IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., *Plaintiff,* ALKEM LABORATORIES LTD. AND S&B PHARMA, 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") No. 215155 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) prior to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent").

2. Alkem Laboratories Ltd. notified Merck by letter dated April 22, 2021 ("Alkem's Notice Letter") that it had submitted to the FDA ANDA No. 215155 ("Alkem's 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 ("Alkem's ANDA Product") prior to the expiration of the '708 patent.

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

PARTIES

4. 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.

5. Merck is the holder of New Drug Application ("NDA") No. 21995 for JANUVIA® (sitagliptin phosphate), which has been approved by the FDA.

6. On information and belief, Alkem Laboratories Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, India 400 013. On information and belief, Alkem Laboratories Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including S&B Pharma, Inc.

7. On information and belief, S&B Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, and having a principal place of business at 405 South Motor Avenue, Azusa, California 91702. On information and belief, S&B Pharma, Inc. is in the business of, among other things, manufacturing and selling generic versions of pharmaceutical drug products throughout the United States, including Delaware.

8. On information and belief, S&B Pharma, Inc. is a wholly owned subsidiary of Alkem Laboratories Ltd.

9. On information and belief, Alkem Laboratories Ltd. and S&B Pharma, Inc. acted in concert to prepare and submit ANDA No. 215155 to the FDA.

10. On information and belief, Alkem Laboratories Ltd. and S&B Pharma, Inc. know and intend that upon approval of Alkem's ANDA, Alkem Laboratories Ltd. and/or S&B Pharma, Inc. will manufacture, market, sell, and distribute Alkem's ANDA Product throughout the United States, including in Delaware. On information and belief, Alkem Laboratories Ltd. and S&B Pharma, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Alkem's ANDA Product, and enter into agreements that are nearer than arm's length. On information and belief, Alkem Laboratories Ltd. and S&B Pharma, Inc. participated, assisted, and cooperated in carrying out the acts complained of herein. These two entities are hereafter collectively referred to as "Alkem."

11. On information and belief, following any FDA approval of ANDA No. 215155, Alkem Laboratories Ltd. and S&B Pharma, Inc. will act in concert to distribute and sell Alkem's ANDA Product throughout the United States, including within Delaware.

JURISDICTION

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

13. This Court has personal jurisdiction over Alkem.

14. Alkem Laboratories Ltd. is subject to personal jurisdiction in Delaware because, among other things, Alkem Laboratories Ltd., itself and through its wholly owned subsidiary S&B Pharma, 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, Alkem Laboratories Ltd., itself and through its wholly owned subsidiary

S&B Pharma, 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, Alkem Laboratories Ltd. is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates S&B Pharma, Inc. and therefore the activities of S&B Pharma, Inc. in this jurisdiction are attributed to Alkem Laboratories Ltd.

15. S&B Pharma, 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. S&B Pharma, 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, S&B Pharma, 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

16. On information and belief, if Alkem's ANDA is approved, Alkem will manufacture, market, sell, and/or distribute Alkem's ANDA Product within the United States, including in Delaware, consistent with Alkem's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Alkem 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, Alkem's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Alkem's ANDA Product 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 Alkem's ANDA Product is approved before the '708 patent expires.

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

18. Upon information and belief, Alkem Laboratories Ltd. and S&B Pharma, Inc. have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and have filed counterclaims in such cases. *See, e.g., Bial - Portela & CA S.A. et al v Alkem Laboratories Limited et al.,* C.A. No. 21-186-CFC (D. Del. Mar. 3, 2021) (Alkem Laboratories Ltd. and S&B Pharma, Inc.); *Otsuka Pharmaceutical Co., Ltd. et al v. Alkem Laboratories Ltd.,* C.A. No. 20-1286-LPS (D. Del. Dec. 29, 2020) (Alkem Laboratories Ltd.); *Novartis Pharmaceuticals Corporation v. Alkem Laboratories Ltd. et al,* C.A. No. 19-1979-LPS (D. Del. Jan. 7, 2020) (Alkem Laboratories Ltd. and S&B Pharma, Inc.); *H. Lundbeck A/S et al v. Alkem Laboratories Limited,* C.A. No. 18-89-LPS (D. Del. Apr. 2, 2018) (Alkem Laboratories Ltd. and S&B Pharma, Inc.).

THE ’708 PATENT

19. Merck incorporates each of the preceding paragraphs 1–18 as if fully set forth herein.

20. 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.

21. 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.

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

23. 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.

24. 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.

COUNT I – INFRINGMENT OF THE ’708 PATENT

25. Merck incorporates each of the preceding paragraphs 1–24 as if fully set forth herein.

26. In Alkem’s Notice Letter, Alkem notified Merck of the submission of Alkem’s 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 Alkem’s ANDA Product prior to the expiration of the ’708 patent.

27. In Alkem's Notice Letter, Alkem also notified Merck that, as part of its ANDA, Alkem 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, Alkem 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 Alkem's ANDA Product.

28. In Alkem's Notice Letter, Alkem stated that Alkem's ANDA Product contains sitagliptin phosphate as an active ingredient.

29. Alkem's ANDA Product, and the use of Alkem's 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 Alkem's ANDA Product.

30. In Alkem's Notice Letter, Alkem did not contest infringement of claim 1 of the '708 patent.

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

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

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

34. On information and belief, the manufacture, use, sale, offer for sale, or importation of Alkem's 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.

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

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

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

38. The foregoing actions by Alkem 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.

39. On information and belief, Alkem 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.

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

41. Unless Alkem 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

42. Merck incorporates each of the preceding paragraphs 1–41 as if fully set forth herein.

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

44. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Alkem’s ANDA Product with its proposed labeling, or any other Alkem 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 Alkem’s submission to the FDA of Alkem’s ANDA;

(b) A judgment ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of Alkem’s ANDA Product, 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 Alkem, and all persons acting in concert with Alkem, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Alkem’s ANDA Product, 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 Alkem’s ANDA Product, 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 4, 2021

Respectfully submitted,

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