IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., *Plaintiff,* v. MSN PHARMACEUTICALS INC. and MSN LABORATORIES PRIVATE LIMITED, *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. 216086 and 216288 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import versions of JANUVIA® (sitagliptin phosphate) and JANUMET® (metformin hydrochloride; sitagliptin phosphate) prior to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent").

2. MSN Laboratories Private Limited ("MSN Labs") and MSN Pharmaceuticals Inc., ("MSN Pharmaceuticals") (collectively, "MSN") notified Merck by letter

dated June 30, 2021 ("MSN's '086 Notice Letter") that MSN had submitted to the FDA ANDA No. 216086 ("MSN's '086 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 ("MSN's '086 ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, MSN's '086 ANDA Product is a generic version of Merck's JANUVIA® product.

4. MSN notified Merck by letter dated June 30, 2021 ("MSN's '288 Notice Letter") that MSN had submitted to the FDA ANDA No. 216288 ("MSN's '288 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 oral tablets ("MSN's '288 ANDA Product") prior to the expiration of the '708 patent.

5. On information and belief, MSN's '288 ANDA Product is a generic version of Merck's JANUMET® product.

6. MSN's '086 Notice Letter and MSN's '288 Notice Letter are collectively referred to herein as "MSN's Notice Letters." MSN's '086 ANDA and MSN's '288 ANDA are collectively referred to herein as "MSN's ANDAs." MSN's '086 ANDA Product and MSN's '288 ANDA Product are collectively referred to herein as "MSN'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 New Drug Application ("NDA") No. 21995 for JANUVIA® (sitagliptin phosphate), which has been approved by the FDA.

9. Merck is the holder of NDA No. 22044 for JANUMET® (metformin hydrochloride; sitagliptin phosphate), which has been approved by the FDA.

10. On information and belief, defendant MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, and having a principal place of business at 20 Duke Rd, Piscataway, NJ 08854-3714. On information and belief, MSN Pharmaceuticals Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market.

11. On information and belief, defendant MSN Laboratories Private Ltd. is a corporation organized and existing under the laws of India, organized and existing under the laws of India, having a principal place of business at MSN House, Plot No.: C-24, Industrial Estate, Sanathnagar, Hyderabad, 500018, Telangana, India. Upon information and belief, MSN Laboratories Private Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including MSN Pharmaceuticals Inc.

12. On information and belief, MSN Pharmaceuticals Inc. is a wholly owned subsidiary of MSN Laboratories Private Ltd.

13. On information and belief, MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. acted in concert to prepare and submit MSN's ANDAs to the FDA.

14. On information and belief, MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. know and intend that upon approval of MSN's ANDAs, MSN will manufacture, market, sell, and distribute MSN's ANDA Products throughout the United States, including in Delaware. On information and belief, MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. are agents of each other and/or operate in concert as integrated parts of the

same business group, including with respect to MSN's ANDA Products, and enter into agreements that are nearer than arm's length. On information and belief, MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. participated, assisted, and cooperated in carrying out the acts complained of herein.

15. On information and belief, following any FDA approval of MSN's ANDAs, MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. will act in concert to distribute and sell MSN'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 MSN.

18. MSN Pharmaceuticals Inc. 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. MSN Pharmaceuticals Inc. 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, MSN Pharmaceuticals Inc. 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.

19. MSN Laboratories Private Ltd. is subject to personal jurisdiction in Delaware because, among other things, MSN Laboratories Private Ltd., itself and through its wholly owned subsidiary MSN Pharmaceuticals Inc., 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, MSN Laboratories Private Ltd., itself and through its wholly owned subsidiary MSN Pharmaceuticals Inc., 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, MSN Laboratories Private Ltd is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates MSN Pharmaceuticals Inc., and therefore the activities of MSN Pharmaceuticals Inc.in this jurisdiction are attributed to MSN Laboratories Private Ltd.

20. In addition, this Court has personal jurisdiction over MSN because MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. 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. *See, e.g., Vanda Pharmaceuticals Inc. v. MSN Pharmaceuticals Inc., Civ. Private Limited et al,* No. 20-1214 (D. Del. 2020); *Intercept Pharmaceuticals, Inc. et al v. MSN Laboratories Private Limited et al*, No. 20-1214 (D. Del. 2020); *Otsuka Pharmaceutical Co., Ltd. et al v. MSN Laboratories Private Ltd. et al*., No. 20-1428 (D. Del. 2020); *ACADIA Pharmaceuticals Inc. v. MSN Laboratories Private Limited et al*., No. 20-1029 (D. Del. 2020).

21. On information and belief, if MSN's ANDAs are approved, MSN will manufacture, market, sell, and/or distribute MSN's ANDA Products within the United States, including in Delaware, consistent with MSN's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, MSN 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, MSN's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, MSN'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 MSN's ANDA Products are approved before the patent expires.

22. On information and belief, MSN derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by MSN and/or for which MSN Laboratories Private Ltd. and/or MSN Pharmaceuticals Inc. is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which MSN Laboratories Private Ltd. and/or MSN Pharmaceuticals Inc. 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 MSN Pharmaceuticals Inc. under 28 U.S.C. § 1400(b) because MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

25. Venue is proper in this district as to MSN Laboratories Private Ltd. under 28 U.S.C. § 1391 because MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of India 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®, as well as methods of using JANUMET®, 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® in the FDA's Orange Book.

COUNT I – INFRINGEMENT OF THE '708 PATENT
(MSN'S '086 PRODUCT)

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

34. In MSN's '086 Notice Letter, MSN notified Merck of the submission of MSN's '086 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 MSN's '086 ANDA Product prior to the expiration of the '708 patent.

35. In MSN's '086 Notice Letter, MSN also notified Merck that, as part of its ANDA, MSN 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, MSN 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 MSN's '086 ANDA Product.

36. In MSN's '086 Notice Letter, MSN stated that MSN's '086 ANDA Product contains sitagliptin phosphate as an active ingredient.

37. MSN's '086 ANDA Product, and the use of MSN's '086 ANDA Product, is 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 MSN’s ’086 ANDA Product.

38. In MSN’s ’086 Notice Letter, MSN did not contest infringement of claim 1 of the ’708 patent.

39. MSN’s submission of MSN’s ’086 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN’s ’086 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, MSN will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN’s ’086 ANDA Product immediately and imminently upon approval of its ANDA.

41. The manufacture, use, sale, offer for sale, or importation of MSN’s ’086 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 MSN’s ’086 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, MSN plans and intends to, and will, actively induce infringement of the ’708 patent when MSN’s ’086 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. MSN’s activities will be done with knowledge of the ’708 patent and specific intent to infringe that patent.

44. On information and belief, MSN knows that MSN's '086 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '708 patent, that MSN's '086 ANDA Product is not a staple article or commodity of commerce, and that MSN's '086 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, MSN plans and intends to, and will, contribute to infringement of the '708 patent immediately and imminently upon approval of MSN's '086 ANDA.

45. Notwithstanding MSN's knowledge of the claims of the '708 patent, MSN has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import MSN's '086 ANDA Product with its product labeling following FDA approval of MSN's '086 ANDA prior to the expiration of the '708 patent.

46. The foregoing actions by MSN 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, MSN 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 MSN 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 (MSN'S '086 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 MSN on the other regarding MSN'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 MSN's '086 ANDA Product with its proposed labeling, or any other MSN 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 (MSN'S '288 PRODUCT)

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

54. In MSN's '288 Notice Letter, MSN notified Merck of the submission of MSN's '288 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 MSN's '288 ANDA Product prior to the expiration of the '708 patent.

55. In MSN's '288 Notice Letter, MSN also notified Merck that, as part of its ANDA, MSN 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, MSN 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 MSN's '288 ANDA Product.

56. In MSN's '288 Notice Letter, MSN stated that MSN's '288 ANDA Product contains sitagliptin phosphate as an active ingredient.

57. MSN's '288 ANDA Product, and the use of MSN's '288 ANDA Product, is 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 MSN's '288 ANDA Product.

58. In MSN's '288 Notice Letter, MSN did not contest infringement of claim 1 of the '708 patent.

59. MSN's submission of MSN's '288 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's '288 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, MSN will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's '288 ANDA Product immediately and imminently upon approval of its ANDA.

61. The manufacture, use, sale, offer for sale, or importation of MSN's '288 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 MSN's '288 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, MSN plans and intends to, and will, actively induce infringement of the '708 patent when MSN's '288 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. MSN's activities will be done with knowledge of the '708 patent and specific intent to infringe that patent.

64. On information and belief, MSN knows that MSN's '288 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '708 patent, that MSN's '288 ANDA Product is not a staple article or commodity of commerce, and that MSN's '288 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, MSN plans and intends to, and will, contribute to infringement of the '708 patent immediately and imminently upon approval of MSN's '288 ANDA.

65. Notwithstanding MSN's knowledge of the claims of the '708 patent, MSN has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import MSN's '288 ANDA Product with its product labeling following FDA approval of MSN's '288 ANDA prior to the expiration of the '708 patent.

66. The foregoing actions by MSN 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, MSN 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 MSN 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 (MSN'S '288 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 MSN on the other regarding MSN'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 MSN's '288 ANDA Product with its proposed labeling, or any other MSN 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 MSN's submission to the FDA of MSN's ANDAs;

(b) A judgment ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of MSN'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 MSN, and all persons acting in concert with MSN, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of MSN'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 MSN'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: August 12, 2021

Respectfully submitted,

OF COUNSEL:

Bruce R. Genderson
Jessamyn S. Berniker
Stanley E. Fisher
Alexander S. Zolan
Elise M. Baumgarten
Shaun P. Mahaffy
Anthony H. Sheh
Jingyuan Luo
Sarahi Uribe
Vanessa Omoroghomwan
Jihad Komis*
WILLIAMS &CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
T: (202) 434-5000
F: (202) 434-5029
bgenderson@wc.com
jberniker@wc.com
sfisher@wc.com
azolan@wc.com
ebaumgarten@wc.com
smahaffy@wc.com
asheh@wc.com
jluo@wc.com
suribe@wc.com
vomoroghomwan@wc.com
jkomis@wc.com

**Admitted only in Michigan. Practice supervised by D.C. Bar members pursuant to D.C. Court of Appeals Rule 49(c)(8).*

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
T: (302) 984-6300
mkelly@mccarter.com
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Plaintiff
Merck Sharp & Dohme Corp.