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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,

v.

HAIMEN PHARMA INC.;
SINOTHERAPEUTICS INC.,

Defendants.

Civil Action No. 3:24-cv-09403
(MAS)(RLS) Consolidated

ASTELLAS PHARMA INC.; ASTELLAS
US LLC; ASTELLAS PHARMA US, INC.;
MEDIVATION LLC; MEDIVATION
PROSTATE THERAPEUTICS LLC,

Plaintiffs,

v.

ZYDUS PHARMACEUTICALS (USA)
INC.; ZYDUS LIFESCIENCES LTD.,

Defendants.

**PLAINTIFFS' REPLY TO THE
COUNTERCLAIMS OF DEFENDANTS
ZYDUS PHARMACEUTICALS (USA) INC.
AND ZYDUS LIFESCIENCES LTD.**

Plaintiffs/Counterclaim-Defendants Astellas Pharma Inc. (“API”), Astellas US LLC (“AUS”), and Astellas Pharma US, Inc. (“APUS”) (collectively, “Astellas”), and Medivation LLC (“Medivation”) and Medivation Prostate Therapeutics LLC (“MPT”) (collectively, “Medivation”) (all collectively, “Plaintiffs”), hereby respond to the numbered paragraphs of the January 16, 2025, Counterclaims (C.A. No. 24-09748, D.I. 22 at 29–36)¹ of Defendants/Counterclaim-Plaintiffs Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Ltd. (collectively, “Defendants”) as follows:

GENERAL DENIAL

Any allegation in Defendants’ Counterclaims not expressly admitted by Plaintiffs is hereby denied. Plaintiffs deny that Defendants are entitled to the relief requested in Defendants’ Prayer for Relief or to any relief whatsoever. Any headings in Defendants’ Counterclaims are copied herein for convenience only, and any allegations in such headings are denied.

THE PARTIES

1. Admitted.
2. Admitted.
3. Admitted.
4. Admitted.
5. Admitted.
6. Admitted.
7. Admitted.

¹ C.A. No. 24-09748 was consolidated with C.A. No. 24-09403 on January 17, 2025.

JURISDICTION AND VENUE

8. Paragraph No. 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Plaintiffs admit that this Court has subject matter jurisdiction over this action based on 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. Paragraph No. 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Plaintiffs admit this Court has personal jurisdiction over Plaintiffs for the purposes of this action only.

10. Paragraph No. 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Plaintiffs admit that venue in this judicial district is proper for the purposes of this action only.

REGULATORY FRAMEWORK

11. Paragraph No. 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Plaintiffs deny the allegations in Paragraph No. 11.

12. Paragraph No. 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Plaintiffs deny the allegations in Paragraph No. 12.

ORANGE-BOOK-LISTED PATENTS FOR XTANDI®

13. Admitted.

14. Plaintiffs admit that United States Patent No. 11,839,689 (“the ’689 patent”), titled “Formulations of Enzalutamide,” issued on December 12, 2023, and that a true and correct copy thereof is attached to Plaintiffs’ Amended Complaint (C.A. No. 24-09748, D.I. 18) as Exhibit A. Plaintiffs admit that API and MPT are the assignees of the ’689 patent. Plaintiffs admit that the

'689 patent is listed in the U.S. Food and Drug Administration ("FDA")'s Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") for Xtandi® (enzalutamide) 40 mg and 80 mg tablets and that the Orange Book currently states "09/11/2033" under "Patent Expiration" for the '689 patent. Plaintiffs deny any remaining allegations in Paragraph No. 14.

15. Plaintiffs admit that the '689 patent is listed in the Orange Book for Xtandi® (enzalutamide) 40 mg and 80 mg tablets with a "Submission Date" of "12/19/2023" but deny any remaining allegations in Paragraph No. 15.

16. Plaintiffs admit that United States Patent No. 12,161,628 ("the '628 patent"), titled "Combination Therapy," issued on December 10, 2024, and that a true and correct copy thereof is attached to Plaintiffs' Amended Complaint (C.A. No. 24-09748, D.I. 18) as Exhibit B. Plaintiffs admit that API and MPT are the assignees of the '628 patent. Plaintiffs deny any remaining allegations in Paragraph No. 16.

17. Plaintiffs admit that the '628 patent has been submitted for listing in the Orange Book for Xtandi® (enzalutamide) 40 mg and 80 mg tablets but deny any remaining allegations in Paragraph No. 17.

ZYDUS USA'S ANDA

18. Admitted.

19. Plaintiffs admit that Defendants submitted ANDA No. 217322 seeking FDA approval to engage in the commercial manufacture, importation, use, and sale of the proposed products described in that ANDA as generic versions of Xtandi® tablets prior to the expiration of the '689 patent and that ANDA No. 217322 includes a Paragraph IV Certification regarding the '689 patent. Plaintiffs deny any remaining allegations in Paragraph No. 19.

20. Plaintiffs admit that by a letter dated September 3, 2024, Defendants advised APUS, API, and MPT that Defendants had submitted ANDA No. 217322 to the FDA seeking FDA approval to engage in the commercial manufacture, importation, use, and sale of enzalutamide 40 mg and 80 mg tablets as generic versions of Xtandi® tablets prior to the expiration of the '689 patent and that ANDA No. 217322 included a Paragraph IV certification regarding the '689 patent. Plaintiffs deny any remaining allegations in Paragraph No. 20.

21. Plaintiffs admit that by a letter dated December 27, 2024, Defendants advised APUS, API, and MPT that Defendants had submitted a supplement to ANDA No. 217322 seeking FDA approval to engage in the commercial manufacture, importation, use, and sale of enzalutamide 120 mg and 160 mg tablets as generic versions of Xtandi® tablets prior to the expiration of the '689 patent and that ANDA No. 217322 included a Paragraph IV certification regarding the '689 patent. Plaintiffs deny any remaining allegations in Paragraph No. 21.

COUNT I
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,839,689)

22. Plaintiffs repeat and re-allege their answers to each of the preceding paragraphs 1-21, as if fully set forth herein.

23. Paragraph No. 23 contains legal conclusions to which no answer is required. To the extent an answer may be required, Plaintiffs admit that a case or controversy exists between Defendants and Plaintiffs related to Defendants' counterclaims but deny any remaining allegations in Paragraph No. 23.

24. Denied.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,839,689)

25. Plaintiffs repeat and re-allege their answers to each of the preceding paragraphs 1-24, as if fully set forth herein.

26. Paragraph No. 26 contains legal conclusions to which no answer is required. To the extent an answer may be required, Plaintiffs admit that a case or controversy exists between Defendants and Plaintiffs related to Defendants' counterclaims but deny any remaining allegations in Paragraph No. 26.

27. Denied.

COUNT III
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,161,628)

28. Plaintiffs repeat and re-allege their answers to each of the preceding paragraphs 1-27, as if fully set forth herein.

29. Paragraph No. 29 contains legal conclusions to which no answer is required. To the extent an answer may be required, Plaintiffs admit that a case or controversy exists between Defendants and Plaintiffs related to Defendants' counterclaims but deny any remaining allegations in Paragraph No. 29.

30. Denied.

COUNT IV²
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,161,628)

31. Plaintiffs repeat and re-allege their answers to each of the preceding paragraphs 1-30, as if fully set forth herein.

² Defendants' Counterclaims refer to "Count II" instead of "Count IV" on page 35. Plaintiffs respond herein as though the counts were numbered in consecutive order.

32. Paragraph No. 32 contains legal conclusions to which no answer is required. To the extent an answer may be required, Plaintiffs admit that a case or controversy exists between Defendants and Plaintiffs related to Defendants' counterclaims but deny any remaining allegations in Paragraph No. 32.

33. Denied.

PRAYER FOR RELIEF

Plaintiffs deny that Defendants are entitled to any relief, either as prayed for in the Counterclaims or otherwise.

Dated: February 6, 2025

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