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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,

Civil Action No. _____

v.

HUMANWELL PURACAP
PHARMACEUTICALS (WUHAN) CO.,
LTD.; EPIC PHARMA, LLC,

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Astellas Pharma Inc., Astellas US LLC, and Astellas Pharma US, Inc. (collectively, "Astellas"), Medivation LLC and Medivation Prostate Therapeutics LLC (collectively, "Medivation"), and The Regents of the University of California ("The Regents") (all collectively, "Plaintiffs"), for their Complaint against Defendants Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd. ("Humanwell") and Epic Pharma, LLC ("Epic") (both collectively, "PuraCap") hereby allege as follows:

THE PARTIES

1. Plaintiff Astellas Pharma Inc. 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 Astellas US LLC is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062, United States.

3. Plaintiff Astellas Pharma US, Inc. is a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 1 Astellas Way, 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 Medivation Prostate Therapeutics 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.

6. Plaintiff The Regents of the University of California 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 Humanwell is a corporation organized and existing under the laws of China having a principal place of business at No. 99 Shendun Second Road, Donghu New Tech Development Zone, Wuhan, Hubei 430076 China.

8. On information and belief, Humanwell, 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 Epic is a limited liability company organized and existing under the laws of the State of Delaware having a principal place of business at 227-15 N. Conduit Avenue, Laurelton, New York, 11413-3134.

10. On information and belief, Epic by itself and/or through its affiliates and agents, has participated 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, Humanwell and Epic are both indirect subsidiaries of the same parent company, Humanwell Healthcare (Group) Co., Ltd., a corporation organized and existing under the laws of China, having a principal place of business at No. 666 Gaoxin Road, East Lake High-tech Development Zone, Wuhan, Hubei, China.

12. On information and belief, Epic is the United States agent for Humanwell.

13. On information and belief, Humanwell and Epic 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 Humanwell and Epic complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

14. On information and belief, Defendants Humanwell and Epic have cooperated and assisted in the preparation and filing of PuraCap's ANDA No. 217920 and will be involved in the

manufacture, importation, marketing, and sale of the drug that is the subject of ANDA No. 217920 if it is approved.

NATURE OF THE ACTION

15. This is a civil action for the infringement of United States Patent Nos. 7,709,517 (“the ’517 patent”) and 8,183,274 (“the ’274 patent”) (collectively, “the Xtandi® patents”) under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., arising from PuraCap’s filing of ANDA No. 217920 with the United States Food and Drug Administration (“FDA”) seeking approval to market generic versions of the pharmaceutical product Xtandi® capsules before the expiration of the Plaintiffs’ patents covering Xtandi® and its use.

JURISDICTION AND VENUE

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

17. This Court has personal jurisdiction over PuraCap by virtue of the fact that, *inter alia*, PuraCap 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.

18. This Court has personal jurisdiction over PuraCap by virtue of the fact PuraCap 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, PuraCap 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 PuraCap's ANDA No. 217920 is approved, it will market and sell its generic versions of Xtandi® capsules in New Jersey.

19. This Court has personal jurisdiction over Epic. On information and belief, Epic regularly conducts business in New Jersey and has an established place of business in New Jersey.

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

21. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b). Venue is proper in this judicial district for Humanwell pursuant to 28 U.S.C. § 1391(c)(3), because Humanwell is a foreign defendant that does not reside in the United States. Venue is proper in this judicial district for Epic, pursuant to 28 U.S.C. § 1400(b), because, upon information and belief, Epic's acts of infringement relating to the preparation and submission of ANDA No. 217920 to the FDA occurred in New Jersey, and Epic has a regular and established place of business in New Jersey.

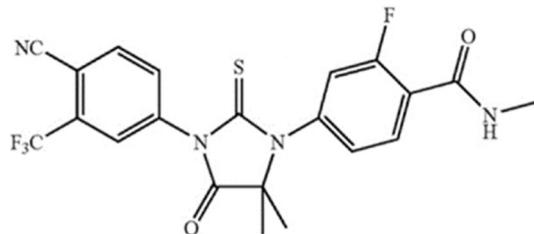
THE XTANDI® CAPSULE NDA

22. Medivation, Inc. filed New Drug Application ("NDA") No. 203415 for Xtandi® (enzalutamide) capsules, 40 mg. The FDA approved NDA No. 203415 for Xtandi® 40 mg

capsules on August 31, 2012 for the treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel. On September 10, 2014, the FDA approved an expanded indication for the use of Xtandi® 40 mg capsules to treat patients with metastatic castration-resistant prostate cancer. On July 13, 2018, the FDA approved an expanded indication for the use of Xtandi® 40 mg capsules to treat patients with castration-resistant prostate cancer. On December 16, 2019, the FDA approved an additional indication for the use of Xtandi® 40 mg capsules to treat patients with metastatic castration-sensitive prostate cancer.

23. Effective September 13, 2012, Medivation, Inc. assigned all rights, title, and interest to NDA No. 203415 to Astellas Pharma US, Inc. Xtandi® capsules are sold and co-promoted by Astellas Pharma US, Inc. and Pfizer Inc. in the United States.

24. 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

25. 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.

26. On May 22, 2012, the '274 patent, entitled "Treatment of Hyperproliferative Disorders with Diarylhydantoin Compounds," was duly and legally issued to The Regents. A true and correct copy of the '274 patent is attached hereto as Exhibit B.

27. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the Xtandi® patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") for Xtandi® 40 mg capsules.

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 and '274 patents, with the right to sue for infringement of the Xtandi® patents in the United States.

29. Pursuant to an agreement entered into between Astellas Pharma Inc., Medivation, Inc., and Medivation Prostate Therapeutics, Inc., Astellas Pharma Inc. was granted an exclusive sublicense to the '517 and '274 patents, with the right to sue for infringement of the Xtandi® patents in the United States.

30. Pursuant to an agreement entered into between Astellas Pharma Inc. and Astellas US LLC, Astellas US LLC was granted a sublicense to the '517 and '274 patents, with the right to sue for infringement of the Xtandi® patents in the United States.

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. By a letter dated January 31, 2023 (the “PuraCap Notice Letter”), PuraCap advised Plaintiffs that it had submitted ANDA No. 217920 to the FDA seeking approval to manufacture, use, or sell enzalutamide 40 mg capsules (“PuraCap’s Generic Product”) prior to the expiration of the Xtandi® patents.

35. On information and belief, PuraCap submitted ANDA No. 217920 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 PuraCap’s Generic Product as a generic version of Xtandi® 40 mg capsules.

36. On information and belief, ANDA No. 217920 seeks FDA approval of PuraCap’s Generic Product for the indications of treatment of castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer.

37. The PuraCap Notice Letter also advised Plaintiffs that PuraCap’s ANDA submission included certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in PuraCap’s opinion, certain claims of the Xtandi® patents are invalid, unenforceable, and/or not infringed.

38. The PuraCap Notice Letter does not allege non-infringement of certain claims of the Xtandi® patents.

39. By not identifying non-infringement defenses for certain claims of the Xtandi® patents in the PuraCap Notice Letter, PuraCap admits PuraCap's Generic Product meets all limitations of those claims.

40. The PuraCap Notice Letter does not allege invalidity of certain claims of the Xtandi® patents.

41. By not identifying invalidity defenses for certain claims of the Xtandi® patents in the PuraCap Notice Letter, PuraCap admits the claims of the Xtandi® patents for which invalidity defenses have not been raised are valid.

42. The PuraCap Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, or 112, or unenforceability of any claim of the Xtandi® patents.

43. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, or 112, or unenforceability defenses for the Xtandi® patents in the PuraCap Notice Letter, PuraCap admits the claims of the Xtandi® patents are valid under 35 U.S.C. §§ 101, 102, and 112, and are enforceable.

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

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

COUNT I
(Infringement of the '517 Patent)

46. Plaintiffs incorporate each of the preceding paragraphs 1 to 45 as if fully set forth herein.

47. By submitting ANDA No. 217920 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 PuraCap's Generic Product throughout the United States, including New Jersey, prior to expiration of the '517 patent, PuraCap committed an act of infringement of the '517 patent under 35 U.S.C. § 271(e)(2)(A).

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

49. On information and belief, PuraCap's Generic Product, 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.

50. On information and belief, PuraCap's manufacture, use, sale, offer for sale, and/or importation into the United States of PuraCap's Generic Product 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). PuraCap will infringe one or more of the claims of the '517 patent.

51. On information and belief, PuraCap's Generic Product 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, PuraCap's Generic Product will infringe Claim 1 of the '517 patent because PuraCap's Generic Product will contain enzalutamide.

52. On information and belief, PuraCap was aware of the existence of the '517 patent and its listing in the Orange Book as demonstrated by PuraCap's reference to the '517 patent in the PuraCap Notice Letter.

53. On information and belief, PuraCap knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of PuraCap's Generic Product prior to patent expiry will infringe one or more claims of the '517 patent.

54. On information and belief, PuraCap's statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '517 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

55. 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 '274 Patent)

56. Plaintiffs incorporate each of the preceding paragraphs 1 to 55 as if fully set forth herein.

57. By submitting ANDA No. 217920 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 PuraCap's Generic Product throughout the United States, including New Jersey, prior to expiration of the '274 patent, PuraCap committed an act of infringement of the '274 patent under 35 U.S.C. § 271(e)(2)(A).

58. The '274 patent claims, *inter alia*, methods of treating prostate cancer with enzalutamide.

59. On information and belief, PuraCap's Generic Product, if approved by the FDA, will be prescribed and administered to human patients to treat castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer, which will constitute infringement of claims of the '274 patent.

60. On information and belief, PuraCap's manufacture, use, sale, offer for sale, and/or importation into the United States of PuraCap's Generic Product prior to the expiration of the '274 patent, including any applicable exclusivities or extensions, will actively induce infringement of the '274 patent under 35 U.S.C. § 271(b) and will constitute contributory infringement of the '274 patent under 35 U.S.C. § 271(c). PuraCap will aid another in the infringement of one or more claims of the '274 patent.

61. On information and belief, PuraCap will infringe at least Claim 1 of the '274 patent which claims a "method for treating prostate cancer comprising administering a therapeutically effective amount of a compound" selected from a group of compounds including enzalutamide "or a pharmaceutically acceptable salt thereof to a subject in need of such treatment, thereby treating the prostate cancer." On information and belief, PuraCap will infringe at least Claim 1 of the '274 patent because PuraCap's Generic Product will contain enzalutamide and will be used to treat prostate cancer.

62. On information and belief, PuraCap's Generic Product will have instructions for use that substantially copy the instruction for Xtandi® capsules. Upon information and belief, the proposed labeling for PuraCap's Generic Product will direct the use of PuraCap's Generic Product for the following indications: treatment of patients with castration-resistant prostate cancer and treatment of patients with metastatic castration-sensitive prostate cancer.

63. On information and belief, this directly infringing use will occur with PuraCap's specific intent and encouragement, and will be a use that PuraCap knows or should know will occur.

64. On information and belief, PuraCap will actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that this use will be in contravention of Plaintiffs' rights under the '274 patent.

65. On information and belief, PuraCap knows or should know PuraCap's Generic Product will be especially made or especially adapted for use in a manner that will constitute infringement of the '274 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

66. On information and belief, PuraCap knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of PuraCap's Generic Products prior to patent expiry will contribute to the direct infringement of one or more claims of the '274 patent.

67. On information and belief, PuraCap's acts will be performed with knowledge of the '274 patent and with intent to encourage infringement prior to patent expiry.

68. On information and belief, PuraCap was aware of the existence of the '274 patent and its listing in the Orange Book as demonstrated by PuraCap's reference to the '274 patent in the PuraCap Notice Letter.

69. On information and belief, PuraCap's statement of factual and legal bases for its opinions regarding non-infringement and invalidity of the '274 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

70. 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 PuraCap has infringed one or more claims of United States Patent Nos. 7,709,517 and 8,183,274 by submitting ANDA No. 217920 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of PuraCap's Generic Product before the expiration of the Xtandi® patents under 35 U.S.C. § 271(e)(2)(A);
- B. A judgment that PuraCap's commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of PuraCap's Generic Product will infringe one or more claims of United States Patent Nos. 7,709,517 and 8,183,274 under 35 U.S.C. §§ 271(a), (b), and/or (c);
- C. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining PuraCap, 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 PuraCap's Generic Product prior to the expiration dates of United States Patent Nos. 7,709,517 and 8,183,274, 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. 217920 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 dates of United States Patent Nos. 7,709,517 and 8,183,274, 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: February 21, 2023

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Attorneys for Plaintiffs

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. Zydus Pharms. (USA) Inc., et al.*, Case No. 2:22-cv-04499 (JMV-JSA), pending in the United States District Court for the District of New Jersey; and
- *Astellas Pharma Inc., et al. v. Sun Pharmaceutical Industries, Inc.*, Case No. 2:22-cv-07357 (JMV-JSA), pending in the United States District Court for the District of New Jersey.

Dated: February 21, 2023

/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: February 21, 2023

/s/ Liza M. Walsh

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