IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., *Plaintiff,* SCIEGEN PHARMACEUTICALS, INC. and BACTOLAC PHARMACEUTICAL 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. 216337 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. ScieGen Pharmaceuticals, Inc. notified Merck by letter dated October 5, 2021 ("ScieGen's Notice Letter") that ScieGen had submitted to the FDA ANDA No. 216337 ("ScieGen'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 ("ScieGen's ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, ScieGen'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, defendant ScieGen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of New York, and having a principal place of business at 20 Davids Drive, Hauppauge, New York 11788. On information and belief, ScieGen Pharmaceuticals, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market.

7. On information and belief, defendant Bactolac Pharmaceutical Inc. is a corporation organized and existing under the laws of the State of Delaware, and having a principal place of business at 7 Oser Avenue, Hauppauge, New York, 11788. Upon information and belief, Bactolac Pharmaceutical Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including ScieGen Pharmaceuticals, Inc.

8. On information and belief, ScieGen Pharmaceuticals, Inc. is a wholly owned subsidiary of Bactolac Pharmaceutical Inc.

9. On information and belief, ScieGen Pharmaceuticals, Inc. and Bactolac Pharmaceutical Inc. (collectively, "ScieGen") acted in concert to prepare and submit ScieGen's ANDA to the FDA.

10. On information and belief, ScieGen knows and intend that upon approval of ScieGen's ANDA, ScieGen will manufacture, market, sell, and distribute ScieGen's ANDA Product throughout the United States, including in Delaware. On information and belief, ScieGen Pharmaceuticals, Inc. and Bactolac Pharmaceutical Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to ScieGen's ANDA Product, and enter into agreements that are nearer than arm's length. On information and belief, ScieGen Pharmaceuticals, Inc. and Bactolac Pharmaceutical Inc. participated, assisted, and cooperated in carrying out the acts complained of herein.

11. On information and belief, following any FDA approval of ScieGen's ANDA, ScieGen Pharmaceuticals, Inc. and Bactolac Pharmaceutical Inc. will act in concert to distribute and sell ScieGen'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 ScieGen.

14. Bactolac Pharmaceutical 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. Bactolac Pharmaceutical 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, Bactolac Pharmaceutical 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.

15. ScieGen Pharmaceuticals, Inc. is subject to personal jurisdiction in Delaware because, among other things, ScieGen Pharmaceuticals, Inc., itself and through its parent company Bactolac Pharmaceutical 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, ScieGen Pharmaceuticals, Inc., itself and through its parent company Bactolac Pharmaceutical 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.

16. In addition, this Court has personal jurisdiction over ScieGen because ScieGen Pharmaceuticals, Inc. and Bactolac Pharmaceutical Inc. engage in patent litigation concerning FDA-approved branded drug products in this district, have consented to 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.*, *Genentech, Inc. et al v. ScieGen Pharmaceuticals Inc.*, No. 19-132-RGA (D. Del. 2019); *UCB Inc. et al v ScieGen Pharmaceuticals Inc. et al*, No. 13-1217-LPS (D. Del. 2013).

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

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

VENUE

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

20. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 28 U.S.C. § 1400(b).

21. Venue is proper in this district as to Bactolac Pharmaceutical Inc. under 28 U.S.C. § 1400(b) because Bactolac Pharmaceutical 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.

22. Venue is proper in this district as to ScieGen Pharmaceuticals, Inc.. under 28 U.S.C. § 1391 because ScieGen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of NY and a substantial part of the events or omissions giving rise to the claims occurred or will occur in the State of Delaware.

THE ’708 PATENT

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

24. 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.

25. 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.

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

27. 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.

28. 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 – INFRINGEMENT OF THE ’708 PATENT

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

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

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

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

33. ScieGen’s ANDA Product, and the use of ScieGen’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 ScieGen’s ANDA Product.

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

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

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

37. The manufacture, use, sale, offer for sale, or importation of ScieGen's 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 ScieGen'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.

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

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

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

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

42. The foregoing actions by ScieGen 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, ScieGen 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 ScieGen 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

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 ScieGen on the other regarding ScieGen'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 ScieGen's ANDA Product with its proposed labeling, or any other ScieGen 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 ScieGen's submission to the FDA of ScieGen's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of ScieGen'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 ScieGen, and all persons acting in concert with ScieGen, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of ScieGen'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 ScieGen'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: November 15, 2021

Respectfully submitted,

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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