IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Sitagliptin Phosphate ('708 & '921) Patent Litigation	C.A. No. 19-md-2902-RGA
MERCK SHARP & DOHME CORP., *Plaintiff*, v. ZYDUS WORLDWIDE DMCC, ZYDUS PHARMACEUTICALS (USA) INC., and CADILA HEALTHCARE LTD, *Defendants*.	C.A. No. 1:21-cv-00315-RGA

ZYDUS WORLDWIDE DMCC, ZYDUS PHARMACEUTICALS (USA) INC., AND CADILA HEALTHCARE LIMITED'S
ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S COMPLAINT

Zydus Worldwide DMCC ("Zydus Worldwide"), Zydus Pharmaceuticals (USA) Inc. ("Zydus USA"), and Cadila Healthcare Limited ("Cadila") (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 Merck'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 Zydus Worldwide submitted New Drug Application ("NDA") No. 211566 to the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(b)(2), seeking FDA approval to engage in the commercial

manufacture, use, offer for sale, sale, and/or importation of sitagliptin tablets, 25 mg, 50 mg, and 100 mg. Defendants further admit that NDA No. 211566 identifies JANUVIA® (sitagliptin phosphate) tablets, 25 mg, 50 mg, and 100 mg, as the Reference Listed Drug. Defendants further admit that NDA No. 211566 included a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(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 NDA No. 211566. Defendants deny all other allegations in paragraph 1.

2. Defendants admit that Zydus USA sent a letter on behalf of Zydus Worldwide dated January 14, 2021 ("Notice Letter") to Merck pursuant to 21 U.S.C. § 355(b)(3), notifying Merck that Zydus Worldwide submitted NDA No. 211566 to the FDA under 21 U.S.C. § 355(b)(2), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of sitagliptin tablets, 25 mg, 50 mg, and 100 mg, and that NDA No. 211566 included a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(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 NDA No. 211566. Defendants deny all other allegations in paragraph 2.

3. Defendants admit that Zydus Worldwide submitted NDA No. 211566 to the FDA under 21 U.S.C. § 355(b)(2), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of sitagliptin tablets, 25 mg, 50 mg, and 100 mg. Defendants further admit that NDA No. 211566 identifies JANUVIA® (sitagliptin phosphate) tablets, 25 mg, 50 mg, and 100 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, "JANUVIA" as the Proprietary Name, and "SITAGLIPTIN PHOSPHATE" as the Active Ingredient in connection with NDA No. 021995. Defendants further admit that the Orange Book lists October 16, 2006 as the Approval Date for NDA No. 021995. Defendants deny all other allegations in paragraph 5.

6. Defendants admit that Zydus USA is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Defendants further admit that Zydus USA sells pharmaceutical products, including generic pharmaceutical products, in the United States. Defendants deny all other allegations in paragraph 6.

7. Defendants admit that Zydus Worldwide is a corporation organized and existing under the laws of the United Arab Emirates, with a principal place of business at Unit No. 908, Armada Tower 2, Plot No. JLT-PH2-P2A, Jumeirah Lakes Tower, P.O. Box 113536, Dubai, United Arab Emirates. Defendants deny all other allegations in paragraph 7.

8. Defendants admit that Cadila is a corporation organized and existing under the laws of India, with a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, India. Defendants further admit that Cadila manufactures pharmaceutical products, including generic pharmaceutical products, and that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Cadila, in the United States. Defendants further admit

that Zydus USA and Zydus Worldwide are wholly owned subsidiaries of Cadila. Defendants deny all other allegations in paragraph 8.

9. Admitted.

10. Paragraph 10 contains no allegations to which an answer is required. To the extent an answer is required, Defendants admit that Plaintiff occasionally appears to refer to Zydus Worldwide, Zydus USA, and Cadila collectively in Plaintiff's Complaint. Defendants deny all other allegations in paragraph 10.

11. Defendants admit that Zydus Worldwide submitted NDA No. 211566 to the FDA and Cadila assisted in the preparation of NDA No. 211566. Defendants deny all other allegations in paragraph 11.

12. The allegations in paragraph 12 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Worldwide submitted NDA No. 211566 to the FDA under 21 U.S.C. § 355(b)(2), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of sitagliptin tablets, 25 mg, 50 mg, and 100 mg, and that Cadila is the manufacturer of the sitagliptin tablets, 25 mg, 50 mg, and 100 mg, described in NDA No. 211566. Defendants further admit that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Cadila, in the United States. Defendants further admit that Zydus USA and Zydus Worldwide are wholly owned subsidiaries of Cadila. 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 admit that Zydus Worldwide submitted NDA No. 211566 to the FDA under 21 U.S.C. § 355(b)(2), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of sitagliptin tablets, 25

mg, 50 mg, and 100 mg. Defendants further admit that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Cadila, in the United States. Defendants further admit that Zydus USA and Zydus Worldwide are wholly owned subsidiaries of Cadila. Defendants deny all other allegations in paragraph 13.

JURISDICTION

14. The allegations in paragraph 14 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 limited purpose 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 NDA No. 211566. 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, Defendants do not contest personal jurisdiction in this Court solely for the limited purpose 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 NDA No. 211566. 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, Zydus USA does not contest personal jurisdiction in this Court solely for the limited purpose of Merck's claims against Zydus USA in this case and solely as they apply to the sitagliptin tablets, 25 mg, 50 mg, and 100 mg, described in NDA No. 211566. Defendants admit that Zydus USA sells pharmaceutical products, including generic pharmaceutical products, in the United States. 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, Zydus Worldwide does not contest personal jurisdiction in this Court solely for the limited purpose of Merck's claims against Zydus Worldwide in this case and solely as they apply to the sitagliptin tablets, 25 mg, 50 mg, and 100 mg, described in NDA No. 211566. Defendants deny all other allegations in paragraph 17.

18. The allegations in paragraph 18 are legal conclusions to which no answer is required. To the extent an answer is required, Cadila does not contest personal jurisdiction in this Court solely for the limited purpose of Merck's claims against Cadila in this case and solely as they apply to the sitagliptin tablets, 25 mg, 50 mg, and 100 mg, described in NDA No. 211566. Defendants admit that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Cadila, in the United States. Defendants deny all other allegations in paragraph 18.

19. The allegations in paragraph 19 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. Zydus Pharmaceuticals (USA) Inc.*, No. 1:19-cv-00314-RGA (D. Del. Mar. 18, 2019), Zydus USA and Cadila stated that "[Zydus USA and Cadila] do not contest personal jurisdiction in this Court solely for the purposes of Merck's claims against [Zydus USA and Cadila] in this case and solely as they apply to the sitagliptin tablets, 25 mg, 50 mg, and 100 mg, sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg and 50 mg/1000 mg, and sitagliptin and metformin hydrochloride tablets, 50 mg/500 mg, 50 mg/1000 mg, and 100 mg/1000 mg, described in ANDA Nos. 208186, 208535, and 209573, respectively"; in *Pfizer, Inc. v. Zydus Pharmaceuticals (USA) Inc.*, No. 1:20-cv-01396-CFC (D. Del. Nov. 9, 2020), Defendants stated that "[Zydus USA, Zydus Worldwide, and Cadila] do[]"not contest personal jurisdiction in this

Court solely for purposes of Plaintiffs' claims against [Zydus USA, Zydus Worldwide, and Cadila] in this case and solely as they apply to the proposed product described in ANDA No 213098"; in *Pharmacyclics LLC v. Zydus Worldwide DMCC*, No. 1:19-cv-00143-CFC (D. Del. Mar. 22, 2019) Zydus Worldwide and Cadila stated that "[Zydus Worldwide and Cadila] do[] not contest this Court's personal jurisdiction over [Zydus Worldwide and Cadila] solely for the limited purposes of this action only, and reserve[] the right to contest personal jurisdiction in any other case" and asserted counterclaims; in *AstraZeneca AB v. Zydus Pharmaceuticals (USA) Inc.*, No. 1:18-cv-00664-RGA (D. Del. June 22, 2018), Zydus USA stated that "Zydus [USA] does not contest personal jurisdiction in this Court solely for purposes of AstraZeneca's claims against Zydus [USA] in this case" and asserted counterclaims; in *Biogen International GmbH v. Zydus Pharmaceuticals (USA) Inc.*, No. 1:18-cv-00623-LPS (D. Del. June 1, 2018), Zydus USA stated that "Zydus [USA] does not contest personal jurisdiction in this Court solely for purposes of Biogen's alleged claims arising under 35 U.S.C. § 271(e)(2) against Zydus [USA] related to the [asserted patent] in this case"; in *H. Lundbeck A/S v. Zydus Pharmaceuticals (USA) Inc.*, No. 1:18-cv-00150-LPS (D. Del. Apr. 2, 2018), Zydus USA and Cadila stated that "Defendants do not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Defendants in this case"; and in *Millennium Pharmaceuticals, Inc. v. Zydus Pharmaceuticals (USA) Inc.*, No. 1:17-cv-00423-GMS (D. Del. May 24, 2017), Zydus USA and Cadila stated that "Defendants do not contest personal jurisdiction in this Court for the limited purposes of this action only" and asserted counterclaims. Defendants deny all other allegations in paragraph 19.

20. The allegations in paragraph 20 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Worldwide submitted NDA No. 211566 to the FDA under 21 U.S.C. § 355(b)(2), seeking FDA approval to engage in

the commercial manufacture, use, offer for sale, sale, and/or importation of sitagliptin tablets, 25 mg, 50 mg, and 100 mg. Defendants further admit that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Cadila, 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 20 and therefore deny them. 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 paragraph 21 and therefore deny them, except that Defendants admit that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Cadila, in the United States.

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.

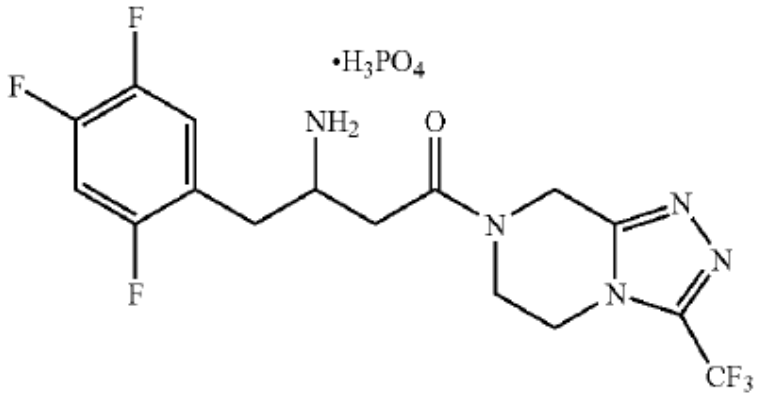
24. The allegations in paragraph 24 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the '708 patent is titled "Phosphoric Acid Salt of a Dipeptidyl Peptidase-IV Inhibitor" and lists February 5, 2008, as the Date of Patent. Defendants further 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, "JANUVIA" as the Proprietary Name, and "SITAGLIPTIN PHOSPHATE" as the Active Ingredient in connection with NDA No. 021995. Defendants lack knowledge or

information sufficient to form a belief about the truth of all other allegations in paragraph 27 and therefore deny them.

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 Zydus USA, on behalf of Zydus Worldwide, sent the Notice Letter to Merck pursuant to 21 U.S.C. § 355(b)(3), notifying Merck that Zydus Worldwide submitted NDA No. 211566 to the FDA under 21 U.S.C. § 355(b)(2), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of sitagliptin tablets, 25 mg, 50 mg, and 100 mg, and that NDA No. 211566 included a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(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 NDA No. 211566. Defendants deny all other allegations in paragraph 29.

30. Defendants admit that Zydus USA, on behalf of Zydus Worldwide, sent the Notice Letter to Merck pursuant to 21 U.S.C. § 355(b)(3), notifying Merck that Zydus Worldwide submitted NDA No. 211566 to the FDA under 21 U.S.C. § 355(b)(2), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of sitagliptin tablets, 25 mg, 50 mg, and 100 mg, and that NDA No. 211566 included a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(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 NDA No. 211566. Defendants deny all other allegations in paragraph 30.

31. Defendants admit that Zydus USA, on behalf of Zydus Worldwide, sent the Notice Letter to Merck pursuant to 21 U.S.C. § 355(b)(3), notifying Merck that Zydus Worldwide

submitted NDA No. 211566 to the FDA under 21 U.S.C. § 355(b)(2), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of sitagliptin tablets, 25 mg, 50 mg, and 100 mg. Defendants deny all other allegations in paragraph 31.

32. Defendants admit that a document titled "Zydus's Detailed Factual and Legal Bases in Support of Its Paragraph IV Certification for Sitagliptin Tablets, 25 mg, 50 mg, and 100 mg" ("Detailed Statement") was attached to the Notice Letter as Exhibit A. Defendants further admit that the Detailed Statement "contain[ed] the detailed factual and legal bases for Zydus Worldwide DMCC's … certification that, in its opinion and to the best of its knowledge, no valid and enforceable claim of [the '708 patent] will be infringed by the commercial manufacture, use, or sale of the proposed drug product described in … NDA No. 211566." Defendants deny all other allegations in paragraph 32.

33. Defendants admit that the parties agreed to terms under which Merck would gain access to Defendants' technical documents. Defendants deny all other allegations in paragraph 33.

34. Denied.

35. Denied.

36. Denied.

37. Defendants admit that Zydus Worldwide submitted NDA No. 211566 to the FDA under 21 U.S.C. § 355(b)(2), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of sitagliptin tablets, 25 mg, 50 mg, and 100 mg, and that NDA No. 211566 included a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(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 NDA No. 211566. Defendants deny all other allegations in paragraph 37.

38. Denied.

39. Denied.

40. Denied.

41. Denied.

42. The allegations in paragraph 42 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Worldwide submitted NDA No. 211566 to the FDA under 21 U.S.C. § 355(b)(2), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of sitagliptin tablets, 25 mg, 50 mg, and 100 mg, and that NDA No. 211566 included a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(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 NDA No. 211566. Defendants deny all other allegations in paragraph 42.

43. Denied.

44. Defendants deny the allegations in paragraph 44, except that Defendants admit that Zydus Worldwide submitted NDA No. 211566 to the FDA under 21 U.S.C. § 355(b)(2), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of sitagliptin tablets, 25 mg, 50 mg, and 100 mg, and that NDA No. 211566 included a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(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 NDA No. 211566.

45. Denied.

46. 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, a finding that Merck lacked a reasonable basis to initiate and continue prosecuting this action and that this case is exceptional, 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, offer for sale, sale, and/or importation of the sitagliptin tablets, 25 mg, 50 mg, and 100 mg, described in NDA No. 211566 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: April 19, 2021

Respectfully submitted,

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

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