

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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MERCK SHARP & DOHME CORP.,	)
	)
Plaintiff,	)
	)
v.	) C.A. No. 20-776-RGA
	)
LUPIN LIMITED and LUPIN	)
PHARMACEUTICALS, INC.,	)
	)
Defendant.	)
	)
LUPIN LIMITED,	)
Counterclaimant,	)
	)
v.	)
	)
MERCK SHARP & DOHME CORP.,	)
	)
Counterdefendant.	)
	)

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**DEFENDANTS LUPIN LIMITED AND LUPIN PHARMACEUTICALS, INC.’S  
ANSWER, DEFENSES AND COUNTERCLAIMS**

Defendants Lupin Limited (“Lupin Ltd.”) and Lupin Pharmaceuticals, Inc. (“LPI”) (collectively, “Lupin”), through their undersigned counsel, hereby answer the Complaint of Plaintiff Merck Sharp & Dohme Corp. (“Plaintiff”) as follows:

To the extent not specifically admitted herein, the allegations of the Complaint are denied.

1. Lupin admits that the Complaint filed by Plaintiff purports to state a civil action for patent infringement under the United States patent laws, Title 35, United States Code and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code. Lupin admits that the Complaint purports to allege infringement of U.S. Patent No. 7,326,708 (“the ’708 patent”). Lupin admits that the

Complaint purports to concern Lupin Ltd.’s filing of ANDA Nos. 214433 and 214399 with the United States Food and Drug Administration (“FDA”) seeking approval to market a generic products containing sitagliptin phosphate. Except as expressly admitted, Lupin denies each and every allegation in Paragraph 1 of the Complaint.

2. Lupin admits that Lupin Ltd. sent a letter dated April 27, 2020 to Plaintiff entitled “Notice of Paragraph IV Certification Regarding NDA 021995 (Sitagliptin Phosphate, 25 mg, 50 mg, 100 mg) with respect to U.S. Patent No. 7,326,708” (“Lupin Ltd.’s ’433 Notice Letter”). Lupin admits that Lupin Ltd. submitted ANDA No. 214433 to the FDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of drug products containing sitagliptin phosphate prior to the expiration of the ’708 patent. Except as expressly admitted, Lupin denies each and every allegation in Paragraph 2 of the Complaint.

3. Lupin admits that Januvia® is the reference listed drug for Lupin Ltd.’s ANDA No. 214433. Except as expressly admitted, Lupin denies each and every allegation in Paragraph 3 of the Complaint.

4. Lupin admits that Lupin Ltd. sent a letter dated May 27, 2020 to Plaintiff entitled “Notice of Paragraph IV Certification Regarding NDA 202270 (50 mg Sitagliptin Phosphate/500 mg Metformin HCl; 50 mg Sitagliptin Phosphate/1000 mg Metformin HCl; 100 mg Sitagliptin Phosphate/1000 mg Metformin HCl) with respect to U.S. Patent No. 7,326,708” (“Lupin Ltd.’s ’399 Notice Letter”). Lupin admits that Lupin Ltd. submitted ANDA No. 214399 to the FDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of drug products containing metformin hydrochloride and sitagliptin phosphate prior to the expiration of the ’708 patent. Except as expressly admitted, Lupin denies each and every allegation in Paragraph 4 of the Complaint.

5. Lupin admits that Janumet XR® is the reference listed drug for Lupin Ltd.'s ANDA No. 214399. Except as expressly admitted, Lupin denies each and every allegation in Paragraph 5 of the Complaint.

6. Paragraph 6 of the Complaint does not contain any allegations, and thus no response is required. To the extent a response is required, Lupin collectively refers herein to Lupin Ltd.'s '433 Notice Letter and Lupin Ltd.'s '399 Notice Letter as "Lupin Ltd.'s Notice Letters"; Lupin Ltd.'s ANDA Nos. 214433 and 214399 as "Lupin Ltd.'s ANDAs"; and the drug products described in Lupin Ltd.'s ANDAs as "Lupin Ltd.'s ANDA Products." Except as expressly admitted, Lupin denies each and every allegation in Paragraph 6 of the Complaint.

#### **PARTIES<sup>1</sup>**

7. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 7 of the Complaint and, therefore, denies each and every allegation in Paragraph 7.

8. Lupin admits that the FDA lists "Merck Sharp Dohme Corp." as the holder of NDA No. 021995 for Januvia®. Except as expressly admitted, Lupin denies each and every remaining allegation in Paragraph 8 of the Complaint.

9. Lupin admits that the FDA lists "Merck Sharp Dohme Corp." as the holder of NDA No. 202270 for Janumet XR®. Except as expressly admitted, Lupin denies each and every remaining allegation in Paragraph 9 of the Complaint.

10. Lupin admits that Lupin Ltd. is a corporation organized and existing under the laws of India, with a registered office at 3<sup>rd</sup> Floor, Kalpataru Inspire, Off. Western Expressway

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<sup>1</sup> For the Court's convenience, Lupin has incorporated the section titles that appear in the Complaint. Lupin does not necessarily agree with the characterizations of such section titles and does not waive any right to object to those characterizations.

Highway, Santacruz (East), Mumbai 400 055, India. Lupin admits that Lupin Ltd. develops and manufactures generic pharmaceutical products. Except as expressly admitted, Lupin denies each and every remaining allegation in Paragraph 10 of the Complaint.

11. Lupin admits that LPI is a corporation organized and existing under the laws of Delaware and has its principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Lupin admits that LPI sells and distributes generic pharmaceutical drug products in the United States. Lupin denies that LPI is a proper party to this action. Except as expressly admitted, Lupin denies each and every remaining allegation in Paragraph 11 of the Complaint.

12. Lupin admits that LPI is an indirect wholly-owned subsidiary of Lupin Ltd. Lupin admits that the Complaint purports to refer to Lupin Ltd. and LPI collectively as "Lupin." Except as expressly admitted, Lupin denies each and every remaining allegation in Paragraph 12 of the Complaint.

13. Lupin admits that Lupin Ltd. submitted Lupin's ANDAs to the FDA. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 13 of the Complaint.

14. Lupin admits that Lupin Ltd. submitted Lupin Ltd.'s ANDAs to the FDA, seeking approval of the drug products described therein in the United States. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 14 of the Complaint.

15. Lupin admits that Lupin Ltd. submitted Lupin Ltd.'s ANDAs to the FDA, seeking approval of the drug products described therein in the United States. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 15 of the Complaint.

**JURISDICTION**

16. Paragraph 16 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) solely for the claims directed against Lupin Ltd. under 35 U.S.C. § 271(e)(2). Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 16 of the Complaint.

17. Paragraph 17 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin does not contest personal jurisdiction in this Court for the purposes of this civil action only. Lupin further denies that LPI is a proper party to this action. Except as expressly admitted, Lupin denies each and every allegation contained in Paragraph 17 of the Complaint.

18. Paragraph 18 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin does not contest personal jurisdiction in this Court for the purposes of this civil action only. Lupin further denies that LPI is a proper party to this action. Lupin admits that Lupin Ltd. develops and manufactures generic pharmaceutical products. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 18 of the Complaint.

19. Paragraph 19 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin does not contest personal jurisdiction in this Court for the purposes of this civil action only. Lupin further denies that LPI is a proper party to this action. Lupin admits that LPI is a corporation organized and existing under the laws of Delaware and has appointed a registered agent for service of process in Delaware. Lupin further admits that LPI sells and distributes generic pharmaceutical drug products in the United States.

Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 19 of the Complaint.

20. Paragraph 20 contains legal conclusions to which no answer is required. For the purposes of this case only, Lupin does not contest personal jurisdiction in this Court. To the extent an answer is required, Lupin admits that at least one of Lupin Ltd. and LPI was a named defendant in each of the following actions: *Merck Sharp & Dohme Corp. v. Lupin Limited and Lupin Pharmaceuticals, Inc.*, Case No. 19-347-RGA (D. Del.); *Anacor Pharm., Inc. v. Lupin Ltd.*, No. 18-1606-RGA (D. Del.); *H. Lundbeck A/S v. Lupin Ltd.*, No. 18-777-LPS (D. Del.); *Bial-Portela & CA S.A. v. Lupin Ltd.*, No. 18-312-CFC (D. Del.); *Bayer Intellectual Prop. GmbH v. Lupin Ltd.*, No. 17-1047-RGA (D. Del.); *ViiV Healthcare Co. v. Lupin Ltd.*, No. 17-1576-MSG-RL (D. Del.); *Astellas Pharma Inc. v. Lupin Ltd.*, No. 16-908-JFB-CJB (D. Del.); *Arena Pharms., Inc. v. Lupin Ltd.*, No. 16-887-RGA (D. Del.). Lupin further denies that LPI is a proper party to this action. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 20 of the Complaint.

21. Lupin admits that LPI sells and distributes generic pharmaceutical drug products in the United States. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 21 of the Complaint.

22. Lupin admits that Lupin Ltd. develops and manufactures generic pharmaceutical products for the U.S. market and that Lupin Ltd. therefrom derives some of its revenue. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 22 of the Complaint.

**VENUE**

23. Lupin restates and incorporates by reference its responses to Paragraphs 1-22 of this Answer as if fully set forth herein.

24. Paragraph 24 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin does not contest venue in this Court for the purposes of this civil action only. Lupin admits that Lupin Ltd. is a corporation organized and existing under the laws of India. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 24 of the Complaint.

25. Paragraph 25 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin does not contest venue in this Court for the purposes of this civil action only. Lupin admits that LPI is a corporation organized and existing under the laws of Delaware. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 25 of the Complaint.

**THE '708 PATENT**

26. Lupin restates and incorporates by reference its responses to Paragraphs 1-25 of this Answer as if fully set forth herein.

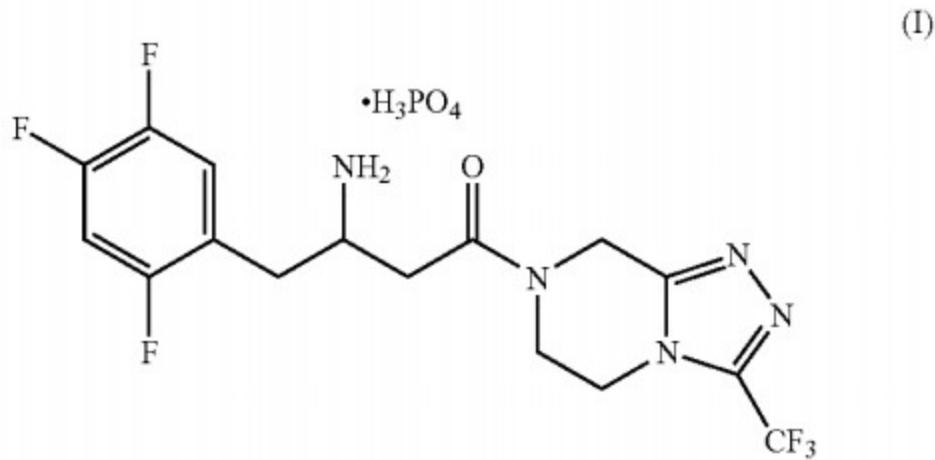
27. Lupin admits that, according to the face of the '708 patent, the inventors named on the '708 patent are Stephen Howard Cypes, Alex Minhua Chen, Russell R. Ferlita, Karl Hansen, Ivan Lee, Vicky K. Vydra, and Robert M. Wenslow, Jr. (collectively, "the Named Inventors"). Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 27 of the Complaint.

28. Lupin admits that, according to the face of the '708 patent, the '708 patent is entitled "Phosphoric Acid Salt of a Dipeptidyl Peptidase-IV Inhibitor" and issued on February 5, 2008, to

Merck & Co., Inc., as assignee of the Named Inventors. Lupin admits that what purports to be a copy of the '708 patent is attached to the Complaint as Exhibit A. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 28 of the Complaint.

29. Paragraph 29 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the records of the U.S. Patent and Trademark Office identify "Merck Sharp & Dohme Corp." as the purported assignee of the '708 patent. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 29 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 29.

30. Lupin admits that Claim 1 of the '708 patent recites: "A dihydrogenphosphate salt of 4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazine-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine of structural formula I:



or a hydrate thereof." Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 30 of the Complaint.

31. Paragraph 31 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the '708 patent has been listed in

connection with JANUVIA® in the 40th edition of FDA's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (2020) ("Orange Book"). Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 31 of the Complaint.

32. Paragraph 32 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the '708 patent has been listed in connection with JANUMET XR® in the Orange Book. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 32 of the Complaint.

**COUNT I – INFRINGEMENT OF THE '708 PATENT  
(LUPIN'S '433 ANDA PRODUCT)**

33. Lupin restates and incorporates by reference its responses to Paragraphs 1-32 of this Answer as if fully set forth herein.

34. Lupin admits that, in Lupin Ltd.'s '433 Notice Letter, Lupin Ltd. notified Plaintiff of the submission of Lupin Ltd.'s ANDA No. 214433 to the FDA. Lupin admits that Lupin Ltd.'s ANDA No. 214433 seeks approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, importation, offer for sale, or sale of the product described therein prior to the expiration of the '708 patent. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 34 of the Complaint.

35. Lupin admits that Lupin Ltd.'s '433 Notice Letter states that Lupin Ltd.'s "ANDA No. 214433 includes a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV, with respect to the '708 patent, indicating that in the opinion of Lupin and to the best of its knowledge, no valid, enforceable claim of this patent will be infringed by the manufacture, importation, use, sale, or offer for sale of the drug product for which ANDA No. 214433 has been submitted."

Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 35 of the Complaint.

36. Lupin admits that Lupin Ltd.'s '433 Notice Letter states that Lupin Ltd.'s '433 ANDA Product contains sitagliptin phosphate as an active ingredient. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 36 of the Complaint.

37. Lupin denies each and every allegation contained in Paragraph 37 of the Complaint.

38. Lupin admits that Lupin Ltd.'s '433 Notice Letter states that each claim of the '708 patent is invalid. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 38 of the Complaint.

39. Lupin denies each and every allegation contained in Paragraph 39 of the Complaint.

40. Lupin admits that Lupin Ltd. submitted ANDA No. 214433 to the FDA, seeking approval to market the drug product described therein in the United States. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 40 of the Complaint.

41. Lupin denies each and every allegation contained in Paragraph 41 of the Complaint.

42. Lupin denies each and every allegation contained in Paragraph 42 of the Complaint.

43. Lupin denies each and every allegation contained in Paragraph 43 of the Complaint.

44. Lupin denies each and every allegation contained in Paragraph 44 of the Complaint.

45. Lupin admits that Lupin Ltd. submitted ANDA No. 214433 to the FDA, seeking approval to market the drug product described therein in the United States. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 45 of the Complaint.

46. Lupin denies each and every allegation contained in Paragraph 46 of the Complaint.
47. Lupin denies each and every allegation contained in Paragraph 47 of the Complaint.
48. Lupin denies each and every allegation contained in Paragraph 48 of the Complaint.
49. Lupin denies each and every allegation contained in Paragraph 49 of the Complaint.

**COUNT II – DECLARATORY JUDGMENT  
OF INFRINGEMENT OF THE '708 PATENT  
(LUPIN'S '433 ANDA PRODUCT)**

50. Lupin restates and incorporates by reference its responses to Paragraphs 1-49 of this Answer as if fully set forth herein.

51. Paragraph 51 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the Complaint purports to state a declaratory judgment claim arising under 28 U.S.C. §§ 2201 and 2202. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 51 of the Complaint.

52. Lupin denies each and every allegation contained in Paragraph 52 of the Complaint.

**COUNT III – INFRINGEMENT OF THE 708 PATENT  
(LUPIN'S '399 ANDA PRODUCT)**

53. Lupin restates and incorporates by reference its responses to Paragraphs 1-52 of this Answer as if fully set forth herein.

54. Lupin admits that, in Lupin Ltd.'s '399 Notice Letter, Lupin Ltd. notified Plaintiff of the submission of Lupin Ltd.'s ANDA No. 214399 to the FDA. Lupin admits that Lupin Ltd.'s ANDA No. 214399 seeks approval under the FDCA to engage in the commercial manufacture, use, importation, offer for sale, or sale of the product described therein prior to the expiration of the '708 patent. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 54 of the Complaint.

55. Lupin admits that Lupin Ltd.'s '399 Notice Letter states that Lupin Ltd.'s "ANDA No. 214399 includes a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV, with respect to the '708 patent, indicating that in the opinion of Lupin and to the best of its knowledge, no valid, enforceable claim of this patent will be infringed by the manufacture, importation, use, sale, or offer for sale of the drug product for which ANDA No. 214399 has been submitted." Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 55 of the Complaint.

56. Lupin admits that Lupin Ltd.'s '399 Notice Letter states that Lupin's ANDA Product contains sitagliptin phosphate as an active ingredient. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 56 of the Complaint.

57. Lupin denies each and every allegation contained in Paragraph 57 of the Complaint.

58. Lupin admits that Lupin Ltd.'s '399 Notice Letter states that each claim of the '708 patent is invalid. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 58 of the Complaint.

59. Lupin denies each and every allegation contained in Paragraph 59 of the Complaint.

60. Lupin admits that Lupin Ltd. submitted ANDA No. 214399 to the FDA, seeking approval to market the drug product described therein in the United States. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 60 of the Complaint.

61. Lupin denies each and every allegation contained in Paragraph 61 of the Complaint.

62. Lupin denies each and every allegation contained in Paragraph 62 of the Complaint.

63. Lupin denies each and every allegation contained in Paragraph 63 of the Complaint.

64. Lupin denies each and every allegation contained in Paragraph 64 of the Complaint.

65. Lupin admits that Lupin Ltd. submitted ANDA No. 214399 to the FDA, seeking approval to market the drug product described therein in the United States. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 65 of the Complaint.

66. Lupin denies each and every allegation contained in Paragraph 66 of the Complaint.

67. Lupin denies each and every allegation contained in Paragraph 67 of the Complaint.

68. Lupin denies each and every allegation contained in Paragraph 68 of the Complaint.

69. Lupin denies each and every allegation contained in Paragraph 69 of the Complaint.

**COUNT VI – DECLARATORY JUDGMENT  
OF INFRINGEMENT OF THE '708 PATENT  
(LUPIN'S '399 ANDA PRODUCT)**

70. Lupin restates and incorporates by reference its responses to Paragraphs 1-69 of this Answer as if fully set forth herein.

71. Paragraph 71 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the Complaint purports to state a declaratory judgment claim arising under 28 U.S.C. §§ 2201 and 2202. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 71 of the Complaint.

72. Lupin denies each and every allegation contained in Paragraph 72 of the Complaint.

**RESPONSE TO PRAYER FOR RELIEF**

Lupin denies all allegations not specifically admitted herein, and further denies that Plaintiffs are entitled to the judgment and relief requested in Paragraphs (a)-(g) of the Complaint or to any other relief.

## **DEFENSES**

Without prejudice to the denials set forth in its responses to Paragraphs 1 through 72 of the Complaint, and without undertaking any of the burdens imposed by law on the Plaintiffs, Lupin avers and asserts the following separate defenses to the Complaint. Lupin expressly reserves the right to allege additional defenses as they become known through the course of discovery.

### **FIRST AFFIRMATIVE DEFENSE**

(Failure to State a Claim)

Plaintiff has failed to state a claim for which relief can be granted because, *inter alia*, LPI has not committed an act of infringement as prescribed in 35 U.S.C. § 271(e)(2).

### **SECOND AFFIRMATIVE DEFENSE**

(Lack of Subject Matter Jurisdiction)

This Court lacks subject matter jurisdiction over any and all claims asserted against LPI.

### **THIRD AFFIRMATIVE DEFENSE**

(Non-Infringement)

The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable claim of the '708 patent.

### **FOURTH AFFIRMATIVE DEFENSE**

(Invalidity)

One or more claims of the '708 patent is invalid for failure to comply with one or more of the conditions set forth in Title 35 of the United States Code, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112 and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patents and/or the defenses recognized in 35 U.S.C. § 282.

**FIFTH AFFIRMATIVE DEFENSE**  
(Failure to State a Claim for Exceptional Case)

To the extent the Complaint purports to seek an “exceptional case” determination, the Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285 and/or 35 U.S.C. § 271(e)(4). Moreover, Lupin’s actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

**SIXTH AFFIRMATIVE DEFENSE**  
(Improper Party)

LPI is not a proper party to this action.

**SEVENTH AFFIRMATIVE DEFENSE**  
(Additional Defenses)

Lupin reserves the right to present any additional defenses or counterclaims that discovery may reveal.

**COUNTERCLAIMS**

Defendant/Counterclaimant Lupin Limited (“Lupin Ltd.”) brings the following Counterclaims against Plaintiff/Counterdefendant Merck Sharp & Dohme Corp. (“Merck”) for a declaratory judgment that U.S. Patent No. 7,326,708 (“the ’708 patent”) is invalid and/or not infringed by the manufacture, use, sale, offer for sale, or importation of the sitagliptin products described in Lupin Ltd.’s ANDA No. 214433 (“Lupin Ltd.’s ANDA No. 214433 Product”) and Lupin Ltd.’s ANDA No. 214399 (“Lupin Ltd.’s ANDA No. 214399 Products”) (collectively, “Lupin Ltd.’s ANDA Products”).

**PARTIES**

1. Lupin Ltd. is a corporation organized and existing under the laws of India, having a registered office at 3<sup>rd</sup> Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

2. On information and belief, and based on Merck's allegations, Merck is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

**JURISDICTION AND VENUE**

3. Lupin Ltd. seeks a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

4. The Court has jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and 35 U.S.C. § 271(e)(2).

5. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b), and by Merck's choice of forum.

6. This is an action based upon an actual controversy between the parties concerning the invalidity and/or non-infringement of the '708 patent and Lupin Ltd.'s right to continue to seek approval of ANDA Nos. 214433 and 214399 ("Lupin Ltd.'s ANDAs") for Lupin Ltd.'s ANDA Products.

7. Lupin Ltd. has been and presently is engaged in the submission of documents to the United States Food and Drug Administration ("FDA"), and those documents seek approval to engage in the commercial manufacture, importation, use, offer for sale, or sale of Lupin Ltd.'s ANDA Products. Merck has alleged that the submission of Lupin Ltd.'s ANDAs infringe, will infringe, will induce infringement, or will contribute to infringement of one or more claims of the '708 patent.

8. Merck has filed in this Court an infringement action to enforce the '708 patent against Lupin.

9. On information and belief, and according to Merck's allegations, Merck is the assignee of the '708 patent.

10. On information and belief, and according to Merck's allegations, Merck holds New Drug Application ("NDA") No. 021995 for Januvia® (sitagliptin phosphate) and NDA No. 202270 for Janumet XR® (metformin hydrochloride; sitagliptin phosphate).

11. Lupin Ltd. has denied that it has, continues to, or will infringe, induce infringement of, and/or contribute to the infringement of, any valid and enforceable claim of the '708 patent.

12. Lupin Ltd. has further asserted that the '708 patent is invalid for failure to satisfy one or more of the provisions of Title 35 of the United States Code, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent, and the defenses recognized in 35 U.S.C. § 282.

13. The '708 patent is listed in the 40th edition of FDA's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (2020) ("Orange Book") with respect to Januvia® and Janumet XR®.

14. Lupin Ltd.'s ANDA Nos. 214433 and 214399 include a certification under the Federal Food, Drug, and Cosmetic Act ("FDCA") Section 505(J)(2)(A)(vii)(IV), with respect to the '708 patent, that no valid, enforceable claim of the patent will be infringed by the manufacture, importation, use, sale, or offer for sale of the drug products for which ANDA Nos. 214433 and 214399 have been submitted. On April 27, 2020 and May 27, 2020, pursuant to Section 505(j)(2)(B) of the FDCA, Lupin Ltd. provided written notification to Merck ("Lupin Ltd.'s Notice Letters") that Lupin Ltd. filed ANDA Nos. 214433 and 214399 with the FDA containing certifications pursuant to FDCA Section 505(j)(2)(A)(vii)(IV) that the '708 patent is invalid and/or would not be infringed by Lupin Ltd.'s ANDA Products. Lupin Ltd.'s Notice Letters were accompanied by offers of confidential access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc). On

information and belief, and according to Merck's allegations, Merck received Lupin Ltd.'s Notice Letters dated April 27, 2020 and May 27, 2020.

15. In view of the foregoing, a conflict of asserted rights has arisen between Lupin Ltd. and Merck with respect to the non-infringement and invalidity of the relevant claims of the '708 patent, and as to Lupin Ltd.'s right to obtain FDA approval to engage in the commercial manufacture, importation, use, offer for sale, or sale of Lupin Ltd.'s ANDA Products. An actual controversy therefore exists between Merck and Lupin Ltd.

**FIRST COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT**

**(ANDA NO. 214433)**

**(U.S. PATENT NO. 7,326,708)**

16. Lupin Ltd. realleges Paragraphs 1-15 as though fully set forth herein.

17. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA No. 214433 Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable claim of the '708 patent.

18. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA No. 214433 Product does not, and would not if marketed, infringe any valid and enforceable claim of the '708 patent.

**SECOND COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT**

**(ANDA NO. 214399)**

**(U.S. PATENT NO. 7,326,708)**

19. Lupin Ltd. realleges Paragraphs 1-18 as though fully set forth herein.

20. The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA No. 214399 Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable claim of the '708 patent.

21. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin Ltd.'s ANDA No. 214399 Product does not, and would not if marketed, infringe any valid and enforceable claim of the '708 patent.

**THIRD COUNTERCLAIM – DECLARATION OF INVALIDITY**

**(U.S. PATENT NO. 7,326,708)**

22. Lupin Ltd. realleges Paragraphs 1-19 as though fully set forth herein.

23. The claims of the '708 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282. For at least the reasons explained in Lupin Ltd.'s Notice Letters, each of the claims of the '708 patent is invalid at least under 35 U.S.C. § 103 in view of the prior art, including but not limited to Bastin, R. et al., "Salt Selection and Optimisation Procedures for Pharmaceutical New Chemical Entities," 4 ORGANIC PROCESS RES. & DEV. 427-435 (2000) ("Bastin"); Brittain, Polymorphism in Pharmaceutical Solids, Chapter 5, pp. 183-219, "Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids," 1999 ("Brittain"); Byrn, S. et al., "Pharmaceutical Solids: A Strategic Approach to Regulatory Considerations," 12 ORGANIC PROCESS RES. & DEV. 945-954 (1995) ("Byrn"); International Application Publication No. WO03/004498 ("Edmonson I"); U.S. Publication No. 2003/0144510

(“Gala”); Solomons, Organic Chemistry, 6<sup>th</sup> Ed., Chapter 3, pp. 87-118, “An Introduction to Organic Reactions: Acids and Bases,” 1996 (“Solomons”); and/or U.S. Patent No. 6,699,871 (“Edmonson II”).

24. Lupin Ltd. is entitled to a judicial declaration that the claims of the ’708 patent are invalid.

**DEMAND FOR JUDGMENT**

WHEREFORE, Lupin Ltd. prays for the following relief:

- A. That the Court order the Complaint dismissed with prejudice and judgment be entered in favor of Lupin Ltd.;
- B. That a judgment be entered declaring that the manufacture, import, use, sale, and/or offer to sell Lupin Ltd.’s ANDA Products, 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, enforceable claim of the ’708 patent;
- C. That a judgment be entered declaring the claims of the ’708 patent invalid;
- D. That the Court declare that Lupin Ltd. has the lawful right to manufacture, import, use, sell, and/or offer to sell Lupin Ltd.’s ANDA Products in the United States once the products are approved by the FDA;
- E. That Merck and its agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Lupin Ltd. or any of its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Lupin Ltd., or charging any of them either orally or in writing with infringement of the ’708 patent;

F. That a judgment be entered, declaring that this action is an exceptional case within the meaning of 35 U.S.C. § 285 and that Lupin Ltd. is therefore entitled to recover its reasonable attorneys' fees upon prevailing in this action;

G. That Lupin Ltd. be awarded costs, attorney's fees, and other relief, both legal and equitable, to which it may be justly entitled; and

H. That Lupin Ltd. be awarded such other and further relief as is just and proper.

*Of Counsel*

William R. Zimmerman  
Jonathan E. Bachand  
Andrea L. Cheek  
KNOBBE, MARTENS, OLSON & BEAR,  
LLP  
1717 Pennsylvania Ave. N.W., Ste. 900  
Washington D.C. 20006  
Tel: (202) 640-6400  
Fax: (202) 640-6401  
[Bill.Zimmerman@knobbe.com](mailto:Bill.Zimmerman@knobbe.com)  
[Jonathan.Bachand@knobbe.com](mailto:Jonathan.Bachand@knobbe.com)  
[Andrea.Cheek@knobbe.com](mailto:Andrea.Cheek@knobbe.com)

*/s/ Frederick L. Cottrell, III*

Frederick L. Cottrell, III (#2555)  
Alexandra M. Ewing (#6407)  
RICHARDS, LAYTON & FINGER, P.A.  
920 N. King Street  
Wilmington, DE 19801  
Tel: (302) 651-7700  
[Cottrell@rlf.com](mailto:Cottrell@rlf.com)  
[Ewing@rlf.com](mailto:Ewing@rlf.com)

*Attorneys for Defendant/Counterclaimant  
Lupin Limited and Defendant Lupin  
Pharmaceuticals, Inc.*

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