

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

MERCK SHARP & DOHME CORP.,

*Plaintiff,*

v.

ALVOGEN PINE BROOK LLC F/K/A  
ALVOGEN PINE BROOK, INC.,  
ALVOGEN MALTA OPERATIONS LTD.,  
ALVOGEN LUX HOLDINGS S.À.R.L.,

*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. 205341 to the U.S. Food and Drug Administration (“FDA”) seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of JANUMET XR<sup>®</sup> (metformin hydrochloride; sitagliptin phosphate extended release tablets) prior to the expiration of U.S. Patent No. 7,326,708 (“the ’708 patent”).

2. Alvogen Pine Brook, LLC, formerly known as Alvogen Pine Brook, Inc. notified Merck by letter dated June 25, 2014 (“Alvogen’s Notice Letter”) that it had submitted to the FDA ANDA No. 205341 (“Alvogen’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 (“Alvogen’s ANDA Product”) prior to the expiration of the ’708 patent.

3. On information and belief, Alvogen’s ANDA Product is a generic version of Merck’s JANUMET XR<sup>®</sup>.

### **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<sup>®</sup> (metformin hydrochloride; sitagliptin phosphate extended release tablets), which has been approved by the FDA.

6. On information and belief, Alvogen Pine Brook, Inc. was a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and principal place of business at 10 Bloomfield Avenue, Building B, Pine Brook, NJ 07058. On information and belief, Alvogen Pine Brook, Inc. was in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market, including through various operating agents, affiliates, and subsidiaries.

7. On information and belief, Alvogen Pine Brook, Inc. underwent a conversion to become defendant Alvogen Pine Brook LLC. On information and belief, Alvogen Pine Brook, LLC is the successor-in-interest to Alvogen Pine Brook, Inc.

8. On information and belief, defendant Alvogen Pine Brook LLC is a limited liability company organized and existing under the laws of the State of Delaware having its corporate offices and principal place of business at 10 Bloomfield Avenue, Building B, Pine Brook, NJ 07058. On information and belief, Alvogen Pine Brook LLC is in the business of,

among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market, including through various operating agents, affiliates, and subsidiaries.

9. On information and belief, defendant Alvogen Malta Operations Ltd. (“Alvogen Malta”) is a corporation organized and existing under the laws of Malta, with a principal place of business at Malta Life Science Park, 1 Level, 4 Sir Temi Zammit Buildings, San Gwann Industrial Estate, San Gwann, SGN 3000 Malta. On information and belief, Alvogen Malta 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 Alvogen Pine Brook, Inc. and/or Alvogen Pine Brook LLC.

10. On information and belief, Alvogen Lux Holdings S.à.r.l. (“Alvogen Luxembourg”) is a corporation organized and existing under the laws of Luxembourg, with a place of business at Rue Heienhaff 5, Niederanven, 1736, Luxembourg.

11. On information and belief, Alvogen Luxembourg is the majority owner of Alvogen Malta and dominates and controls the activities of Alvogen Malta, as well as Alvogen Pine Brook LLC, and Alvogen Pine Brook LLC is a wholly owned subsidiary of Alvogen Malta. Alvogen Pine Brook LLC, Alvogen Malta, and Alvogen Luxembourg are collectively referred to herein as “Alvogen.”

12. On information and belief, Alvogen Pine Brook LLC, together with Alvogen Malta and Alvogen Luxembourg, acted in concert to prepare and submit Alvogen’s ANDA to the FDA.

13. On information and belief, Alvogen knows and intends that upon approval of Alvogen’s ANDA, Alvogen Pine Brook LLC, Alvogen Malta, and Alvogen Luxembourg will act in concert to manufacture, market, sell, and distribute Alvogen’s ANDA Product throughout the

United States, including in Delaware. On information and belief, Alvogen Pine Brook LLC, Alvogen Malta, and Alvogen Luxembourg are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Alvogen's ANDA Product, and enter into agreements that are nearer than arm's length. On information and belief, Alvogen Pine Brook LLC, Alvogen Malta, and Alvogen Luxembourg participated, assisted, and cooperated in carrying out the acts complained of herein.

14. On information and belief, following any FDA approval of Alvogen's ANDA, Alvogen Pine Brook LLC, Alvogen Malta, and Alvogen Luxembourg will act in concert to distribute and sell Alvogen's ANDA Product throughout the United States, including within Delaware.

#### **JURISDICTION**

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

16. This Court has personal jurisdiction over Alvogen.

17. Alvogen Pine Brook LLC 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 they should reasonably anticipate being haled into court here. Alvogen Pine Brook LLC is a limited liability company 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, Alvogen Pine Brook LLC 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.

18. Alvogen Malta is subject to personal jurisdiction in Delaware because, among other things, Alvogen Malta, itself and through its wholly owned subsidiary Alvogen Pine Brook LLC, 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, Alvogen Malta, itself and through its wholly owned subsidiary Alvogen Pine Brook LLC, 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, Alvogen Malta is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Alvogen Pine Brook LLC, and therefore the activities of Alvogen Pine Brook LLC in this jurisdiction are attributed to Alvogen Malta.

19. Alvogen Luxembourg is subject to personal jurisdiction in Delaware because, among other things, Alvogen Luxembourg, itself and through Alvogen Malta and Alvogen Pine Brook LLC, 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, Alvogen Luxembourg, itself and through Alvogen Malta and Alvogen Pine Brook LLC, 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, Alvogen Luxembourg is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Alvogen Malta and

Alvogen Malta's wholly owned subsidiary, Alvogen Pine Brook LLC, and therefore the activities of Alvogen Pine Brook LLC in this jurisdiction are attributed to Alvogen Luxembourg.

20. In addition, this Court has personal jurisdiction over Alvogen because Alvogen Pine Brook LLC and Alvogen Malta 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., BioDelivery Sci. Int'l, Inc. v. Alvogen PB Research & Dev. LLC*, No. 18-1395-CFC (D. Del. Nov. 30, 2018) (Alvogen Pine Brook LLC and Alvogen Malta); *Noven Pharms., Inc. v. Alvogen Pine Brook LLC*, No. 17-1429-LPS (D. Del. Oct. 11, 2017) (Alvogen Pine Brook LLC); *Purdue Pharma L.P. v. Alvogen Pine Brook LLC*, No. 17-677-TBD, D.I. 11 (D. Del. July 28, 2018) (Alvogen Pine Brook LLC); *Recro Gainesville LLC v. Alvogen Malta Operations Ltd.*, No. 14-1364-GMS, D.I. 7, 41 (D. Del. Nov. 24 & 25, 2015) (Alvogen Pine Brook, Inc., Alvogen Pine Brook, LLC, and Alvogen Malta); *Reckitt Benckiser Pharms. Inc. v. Alvogen Pine Brook, Inc.*, No. 13-2003-RGA (D. Del. Feb. 4, 2014) (Alvogen Pine Brook, Inc.); *Novartis Pharms. Corp. v. Alvogen Pine Brook, Inc.*, No. 13-52-RGA, D.I. 14 (D. Del. Jan. 31, 2013) (Alvogen Pine Brook, Inc.).

21. On information and belief, if Alvogen's ANDA is approved, Alvogen will manufacture, market, sell, and/or distribute Alvogen's ANDA Product within the United States, including in Delaware, consistent with Alvogen's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Alvogen 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, Alvogen's generic pharmaceutical products

are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Alvogen'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 Alvogen's ANDA Product is approved before the patent expires.

22. On information and belief, Alvogen derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and that are manufactured by Alvogen and/or for which Alvogen Pine Brook LLC, Alvogen Malta, and/or Alvogen Luxembourg is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which Alvogen Pine Brook LLC, Alvogen Malta, and/or Alvogen Luxembourg 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 Alvogen Pine Brook LLC under 28 U.S.C. § 1400(b) because Alvogen Pine Brook LLC is a limited liability company 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 Alvogen Malta under 28 U.S.C. § 1391 because Alvogen Malta is a corporation organized and existing under the laws of Malta and is subject to personal jurisdiction in this judicial district.

26. Venue is proper in this district as to Alvogen Luxembourg under 28 U.S.C. § 1391 because Alvogen Luxembourg is a corporation organized and existing under the laws of Luxembourg and is subject to personal jurisdiction in this judicial district.

**THE '708 PATENT**

27. Merck incorporates each of the preceding paragraphs 1–26 as if fully set forth herein.

28. 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.

29. 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.

30. Merck is the owner and assignee of the '708 patent.

31. 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.

32. JANUMET XR<sup>®</sup>, as well as methods of using JANUMET XR<sup>®</sup>, 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<sup>®</sup> in the FDA's Orange Book.

**COUNT I – INFRINGEMENT OF THE '708 PATENT**

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

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

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

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

37. Alvogen's ANDA Product, and the use of Alvogen'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 Alvogen's ANDA Product.

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

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

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

41. The manufacture, use, sale, offer for sale, or importation of Alvogen's 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 Alvogen'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.

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

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

45. Notwithstanding Alvogen's knowledge of the claims of the '708 patent, Alvogen has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import

Alvogen's ANDA Product with its product labeling following FDA approval of Alvogen's ANDA prior to the expiration of the '708 patent.

46. The foregoing actions by Alvogen 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, Alvogen 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 Alvogen 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**

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 Alvogen on the other regarding Alvogen'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 Alvogen's ANDA Product with its proposed labeling, or any other

Alvogen 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 Alvogen's submission to the FDA of Alvogen's ANDA;

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

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

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.*

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