IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., *Plaintiff,* v. LUPIN LIMITED, and LUPIN PHARMACEUTICALS, INC., *Defendants*.	C.A. No. _____

COMPLAINT

Plaintiff Merck Sharp & Dohme Corp. ("Merck"), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, 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, that arises out of defendants' submission of Abbreviated New Drug Application ("ANDA") Nos. 214433 and 214339 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a version of JANUVIA® (sitagliptin phosphate) and JANUMET XR® (metformin hydrochloride; sitagliptin phosphate extended release tablets) prior to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent").

2. Lupin Limited notified Merck by letter dated April 27, 2020 ("Lupin's '433 Notice Letter") that it had submitted to the FDA ANDA No. 214433 ("Lupin's '433 ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale,

sale, and/or importation of generic sitagliptin phosphate oral tablets ("Lupin's '433 ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, Lupin's '433 ANDA Product is a generic version of Merck's JANUVIA®.

4. Lupin Limited notified Merck by letter dated May 27, 2020 ("Lupin's '339 Notice Letter") that it had submitted to the FDA ANDA No. 214339 ("Lupin's '339 ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic metformin hydrochloride and sitagliptin phosphate extended release oral tablets ("Lupin's '339 ANDA Product") prior to the expiration of the '708 patent.

5. On information and belief, Lupin's '339 ANDA Product is a generic version of Merck's JANUMET XR® product.

6. Lupin's '433 Notice Letter and Lupin's '339 Notice Letter are collectively referred to herein as "Lupin's Notice Letters." Lupin's '433 ANDA and Lupin's '339 ANDA are collectively referred to herein as "Lupin's ANDAs." Lupin's '433 ANDA Product and Lupin's '339 ANDA Product are collectively referred to herein as "Lupin's ANDA Products."

PARTIES

7. Plaintiff Merck is a corporation organized and existing under the laws of New Jersey, having its corporate offices and principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

8. Merck is the holder of NDA No. 021995 for JANUVIA® (sitagliptin phosphate), which has been approved by the FDA.

9. Merck is the holder of NDA No. 202270 for JANUMET XR® (metformin hydrochloride; sitagliptin phosphate extended release tablets), which has been approved by the FDA.

10. On information and belief, defendant Lupin Limited ("Lupin Ltd.") is a corporation organized and existing under the laws of India, with a principal place of business of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India. Upon information and belief, Lupin Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Lupin Pharmaceuticals, Inc.

11. On information and belief, defendant Lupin Pharmaceuticals, Inc. ("Lupin Pharma") is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. On information and belief, Lupin Pharma is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market.

12. On information and belief, Lupin Pharma is a wholly owned subsidiary of Lupin Ltd. Lupin Ltd. and Lupin Pharma are collectively referred to herein as "Lupin."

13. On information and belief, Lupin Ltd. and Lupin Pharma acted in concert to prepare and submit Lupin's ANDAs to the FDA.

14. On information and belief, Lupin Ltd. and Lupin Pharma know and intend that upon approval of Lupin's ANDAs, Lupin will manufacture, market, sell, and distribute Lupin's ANDA Products throughout the United States, including in Delaware. On information and belief, Lupin Ltd. and Lupin Pharma are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Lupin's ANDA Products, and enter into agreements that are nearer than arm's length. On information and belief, Lupin

Ltd. and Lupin Pharma participated, assisted, and cooperated in carrying out the acts complained of herein.

15. On information and belief, following any FDA approval of Lupin's ANDAs, Lupin Ltd. and Lupin Pharma will act in concert to distribute and sell Lupin's ANDA Products throughout the United States, including within Delaware.

JURISDICTION

16. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

17. This Court has personal jurisdiction over Lupin.

18. Lupin Ltd. is subject to personal jurisdiction in Delaware because, among other things, Lupin Ltd., itself and through its wholly owned subsidiary Lupin Pharma, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Ltd., itself and through its wholly owned subsidiary Lupin Pharma, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Lupin Ltd. is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Lupin Pharma and therefore the activities of Lupin Pharma in this jurisdiction are attributed to Lupin Ltd.

19. Lupin Pharma is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Lupin Pharma is a corporation organized and existing under the laws of the State of Delaware, is qualified to do

business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Lupin Pharma develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

20. In addition, this Court has personal jurisdiction over Lupin because Lupin Ltd. and Lupin Pharma regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court, including regarding the '708 patent. *See Merck Sharp & Dohme Corp. v. Lupin Limited and Lupin Pharmaceuticals, Inc.*, Case No. 19-347-RGA (D. Del. Feb. 19, 2019) (Lupin Ltd. and Lupin Pharma); *see also Anacor Pharm., Inc. v. Lupin Ltd.*, No. 18-1606-RGA, D.I. 16 (D. Del. Nov. 8, 2018) (Lupin Ltd.); *H. Lundbeck A/S v. Lupin Ltd.*, No. 18-777-LPS, D.I. 11 (D. Del. Jun. 12, 2018) (Lupin Ltd.); *Bial-Portela & CA S.A. v. Lupin Ltd.*, No. 18-312-VAC-MPT, D.I. 8 (D. Del. Apr. 18, 2018) (Lupin Ltd.); *Bayer Intellectual Prop. GmbH v. Lupin Ltd.*, No. 17-1047-RGA, D.I. 9 (D. Del. Aug. 22, 2017) (Lupin Ltd. and Lupin Pharma); *ViiV Healthcare Co. v. Lupin Ltd.*, 17-1576-VAC-CJB, D.I. 17 (D. Del. Dec. 19, 2017) (Lupin Ltd. and Lupin Pharma); *Astellas Pharma Inc. v. Lupin Ltd.*, No. 16-908, D.I. 20 (D. Del. Jan. 17, 2017) (Lupin Ltd. and Lupin Pharma); *Arena Pharm., Inc. v. Lupin Ltd.*, No. 16-887, D.I. 12 (D. Del. Jan. 11, 2017) (Lupin Ltd. and Lupin Pharma).

21. On information and belief, if Lupin's ANDAs are approved, Lupin will manufacture, market, sell, and/or distribute Lupin's ANDA Products within the United States,

including in Delaware, consistent with Lupin's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Lupin regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. On information and belief, Lupin's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Lupin's ANDA Products will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Merck's patent in the event that Lupin's ANDA Products are approved before the patent expires.

22. On information and belief, Lupin derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Lupin and/or for which Lupin Ltd. and/or Lupin Pharma is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which Lupin Ltd. and/or Lupin Pharma is/are the named applicant(s) on approved ANDAs are available at retail pharmacies in Delaware.

VENUE

23. Merck incorporates each of the preceding paragraphs 1–22 as if fully set forth herein.

24. Venue is proper in this district as to Lupin Ltd. under 28 U.S.C. § 1391 because Lupin Ltd. is a corporation organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

25. Venue is proper in this district as to Lupin Pharma under 28 U.S.C. § 1400(b) because Lupin Pharma is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

THE '708 PATENT

26. Merck incorporates each of the preceding paragraphs 1–25 as if fully set forth herein.

27. 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.

28. The '708 patent, entitled "Phosphoric Acid Salt of a Dipeptidyl Peptidase-IV Inhibitor" (attached as Exhibit A), was duly and legally issued on February 5, 2008.

29. Merck is the owner and assignee of the '708 patent.

30. The '708 patent claims, *inter alia*, a dihydrogenphosphate salt of 4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine of structural formula I, or a hydrate thereof, as recited in claim 1 of the '708 patent.

31. JANUVIA®, as well as methods of using JANUVIA®, are covered by one or more claims of the '708 patent, including claim 1 of the '708 patent, and the '708 patent has been listed in connection with JANUVIA® in the FDA's Orange Book.

32. JANUMET XR®, as well as methods of using JANUMET XR®, are covered by one or more claims of the '708 patent, including claim 1 of the '708 patent, and the '708 patent has been listed in connection with JANUMET XR® in the FDA's Orange Book.

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

33. Merck incorporates each of the preceding paragraphs 1–32 as if fully set forth herein.

34. In Lupin's '433 Notice Letter, Lupin notified Merck of the submission of Lupin's '433 ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Lupin's '433 ANDA Product prior to the expiration of the '708 patent.

35. In Lupin's '433 Notice Letter, Lupin also notified Merck that, as part of its ANDA, Lupin had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '708 patent. On information and belief, Lupin submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '708 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Lupin's '433 ANDA Product.

36. In Lupin's '433 Notice Letter, Lupin stated that Lupin's '433 ANDA Product contains sitagliptin phosphate as an active ingredient.

37. Lupin's '433 ANDA Product, and the use of Lupin's '433 ANDA Product, are covered by one or more claims of the '708 patent, including at least claim 1 of the '708 patent, because claim 1 of the '708 patent covers the sitagliptin phosphate contained in Lupin's '433 ANDA Product.

38. In Lupin's '433 Notice Letter, Lupin did not contest infringement of claim 1 of the '708 patent.

39. Lupin's submission of its '433 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's '433 ANDA Product before the expiration of the '708 patent was an act of infringement of the '708 patent under 35 U.S.C. § 271(e)(2)(A).

40. On information and belief, Lupin will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Lupin's '433 ANDA Product immediately and imminently upon approval of its ANDA.

41. The manufacture, use, sale, offer for sale, or importation of Lupin's '433 ANDA Product would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

42. On information and belief, the manufacture, use, sale, offer for sale, or importation of Lupin's '433 ANDA Product in accordance with, and as directed by its proposed product labeling would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

43. On information and belief, Lupin plans and intends to, and will, actively induce infringement of the '708 patent when Lupin's '433 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Lupin's activities will be done with knowledge of the '708 patent and specific intent to infringe that patent.

44. On information and belief, Lupin knows that Lupin's '433 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '708 patent, that Lupin's '433 ANDA Product is not a staple article or commodity of commerce, and that Lupin's '433 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use.

On information and belief, Lupin plans and intends to, and will, contribute to infringement of the ’708 patent immediately and imminently upon approval of Lupin’s ’433 ANDA.

45. Notwithstanding Lupin’s knowledge of the claims of the ’708 patent, Lupin has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Lupin’s ’433 ANDA Product with its product labeling following FDA approval of Lupin’s ’433 ANDA prior to the expiration of the ’708 patent.

46. The foregoing actions by Lupin constitute and/or will constitute infringement of the ’708 patent; active inducement of infringement of the ’708 patent; and contribution to the infringement by others of the ’708 patent.

47. On information and belief, Lupin has acted with full knowledge of the ’708 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’708 patent; active inducement of infringement of the ’708 patent; and/or contribution to the infringement by others of the ’708 patent.

48. Merck will be substantially and irreparably damaged by infringement of the ’708 patent.

49. Unless Lupin is enjoined from infringing the ’708 patent, actively inducing infringement of the ’708 patent, and contributing to the infringement by others of the ’708 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.

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

50. Merck incorporates each of the preceding paragraphs 1–49 as if fully set forth herein.

51. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Lupin on the other regarding Lupin's infringement, active inducement of infringement, and contribution to the infringement by others of the '708 patent.

52. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Lupin's '433 ANDA Product with its proposed labeling, or any other Lupin drug product that is covered by or whose use is covered by the '708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '708 patent, and that the claims of the '708 patent are valid.

COUNT III – INFRINGEMENT OF THE '708 PATENT (LUPIN'S '339 ANDA PRODUCT)

53. Merck incorporates each of the preceding paragraphs 1–52 as if fully set forth herein.

54. In Lupin's '339 Notice Letter, Lupin notified Merck of the submission of Lupin's '339 ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Lupin's '339 ANDA Product prior to the expiration of the '708 patent.

55. In Lupin's '339 Notice Letter, Lupin also notified Merck that, as part of its ANDA, Lupin had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '708 patent. On information and belief, Lupin submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '708 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Lupin's '339 ANDA Product.

56. In Lupin's '339 Notice Letter, Lupin stated that Lupin's '339 ANDA Product contains sitagliptin phosphate as an active ingredient.

57. Lupin's '339 ANDA Product, and the use of Lupin's '339 ANDA Product, are covered by one or more claims of the '708 patent, including at least claim 1 of the '708 patent, because claim 1 of the '708 patent covers the sitagliptin phosphate contained in Lupin's '339 ANDA Product.

58. In Lupin's '339 Notice Letter, Lupin did not contest infringement of claim 1 of the '708 patent.

59. Lupin's submission of its '339 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's '339 ANDA Product before the expiration of the '708 patent was an act of infringement of the '708 patent under 35 U.S.C. § 271(e)(2)(A).

60. On information and belief, Lupin will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Lupin's '339 ANDA Product immediately and imminently upon approval of its ANDA.

61. The manufacture, use, sale, offer for sale, or importation of Lupin's '339 ANDA Product would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

62. On information and belief, the manufacture, use, sale, offer for sale, or importation of Lupin's '339 ANDA Product in accordance with, and as directed by its proposed product labeling would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

63. On information and belief, Lupin plans and intends to, and will, actively induce infringement of the ’708 patent when Lupin’s ’339 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Lupin’s activities will be done with knowledge of the ’708 patent and specific intent to infringe that patent.

64. On information and belief, Lupin knows that Lupin’s ’339 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’708 patent, that Lupin’s ’339 ANDA Product is not a staple article or commodity of commerce, and that Lupin’s ’339 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Lupin plans and intends to, and will, contribute to infringement of the ’708 patent immediately and imminently upon approval of Lupin’s ’339 ANDA.

65. Notwithstanding Lupin’s knowledge of the claims of the ’708 patent, Lupin has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Lupin’s ’339 ANDA Product with its product labeling following FDA approval of Lupin’s ’339 ANDA prior to the expiration of the ’708 patent.

66. The foregoing actions by Lupin constitute and/or will constitute infringement of the ’708 patent; active inducement of infringement of the ’708 patent; and contribution to the infringement by others of the ’708 patent.

67. On information and belief, Lupin has acted with full knowledge of the ’708 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’708 patent; active inducement of infringement of the ’708 patent; and/or contribution to the infringement by others of the ’708 patent.

68. Merck will be substantially and irreparably damaged by infringement of the ’708 patent.

69. Unless Lupin is enjoined from infringing the ’708 patent, actively inducing infringement of the ’708 patent, and contributing to the infringement by others of the ’708 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’708 PATENT (LUPIN’S ’339 ANDA PRODUCT)

70. Merck incorporates each of the preceding paragraphs 1–69 as if fully set forth herein.

71. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Lupin on the other regarding Lupin’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’708 patent.

72. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Lupin’s ’339 ANDA Product with its proposed labeling, or any other Lupin drug product that is covered by or whose use is covered by the ’708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’708 patent, and that the claims of the ’708 patent are valid.

PRAYER FOR RELIEF

WHEREFORE, Merck requests the following relief:

(a) A judgment that the ’708 patent has been infringed under 35 U.S.C. § 271(e)(2) by Lupin’s submission to the FDA of Lupin’s ANDAs;

(b) A judgment ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of Lupin’s ANDA Products, or any other drug product that infringes or the use of which infringes the ’708 patent, be not earlier than the latest of the

expiration date of the ’708 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Lupin, and all persons acting in concert with Lupin, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin’s ANDA Products, or any other drug product covered by or whose use is covered by the ’708 patent, prior to the expiration of the ’708 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Lupin’s ANDA Products, or any other drug product that is covered by or whose use is covered by the ’708 patent, prior to the expiration of the ’708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of, the ’708 patent;

(e) A declaration that this is an exceptional case and an award of attorney’s fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Dated: June 9, 2020

Respectfully submitted,

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