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Attorneys for Plaintiffs

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; THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, Plaintiffs, v. HAIMEN PHARMA INC.; SINOTHERAPEUTICS INC., 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"), Medivation LLC ("Medivation") and Medivation Prostate Therapeutics LLC ("MPT") (collectively, "Medivation"), and The Regents of the University of California ("The Regents") (all collectively, "Plaintiffs"), for their Complaint against Defendants Haimen Pharma Inc. ("Haimen Pharma") and SinoTherapeutics Inc. ("SinoTherapeutics") (collectively, "Defendants"), 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 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. Plaintiff The Regents is a public corporation organized and existing under the laws of the State of California operating under Article 9, Section 9 of the California Constitution, having its corporate offices located at 1111 Franklin Street, Oakland, California 94607-5200, United States.

7. On information and belief, Defendant Haimen Pharma is a corporation organized and existing under the laws of China having a principal place of business at 99 Haike Road, Bldg. 3, 1st Flr., Pudong District, Shanghai, 201210, China.

8. On information and belief, Haimen Pharma, 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.

9. On information and belief, Defendant SinoTherapeutics is a corporation organized and existing under the laws of China having a principal place of business at 99 Haike Road, Bldg. 3, 1st Flr., Pudong District, Shanghai, 201210, China.

10. On information and belief, SinoTherapeutics, 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.

11. On information and belief, Haimen Pharma is a wholly-owned subsidiary of SinoTherapeutics.

12. On information and belief, Haimen Pharma and SinoTherapeutics 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 Haimen Pharma and SinoTherapeutics complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

13. On information and belief, Defendants Haimen Pharma and SinoTherapeutics have cooperated and assisted in the preparation and filing of Defendants' Abbreviated New Drug Application ("ANDA") No. 219675 and will be involved in the manufacture, importation, marketing, and sale of the drug that is the subject of ANDA No. 219675 if it is approved.

NATURE OF THE ACTION

14. This is a civil action for the infringement of United States Patent Nos. 7,709,517 ("the '517 patent") and 11,839,689 ("the '689 patent") (collectively, "the Xtandi® patents") under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., arising from Defendants' filing of ANDA No. 219675 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 Plaintiffs' patents covering Xtandi®.

JURISDICTION AND VENUE

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

16. This Court has personal jurisdiction over Defendants by virtue of the fact that, *inter alia*, Defendants have 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.

17. On information and belief, if Defendants' ANDA No. 219675 is approved, Defendants' generic versions of Xtandi® tablets, 40 and 80 mg, will be marketed and distributed by Defendants in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and/or used by patients in the State of New Jersey.

18. Defendants' infringing activities with respect to their ANDA No. 219675 have led and/or will lead to foreseeable harm and injury to Plaintiffs in the State of New Jersey.

19. This Court also has personal jurisdiction over Defendants by virtue of the fact that they are at home in New Jersey as reflected by the fact that, on information and belief, they

regularly do or solicit business in New Jersey, engage in other persistent courses of conduct in New Jersey, and/or derive substantial revenue from services or things used or consumed in New Jersey, including by selling their 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, Defendants conduct 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.

20. Alternatively, assuming that the above facts do not establish personal jurisdiction over Defendants, this Court may exercise jurisdiction over them pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Defendants are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) Defendants have 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 Defendants satisfies due process.

21. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391.

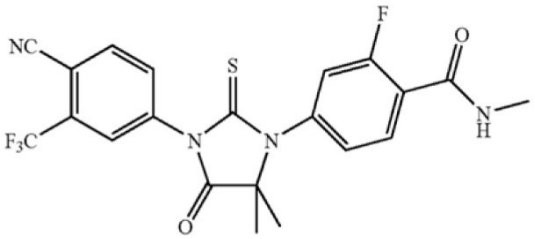
22. Venue is proper in this Judicial District for Defendants pursuant to 28 U.S.C. § 1391(c)(3) because, among other things, Defendants are foreign corporations not residing in any United States district and may be sued in any judicial district.

23. Venue is further proper in this Court as to Defendants because, among other things, Defendants have 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 PATENTS-IN-SUIT

26. On May 4, 2010, the '517 patent, entitled "Diarylhydantoin Compounds," was duly and legally issued to The Regents. A true and correct copy of the '517 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 '517 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") for Xtandi® 40 mg and 80 mg tablets.

28. Pursuant to an agreement, as amended, entered into between Medivation, Inc., Medivation Prostate Therapeutics, Inc., and The Regents, Medivation, Inc. and Medivation Prostate Therapeutics, Inc. were granted an exclusive license to the '517 patent, with the right to sue for infringement of the '517 patent in the United States.

29. Pursuant to an agreement entered into between API, AUS, Medivation, Inc., and Medivation Prostate Therapeutics, Inc., API was granted an exclusive sublicense to the '517 patent, with the right to sue for infringement of the '517 patent in the United States.

30. Pursuant to an agreement entered into between API and AUS, AUS was granted a sublicense to the '517 patent, with the right to sue for infringement of the '517 patent in the United States.

31. Pursuant to an agreement entered into between AUS and APUS, APUS was granted a sublicense to the '517 patent, with the right to sue for infringement of the '517 patent in the United States.

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

33. 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.

34. 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.

35. 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 B.

36. 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.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

37. By a letter dated August 15, 2024 ("Defendants' Notice Letter"), Defendants advised Plaintiffs that they had submitted ANDA No. 219675 to the FDA seeking approval to manufacture, use, or sell enzalutamide 40 mg and 80 mg tablets ("Defendants' Generic Products") prior to the expiration of the Xtandi® patents.

38. On information and belief, Defendants submitted ANDA No. 219675 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, and sale of Defendants' Generic Products as generic versions of Xtandi® 40 mg and 80 mg tablets.

39. On information and belief, ANDA No. 219675 seeks FDA approval of Defendants' 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. Defendants' Notice Letter also advised Plaintiffs that Defendants' ANDA submission included certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Defendants' opinion, certain claims of the Xtandi® patents are invalid, unenforceable, and/or not infringed.

41. Defendants' Notice Letter does not allege non-infringement of the '517 patent.

42. By not identifying non-infringement defenses for the '517 patent in Defendants' Notice Letter, Defendants admit that Defendants' Generic Products meet all limitations of at least some claims of that patent.

43. Defendants' Notice Letter does not allege invalidity under 35 U.S.C. §§ 101 or 112 or unenforceability for any claim of the '517 patent.

44. By not identifying invalidity defenses under 35 U.S.C. §§ 101 or 112 or unenforceability for any claim of the '517 patent, Defendants admit that the '517 patent is valid under 35 U.S.C. §§ 101 and 112 and enforceable.

45. Defendants' Notice Letter does not allege invalidity of any claim of the '689 patent.

46. By not identifying invalidity defenses for the '689 patent in Defendants' Notice Letter, Defendants admit that the '689 patent is valid.

47. There is an actual, real, immediate, and justiciable controversy between Plaintiffs and Defendants regarding the infringement, validity, and enforceability of the Xtandi® patents.

48. Plaintiffs are commencing this action within 45 days of receiving Defendants' Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I
(Infringement of the '517 Patent)

49. Plaintiffs incorporate each of the preceding paragraphs 1 to 48 as if fully set forth herein.

50. By submitting ANDA No. 219675 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' Generic Products throughout the United States, including New Jersey, prior to expiration of the '517 patent, Defendants committed an act of infringement of the '517 patent under 35 U.S.C. § 271(e)(2)(A).

51. The '517 patent claims, *inter alia*, the compound, and pharmaceutical compositions of, enzalutamide.

52. On information and belief, Defendants' Generic Products, if approved by the FDA, will contain the compound enzalutamide and/or pharmaceutical compositions thereof, which will constitute infringement of claims of the '517 patent.

53. On information and belief, Defendants' manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' Generic Products prior to the expiration of the '517 patent, including any applicable exclusivities or extensions, will directly infringe the '517 patent under 35 U.S.C. § 271(a). Defendants will infringe one or more of the claims of the '517 patent.

54. On information and belief, Defendants' Generic Products will infringe at least Claim 1 of the '517 patent which recites "[a] compound selected from the group consisting of" a group of compounds including enzalutamide. On information and belief, Defendants' Generic Products will infringe Claim 1 of the '517 patent because Defendants' Generic Products will contain enzalutamide.

55. On information and belief, Defendants were aware of the existence of the '517 patent and its listing in the Orange Book as demonstrated by the reference to the '517 patent in Defendants' Notice Letter.

56. On information and belief, Defendants copied the claimed invention of the '517 patent.

57. On information and belief, Defendants know or should know that their commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' Generic Products prior to patent expiry will infringe one or more claims of the '517 patent.

58. On information and belief, the statements in Defendants' Notice Letter of the purported factual and legal bases for Defendants' opinions regarding invalidity of the '517 patent are 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.

COUNT II
(Infringement of the '689 Patent)

60. Plaintiffs incorporate each of the preceding paragraphs 1 to 59 as if fully set forth herein.

61. By submitting ANDA No. 219675 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' Generic Products throughout the United States, including New Jersey, prior to expiration of the '689 patent, Defendants committed an act of infringement of the '689 patent under 35 U.S.C. § 271(e)(2)(A).

62. 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.

63. 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.

64. Defendants’ Notice Letter does not dispute that Defendants’ Generic Products are tablets that contain a solid dispersion of enzalutamide and also contain HPMCAS.

65. On information and belief, Defendants copied the claimed invention of the ’689 patent.

66. On information and belief, Defendants were not required to copy the claimed invention of the ’689 patent or the Xtandi® tablets formulation.

67. On information and belief, Defendants’ 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 at least one claim of the ’689 patent.

68. On information and belief, Defendants’ manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants’ 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. Defendants will infringe one or more of the claims of the ’689 patent.

69. On information and belief, Defendants were aware of the existence of the '689 patent and its listing in the Orange Book as demonstrated by the reference to the '689 patent in Defendants' Notice Letter.

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

71. On information and belief, the statements in Defendants' Notice Letter of the purported factual and legal bases for Defendants' opinions regarding noninfringement of the '689 patent are devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

72. 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 Defendants have infringed one or more claims of United States Patent Nos. 7,709,517 and 11,839,689 by submitting ANDA No. 219675 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' Generic Products before the expiration of the patents under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that Defendants' commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Defendants' Generic Products will infringe one or more claims of United States Patent Nos. 7,709,517 and 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 Defendants, their 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 Defendants' Generic Products prior to the expiration date of United States Patent Nos. 7,709,517 and 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. 219675 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 Nos. 7,709,517 and 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: September 24, 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 action:

- *Astellas Pharma Inc., et al. v. Qilu Pharmaceutical (Hainan) Co., Ltd., et al.*, Case No. 2:24-cv-08217 (MAS), pending in the United States District Court for the District of New Jersey.

Dated: September 24, 2024

s/Liza M. Walsh
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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: September 24, 2024

s/Liza M. Walsh
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