Ian Scott, Esq.
Taft Stettinius & Hollister LLP
111 East Wacker, Suite 2600
Chicago, IL 60601-4208
T: (312) 527-4000
iscott@taftlaw.com

Attorneys For Defendants
Qilu Pharmaceutical (Hainan) Co., Ltd.
and Qilu Pharma, Inc.

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; and THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, *Plaintiffs*, *v.* QILU PHARMACEUTICAL (HAINAN) CO., LTD. and QILU PHARMA, INC., *Defendants*.	Civil Action No. 3:24-cv-08217-MAS-RLS

DEFENDANTS QILU PHARMACEUTICAL (HAINAN) CO., LTD AND QILU PHARMA INC.'S ANSWER AND COUNTERCLAIMS

Defendants Qilu Pharmaceutical (Hainan) Co., Ltd. ("Qilu Ltd.") and Qilu Pharma, Inc. ("Qilu Inc."), (collectively, "Qilu" or "Defendants"), by their undersigned attorneys, for their Answer to the Complaint for Patent Infringement

filed by 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"), state as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Qilu denies all allegations in Plaintiffs' Complaint except those expressly admitted below.

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.

ANSWER: Paragraph 1 contains legal conclusions and allegations to which no answer is required. Qilu lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies the same.

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.

ANSWER: Paragraph 2 contains legal conclusions and allegations to which no answer is required. Qilu lacks knowledge or information sufficient to form a

belief about the truth of the allegations in this paragraph, and therefore denies the same.

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.

ANSWER: Paragraph 3 contains legal conclusions and allegations to which no answer is required. Qilu lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies the same.

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.

ANSWER: Paragraph 4 contains legal conclusions and allegations to which no answer is required. Qilu lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies the same.

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.

ANSWER: Paragraph 5 contains legal conclusions and allegations to which no answer is required. Qilu lacks knowledge or information sufficient to form a

belief about the truth of the allegations in this paragraph, and therefore denies the same.

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.

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. Qilu lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies the same.

7. On information and belief, Defendant Qilu Ltd. is a corporation organized and existing under the laws of China having a principal place of business at Room A, No.273, Nanhai Boulevard, State Hi-and-New Tech Park, Haikou, Hainan, 570314, China.

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Ltd. is a company organized and existing under the laws of China, having a principal place of business at Room A, No.273, Nanhai Boulevard, State Hi-and-New Tech Park, Haikou, Hainan, 570314, China. Qilu denies any and all remaining allegations of this paragraph.

8. On information and belief, Qilu 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.

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Ltd. manufactures and sells generic pharmaceutical products. Qilu denies any and all remaining allegations contained in this paragraph.

9. On information and belief, Defendant Qilu Inc. is a corporation organized and existing under the laws of Pennsylvania having a principal place of business at 101 Lindenwood Drive Suite 225, Malvern, Pennsylvania 19355.

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Inc. is a company organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 101 Lindenwood Drive, Suite 225, Malvern, PA 19355. Qilu denies any and all remaining allegations of this paragraph.

10. On information and belief, Qilu 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.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that

Qilu Ltd. manufactures and sells generic pharmaceutical products. Qilu denies any and all remaining allegations contained in this paragraph.

11. On information and belief, Qilu Inc. is a wholly-owned subsidiary and the United States agent of Qilu Ltd.

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Inc. is the United States agent of Qilu Ltd. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Inc. is the United States agent of Qilu Ltd. Qilu denies any and all remaining allegations contained in this paragraph.

13. On information and belief, Defendants Qilu Ltd. and Qilu Inc. have cooperated and assisted in the preparation and filing of Qilu's Abbreviated New Drug Application ("ANDA") No. 219140 and will be involved in the manufacture, importation, marketing, and sale of the drug that is the subject of ANDA No. 219140 if it is approved.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that it filed ANDA No. 219140 with the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products. Qilu further admits that Qilu Pharma is the U.S. agent for Qilu Ltd. with respect to ANDA No. 219140. Qilu denies any and all remaining allegations contained in this paragraph.

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 Qilu's filing of ANDA No. 219140 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®.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits Plaintiffs purport to bring this civil action for infringement of United States Patent Nos. 7,709,517 ("the '517 patent") and ("the '689 patent") (the '517 patent and the '689 patent together "the Patents-In-Suit"). Qilu admits that it filed Abbreviated New Drug Application ("ANDA") No. 219140 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of Qilu's enzalutamide oral tablets, 40 and 80 mg, (the "Qilu ANDA Products"), which are

generic versions of Xtandi®, prior to expiration of the '517 and '689 patents. Qilu denies any and all remaining allegations contained in this paragraph.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that Plaintiffs' Complaint is for alleged patent infringement and for declaratory judgment of patent infringement, but denies that Plaintiffs are entitled to any relief. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

17. This Court has personal jurisdiction over Qilu by virtue of the fact that Qilu 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, Qilu 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 Qilu's ANDA No. 219140 is approved, it will market and sell its generic versions of Xtandi® tablets in New Jersey.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Inc. is the U.S. agent for Qilu Ltd. with respect to ANDA No. 219140. Solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

18. This Court has personal jurisdiction over Qilu Inc. On information and belief, Qilu Inc. regularly conducts business in New Jersey and has an established place of business in New Jersey. Qilu Inc. has an active business entity status registered with the New Jersey Department of Treasury under the business entity identification number 0400704255, maintains a business address at 104 Carnegie Center, Suite 212, Princeton, New Jersey 08540, and has a corporate agent for service of process at 820 Bear Tavern Road, West Trenton, New Jersey 08628.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Inc. is the U.S. agent for Qilu Ltd. with respect to ANDA No. 219140, and that Qilu

Healthcare, Inc. is a company registered with the State of New Jersey's Department of Health (Reg. No. 5005245) as a drug manufacturer and wholesaler with a principal place of business in 104 Carnegie Center Suite 212, Princeton, New Jersey 08540. Solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

19. This Court also has personal jurisdiction over Qilu Inc. by virtue of the fact that, on information and belief, Qilu Inc. regularly and continuously transacts business within New Jersey, either directly or through its affiliates—including Qilu Healthcare Inc., a company registered with the State of New Jersey's Department of Health (Reg. No. 5005245) as a drug manufacturer and wholesaler with a principal place of business in 104 Carnegie Center, Suite 212, Princeton, New Jersey 08540—including by selling pharmaceutical products in New Jersey.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Inc. is the U.S. agent for Qilu Ltd. with respect to ANDA No. 219140, and that Qilu Healthcare, Inc. is a company registered with the State of New Jersey's Department of Health (Reg. no. 5005245) as a drug manufacturer and wholesaler with a principal place of business in 104 Carnegie Center Suite 212, Princeton, New Jersey 08540. Solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this

action only. Qilu denies any and all remaining allegations contained in this paragraph.

20. This Court further has personal jurisdiction over Qilu Inc. by virtue of the fact that Qilu Inc. has 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.*, *Eli Lilly & Co., et al. v. Qilu Pharmaceutical Co., Ltd., et al.*, No. 2:24-cv-05847 (D.N.J.); *Boehringer Ingelheim Pharms. Inc., et al. v. Qilu Pharm. Co., Ltd., et al.*, No. 3:21-cv-01732 (D.N.J.); and *Helsinn Healthcare S.A., et al. v. Qilu Pharm. Co., Ltd., et al.*, No. 2:15-cv-08132 (D.N.J.).

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest venue in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 23 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest venue in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

24. Venue is proper in this Judicial District for Qilu Inc. On information and belief, Qilu Inc. has an active business entity identification number in the State of New Jersey (0400704255) and maintains a regular and established place of business at 104 Carnegie Center, Suite 212, Princeton, New Jersey 08540. On information and belief, Qilu Inc. has employees in New Jersey. On information and belief, based on Qilu Inc.'s presence in and connections to New Jersey, discoverable information in Qilu Inc.'s possession, custody, or control regarding Qilu's ANDA No. 219140 will likely show that Qilu Inc. engaged in activities in New Jersey relevant to the preparation and/or submission of Qilu's ANDA No. 219140.

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Inc. has an active business entity identification number in the State of New Jersey (0400704255), maintains a regular and established place of business at 104 Carnegie Center, Suite 212, Princeton, New Jersey 08540, and has employees in New Jersey. Solely to conserve the resources of the parties and the Court, Qilu does not contest venue in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

25. Venue is further proper in this Court as to Qilu because, among other things, Qilu 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.

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources

of the parties and the Court, Qilu does not contest venue in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

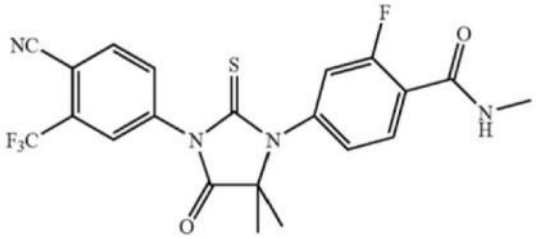
THE XTANDI® TABLET NDA

26. 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.

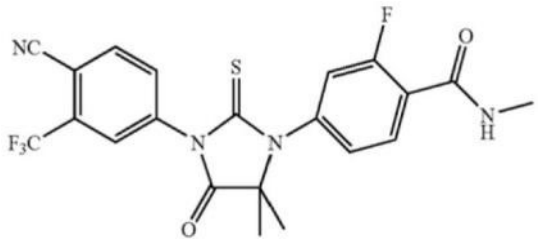
ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that, according to FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (the "Orange Book"), the applicant holder's full name for NDA 213674 for Xtandi® (enzalutamide) oral tablets, 40 mg and 80 mg is APUS, and the approval date is August 4, 2020. The Xtandi® oral tablet prescribing information (revised November 2023) states that it is indicated for the treatment of patients with: castration-resistant prostate cancer; metastatic castration-sensitive prostate cancer; and non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for

metastasis; and that the tablets are marketed by APUS and Pfizer Inc. Qilu denies any and all remaining allegations contained in this paragraph.

27. 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:



ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that the ’689 patent state that enzalutamide’s chemical name is “4-{3-[4-cyano-3-(trifluoromethyl)phenyl]-5,5-dimethyl-4-oxo-2- sulfanylideneimidazolidin-1-yl}-2-fluoro-N-methylbenzamide,” and “[t]he structural formula is



'689 patent, 1:6-2:13. Qilu denies any and all remaining allegations contained in this paragraph.

THE PATENTS-IN-SUIT

28. 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.

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that what purports to be a copy of the '517 patent was attached to the Complaint as Exhibit A, that the patent is entitled "Diarylhydantoin Compounds," and that it bears an issue date of May 4, 2010. Qilu denies that the '517 patent was duly and legally issued and further denies any suggestion that the '517 patent is valid or enforceable.

29. 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.

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that the '517 patent

is listed in the Orange Book in connection with NDA 213674 for Xtandi® 40 mg and 80 mg tablets. Qilu denies any and all remaining allegations contained in this paragraph.

30. 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.

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. Qilu is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

31. 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.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. Qilu is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

32. 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.

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. Qilu is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

33. 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.

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. Qilu is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

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

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. Qilu is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

35. 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.

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. Qilu is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

36. 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.

ANSWER: Paragraph 36 contains legal conclusions to which no answer is required. Qilu is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

37. 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.

ANSWER: Paragraph 37 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that what purports to be a copy of the '689 patent was attached to the Complaint as Exhibit B, that the patent is entitled "Formulations of Enzalutamide," and that it bears an issue date of December 12, 2023. Qilu denies that the '689 patent was duly and legally issued and further denies any suggestion that the '689 patent is valid or enforceable.

38. 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.

ANSWER: Paragraph 38 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that the '689 patent is listed in the Orange Book in connection with NDA 213674 for Xtandi® 40 mg and

80 mg tablets. Qilu is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

39. By a letter dated June 24, 2024 (the "Qilu Notice Letter"), Qilu advised Astellas, Pfizer, Inc., Medivation, Inc., Medivation Prostate Therapeutics, Inc., and The Regents that it had submitted ANDA No. 219140 to the FDA seeking approval to manufacture, use, or sell enzalutamide 40 mg and 80 mg tablets ("Qilu's Generic Products") prior to the expiration of the Xtandi® patents.[1]

ANSWER: Paragraph 39 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiffs, dated June 24, 2024, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 219140 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the '517 and '689 patents, which satisfied all statutory, legal, and regulatory requirements, and that the June 24, 2024 notice letter states that the proposed strengths of the Qilu ANDA Products are 40 mg and 80 mg. Qilu further admits that it filed ANDA No. 219140 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products prior to expiration of the '517 and '689 patents. Qilu denies any and all remaining allegations contained in this paragraph.

[1] Upon information and belief, "Qilu Pharma Inc." referenced in the Qilu Notice Letter is Qilu Pharma, Inc.

40. On information and belief, Qilu submitted ANDA No. 219140 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 Qilu's Generic Products as generic versions of Xtandi® 40 mg and 80 mg tablets.

ANSWER: Paragraph 40 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it filed ANDA No. 219140 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of generic versions of the Qilu ANDA Products, which are generic versions of Xtandi®, prior to expiration of the '517 and '689 patents. Qilu denies any and all remaining allegations contained in this paragraph.

41. On information and belief, ANDA No. 219140 seeks FDA approval of Qilu'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.

ANSWER: Paragraph 41 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it filed ANDA No. 219140 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of generic versions of the Qilu ANDA Products, which are generic versions of Xtandi®, prior to expiration of the '517 and '689 patents. Qilu denies any and all remaining allegations contained in this paragraph.

42. The Qilu Notice Letter also advised Astellas, Pfizer, Inc., Medivation, Inc., Medivation Prostate Therapeutics, Inc., and The Regents that Qilu's ANDA submission included certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Qilu's opinion, certain claims of the Xtandi® patents are invalid, unenforceable, and/or not infringed.

ANSWER: Paragraph 42 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiffs, dated June 24, 2024, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 219140 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the '517 and '689 patents, which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

43. The Qilu Notice Letter does not allege non-infringement of certain claims of the '517 patent, or of any claim of the '689 patent.

ANSWER: Paragraph 43 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiffs, dated June 24, 2024, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 219140 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the '517 and '689 patents, which satisfied all statutory, legal, and regulatory

requirements. Qilu denies any and all remaining allegations contained in this paragraph.

44. By not identifying non-infringement defenses for certain claims of the '517 patent or any claim of the '689 patent in the Qilu Notice Letter, Qilu admits Qilu's Generic Products meet all limitations of those claims.

ANSWER: Paragraph 44 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiffs, dated June 24, 2024, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 219140 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the '517 and '689 patents, which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 45 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiffs, dated June 24, 2024, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 219140 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the

'517 and '689 patents, which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 46 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiffs, dated June 24, 2024, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 219140 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the '517 and '689 patents, which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 47 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies the allegations contained in this paragraph.

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

ANSWER: Paragraph 48 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiffs, dated June 24, 2024, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 219140 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the '517 and '689 patents, which satisfied all statutory, legal, and regulatory requirements, and that Plaintiffs filed their Complaint on August 1, 2024. Qilu denies any and all remaining allegations contained in this paragraph.

COUNT I

(Infringement of the '517 Patent)

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

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 48 as if fully set forth herein.

50. By submitting ANDA No. 219140 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 Qilu's Generic Products throughout the United States, including New Jersey, prior to expiration of the '517 patent, Qilu committed an act of infringement of the '517 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 50 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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

ANSWER: Paragraph 51 contains legal conclusions to which no answer is required. To the extent the allegations of this paragraph seek to paraphrase or characterize the purported contents of the '517 patent, the patent speaks for itself. Qilu denies any and all remaining allegations contained in this paragraph.

52. On information and belief, Qilu's 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.

ANSWER: Paragraph 52 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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

ANSWER: Paragraph 53 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

54. On information and belief, Qilu's 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, Qilu's Generic Products will infringe Claim 1 of the '517 patent because Qilu's Generic Products will contain enzalutamide.

ANSWER: Paragraph 54 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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

ANSWER: Paragraph 55 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the '517 patent and its listing in the Orange Book as of the date of mailing of Qilu's June 24, 2024 notice letter. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 56 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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

ANSWER: Paragraph 57 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

58. On information and belief, Qilu'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.

ANSWER: Paragraph 58 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 59 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

COUNT II

(Infringement of the '689 Patent

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

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 59 as if fully set forth herein.

61. By submitting ANDA No. 219140 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 Qilu's Generic Products throughout the United States, including New Jersey, prior to expiration of the '689 patent, Qilu committed an act of infringement of the '689 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 61 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 62 contains legal conclusions to which no answer is required. To the extent the allegations of this paragraph seek to paraphrase or characterize the purported contents of the '689 patent, the patent speaks for itself. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 63 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

64. The Qilu Notice Letter does not dispute infringement of any claim of the '689 patent.

ANSWER: Paragraph 64 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

65. On information and belief, Qilu copied the claimed invention of the '689 patent.

ANSWER: Paragraph 65 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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

ANSWER: Paragraph 66 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

67. On information and belief, Qilu'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 at least one claim of the '689 patent.

ANSWER: Paragraph 67 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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

ANSWER: Paragraph 68 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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

ANSWER: Paragraph 69 contains legal conclusions to which no answer is required. Qilu admits that it was aware of the '689 patent and its listing in the Orange Book as of the date of mailing of Qilu's June 24, 2024 notice letter. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 70 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

71. On information and belief, Qilu'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.

ANSWER: Paragraph 71 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 72 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Qilu has infringed one or more claims of United States Patent Nos. 7,709,517 and 11,839,689 by submitting ANDA No. 219140 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Qilu's Generic Products before the expiration of the patents under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that Qilu's commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Qilu's 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 Qilu, 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 Qilu's 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. 219140 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.

RESPONSE TO PRAYER FOR RELIEF

Qilu denies all allegations not expressly admitted herein. Qilu further denies that Plaintiffs are entitled to any of the relief requested in paragraphs (A) through (G), and requests that Plaintiffs' Complaint be dismissed with prejudice and that Qilu be awarded its fees and costs incurred defending this suit under 35. U.S.C. § 285.

QILU'S ADDITIONAL DEFENSES

Qilu asserts the following additional defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. Qilu asserts these additional defenses without conceding that it bears a burden of proof on them, and reserves the right to assert additional defenses as warranted.

FIRST ADDITIONAL DEFENSE

(Invalidity of the Patents-in-Suit)

The claims of the Patents-in-Suit are invalid and/or unenforceable under 35 U.S.C. §§ 101, et seq. or under other judicially-created bases for invalidation.

SECOND ADDITIONAL DEFENSE

(No Direct Infringement of the Patents-in-Suit)

Qilu does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the Patents-in-Suit and Qilu's products that are the subject of ANDA No. 219140 do not infringe any valid and enforceable claim of the Patents-in-Suit.

THIRD ADDITIONAL DEFENSE

(No Infringement of the Patents-in-Suit)

Qilu has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-in-Suit, and the marketing, sale, and/or distribution of Qilu's products that are the subject of ANDA No. 219140 does not induce the infringement of, or contribute to the infringement of any valid and enforceable claim of the Patents-in-Suit.

FOURTH ADDITIONAL DEFENSE

(Failure to State a Claim)

Plaintiffs' complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

FIFTH ADDITIONAL DEFENSE

(Failure to State a Claim for Exceptional or Willful Infringement)

Plaintiffs fail to state a proper claim for an exceptional case and/or willful infringement.

RESERVATION OF ADDITIONAL DEFENSES

Qilu reserves the right to plead additional affirmative defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Qilu Pharmaceutical (Hainan) Co., Ltd. ("Qilu Ltd.") and Qilu Pharma, Inc. ("Qilu Inc."), (together "Defendants/Counterclaim-Plaintiffs" or "Qilu"), by way of its attorneys, hereby states for its Counterclaims against 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"), and The Regents of the University of California ("The Regents") (collectively, "Plaintiffs/Counterclaim-Defendants"), the following:

THE PARTIES

1. Qilu repeats and incorporates by reference each of the foregoing paragraphs of Qilu's Answer and Additional Defenses to the Complaint.

2. Qilu Ltd. is a corporation organized and existing under the laws of China, having a place of business at Room A, No.273, Nanhai Boulevard, State Hi-and-New Tech Park, Haikou, Hainan, 570314, China.

3. Qilu Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a place of business at 101 Lindenwood Drive, Suite 225, Malvern, PA 19355.

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

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

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

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

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

9. Upon information and belief, 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 a principal place of business at 1111 Franklin Street, Oakland, California 94607-5200, United States.

JURISDICTION

10. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

11. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

12. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Qilu, and

Plaintiffs/Counterclaim-Defendants, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

13. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants based, *inter alia*, on the filing of this lawsuit in this jurisdiction and because Plaintiffs/Counterclaim-Defendants are doing business in this jurisdiction.

14. Venue is proper in this judicial district under 28 U.S. C. §§ 1391(b) and (c), and 1400(b).

FACTS COMMON TO ALL COUNTS

15. This is an action for a declaratory judgment of invalidity and noninfringement of one or more claims of United States Patent Nos. 7,709,517 ("the '527 patent") and 11,839,689 ("the '689 patent") (together "the Patents-in-Suit"). Upon information and belief, true and correct copies of the Patents-in-Suit are attached to the Complaint as Exhibits A and B.

16. On or about May 4, 2010, the U.S. Patent & Trademark Office ("USPTO") issued the '517 patent.

17. Upon information and belief, The Regents is the assignee of the '517 patent.

18. On or about December 12, 2023, the U.S. Patent & Trademark Office ("USPTO") issued the '689 patent.

19. Upon information and belief, API and MPT are the assignees of the '689 patent.

20. APUS purports to be the holder of New Drug Application ("NDA") No. 213674 for enzalutamide tablets, 40 mg and 80 mg. APUS sells its enzalutamide oral tablets in the United States under the trademark Xtandi®.

21. Plaintiffs/Counterclaim-Defendants Astellas Pharma US Inc. purport and claim to have the rights to enforce the Patents-in-Suit, and have listed the Patent-in-Suit in the FDA's *Approved Drug Products and Therapeutic Equivalence Evaluations* (the "Orange Book") in connection with Xtandi®.

22. Qilu has filed the Abbreviated New Drug Application ("ANDA) No. 219140 with the U.S. Food and Drug Administration (the "FDA") seeking approval for Qilu's proposed enzalutamide tablets described therein (the "Qilu ANDA Products").

23. Qilu's ANDA seeks FDA approval to market the Qilu ANDA Products described within ANDA No. 219140 before the expiration of the '517 and '689 patents listed in the Orange Book, and Qilu's ANDA includes a certification under

21 U.S.C. § 355(j)(2)(A)(vii)(IV) (also called a "Paragraph IV Certification") as to the ’517 and ’689 patents.

24. Plaintiffs/Counterclaim-Defendants sued Qilu in this District for alleged infringement of the ’517 and ’689 patents.

COUNT I:

(Declaratory Judgment of Invalidity of the ’517 Patent)

25. Qilu realleges and incorporates by reference the allegations of paragraphs 1-24 as though full set forth herein.

26. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiffs/Counterclaim-Defendants regarding *inter alia,* the invalidity of the ’517 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the ’517 patent.

27. The claims of the ’517 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

28. The claims of the ’517 patent are invalid under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Qilu’s Notice Letter to Plaintiffs/Counterclaim-Defendants, because each and every

element of each and every claim of the '517 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '517 patent, including, but not limited to:

1. WO 2005/099693, "Methods and Materials For Assessing Prostate Cancer Therapies and Compounds;"

2. Nesnow, S., *et al*., "Chemical Carcinogens A Review and Analysis of the Literature of Selected Chemicals and the Establishment of the Gene-Tox Carcinogen Data Base A Report of the U.S. Environmental Protection Agency Gene-Tox Program *" Mutation Research (1986) 185:1-195;

3. U.S. Patent No. 6,087,509, "1-Imidazolidinyl-Phenyls;"

4. Patani, G. A., *et al*., "Bioisosterism: A Rational Approach in Drug Design" Chem. Rev. (1996) 96:3147-3176; and

5. Park, B. K., *et al*., "Metabolism of Fluorine-Containing Drugs" Annu. Rev. Pharmacol. Toxicol. (2001) 41:443-70.

29. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '517 patent, and would have had a reasonable expectation of success in doing so.

30. There is no objective evidence of non-obviousness of the claims of the '517 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '517 patent.

31. Qilu is entitled to a judicial declaration that the claims of the '517 patent are invalid.

32. Qilu reserves the right to provide additional bases for invalidity of each claim of the '517 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT II:
(Declaratory Judgment of Noninfringement of the '517 Patent)

33. Apotex realleges and incorporates by reference the allegations of paragraphs 1-32 as though fully set forth herein.

34. There is an actual, substantial, and continuing case or controversy between Apotex and the Plaintiff/Counterclaim-Defendant regarding, inter alia, non-infringement of the claims of the '517 patent.

35. The manufacture, use, offer for sale, sale, importation, and/or marketing of Apotex's ANDA Product described in Apotex's ANDA has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '517 patent, either literally or under the doctrine of equivalents.

36. Apotex is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Apotex's ANDA Product described in Apotex's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '517 patent, either literally or under the doctrine of equivalents.

COUNT III:

(Declaratory Judgment of Invalidity of the '689 Patent)

37. Qilu realleges and incorporates by reference the allegations of paragraphs 1-36 as though full set forth herein.

38. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiffs/Counterclaim-Defendants regarding *inter alia*, the invalidity of the '689 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the '689 patent.

39. The claims of the '689 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

40. The claims of the '689 patent are invalid under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Qilu's Notice Letter to Plaintiffs/Counterclaim-Defendants, because each and every element of each and every claim of the '689 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '689 patent, including, but not limited to:

1. U.S. Application Publication No. 2007/0004753, "Diarylhydantoin Compounds;"
2. WO 2003/063821, "Method For Making Homogeneous Spray-Dried Solid Amorphous Drug Dispersions Using Pressure Nozzles; and
3. Friesen, D. T., et al., "Hydroxypropyl Methylcellulose Acetate Succinate-Based Spray-Dried Dispersions: An Overview" Molecular Pharmaceuticals (2008) 5(6):1003-1019.

41. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '689 patent, and would have had a reasonable expectation of success in doing so.

42. There is no objective evidence of non-obviousness of the claims of the '689 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '689 patent.

43. Qilu is entitled to a judicial declaration that the claims of the '689 patent are invalid.

44. Qilu reserves the right to provide additional bases for invalidity of each claim of the '689 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT IV:

(Declaratory Judgment of Noninfringement of the '689 Patent)

45. Apotex realleges and incorporates by reference the allegations of paragraphs 1-44 as though fully set forth herein.

46. There is an actual, substantial, and continuing case or controversy between Apotex and the Plaintiff/Counterclaim-Defendant regarding, inter alia, non-infringement of the claims of the '689 patent.

47. The manufacture, use, offer for sale, sale, importation, and/or marketing of Apotex's ANDA Product described in Apotex's ANDA has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '689 patent, either literally or under the doctrine of equivalents.

48. Apotex is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Apotex's ANDA Product described in Apotex's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '689 patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Qilu respectfully requests that the Court enter judgment in its favor and against Plaintiffs/Counterclaim Defendants Astellas Pharma Inc., Astellas US LLC, and Astellas Pharma US, Inc., Medivation LLC and Medivation Prostate Therapeutics LLC, and The Regents of the University of California, as follows:

A. Dismissing Plaintiffs' Complaint, and each and every claim by Plaintiffs against Qilu for relief contained therein, with prejudice;

B. Declaring that Qilu does not infringe any valid claim of the '517 and '689 patents, and that the claims of the '517 and '689 patents are invalid for failure to comply with one or more provisions of 35 U.S.C. § 101, et seq.;

C. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Qilu ANDA Products in Qilu's ANDA No. 219140 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claims of the '517 and '689 patents, either literally or under the doctrine of equivalents;

D. Declaring this case exceptional and awarding Qilu reasonable attorneys' fees and costs under 35 U.S.C. § 285;

E. Awarding Qilu its costs and expenses

F. Ordering that Plaintiffs/Counterclaim-Defendants and its officers, agents, servants, employees, attorneys, successors and any person who acts in concert or participation with it or any of them, be preliminarily and permanently enjoined from using the ’517 and ’689 patents to block, hamper, hinder or obstruct FDA approval of the products described in Qilu’s ANDA; and

G. Awarding Qilu such other and further relief as the Court may deem just and proper.

Dated: October 7, 2024

TAFT, STETTINIUS & HOLLISTER, LLP

By: */s / Ian Scott*
IAN SCOTT

Attorneys for Defendants
Qilu Pharmaceutical (Hainan) Co., Ltd. and
Qilu Pharma Inc.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matter in controversy is not related to any other action pending in this Judicial District.

I hereby certify that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: October 7, 2024

TAFT, STETTINIUS & HOLLISTER, LLP

By: */s / Ian Scott*
IAN SCOTT

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, I hereby certify that the causes of action asserted herein as counterclaims seek primarily declaratory judgment relief and as such, this is not appropriate for compulsory arbitration.

Dated: October 7, 2024

TAFT, STETTINIUS & HOLLISTER, LLP

By: */s/ Ian Scott*
IAN SCOTT

CERTIFICATE OF SERVICE

The undersigned certifies that, on October 7, 2024, a true and accurate copy of DEFENDANTS QILU PHARMACEUTICAL (HAINAN) CO., LTD and QILU PHARMA, INC.'S ANSWER AND COUNTERCLAIMS was filed with the Court and served on all counsel of record for Plaintiffs via the Court's electronic filing system.

Dated: October 7, 2024

TAFT, STETTINIUS & HOLLISTER, LLP

By: */s/ Ian Scott*
IAN SCOTT