IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., *Plaintiff,* v. ZYDUS WORLDWIDE DMCC, ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LTD., *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 that arises out of defendants' submission of New Drug Application ("NDA") No. 211566 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 JANUVIA® (sitagliptin phosphate) prior to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent").

2. Zydus Worldwide DMCC ("Zydus Worldwide") and Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") notified Merck by letter dated January 14, 2021 ("Zydus's Notice Letter") that it had submitted to the FDA NDA No. 211566 ("Zydus's NDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic sitagliptin oral tablets ("Zydus's NDA Product") prior to the expiration of the '708 patent.

3. On information and belief, Zydus's NDA Product is a generic version of Merck's JANUVIA®.

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 Zydus USA is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. On information and belief, Zydus USA is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

7. On information and belief, Zydus Worldwide is a company organized and existing under the laws of the United Arab Emirates, with a principal place of business at Unit No 908, Armada 2, Plot No JLT PH2 P2A, Jumeirah Lakes, Dubai, United Arab Emirates. On information and belief, Zydus Worldwide is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

8. On information and belief, defendant Cadila Healthcare Ltd. ("Cadila") is a corporation organized and existing under the laws of India, with its principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380 015, Gujarat, India. On information and belief, Cadila is in the business of, among other things, manufacturing and selling generic

versions of branded pharmaceutical products through various operating subsidiaries, including Zydus Worldwide and Zydus USA.

9. On information and belief, Zydus USA and Zydus Worldwide are wholly owned subsidiaries of Cadila.

10. Zydus Worldwide, Zydus USA, and Cadila are collectively referred to herein as "Defendants."

11. On information and belief, Zydus Worldwide, Zydus USA, and Cadila acted in concert to prepare and submit Zydus's NDA to the FDA.

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

13. On information and belief, following any FDA approval of Zydus's NDA, Zydus Worldwide, Zydus USA, and Cadila will act in concert to distribute and sell Zydus's NDA Product throughout the United States, including within Delaware.

JURISDICTION

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

15. This Court has personal jurisdiction over Defendants.

16. Zydus USA 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. On information and belief, Zydus USA 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.

17. Zydus Worldwide 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. Upon information and belief, Zydus Worldwide 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. Cadila is subject to personal jurisdiction in Delaware because, among other things, Cadila, itself and through its wholly owned subsidiaries Zydus Worldwide and Zydus USA., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Cadila, itself and through its wholly owned indirect subsidiaries Zydus Worldwide and Zydus USA, 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, Cadila is subject to personal jurisdiction in Delaware because,

upon information and belief, it controls Zydus USA and Zydus Worldwide, and therefore the activities of Zydus USA and Zydus Worldwide in this jurisdiction are attributed to Cadila.

19. In addition, this Court has personal jurisdiction over Defendants because Zydus Worldwide, Zydus USA, and Cadila 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, including regarding the '708 patent. *See, e.g.*, *Merck Sharp & Dohme Corp. v. Zydus Pharmaceuticals (USA) Inc., et al.*, No. 19-314-RGA D.I. 11 (D. Del. Mar. 18, 2019) (Zydus USA and Cadila); *see also Pfizer, Inc. v. Zydus Pharmaceuticals (USA) Inc., et al.*, No. 20-1396-CFC, D.I. 10 (D. Del. Nov. 9, 2020) (Zydus USA, Zydus Worldwide, and Cadila); *Pharmacyclics LLC v. Zydus Worldwide DMCC et al.*, No. 19-143-CFC D.I. 10 (D. Del. Mar. 22, 2019) (Zydus Worldwide and Cadila); *Astrazeneca AB v. Zydus Pharms. (USA) Inc.*, No. 18-664-RGA, D.I. 9 (D. Del. June 22, 2018) (Zydus USA); *Biogen Int'l GmbH v. Zydus Pharms. (USA) Inc.*, No. 18-623-LPS, D.I. 8 (D. Del. June 1, 2018) (Zydus USA); *H. Lundbeck A/S v. Zydus Pharms. (USA) Inc.*, No. 18-150-LPS, D.I. 13 (D. Del. Apr. 2, 2018) (Zydus USA and Cadila); *Millennium Pharms., Inc. v. Zydus Pharms. (USA) Inc.*, No. 17-423-CFC, D.I. 9 (D. Del. May 24, 2017) (Zydus USA and Cadila).

20. On information and belief, if Zydus's NDA is approved, Zydus Worldwide, Zydus USA, and Cadila will manufacture, market, sell, and/or distribute Zydus's NDA Product within the United States, including in Delaware, consistent with Defendants' practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Zydus Worldwide, Zydus USA, and Cadila regularly do business in Delaware, and Zydus Worldwide, Zydus USA, and Cadila'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, Zydus Worldwide, Zydus USA, and Cadila's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Zydus's NDA 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 Zydus's NDA Product is approved before the patent expires.

21. On information and belief, Zydus Worldwide, Zydus USA, and Cadila derive substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Zydus Worldwide, Zydus USA, and/or Cadila, and/or for which Zydus Worldwide, Zydus USA, and/or Cadila is/are the named applicant(s) on approved NDAs and/ or Abbreviated New Drug Applications ("ANDAs"). On information and belief, various products for which Zydus Worldwide, Zydus USA and/or Cadila is/are the named applicant(s) on approved NDAs or ANDAs are available at retail pharmacies in Delaware.

THE '708 PATENT

22. Merck incorporates each of the preceding paragraphs 1–21 as if fully set forth herein.

23. 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.

24. 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.

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

26. 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.

27. 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

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

29. In Zydus’s Notice Letter, Defendants notified Merck of the submission of Zydus’s NDA 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 Zydus’s NDA Product prior to the expiration of the ’708 patent.

30. In Zydus’s Notice Letter, Defendants also notified Merck that, as part of its NDA, Defendants had filed certifications of the type described in Section 505(b)(3) of the FDCA, 21 U.S.C. § 355(b)(3), with respect to the ’708 patent. Defendants submitted Zydus’s NDA to the FDA containing certifications 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 Zydus’s NDA Product.

31. In Zydus’s Notice Letter, Defendants stated that Zydus’s NDA Product contains sitagliptin as an active ingredient.

32. Zydus’s Notice Letter appends a document titled “Zydus’s Detailed Factual and Legal Bases In Support of its Paragraph IV Certification” asserting that the commercial

manufacture, use, or sale of Zydus's NDA Product will not infringe the '708 patent. However, Zydus's Notice Letter and accompanying document do not provide information regarding Zydus's NDA Product sufficient to evaluate Zydus's assertions of non-infringement.

33. Merck requested that Zydus provide its DMF and NDA, and the parties agreed to terms under which Merck would gain access to Zydus's technical documents; however, Merck has yet to receive Zydus's NDA, DMF, or any other similar internal documents and data relevant to infringement.

34. Merck brings forward this Complaint now on good faith belief that the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's NDA Product will infringe the '708 patent, while still awaiting access to Zydus's NDA and DMF, in order to commence this action before the expiration of forty-five days from the date of the receipt of Zydus's Notice Letter.

35. On information and belief, Zydus's NDA Product, and the use of Zydus's NDA Product, are covered by one or more claims of the '708 patent.

36. Defendants' submission of Zydus's NDA with a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's NDA Product before the expiration of the '708 patent was an act of infringement of the '708 patent under 35 U.S.C. § 271(e).

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

38. On information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's NDA Product would infringe one or more claims of the '708 patent.

39. On information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's NDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '708 patent.

40. On information and belief, Defendants plan and intend to, and will, actively induce infringement of the '708 patent when Zydus's NDA 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.

41. On information and belief, Defendants know that Zydus's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '708 patent, that Zydus's NDA Product is not a staple article or commodity of commerce, and that Zydus's NDA 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 Zydus's NDA.

42. 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 Zydus's NDA Product with its product labeling following FDA approval of Zydus's NDA prior to the expiration of the '708 patent.

43. 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.

44. 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.

45. Merck will be substantially and irreparably damaged by infringement of the ’708 patent.

46. 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.

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 Zydus’s NDA;

(b) A judgment ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of Zydus’s NDA 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 Zydus’s NDA 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 declaration that this is an exceptional case and an award of attorney’s fees pursuant to 35 U.S.C. § 285;

(e) Costs and expenses in this action; and

(f) Such further and other relief as this Court may deem just and proper.

Dated: March 1, 2021

Respectfully submitted,

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