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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTELLAS PHARMA INC.; ASTELLAS US LLC; ASTELLAS PHARMA US, INC.; MEDIVATION LLC; MEDIVATION PROSTATE THERAPEUTICS LLC, Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA) INC.; ZYDUS LIFESCIENCES LTD., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Astellas Pharma Inc. ("API"), Astellas US LLC ("AUS"), and Astellas Pharma US, Inc. ("APUS") (collectively, "Astellas"), and Medivation LLC and Medivation Prostate Therapeutics LLC ("MPT") (collectively, "Medivation") (all collectively, "Plaintiffs"), for their Complaint against Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus USA Inc.") and Zydus Lifesciences Ltd. ("Zydus Ltd.") (collectively, "Zydus"), hereby allege as follows:

THE PARTIES

1. Plaintiff API is a corporation organized and existing under the laws of Japan having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan.

2. Plaintiff AUS is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 2375 Waterview Drive, Northbrook, Illinois 60062, United States.

3. Plaintiff APUS is a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 2375 Waterview Drive, Northbrook, Illinois 60062, United States.

4. Plaintiff Medivation LLC is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 66 Hudson Boulevard East, New York, New York 10001-2192, United States.

5. Plaintiff MPT is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 66 Hudson Boulevard East, New York, New York 10001-2192, United States.

6. On information and belief, Defendant Zydus USA Inc. is a corporation organized and existing under the laws of the State of New Jersey having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

7. On information and belief, Zydus USA Inc., by itself and/or through its affiliates and agents, is in the business of among other things, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

8. On information and belief, Defendant Zydus Ltd. is a corporation organized and existing under the laws of India having a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, Ahmedabad 382481, India.

9. On information and belief, Zydus Ltd., by itself and/or through its affiliates and agents, is in the business of among other things, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

10. On information and belief, Zydus USA Inc. is a wholly-owned subsidiary and the U.S. division of Zydus Ltd.

11. On information and belief, Zydus USA Inc. and Zydus Ltd. are agents of each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of generic products. On information and belief, the acts of Zydus USA Inc. and Zydus Ltd. complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

12. On information and belief, Defendants Zydus USA Inc. and Zydus Ltd. have cooperated and assisted in the preparation and filing of Zydus's Abbreviated New Drug Application ("ANDA") No. 217322 and will be involved in the manufacture, importation, marketing, and sale of the drug that is the subject of ANDA No. 217322 if it is approved.

NATURE OF THE ACTION

13. This is a civil action for the infringement of United States Patent No. 11,839,689 ("the '689 patent") under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., arising from Zydus's filing of ANDA No. 217322 with the United States Food and Drug Administration

("FDA") seeking approval to market generic versions of the pharmaceutical products Xtandi® tablets, 40 and 80 mg, before the expiration of the '689 patent covering Xtandi®.

JURISDICTION AND VENUE

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

15. This Court has personal jurisdiction over Zydus by virtue of the fact that, *inter alia*, Zydus has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of New Jersey and throughout the United States.

16. This Court has personal jurisdiction over Zydus by virtue of the fact that Zydus is at home in New Jersey as reflected by the fact that, on information and belief, it regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, including by selling its pharmaceutical products in New Jersey and, therefore, can reasonably expect to be subject to jurisdiction in the New Jersey courts. Among other things, on information and belief, Zydus conducts marketing and sales activities in the State of New Jersey, including but not limited to, distribution, marketing, and sales of pharmaceutical products to New Jersey residents that are continuous and systematic. On information and belief, if Zydus's ANDA No. 217322 is approved, it will market and sell its generic versions of Xtandi® tablets in New Jersey.

17. This Court has personal jurisdiction over Zydus USA Inc. On information and belief, Zydus USA Inc. is a New Jersey corporation having a principal place of business in New Jersey.

18. This Court also has personal jurisdiction over Zydus USA Inc. and Zydus Ltd. (formerly known as Cadila Healthcare Ltd.) by virtue of the fact that each previously submitted to the jurisdiction of this Court and availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in civil actions initiated in this jurisdiction including, but not limited to, *e.g.*, *American Regent, Inc. v. Zydus Pharms. (USA) Inc.*, No. 2:24-cv-07812 (D.N.J.); *AbbVie Inc. v. Zydus Pharms. (USA) Inc.*, No. 3:24-cv-04603 (D.N.J.); *Astellas Pharma Inc. v. Zydus Pharms. (USA) Inc.*, No. 2:22-cv-04499 (D.N.J); *Fresenius Kabi USA, LLC v. Zydus Pharms. (USA) Inc.*, No. 3:22-cv-01702 (D.N.J.); *Supernus Pharms., Inc., v. Zydus Pharms. (USA) Inc.*, No. 3:21-cv-17104 (D.N.J.); *Almirall, LLC v. Zydus Pharms. (USA) Inc.*, No. 3:20-cv-00343 (D.N.J.); *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, No. 3:18-cv-11792 (D.N.J.); *Shionogi Inc. v. Zydus Pharms. (USA) Inc.*, No. 3:18-cv-12898 (D.N.J.); *Valeant Pharms. N. Am., LLC v. Zydus Pharms. (USA) Inc.*, No. 2:18-cv-13635 (D.N.J.); and *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc*., No. 3:18-cv-01994 (D.N.J.). On information and belief, Zydus USA Inc. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey by having filed suit in this jurisdiction. *See, e.g.*, *Zydus Pharms. (USA) Inc. v. Novartis Pharms. Co.*, No. 2:19-cv-21259 (D.N.J.); *Zydus Pharms. (USA) Inc. v. Eli Lilly & Co.*, 2:10-cv-05584 (D.N.J.).

19. Alternatively, assuming that the above facts do not establish personal jurisdiction over Zydus Ltd., this Court may exercise jurisdiction over Zydus Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Zydus Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Zydus Ltd. has sufficient contacts with the United States as a whole, including but not limited

to manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Zydus Ltd. satisfies due process.

20. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

21. Venue is proper in this judicial district for Zydus USA Inc. because, among other things, on information and belief, Zydus USA Inc. is a New Jersey corporation having a principal place of business in New Jersey.

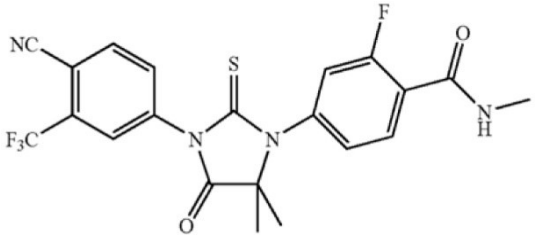
22. Venue is proper in this judicial district for Zydus Ltd. because, among other things, Zydus Ltd. is a foreign corporation not residing in any United States district and may be sued in any judicial district.

23. Venue is further proper as to Zydus because, among other things, Zydus has committed, or aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture Xtandi® for sale and use throughout the United States, including within the State of New Jersey.

THE XTANDI® TABLET NDA

24. APUS filed New Drug Application ("NDA") No. 213674 for Xtandi® (enzalutamide) tablets, 40 mg and 80 mg. The FDA approved NDA No. 213674 for Xtandi® 40 mg and 80 mg tablets on August 4, 2020, for the treatment of patients with castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer. On November 16, 2023, the FDA approved an expanded indication for the use of Xtandi® 40 mg and 80 mg tablets to treat patients with non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis. Xtandi® tablets are sold and co-promoted by APUS and Pfizer Inc. in the United States.

25. Enzalutamide is a compound that can be referred to by any of several chemical names, including 4-{3-[4-cyano-3-(trifluoromethyl)phenyl]-5,5-dimethyl-4-oxo-2-sulfanylideneimidazolidin-1-yl}-2-fluoro-N-methylbenzamide, 4-{3-(4-cyano-3-(trifluoromethyl)phenyl)-5,5-dimethyl-4-oxo-2-thioxoimidazolidin-1-yl}-2-fluoro-N-methylbenzamide, 4-[3-[4-cyano-3-(trifluoromethyl)phenyl]-4-keto-5,5-dimethyl-2-thioxo-imidazolidin-1-yl]-2-fluoro-N-methyl-benzamide, and 4-[3-[4-cyano-3-(trifluoromethyl)phenyl]-5,5-dimethyl-4-oxo-2-sulfanylidene-1-imidazolidinyl]-2-fluoro-N-methylbenzamide, and which has the following chemical structure:



THE PATENT-IN-SUIT

26. On December 12, 2023, the ’689 patent, entitled “Formulations of Enzalutamide,” was duly and legally issued to API and MPT. A true and correct copy of the ’689 patent is attached hereto as Exhibit A.

27. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the ’689 patent is listed in the Orange Book for Xtandi® 40 mg and 80 mg tablets.

28. Pursuant to an agreement, as amended, entered into between API, AUS, Medivation, Inc., and Medivation Prostate Therapeutics, Inc., API was granted an exclusive license to the ’689 patent.

29. Pursuant to an agreement, as amended, entered into between API and AUS, AUS was granted a sublicense to the ’689 patent.

30. Pursuant to an agreement entered into between AUS and APUS, APUS was granted a sublicense to the ’689 patent.

31. On September 28, 2016, Pfizer Inc. acquired Medivation, Inc. and its wholly owned subsidiary Medivation Prostate Therapeutics, Inc.

32. On August 28, 2017, Medivation, Inc. filed a Certificate of Conversion with the Delaware Secretary of State, in which Medivation, Inc. converted from a corporation to a limited liability company and changed its name to Medivation LLC.

33. On August 28, 2017, Medivation Prostate Therapeutics, Inc. filed a Certificate of Conversion with the Delaware Secretary of State, in which Medivation Prostate Therapeutics, Inc. converted from a corporation to a limited liability company and changed its name to Medivation Prostate Therapeutics LLC.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

34. Before issuance of the ’689 patent, APUS received a notice letter from Zydus dated May 26, 2022 (the “First Zydus Notice Letter”), advising APUS that Zydus submitted ANDA No. 217322 to the FDA seeking approval to manufacture, use, or sell enzalutamide 40 mg and 80 mg tablets (“Zydus’s Generic Products”) prior to the expiration of U.S. Patent No. 7,709,517 (“the ’517 patent”). The ’517 patent, entitled “Diarylhydantoin Compounds,” claims, *inter alia*, the compound, and pharmaceutical compositions of, enzalutamide. It is listed in the Orange Book for Xtandi® 40 mg and 80 mg tablets.

35. Plaintiffs brought suit against Zydus in this judicial district on July 8, 2022, alleging infringement of the ’517 patent. *See Astellas Pharma Inc. v. Zydus Pharms. (USA) Inc.*, No. 2:22-cv-04499 (D.N.J).

36. In that lawsuit, Plaintiffs and Zydus stipulated that all claims and defenses asserted by the parties against each other would be dismissed without prejudice. The Joint Stipulation and Order of Dismissal was entered on April 17, 2023. *See Astellas Pharma Inc. v. Zydus Pharms. (USA) Inc.*, No. 2:22-cv-04499 (D.N.J), D.I. 36.

37. By a letter dated September 3, 2024 (the "Second Zydus Notice Letter"), Zydus advised APUS, API, and MPT that it had submitted ANDA No. 217322 to the FDA seeking approval to manufacture, use, or sell Zydus's Generic Products prior to the expiration of the '689 patent.

38. On information and belief, Zydus submitted ANDA No. 217322 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), seeking approval to engage in the commercial manufacture, use, and sale of Zydus's Generic Products as generic versions of Xtandi® 40 mg and 80 mg tablets.

39. On information and belief, ANDA No. 217322 seeks FDA approval of Zydus's Generic Products for the indications of treatment of castration-resistant prostate cancer, metastatic castration-sensitive prostate cancer, and non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis.

40. The Second Zydus Notice Letter also advised APUS, API, and MPT that Zydus's ANDA submission included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Zydus's opinion, certain claims of the '689 patent are invalid, unenforceable, and/or not infringed.

41. The Second Zydus Notice Letter does not allege invalidity of claims 2-7 of the '689 patent.

42. By not identifying invalidity defenses for claims 2-7 of the '689 patent in the Second Zydus Notice Letter, Zydus admits these claims are valid.

43. The Second Zydus Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, or 112, or unenforceability of any claim of the '689 patent.

44. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, or 112, or unenforceability defenses for the '689 patent in the Second Zydus Notice Letter, Zydus admits the claims of the '689 patent are valid under 35 U.S.C. §§ 101, 102, and 112, and are enforceable.

45. There is an actual, real, immediate, and justiciable controversy between Plaintiffs and Zydus regarding the infringement, validity, and enforceability of the '689 patent.

46. Plaintiffs are commencing this action within 45 days of receiving the Second Zydus Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I
(Infringement of the '689 Patent)

47. Plaintiffs incorporate each of the preceding paragraphs 1 to 46 as if fully set forth herein.

48. By submitting ANDA No. 217322 to the FDA to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's Generic Products throughout the United States, including New Jersey, prior to expiration of the '689 patent, Zydus committed an act of infringement of the '689 patent under 35 U.S.C. § 271(e)(2)(A).

49. The '689 patent claims, *inter alia*, pharmaceutical compositions of enzalutamide. Claim 1 recites "a pharmaceutical composition comprising a solid dispersion consisting essentially of amorphous enzalutamide and hydroxypropyl methylcellulose acetate succinate" ("HPMCAS"). Certain dependent claims specify that the formulation is a tablet.

50. The formulation of Xtandi® tablets, 40 and 80 mg, contains a pharmaceutical composition comprising a solid dispersion consisting essentially of amorphous enzalutamide and HPMCAS. The formulation of Xtandi® tablets, 40 and 80 mg, is covered by the '689 patent.

51. The Second Zydus Notice Letter does not dispute that Zydus's Generic Products are tablets or that those tablets contain a solid dispersion of enzalutamide, amorphous enzalutamide, or HPMCAS.

52. On information and belief, Zydus copied the claimed invention of the '689 patent.

53. On information and belief, Zydus was not required to copy the claimed invention of the '689 patent or the Xtandi® tablets formulation.

54. On information and belief, Zydus's Generic Products, if approved by the FDA, will contain a pharmaceutical composition comprising a solid dispersion consisting essentially of amorphous enzalutamide and HPMCAS, which will constitute infringement of claims of the '689 patent.

55. On information and belief, Zydus's manufacture, use, sale, offer for sale, and/or importation into the United States of Zydus's Generic Products prior to the expiration of the '689 patent, including any applicable exclusivities or extensions, will directly infringe the '689 patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents. Zydus will infringe one or more of the claims of the '689 patent.

56. On information and belief, Zydus was aware of the existence of the '689 patent and its listing in the Orange Book as demonstrated by Zydus's reference to the '689 patent in the Second Zydus Notice Letter.

57. On information and belief, Zydus knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's Generic Products prior to patent expiry will infringe one or more claims of the '689 patent.

58. On information and belief, Zydus's statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '689 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

59. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Zydus has infringed one or more claims of United States Patent No. 11,839,689 by submitting ANDA No. 217322 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's Generic Products before the expiration of that patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that Zydus's commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Zydus's Generic Products will infringe one or more claims of United States Patent No. 11,839,689 under 35 U.S.C. §§ 271(a);

C. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining Zydus, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Zydus's Generic Products prior to the expiration date of United States Patent No. 11,839,689, inclusive of any extensions;

D. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 217322 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of United States Patent No. 11,839,689, inclusive of any extensions;

E. A declaration that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorney fees;

F. An award of costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: October 11, 2024

/s/ Liza M. Walsh

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LOCAL RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending litigation in any court, administrative proceeding, or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action, but this action is related to the following actions:

- *Astellas Pharma Inc., et al. v. Qilu Pharmaceutical (Hainan) Co., Ltd., et al.*, Case No. 3:24-cv-08217 (MAS), pending in the United States District Court for the District of New Jersey; and
- *Astellas Pharma Inc., et al. v. Haimen Pharma Inc., et al.*, Case No. 3:24-cv-09403 (MAS), pending in the United States District Court for the District of New Jersey.

Dated: October 11, 2024

/s/ Liza M. Walsh

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Attorneys for Plaintiffs

LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: October 11, 2024

/s/ Liza M. Walsh
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