV certification that the '383 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 51.

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

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

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-51 of the Complaint.

53. Lupin has infringed the '002 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 '002 patent.

ANSWER: Paragraph 53 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

54. 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. 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 '002 patent would infringe claims 1–2 of the '002 patent.

ANSWER: Paragraph 54 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 55 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

56. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

57. Lupin 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: Lupin admits that Lupin's ANDA includes a Paragraph IV certification that the '002 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 57.

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

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

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-57 of the Complaint.

59. Lupin has infringed the '239 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 '239 patent.

ANSWER: Paragraph 59 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

60. Claims 1–3 of the '239 patent are directed to a dial-down mechanism 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 '239 patent would infringe claims 1–3 of the '239 patent.

ANSWER: Paragraph 60 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 61 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

62. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

63. Lupin 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: Lupin admits that Lupin's ANDA includes a Paragraph IV certification that the '239 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Lupin's Product, as stated in Lupin's Notice Letter. Lupin denies the remaining allegations of paragraph 63.

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

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

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-63 of the Complaint.

65. Lupin has infringed the '154 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 '154 patent.

ANSWER: Paragraph 65 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

66. 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. 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 '154 patent would infringe claims 1–17 of the '154 patent.

ANSWER: Paragraph 66 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 67 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

68. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

69. Lupin 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: Lupin admits that Lupin's ANDA includes a Paragraph IV certification that the '154 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 69.

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

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

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-69 of the Complaint

71. Lupin has infringed the '180 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 '180 patent.

ANSWER: Paragraph 71 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

72. 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. 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 '180 patent would infringe claims 1–14 of the '180 patent.

ANSWER: Paragraph 72 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 73 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

74. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

75. Lupin 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: Lupin admits that Lupin's ANDA includes a Paragraph IV certification that the '180 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 75.

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

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

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-75 of the Complaint

77. Lupin has infringed the '611 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 '611 patent.

ANSWER: Paragraph 77 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

78. 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. 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 '611 patent would infringe claims 1–15 of the '611 patent.

ANSWER: Paragraph 78 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 79 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

80. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

81. Lupin 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: Lupin admits that Lupin's ANDA includes a Paragraph IV certification that the '611 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 81.

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

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

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-81 of the Complaint

83. Lupin has infringed the '953 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 '953 patent.

ANSWER: Paragraph 83 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

84. 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. 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 '953 patent would infringe claims 1–25 of the '953 patent.

ANSWER: Paragraph 84 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 85 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

86. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

87. Lupin 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: Lupin admits that Lupin's ANDA includes a Paragraph IV certification that the '953 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 87.

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

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

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-87 of this Complaint.

89. Lupin has infringed the '757 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 '757 patent.

ANSWER: Paragraph 89 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

90. 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. 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 '757 patent would infringe claims 1–12 of the '757 patent.

ANSWER: Paragraph 90 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 91 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

92. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

93. Lupin 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: Lupin admits that Lupin's ANDA includes a Paragraph IV certification that the '757 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 93.

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

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

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-93 of the Complaint.

95. Lupin has infringed the '155 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 '155 patent.

ANSWER: Paragraph 95 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

96. 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. 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 '155 patent would infringe claims 1–8 of the '833 patent.

ANSWER: Paragraph 96 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 97 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

98. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

99. Lupin 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: Lupin admits that Lupin's ANDA includes a Paragraph IV certification that the '155 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 99.

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

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

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-99 of the Complaint.

101. Lupin has infringed the '616 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 '616 patent.

ANSWER: Paragraph 101 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

102. 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. 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 '616 patent would infringe claims 1–9 of the '616 patent.

ANSWER: Paragraph 102 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 103 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

104. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

105. Lupin 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: Lupin admits that Lupin's ANDA includes a Paragraph IV certification that the '616 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Lupin's Product, as stated in Lupin's Notice Letter. Lupin denies the remaining allegations of paragraph 105.

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

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

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-105 of the Complaint.

107. Lupin has infringed the '652 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 '652 patent.

ANSWER: Paragraph 107 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

108. 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. 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 '652 patent would infringe claims 1–15 of the '652 patent.

ANSWER: Paragraph 108 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 109 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

110. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

111. Lupin 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: Lupin admits that Lupin's ANDA includes a Paragraph IV certification that the '652 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 111.

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

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

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-111 of the Complaint

113. Lupin has infringed the '063 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 '063 patent.

ANSWER: Paragraph 113 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

114. 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. 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 '063 patent would infringe claims 1–7 of the '063 patent.

ANSWER: Paragraph 114 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 115 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

116. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

117. Lupin 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: Lupin admits that Lupin's ANDA includes a Paragraph IV certification that the '063 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 117.

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

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

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-117 of the Complaint

119. Lupin has infringed the '679 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 '611 patent.

ANSWER: Paragraph 119 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

120. 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. 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 '679 patent would infringe claims 1–6 of the '679 patent.

ANSWER: Paragraph 120 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 121 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

122. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

123. Lupin 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: Lupin admits that Lupin's ANDA includes a Paragraph IV certification that the '679 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 123.

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

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

ANSWER: Lupin repeats and incorporates by references its responses to paragraphs 1-123 of the Complaint

125. Lupin has infringed the '363 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 '363 patent.

ANSWER: Paragraph 125 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

126. 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. 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 '363 patent would infringe claims 1–11 of the '363 patent.

ANSWER: Paragraph 126 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

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

ANSWER: Paragraph 127 contains conclusions of law for which no response is required. To the extent an answer is required, denied.

128. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

129. Lupin 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: Lupin admits that Lupin's ANDA includes a Paragraph IV certification that the '363 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 129.

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. 218382 was marketed, Lupin would not infringe any valid and enforceable claim of the Patents-in-Suit.

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. 218382 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"), 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"), and RE46,363 (the "'363 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, 6 mg/mL ("Lupin's ANDA Product") that is the subject of Abbreviated New Drug Application ("ANDA") No. 218382 ("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, '969, '383, '002, '239, '154, '180, '611, '953, '757, '155, '616, '652, '063, '679, and '363 patents and Lupin's right to continue to seek approval of Lupin's ANDA for Lupin's ANDA Product.

8.

9. 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, '969, '383, '002, '239, '154, '180, '611,'953, '757, '155, '616, '652, '063, '679, and '363 patents.

10. On July 27, 2023, Counterclaim Defendants filed in this Court an infringement action to enforce the '833, '969, '383, '002, '239, '154, '180, '611,'953, '757, '155, '616, '652, '063, '679, and '363 patents against Lupin.

11. On information and belief, and according to Counterclaim Defendants' allegations, Counterclaim Defendants are the assignees of the '833, '969, '383, '002, '239, '154, '180, '611,'953, '757, '155, '616, '652, '063, '679, and '363 patents. Upon information and belief, NNI holds approved New Drug Application ("NDA") No. 206321 for liraglutide recombinant solution, 18 mg/3 mL (6 mg/mL), and markets the drug approved with this NDA as SAXENDA®.

12. 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).

13. 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).

14. 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. 206321, which is held by NNI.

15. 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.

16. 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, '969, '383, '002, '239, '154, '180, '611, '953, '757, '155, '616, '652, '063, '679, and '363 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)

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

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

19. 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.

20. 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.

21. 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.

22. 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)

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

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

25. 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.

26. 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.

27. 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.

28. 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.

29.

30. 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.

31. 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 '969 Patent)

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

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

34. 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 '969 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 '969 patent.

35. 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 '969 patent.

36. Lupin 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.

37. 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 '969 patent.

COUNT IV
(Declaratory Judgment of Invalidity and/or Unenforceability of the '969 Patent)

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

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

40. 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.

41. 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.

42. 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.

43. 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.

44.

45. 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 '969 patent.

46. Lupin 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 Noninfringement of the '383 Patent)

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

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

49. 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 '383 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 '383 patent.

50. 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 '383 patent.

51. Lupin 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.

52. 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 '383 patent.

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

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

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

55. 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.

56. 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.

57. 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.

58. 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.

59.

60. 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 ’383 patent.

61. Lupin 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 Noninfringement of the '002 Patent)

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

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

64. 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 '002 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 '002 patent.

65. 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 '002 patent.

66. Lupin 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.

67. 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 '002 patent.

COUNT VIII
(Declaratory Judgment of Invalidity and/or Unenforceability of the '002 Patent)

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

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

70. 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.

71. 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.

72. 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.

73. 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.

74.

75. 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 '002 patent.

76. Lupin 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 Noninfringement of the '239 Patent)

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

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

79. 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 '239 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 '239 patent.

80. 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 '239 patent.

81. Lupin 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.

82. 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 '239 patent.

COUNT X
(Declaratory Judgment of Invalidity and/or Unenforceability of the '239 Patent)

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

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

85. 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.

86. 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.

87. 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.

88. 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.

89.

90. 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 '239 patent.

91. Lupin 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 Noninfringement of the '154 Patent)

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

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

94. 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 '154 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 '154 patent.

95. 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 '154 patent.

96. Lupin 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.

97. 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 '154 patent.

COUNT XII
(Declaratory Judgment of Invalidity and/or Unenforceability of the '154 Patent)

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

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

100. 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.

101. 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.

102. 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.

103. 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.

104.

105. 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 '154 patent.

106. Lupin 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 Noninfringement of the '180 Patent)

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

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

109. 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 '180 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 '180 patent.

110. 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 '180 patent.

111. Lupin 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.

112. 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 '180 patent.

COUNT XIV
(Declaratory Judgment of Invalidity and/or Unenforceability of the '180 Patent)

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

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

115. 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.

116. 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.

117. 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.

118. 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.

119. 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 ’180 patent.

120. Lupin 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 Noninfringement of the ’611 Patent)

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

122. Counterclaim Defendants allege ownership of the ’611 patent, and have brought claims against Lupin alleging infringement of the ’611 patent.

123. 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 ’611 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 ’611 patent.

124. 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 ’611 patent.

125. Lupin 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.

126. 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 ’611 patent.

COUNT XVI
(Declaratory Judgment of Invalidity and/or Unenforceability of the ’611 Patent)

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

128. Counterclaim Defendants allege ownership of the ’611 patent, and have brought claims against Lupin alleging infringement of the ’611 patent.

129. 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.

130. 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.

131. 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.

132. 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.

133.

134. 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 ’611 patent.

135. Lupin 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 Noninfringement of the '953 Patent)

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

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

138. 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 '953 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 '953 patent.

139. 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 '953 patent.

140. Lupin 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.

141. 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 '953 patent.

COUNT XVIII
(Declaratory Judgment of Invalidity and/or Unenforceability of the '953 Patent)

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

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

144. 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.

145. 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.

146. 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.

147. 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.

148. 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 '953 patent.

149. Lupin 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 Noninfringement of the '757 Patent)

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

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

152. 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 '757 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 '757 patent.

153. 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 '757 patent.

154. Lupin 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.

155. 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 '757 patent.

COUNT XX
(Declaratory Judgment of Invalidity and/or Unenforceability of the '757 Patent)

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

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

158. 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.

159. 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.

160. 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.

161. 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.

162.

163. 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 '757 patent.

164. Lupin 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 Noninfringement of the '155 Patent)

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

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

167. 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 '155 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 '155 patent.

168. 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 '155 patent.

169. Lupin 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.

170. 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 '155 patent.

COUNT XXII
(Declaratory Judgment of Invalidity and/or Unenforceability of the '155 Patent)

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

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

173. 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.

174. 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.

175. 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.

176. 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.

177.

178. 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 '155 patent.

179. Lupin 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 Noninfringement of the '616 Patent)

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

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

182. 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 '616 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 '616 patent.

183. 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 '616 patent.

184. Lupin 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.

185. 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 '616 patent.

COUNT XXIV
(Declaratory Judgment of Invalidity and/or Unenforceability of the '616 Patent)

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

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

188. 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.

189. 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.

190. 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.

191. 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.

192.

193. 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 ’616 patent.

194. Lupin 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 Noninfringement of the ’652 Patent)

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

196. Counterclaim Defendants allege ownership of the ’652 patent, and have brought claims against Lupin alleging infringement of the ’652 patent.

197. 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 ’652 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 ’652 patent.

198. 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 ’652 patent.

199. Lupin 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.

200. 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 ’652 patent.

COUNT XXVI
(Declaratory Judgment of Invalidity and/or Unenforceability of the ’652 Patent)

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

202. Counterclaim Defendants allege ownership of the ’652 patent, and have brought claims against Lupin alleging infringement of the ’652 patent.

203. 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.

204. 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.

205. 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.

206. 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.

207.

208. 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 '652 patent.

209. Lupin 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 Noninfringement of the '063 Patent)

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

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

212. 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 '063 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 '063 patent.

213. 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 '063 patent.

214. Lupin 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.

215. 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 '063 patent.

COUNT XXVIII
(Declaratory Judgment of Invalidity and/or Unenforceability of the '063 Patent)

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

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

218. 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.

219. 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.

220. 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.

221. 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.

222.

223. 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 '063 patent.

224. Lupin 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 Noninfringement of the '679 Patent)

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

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

227. 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 '679 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 '679 patent.

228. 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 '679 patent.

229. Lupin 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.

230. 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 '679 patent.

COUNT XXX
(Declaratory Judgment of Invalidity and/or Unenforceability of the '679 Patent)

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

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

233. 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.

234. 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.

235. 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.

236. 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.

237.

238. 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 '679 patent.

239. Lupin 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 Noninfringement of the '363 Patent)

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

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

242. 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 '363 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 '363 patent.

243. 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 '363 patent.

244. Lupin 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.

245. 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 '363 patent.

COUNT XXXII
(Declaratory Judgment of Invalidity and/or Unenforceability of the '363 Patent)

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

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

248. 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.

249. 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.

250. 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.

251. 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.

252.

253. 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 '363 patent.

254. Lupin 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, 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. 218382 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
jrichter@midlige-richter.com

Dated: October 2, 2023

OF COUNSEL:

Michael Nutter (to be admitted pro hac vice)
MCGUIREWOODS LLP
77 West Wacker Drive, Suite 4100
Chicago, IL 60601
Telephone: (312) 849-8122
Facsimile: (312) 920-0332
mnutter@mcguirewoods.com

Dennis D. Gregory (to be admitted pro hac vice)
MCGUIREWOODS LLP
300 Colorado Street, Suite 2300
Austin, TX 78701
Telephone: (512) 617-4541
Facsimile: (512) 617-4589
dgregory@mcguirewoods.com

Jieun Lee (to be admitted pro hac vice)
MCGUIREWOODS LLP
1750 Tysons Boulevard, Suite 1800
Tysons, VA 22102
Telephone: (703) 712-5115
Facsimile: (702) 712-5215
jilee@mcguirewoods.com

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 4027 (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