IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., *Plaintiff,* v. ANCHEN PHARMACEUTICALS, INC., and PAR 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. 204144 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 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. Anchen Pharmaceuticals, Inc. notified Merck by letters dated August 13, 2012, and October 22, 2012 ("Anchen's Notice Letters") that it had submitted to the FDA ANDA No. 204144 ("Anchen's 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 ("Anchen's ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, Anchen's ANDA Product is a generic version of Merck's JANUMET XR®.

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. 202270 for JANUMET XR® (metformin hydrochloride; sitagliptin phosphate extended release tablets), which has been approved by the FDA.

6. On information and belief, defendant Anchen Pharmaceuticals, Inc. ("Anchen") is a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and principal place of business at 9601 Jeromino Road, Irvine, California 92618. On information and belief, Anchen 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 Par Pharmaceutical, Inc. ("Par") is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, NY 10977. On information and belief, Par is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating agents, affiliates, and subsidiaries, including Anchen.

8. Par is a wholly owned indirect subsidiary of Endo International PLC.

9. On information and belief, Anchen is a wholly owned subsidiary of Par. Anchen and Par are collectively referred to herein as "Defendants."

10. On information and belief, Anchen and Par acted in concert to prepare and submit Anchen's ANDA to the FDA.

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

12. On information and belief, following any FDA approval of Anchen's ANDA, Anchen and Par will act in concert to distribute and sell Anchen's ANDA Product throughout the United States, including within Delaware.

JURISDICTION

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

14. This Court has personal jurisdiction over each of the Defendants.

15. Anchen 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. Anchen 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. Anchen therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Anchen

develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transact business within the State of Delaware related to Merck's claims, and/or have engaged in systematic and continuous business contacts within the State of Delaware.

16. Par is subject to personal jurisdiction in Delaware because, among other things, Par, itself and through its wholly owned subsidiary Anchen, 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, Par, itself and through its wholly owned subsidiary Anchen, 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, Par is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Anchen and therefore the activities of Anchen in this jurisdiction are attributed to Par.

17. In addition, this Court has personal jurisdiction over Defendants because Anchen and Par regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and/or have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Noden Pharma DAC v. Anchen Pharms, Inc.*, No. 17-728-MPT, D.I. 23 (D. Del. Aug. 11, 2017) (Anchen and Par); *Forest Labs., LLC v. Lupin Ltd.*, No. 14-1058-LPS, D.I. 16 (D. Del. Sept. 9, 2014) (Anchen); *Sucampo AG v. Anchen Pharms, Inc.*, No. 13-202-GMS, D.I. 23 (D. Del. July 8, 2013) (Anchen and Par).

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

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

22. Venue is proper in this district as to Par under 28 U.S.C. § 1391 because Par 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

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. 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

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

30. In Anchen's Notice Letters, Defendants notified Merck of the submission of Anchen'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 Anchen's ANDA Product prior to the expiration of the '708 patent.

31. In Anchen's Notice Letters, Defendants also notified Merck that, as part of its ANDA, Defendants had filed certifications of the 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, Defendants submitted Anchen's 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 Anchen's ANDA Product.

32. In Anchen's Notice Letters, Defendants stated that Anchen's ANDA Product contains sitagliptin phosphate as an active ingredient.

33. Anchen's ANDA Product, and the use of Anchen's 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 Anchen's ANDA Product.

34. In Anchen's Notice Letters, Defendants did not contest infringement of claim 1 of the '708 patent.

35. Defendants' submission of Anchen's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Anchen'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, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Anchen's ANDA Product immediately and imminently upon approval of their ANDA.

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

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

41. Notwithstanding Defendants' knowledge of the claims of the '708 patent, Defendants have continued to assert their intent to manufacture, offer for sale, sell, distribute,

and/or import Anchen's ANDA Product with its product labeling following FDA approval of Anchen's ANDA prior to the expiration of the '708 patent.

42. The foregoing actions by Defendants 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, Defendants have acted with full knowledge of the '708 patent and without a reasonable basis for believing that Defendants 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 Defendants are 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 Defendants on the other regarding Defendants' 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 Anchen's ANDA Product with its proposed labeling, or any other drug

product of Defendants 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 Defendants' submission to the FDA of Anchen's ANDA;

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

Respectfully submitted,

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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