IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., *Plaintiff,* v. SANDOZ INC., *Defendant*.	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 defendant's submission of Abbreviated New Drug Application ("ANDA") Nos. 202387 and 202388 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. Sandoz Inc. notified Merck by letter dated December 20, 2010 ("Sandoz's '387 Notice Letter"), that it had submitted to the FDA ANDA No. 202387 ("Sandoz's '387 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 ("Sandoz's '387 ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, Sandoz's '387 ANDA Product is a generic version of Merck's JANUVIA®.

4. Sandoz Inc. notified Merck by letter dated December 20, 2010 ("Sandoz's '388 Notice Letter") that it had submitted to the FDA ANDA No. 202388 ("Sandoz's '388 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 ("Sandoz's '388 ANDA Product") prior to the expiration of the '708 patent.

5. On information and belief, Sandoz's '388 ANDA Product is a generic version of Merck's JANUMET®.

6. Sandoz's '387 Notice Letter and Sandoz's '388 Notice Letter are collectively referred to herein as "Sandoz's Notice Letters." Sandoz's '387 ANDA and Sandoz's '388 ANDA are collectively referred to herein as "Sandoz's ANDAs." Sandoz's '387 ANDA Product and Sandoz's '388 ANDA Product are collectively referred to herein as "Sandoz'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 Sandoz Inc. ("Sandoz") is a corporation organized and existing under the laws of State of Colorado, having its corporate offices and

principal place of business at 100 College Road West, Princeton, NJ 08540. On information and belief, Sandoz 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, Sandoz prepared and submitted Sandoz's ANDAs to the FDA.

12. On information and belief, Sandoz knows and intends that upon approval of Sandoz's ANDAs, Sandoz will manufacture, market, sell, and distribute Sandoz's ANDA Products throughout the United States, including in Delaware.

13. On information and belief, following any FDA approval of Sandoz's ANDAs, Sandoz will distribute and sell Sandoz's ANDA Products throughout the United States, including within Delaware.

JURISDICTION

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

15. This Court has personal jurisdiction over Sandoz.

16. Sandoz 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. On information and belief, Sandoz 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.

17. In addition, this Court has personal jurisdiction over Sandoz because Sandoz regularly engages in patent litigation concerning FDA-approved branded drug products in this

district, does not contest personal jurisdiction in this district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Astellas US LLC v. Sandoz Inc.*, No. 18-1676-CFC, D.I. 13 (D. Del. Nov. 30, 2018); *H. Lundbeck A/S v. Sandoz Inc.*, No. 18-177-LPS, D.I. 9 (D. Del. Apr. 13, 2018).

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

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

VENUE

20. Merck incorporates each of the preceding paragraphs 1–19 as if fully set forth herein.

21. Venue is proper in this district as to Sandoz under 28 U.S.C. § 1391 because Sandoz is subject to personal jurisdiction in this judicial district, has previously consented to venue in this judicial district, and on information and belief will consent to venue for the purpose of this case.

THE ’708 PATENT

22. Merck incorporates each of the preceding paragraphs 1–21 as if fully set forth herein.

23. 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.

24. 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.

25. Merck is the owner and assignee of the ’708 patent.

26. 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.

27. 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.

28. 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
(SANDOZ’S ’387 ANDA PRODUCT)

29. Merck incorporates each of the preceding paragraphs 1–28 as if fully set forth herein.

30. In Sandoz’s ’387 Notice Letter, Sandoz notified Merck of the submission of Sandoz’s ’387 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 Sandoz’s ’387 ANDA Product prior to the expiration of the ’708 patent.

31. In Sandoz’s ’387 Notice Letter, Sandoz also notified Merck that, as part of its ANDA, Sandoz 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, Sandoz 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 Sandoz’s ’387 ANDA Product.

32. In Sandoz’s ’387 Notice Letter, Sandoz stated that Sandoz’s ’387 ANDA Product contains sitagliptin phosphate as an active ingredient.

33. Sandoz’s ’387 ANDA Product, and the use of Sandoz’s ’387 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 Sandoz’s ’387 ANDA Product.

34. In Sandoz's '387 Notice Letter, Sandoz did not contest infringement of claim 1 of the '708 patent.

35. Sandoz's submission of Sandoz's '387 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's '387 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).

36. On information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's '387 ANDA Product immediately and imminently upon approval of its ANDA.

37. The manufacture, use, sale, offer for sale, or importation of Sandoz's '387 ANDA Product would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

38. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's '387 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.

39. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '708 patent when Sandoz's '387 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '708 patent and specific intent to infringe that patent.

40. On information and belief, Sandoz knows that Sandoz's '387 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '708 patent, that Sandoz's '387 ANDA Product is not a staple article or commodity of commerce, and that

Sandoz's '387 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '708 patent immediately and imminently upon approval of Sandoz's '387 ANDA.

41. Notwithstanding Sandoz's knowledge of the claims of the '708 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's '387 ANDA Product with its product labeling following FDA approval of Sandoz's '387 ANDA prior to the expiration of the '708 patent.

42. The foregoing actions by Sandoz 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.

43. On information and belief, Sandoz 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.

44. Merck will be substantially and irreparably damaged by infringement of the '708 patent.

45. Unless Sandoz 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 (SANDOZ'S '387 ANDA PRODUCT)

46. Merck incorporates each of the preceding paragraphs 1–45 as if fully set forth herein.

47. 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 Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, and contribution to the infringement by others of the '708 patent.

48. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Sandoz's '387 ANDA Product with its proposed labeling, or any other Sandoz 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
(SANDOZ'S '388 ANDA PRODUCT)

49. Merck incorporates each of the preceding paragraphs 1–48 as if fully set forth herein.

50. In Sandoz's '388 Notice Letter, Sandoz notified Merck of the submission of Sandoz's '388 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 Sandoz's '388 ANDA Product prior to the expiration of the '708 patent.

51. In Sandoz's '388 Notice Letter, Sandoz also notified Merck that, as part of its ANDA, Sandoz 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, Sandoz 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 Sandoz's '388 ANDA Product.

52. In Sandoz's '388 Notice Letter, Sandoz stated that Sandoz's '388 ANDA Product contains sitagliptin phosphate as an active ingredient.

53. Sandoz's '388 ANDA Product, and the use of Sandoz's '388 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 Sandoz's '388 ANDA Product.

54. In Sandoz's '388 Notice Letter, Sandoz did not contest infringement of claim 1 of the '708 patent.

55. Sandoz's submission of Sandoz's '388 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's '388 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).

56. On information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's '388 ANDA Product immediately and imminently upon approval of its ANDA.

57. The manufacture, use, sale, offer for sale, or importation of Sandoz's '388 ANDA Product would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

58. On information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's '388 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.

59. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the ’708 patent when Sandoz’s ’388 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz’s activities will be done with knowledge of the ’708 patent and specific intent to infringe that patent.

60. On information and belief, Sandoz knows that Sandoz’s ’388 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’708 patent, that Sandoz’s ’388 ANDA Product is not a staple article or commodity of commerce, and that Sandoz’s ’388 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Sandoz plans and intends to, and will, contribute to infringement of the ’708 patent immediately and imminently upon approval of Sandoz’s ’388 ANDA.

61. Notwithstanding Sandoz’s knowledge of the claims of the ’708 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz’s ’388 ANDA Product with its product labeling following FDA approval of Sandoz’s ’388 ANDA prior to the expiration of the ’708 patent.

62. The foregoing actions by Sandoz 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.

63. On information and belief, Sandoz 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.

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

65. Unless Sandoz 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 (SANDOZ’S ’388 ANDA PRODUCT)

66. Merck incorporates each of the preceding paragraphs 1–65 as if fully set forth herein.

67. 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 Sandoz on the other regarding Sandoz’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’708 patent.

68. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Sandoz’s ’388 ANDA Product with its proposed labeling, or any other Sandoz 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 Sandoz’s submissions to the FDA of Sandoz’s ANDAs;

(b) A judgment ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of Sandoz’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 Sandoz, and all persons acting in concert with Sandoz, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz’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 Sandoz’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: February 13, 2019

Respectfully submitted,

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, Delaware 19801
(302) 984-6300
mkelly@mccarter.com
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Plaintiff
Merck Sharpe & Dohme Corp.

OF COUNSEL:

Bruce R. Genderson
Jessamyn S. Berniker
Stanley E. Fisher
Shaun P. Mahaffy
Anthony H. Sheh
Jingyuan Luo*
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
smahaffy@wc.com
asheh@wc.com
jluo@wc.com

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