

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

ASTELLAS PHARMA INC.; ASTELLAS )  
US LLC; ASTELLAS PHARMA US, INC.; )  
MEDIVATION LLC; MEDIVATION )  
PROSTATE THERAPEUTICS LLC; THE )  
REGENTS OF THE UNIVERSITY OF )  
CALIFORNIA, )

Plaintiffs,

v.

SANDOZ, INC.

Defendant.

**Document Electronically Filed**

C.A. No.: 2:21-cv-13177-JMV-JSA

**ANSWER AND AFFIRMATIVE DEFENSES OF SANDOZ, INC.**

Defendant Sandoz Inc. (“Sandoz”) by and through their undersigned counsel, respond to the Complaint filed by 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”), as follows:

**PARTIES**

1. Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 1, and therefore denies them.
2. Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 2, and therefore denies them.
3. Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 3, and therefore denies them.

4. Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 4, and therefore denies them.

5. Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 5, and therefore denies them.

6. Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 6, and therefore denies them.

7. Defendant admits the allegations of paragraph 7.

8. Defendant admits that Sandoz researches and develops high-quality, affordable medicines for patients throughout the United States. Defendant denies any remaining allegations of paragraph 8.

#### **NATURE OF THE ACTION**

9. Paragraph 9 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant admits Plaintiffs brought this action for patent infringement and that Sandoz filed ANDA No. 216068 with the FDA, seeking approval to commercially market 40 mg and 80 mg enzalutamide tablets. Defendant denies the remaining allegations of paragraph 9.

#### **JURISDICTION AND VENUE**

10. Paragraph 10 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant admits for this case only that this Court has subject matter jurisdiction over Plaintiffs' claims.

11. Paragraph 11 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendants do not contest personal jurisdiction in this case only. Defendants deny the remaining allegations of paragraph 11.

12. Paragraph 12 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendants do not contest personal jurisdiction in this case only. Defendant admits that Sandoz researches and develops high-quality, affordable medicines for patients throughout the United States. Defendants deny the remaining allegations of paragraph 12.

13. To the extent paragraph 13 calls for a legal conclusion, no response is required. Insofar as any response is required, Defendant does not contest personal jurisdiction in this case only. While Defendant admits to previously being sued, asserting counterclaims, and bringing suit in this Court, Sandoz denies any remaining allegations of paragraph 13.

14. Paragraph 14 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant does not contest venue in this case only.

**THE XTANDI® TABLET NDA**

15. Defendant admits that according to the FDA's website, NDA No. 213674 for Xtandi® 40 mg and 80 mg tablets was approved on August 4, 2020 for the treatment of patients with castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer. Defendant lacks knowledge and information to form a belief as to the truthfulness of the remaining allegations of paragraph 15, and therefore denies them.

16. Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 16, and therefore denies them.

**THE PATENTS-IN-SUIT**

17. Defendant admits that the '517 patent issued on May 4, 2010 and is entitled "DIARYLHYDANTOIN COMPOUNDS." Defendant lacks knowledge and information to form a belief as to the truthfulness of whether Exhibit A is a true and correct copy of the '517 patent,

and therefore denies this allegation. Defendant denies any remaining allegations of paragraph 17.

18. Defendant admits that the '274 patent issued on May 22, 2012 and is entitled "TREATMENT OF HYPERPROLIFERATIVE DISORDERS WITH DIARYLHYDANTOIN COMPOUNDS." Defendant lacks knowledge and information to form a belief as to the truthfulness of whether Exhibit B is a true and correct copy of the '274 patent, and therefore denies this allegation. Defendant denies any remaining allegations of paragraph 18.

19. To the extent paragraph 19 calls for a legal conclusion, no response is required. Insofar as any response is required, Defendant admits that the '517 and '274 patents appear in the Patent and Exclusivity Information Addendum of the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, in connection with Xtandi® 40 mg and 80 mg tablets. Defendant denies any remaining allegations of paragraph 19.

20. Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 20, and therefore denies them.

21. Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 21, and therefore denies them.

22. Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 22, and therefore denies them.

23. Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 23, and therefore denies them.

24. Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 24, and therefore denies them.

25. Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 25, and therefore denies them.

**CLAIMS FOR RELIEF – PATENT INFRINGEMENT**

26. Defendant admits the allegations of paragraph 26.

27. To the extent paragraph 27 calls for a legal conclusion, no response is required. Insofar as any response is required, Sandoz lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 27, and therefore denies them.

28. To the extent paragraph 28 calls for a legal conclusion, no response is required. Insofar as any response is required, Sandoz lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 28, and therefore denies them.

29. Defendant admits the allegations of paragraph 29.

30. To the extent paragraph 30 calls for a legal conclusion, no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 30.

31. Defendant denies the allegations of paragraph 31.

32. To the extent paragraph 32 calls for a legal conclusion, no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 32.

33. Defendant denies the allegations of paragraph 33.

34. Paragraph 34 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant does not contest subject matter jurisdiction solely for Plaintiffs' infringement claims against Defendant.

35. To the extent paragraph 35 calls for a legal conclusion, no response is required. Insofar as any response is required, Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 35, and therefore denies them.

**COUNT I**  
**(Infringement of the '517 Patent)**

36. Defendant incorporates its responses to paragraphs 1-35 above as if fully set forth herein.

37. Paragraph 37 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 37.

38. Paragraph 38 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 38, and therefore denies them.

39. Paragraph 39 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 39.

40. Paragraph 40 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 40.

41. Paragraph 41 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 41.

42. Paragraph 42 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 42, and therefore denies them.

43. Paragraph 43 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 43.

44. Paragraph 44 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 44.

45. Paragraph 45 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 45.

**COUNT II**  
**(Infringement of the '274 Patent)**

46. Defendant incorporates its responses to paragraphs 1-45 above as if fully set forth herein.

47. Paragraph 47 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 47.

48. Paragraph 48 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 48, and therefore denies them.

49. Paragraph 49 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 49.

50. Paragraph 50 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 50.

51. Paragraph 51 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 51.

52. Paragraph 52 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 52, and therefore denies them.

53. Paragraph 53 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 53.

54. Paragraph 54 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 54.

55. Paragraph 55 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 55.

56. Paragraph 56 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 56.

57. Paragraph 57 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 57.

58. Paragraph 58 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant lacks knowledge and information to form a belief as to the truthfulness of the allegations of paragraph 58, and therefore denies them.

59. Paragraph 59 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 59.

60. Paragraph 60 calls for a legal conclusion, and therefore no response is required. Insofar as any response is required, Defendant denies the allegations of paragraph 60.

#### **ANSWER TO PLAINTIFFS' PRAYER FOR RELIEF**

The remainder of Plaintiffs' Complaint is a prayer for relief, and does not require a response. To the extent any response is required, Defendant denies that Plaintiffs are entitled to any relief whatsoever against Defendant in this action, either as prayed for in the Complaint or otherwise.

#### **AFFIRMATIVE DEFENSES**

Defendant asserts the following defenses to the Complaint, without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Defendant reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery. Assertion of a defense is not a concession that Defendant has the burden of proving the matter asserted.



**FIRST AFFIRMATIVE DEFENSE**  
**(Failure to State a Claim)**

Plaintiffs' claims are barred in whole or in part because Plaintiffs have not stated a claim upon which relief can be granted.

**SECOND AFFIRMATIVE DEFENSE**  
**(Invalidity of the '517 Patent)**

Upon information and belief, the claims of the '517 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112 and general principles of patent law.

**THIRD AFFIRMATIVE DEFENSE**  
**(Non-Infringement of the '517 Patent)**

No acts by any entity related to Defendant has infringed, infringe, or will infringe any valid claim of the '517 patent.

**FOURTH AFFIRMATIVE DEFENSE**  
**(Invalidity of the '274 Patent)**

Upon information and belief, the claims of the '274 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112 and general principles of patent law.

**FIFTH AFFIRMATIVE DEFENSE**  
**(Non-Infringement of the '274 Patent)**

No acts by any entity related to Defendant has infringed, infringe, or will infringe any valid claim of the '274 patent.

**SIXTH AFFIRMATIVE DEFENSE**

Any additional defenses that discovery may reveal.

**PRAYER FOR RELIEF**

WHEREFORE, Sandoz respectfully prays for a judgment as follows:

A. That Plaintiffs take nothing by their claims for relief;

- B. That Plaintiffs' Complaint be dismissed with prejudice and that Plaintiffs' requests for relief be denied with prejudice;
- C. That the Court enter judgment against Plaintiffs and in favor of Defendant in all respects;
- D. That the Court enter judgment that each claim of the '517 and '274 patents are invalid and unenforceable;
- E. That the Court enter judgment that Defendant has not infringed, do not and will not infringe in any manner any valid and enforceable claim of the '517 and '274 patents;
- F. That the Court declare this case exceptional under 35 U.S.C. § 285 and award Defendant attorneys' fees and costs incurred in this action; and
- G. For an award of such other and further relief as the Court may deem just and proper.

Dated: August 31, 2021

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