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

| | | |
|---|---|---|
| ASTELLAS PHARMA INC.; ASTELLAS US LLC; ASTELLAS PHARMA US, INC.; MEDIVATION LLC; MEDIVATION PROSTATE THERAPEUTICS LLC; THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, | ) | |
| Plaintiffs, | ) | C.A. No.: _____ |
| v. | ) | |
| SANDOZ INC. | ) | |
| Defendant. | ) | |

**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") (collectively, "Plaintiffs"), for their Complaint against Defendant Sandoz Inc. ("Sandoz"), hereby allege as follows:

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## 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 235 East 42nd Street, New York, New York 10017, 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 235 East 42nd Street, New York, New York 10017, 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 Sandoz Inc. is a corporation organized and existing under the laws of Delaware, having places of business at One Health Plaza, Building 435, East Hanover, New Jersey, 07936, United States and 100 College Road West, Princeton, New Jersey 08540, United States.

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8. On information and belief, Sandoz 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.

## NATURE OF THE ACTION

9. 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 Sandoz's filing of Abbreviated New Drug Application ("ANDA") No. 216068 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® and its use.

## JURISDICTION AND VENUE

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

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

12. This Court has personal jurisdiction over Sandoz by virtue of the fact that Sandoz is at home in New Jersey as reflected by the fact that, on information and belief, it has places of business in New Jersey, 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

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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, Sandoz 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 Sandoz's ANDA No. 216068 is approved, it will market and sell its generic versions of Xtandi® tablets in New Jersey.

13. This Court also has personal jurisdiction over Sandoz by virtue of the fact that Sandoz 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., Par Pharmaceutical, Inc. et al v. Sandoz Inc.*, No. 3-18-cv-14895 (D.N.J.)*; Celgene Corporation v. Sandoz Inc.*, No. 3-18-cv-11026 (D.N.J.); *Adamas Pharma, LLC v. Sandoz Inc.*, No. 3-18-cv-09032 (D.N.J.). Upon information and belief, Sandoz has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey by having filed suit in this jurisdiction. *See*, *e.g.*, *Sandoz, Inc. v. Daiichi Sankyo, Inc. et al.*, No. 1-16-cv-00994 (D.N.J.).

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

## THE XTANDI® TABLET NDA

15. Astellas Pharma US, Inc. 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.

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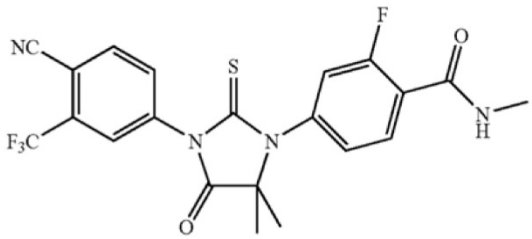
Xtandi® tablets are sold and co-promoted by Astellas Pharma US, Inc. and Pfizer Inc. in the United States.

16. 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**

17. 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.

18. 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.

19. 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 and 80 mg tablets.

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