IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., *Plaintiff,* v. AJANTA PHARMA LIMITED, and AJANTA PHARMA USA INC., *Defendants*.	C.A. No. 1:20-cv-01496-RGA

AJANTA PHARMA LIMITED AND AJANTA PHARMA USA INC.'S
ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S COMPLAINT

Ajanta Pharma Limited ("Ajanta") and Ajanta Pharma USA Inc. ("Ajanta USA") (collectively, "Defendants") for their Answer and Affirmative Defenses to the Complaint of Merck Sharp & Dohme Corp. ("Merck" or "Plaintiff") state as follows:

All averments not expressly admitted are denied.

1. The allegations in paragraph 1 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiff's Complaint purports to be a civil action alleging infringement of United States Patent No. 7,326,708 ("'708 patent") pursuant to Title 35 of the United States Code. Defendants further admit that Ajanta USA submitted Abbreviated New Drug Application ("ANDA") No. 215220 to the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg. Defendants further admit that ANDA No. 215220 identifies JANUMET® (sitagliptin and metformin hydrochloride) tablets, 50 mg/500 mg and 50 mg/1000 mg, as the Reference Listed Drug. Defendants further admit that ANDA No. 215220

included a certification 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 the proposed products described in ANDA No. 215220. Defendants deny all other allegations in paragraph 1.

2. Defendants admit that Ajanta sent a letter dated October 5, 2020 ("Notice Letter") to Merck pursuant to 21 U.S.C. § 355(j)(2)(B), notifying Merck that Ajanta submitted ANDA No. 215220 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg, and that ANDA No. 215220 included a certification 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 the proposed products described in ANDA No. 215220. Defendants deny all other allegations in paragraph 2.

3. Defendants admit that Ajanta submitted ANDA No. 215220 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg. Defendants further admit that ANDA No. 215220 identifies JANUMET® (sitagliptin and metformin hydrochloride) tablets, 50 mg/500 mg and 50 mg/1000 mg, as the Reference Listed Drug. Defendants deny all other allegations in paragraph 3.

PARTIES

4. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 4 and therefore deny them.

5. Defendants admit that the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists "MERCK SHARP AND DOHME CORP" as the Applicant Holder for New Drug Application ("NDA") No. 022044 and "JANUMET" as the Proprietary Name for NDA No. 022044. Defendants further admit that the Orange Book lists March 30, 2007, as the Approval Date for NDA No. 022044. Defendants deny all other allegations in paragraph 5.

6. Defendants admit that Ajanta is a corporation organized and existing under the laws of India, with a principal place of business at No. 98, Ajanta House, Government Industrial Area, Charkop, Kandivali (West), Mumbai, Maharashtra 400067, India. Defendants further admit that Ajanta manufactures pharmaceutical products, including generic pharmaceutical products, and that Ajanta USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Ajanta, in the United States. Defendants further admit that Ajanta USA is a wholly owned subsidiary of Ajanta. Defendants deny all other allegations in paragraph 6.

7. Defendants admit that Ajanta USA is a corporation organized and existing under the laws of the State New Jersey, with a principal place of business at 440 U.S. Highway 22 East, Suite 150, Bridgewater, NJ 08807. Defendants further admit that Ajanta USA sells pharmaceutical products, including generic pharmaceutical products, in the United States. Defendants deny all other allegations in paragraph 7.

8. Defendants admit that Ajanta USA is a wholly owned subsidiary of Ajanta. The second sentence of paragraph 8 contains no allegations to which an answer is required. Defendants deny all other allegations in paragraph 8.

9. Defendants admit that Ajanta submitted ANDA No. 215220 to the FDA. Defendants deny all other allegations in paragraph 9.

10. The allegations in paragraph 10 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Ajanta submitted ANDA No. 215220 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg. Defendants further admit that Ajanta USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Ajanta, in the United States. Defendants further admit that Ajanta USA is a wholly owned subsidiary of Ajanta. Defendants deny all other allegations in paragraph 10.

11. The allegations in paragraph 11 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Ajanta submitted ANDA No. 215220 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg. Defendants further admit that Ajanta USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Ajanta, in the United States. Defendants further admit that Ajanta USA is a wholly owned subsidiary of Ajanta. Defendants deny all other allegations in paragraph 11.

JURISDICTION

12. The allegations in paragraph 12 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest subject matter jurisdiction in this Court solely for the purposes of Merck's claims against Defendants in this case and solely as they apply to the sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg, described in ANDA No. 215220. Defendants deny all other allegations in paragraph 12.

13. The allegations in paragraph 13 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court solely for the purposes of Merck's claims against Defendants in this case and solely as they apply to the sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg, described in ANDA No. 215220. Defendants deny all other allegations in paragraph 13.

14. The allegations in paragraph 14 are legal conclusions to which no answer is required. To the extent an answer is required, Ajanta does not contest personal jurisdiction in this Court solely for the purposes of Merck's claims against Ajanta in this case and solely as they apply to the sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg, described in ANDA No. 215220. Ajanta admits that Ajanta USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Ajanta, in the United States. Defendants further admit that Ajanta USA is a wholly owned subsidiary of Ajanta. Defendants deny all other allegations in paragraph 14.

15. The allegations in paragraph 15 are legal conclusions to which no answer is required. To the extent an answer is required, Ajanta USA does not contest personal jurisdiction in this Court solely for the purposes of Merck's claims against Ajanta USA in this case and solely as they apply to the sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg, described in ANDA No. 215220. Ajanta USA admits that Ajanta USA sells pharmaceutical products, including generic pharmaceutical products, in the United States. Defendants deny all other allegations in paragraph 15.

16. The allegations in paragraph 16 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that: in *Merck Sharp & Dohme Corp. v. Ajanta Pharma Ltd. and Ajanta Pharma USA Inc.*, No. 1:20-cv-00815-RGA (D. Del. July

30, 2020), Defendants stated that "Defendants do not contest personal jurisdiction in this Court solely for the purposes of Merck's claims against Defendants in this case and solely as they apply to the sitagliptin tablets, 25 mg, 50 mg, and 100 mg, described in ANDA No. 214784"; in *Pfizer Inc. v. Ajanta Pharma Ltd.*, No. 1:19-cv-00517-LPS (D. Del. May 13, 2019), Defendants stated that "[Defendants] do[] not contest personal jurisdiction in this Judicial District for the limited purposes of this action only" and asserted counterclaims; in *Otsuka Pharmaceutical Co. v. Ajanta Pharma Ltd.*, No. 1:19-cv-01939-LPS (D. Del. Feb. 12, 2020), Ajanta stated that "[f]or purposes of this action only, Ajanta does not contest that this Court has personal jurisdiction" and asserted counterclaims; in *Amgen Inc. v. Ajanta Pharma Ltd.*, No. 1:16-cv-00899-GMS (D. Del. Nov. 18, 2016), Defendants stated that "for the limited purpose of this action only, … [Defendants] do[] not contest personal jurisdiction in this jurisdictional district" and asserted counterclaims; and in *Allergan Sales, LLC v. Ajanta Pharma Ltd.*, No. 1:19-cv-01249-LPS (D. Del. Dec. 20, 2019), Defendants stipulated that "[t]his Court has … personal jurisdiction over Plaintiffs and [Defendants] only for the purposes of this action." Defendants deny all other allegations in paragraph 16.

17. The allegations in paragraph 17 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Ajanta submitted ANDA No. 215220 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg. Defendants further admit that Ajanta USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Ajanta, in the United States. Defendants lack knowledge or information sufficient to form a belief as to the truth of the

allegations in the third and fourth sentences of paragraph 17 and therefore deny them. Defendants deny all other allegations in paragraph 17.

18. Defendants admit that Ajanta USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Ajanta, in the United States. Defendants lack knowledge or information sufficient to form a belief as to the truth of all other allegations in paragraph 18 and therefore deny them.

VENUE

19. Defendants restate and reallege their answers to each of the preceding paragraphs 1–18, as if fully set forth herein.

20. The allegations in paragraph 20 are legal conclusions to which no answer is required. To the extent an answer is required, Ajanta does not contest venue in this Court solely for the purposes of Merck's claims against Ajanta in this case and solely as they apply to the sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg, described in ANDA No. 215220. Defendants deny all other allegations in paragraph 20.

21. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of paragraph 21 and therefore deny them. The allegations in the second sentence of paragraph 21 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the second sentence of paragraph 21.

THE '708 PATENT

22. Defendants restate and reallege their answers to each of the preceding paragraphs 1–21, as if fully set forth herein.

23. Defendants admit that the '708 patent lists Stephen Howard Cypes, Alex Minhua Chen, Russell R. Ferlita, Karl Hansen, Ivan Lee, Vicky K. Vydra, and Robert M. Wenslow, Jr., as Inventors on the face of the patent. Defendants deny all other allegations in paragraph 23.

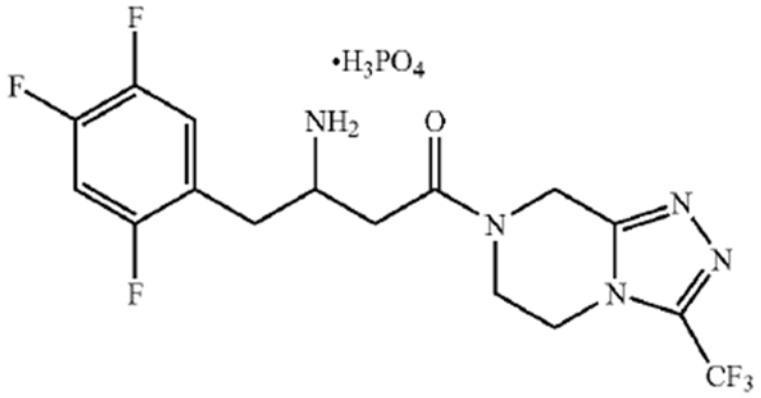
24. The allegations in paragraph 24 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the '708 patent is titled "Phosphoric Acid Salt of a Dipeptidyl Peptidase-IV Inhibitor" and lists February 5, 2008, as the Date of Patent. Defendants further admit, on information and belief, that what purports to be a copy of the '708 patent is attached to Merck's Complaint as Exhibit A. Defendants deny all other allegations in paragraph 24.

25. The allegations in paragraph 25 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the United States Patent and Trademark Office's ("PTO") Patent Assignment Search database, Reel No. 028866, Frame No. 0511, lists "MERCK SHARP & DOHME CORP." as the Assignee of the '708 patent. Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 25 and therefore deny them.

26. The allegations in paragraph 26 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that claim 1 of the '708 patent reads:

> 1. 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:

(I)



or a hydrate thereof.

'708 patent col. 15 l. 64–col. 16 l. 15. Defendants deny all other allegations in paragraph 26.

27. The allegations in paragraph 27 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Orange Book lists the '708 patent in connection with NDA No. 022044, JANUMET® (sitagliptin and metformin hydrochloride) tablets, 50 mg/500 mg and 50 mg/1000 mg. Defendants deny all other allegations in paragraph 27.

COUNT I—INFRINGEMENT OF THE '708 PATENT

28. Defendants restate and reallege their answers to each of the preceding paragraphs 1–27, as if fully set forth herein.

29. Defendants admit that Ajanta sent the Notice Letter to Merck pursuant to 21 U.S.C. § 355(j)(2)(B), notifying Merck that Ajanta submitted ANDA No. 215220 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg, and that ANDA No. 215220 included a certification 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 the proposed products described in ANDA No. 215220. Defendants deny all other allegations in paragraph 29.

30. Defendants admit that Ajanta sent the Notice Letter to Merck pursuant to 21 U.S.C. § 355(j)(2)(B), notifying Merck that Ajanta submitted ANDA No. 215220 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg, and that ANDA No. 215220 included a certification 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 the proposed products described in ANDA No. 215220. Defendants deny all other allegations in paragraph 30.

31. Defendants admit that Ajanta sent the Notice Letter to Merck pursuant to 21 U.S.C. § 355(j)(2)(B), notifying Merck that Ajanta submitted ANDA No. 215220 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg. Defendants deny that the allegations in paragraph 31 accurately and completely recite the Notice Letter and therefore deny them.

32. The allegations in paragraph 32 are legal conclusions to which no answer is required. To the extent an answer is required, denied.

33. Defendants deny that the allegations in paragraph 33 accurately and completely recite the Notice Letter and therefore deny them. Defendants do not waive, and expressly reserve, the right to raise additional defenses and arguments concerning noninfringement, invalidity, and unenforceability of the '708 patent in this or any other litigation or other proceeding. *See Abbott Labs., Inc. v. Apotex Inc.*, 725 F. Supp. 2d 724, 728 (N.D. Ill. 2010) (refusing to strike defense

theories not raised in defendant's notice letter because an ANDA filer is "not limited to the invalidity and noninfringement theories raised in its paragraph IV [notice] letter"); *see also Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99 Civ. 8928 (BSJ), 2000 WL 257125, at *1 (S.D.N.Y. Mar. 8, 2000) ("There is no language in the relevant statutory provisions, legislative history or cases barring [an ANDA filer] from raising defenses and counterclaims not noticed in [its] ANDA."). Defendants deny all other allegations in paragraph 33.

34. Denied.

35. Defendants admit that Ajanta submitted ANDA No. 215220 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg. Defendants deny all other allegations in paragraph 35.

36. Denied.

37. Denied.

38. Denied.

39. Denied.

40. The allegations in paragraph 40 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Ajanta submitted ANDA No. 215220 to the FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg, and that ANDA No. 215220 included a certification 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 the

proposed products described in ANDA No. 215220. Defendants deny all other allegations in paragraph 40.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

COUNT II—DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '708 PATENT

45. Defendants restate and reallege their answers to each of the preceding paragraphs 1–44, as if fully set forth herein.

46. The allegations in paragraph 46 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest subject matter jurisdiction in this Court solely for the purposes of Merck's claims against Defendants in this case and solely as they apply to the sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg, described in ANDA No. 215220. Defendants deny all other allegations in paragraph 46.

47. Denied.

PRAYER FOR RELIEF

Defendants specifically deny that Merck is entitled to the general or specific relief requested against Defendants, or to any relief whatsoever, and pray for judgment in favor of Defendants, dismissing this action with prejudice and awarding Defendants their reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in their Answer and without admitting any allegations of the Complaint not otherwise admitted, Defendants aver and assert the following Affirmative Defenses to Merck's Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 7,326,708)

Merck will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg, described in ANDA No. 215220 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '708 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 7,326,708)

Upon information and belief, the claims of the '708 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and 112.

RESERVATION OF DEFENSES

Defendants hereby reserve any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

Dated: November 24, 2020

Respectfully submitted,

By: */s/ John C. Phillips, Jr.*

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