

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

|                                 |   |                            |
|---------------------------------|---|----------------------------|
| ACADIA PHARMACEUTICALS INC.     | ) |                            |
|                                 | ) |                            |
| Plaintiff,                      | ) |                            |
|                                 | ) | C.A. No. 1:20-cv-01022-RGA |
| v.                              | ) |                            |
|                                 | ) |                            |
| HETERO LABS LIMITED,            | ) |                            |
| HETERO LABS LIMITED UNIT-V, and | ) |                            |
| HETERO USA INC.,                | ) |                            |
|                                 | ) |                            |
| Defendants.                     | ) |                            |

**ACADIA PHARMACEUTICALS INC.’S ANSWER  
TO HETERO USA INC.’S COUNTERCLAIMS**

Plaintiff ACADIA Pharmaceuticals Inc. (“ACADIA” or “Plaintiff”), by and through its undersigned attorneys, hereby reply to the numbered paragraphs of the counterclaims of Defendant/Counterclaimant Hetero USA Inc. (“Hetero USA”), set forth in “Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hetero USA Inc.’s Answer to Acadia Pharmaceutical Inc.’s Complaint” filed on October 5, 2020 (D.I. 14) (hereinafter, “Counterclaims”) as follows:

**HETERO USA INC.’S COUNTERCLAIMS FOR DECLARATORY JUDGMENT**

1. Upon information and belief, ACADIA admits the allegations of paragraph 1.
2. ACADIA admits that ACADIA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 12830 El Camino Real, Suite 400, San Diego, California 92130. Except as admitted, ACADIA denies the remaining allegations of paragraph 2.

3. ACADIA admits that it is the owner of U.S. Patent Nos. 7,601,740 (“the ’740 patent”), 10,449,185 (“the ’185 patent”), and 10,646,480 (“the ’480 patent”) (collectively, “the patents-in-suit”).

4. ACADIA admits that it is the holder of NDA No. 210793.

5. ACADIA admits the allegations of paragraph 5.

6. Upon information and belief, ACADIA admits the allegations of paragraph 6.

7. Upon information and belief, ACADIA admits the allegations of paragraph 7.

8. ACADIA admits that Hetero USA sent ACADIA notice of Hetero USA’s Paragraph IV certification with ANDA No. 214828 (“Hetero USA’s Notice Letter”).

9. ACADIA admits that Hetero USA’s Notice Letter contained an Offer of Confidential Access. Except as admitted, ACADIA denies the remaining allegations of paragraph 9.

10. Paragraph 10 states a legal conclusion for which no response is required. Except as admitted, ACADIA denies the remaining allegations of paragraph 10.

11. ACADIA admits the allegations of paragraph 11.

12. Paragraph 12 states legal conclusions for which no response is required. To the extent a response is required, ACADIA admits that there is an actual and justiciable controversy between ACADIA and Hetero USA as to the validity and infringement of the patents-in-suit. Except as admitted, ACADIA denies the remaining allegations of paragraph 12.

13. Paragraph 13 states legal conclusions for which no response is required. To the extent a response is required, ACADIA admits that there is an actual and justiciable controversy between ACADIA and Hetero USA as to whether the claims of the patents-in-suit are infringed by Hetero USA. Except as admitted, ACADIA denies the remaining allegations of paragraph 13.

14. Paragraph 14 states legal conclusions for which no response is required. To the extent a response is required, ACADIA admits that there is an actual and justiciable controversy between ACADIA and Hetero USA as to whether the claims of the patents-in-suit are valid and enforceable. Except as admitted, ACADIA denies the remaining allegations of paragraph 14.

15. ACADIA denies the allegations of paragraph 15.

### **JURISDICTION**

16. Paragraph 16 states legal conclusions for which no response is required. To the extent a response is required, ACADIA admits that Hetero USA purports to assert declaratory judgment counterclaims, but denies Hetero USA is entitled to any such relief. Except as admitted, ACADIA denies the remaining allegations of paragraph 16.

17. Paragraph 17 states legal conclusions for which no response is required. To the extent a response is required, ACADIA admits that this Court has subject matter jurisdiction with respect to Hetero USA's Counterclaims concerning the patents-in-suit for the purposes of this action. Except as admitted, ACADIA denies the remaining allegations of paragraph 17.

18. Paragraph 18 states legal conclusions for which no response is required. To the extent a response is required, ACADIA does not contest personal jurisdiction in this Court for the purposes of this action. Except as admitted, ACADIA denies the remaining allegations of paragraph 18.

### **FIRST COUNTERCLAIM** **(Declaration of Non-Infringement of U.S. Patent No. 7,601,740)**

19. ACADIA restates and incorporates herein its answers to each allegation of paragraphs 1 through 18.

20. ACADIA admits it has asserted the '740 patent against Hetero USA based on

the filing of ANDA No. 214828 and admits that it alleges that the claims of the '740 patent cover the ANDA product. Except as admitted, ACADIA denies the remaining allegations of paragraph 20.

21. ACADIA denies the allegations of paragraph 21.

22. Paragraph 22 contains legal conclusions for which no response is required.

Except as admitted, ACADIA denies the remaining allegations of paragraph 22.

23. ACADIA denies the allegations of paragraph 23.

**SECOND COUNTERCLAIM**  
**(Declaration of Invalidity of U.S. Patent No. 7,601,740)**

24. ACADIA restates and incorporates herein its answers to each allegation of paragraphs 1 through 23.

25. ACADIA admits it alleges that the '740 patent is valid. Except as admitted, ACADIA denies the remaining allegations of paragraph 25.

26. ACADIA denies the remaining allegations of paragraph 26.

27. Paragraph 27 contains legal conclusions for which no response is required.

Except as admitted, ACADIA denies the remaining allegations of paragraph 27.

28. ACADIA denies the allegations of paragraph 28.

**THIRD COUNTERCLAIM**  
**(Declaration of Non-Infringement of U.S. Patent No. 10,449,185)**

29. ACADIA restates and incorporates herein its answers to each allegation of paragraphs 1 through 28.

30. ACADIA admits it has asserted the '185 patent against Hetero USA based on the filing of ANDA No. 214828 and admits that it alleges that the claims of the '185 patent cover the ANDA product. Except as admitted, ACADIA denies the remaining allegations of

paragraph 30.

31. ACADIA denies the allegations of paragraph 31.

32. Paragraph 32 contains legal conclusions for which no response is required.

Except as admitted, ACADIA denies the remaining allegations of paragraph 32.

33. ACADIA denies the allegations of paragraph 33.

**FOURTH COUNTERCLAIM**  
**(Declaration of Invalidity of U.S. Patent No. 10,449,185)**

34. ACADIA restates and incorporates herein its answers to each allegation of paragraphs 1 through 33.

35. ACADIA admits it alleges that the '185 patent is valid. Except as admitted, ACADIA denies the remaining allegations of paragraph 35.

36. ACADIA denies the allegations of paragraph 36.

37. Paragraph 37 contains legal conclusions for which no response is required.

Except as admitted, ACADIA denies the remaining allegations of paragraph 37.

38. ACADIA denies the allegations of paragraph 38.

**FIFTH COUNTERCLAIM**  
**(Declaration of Non-Infringement of U.S. Patent No. 10,646,480)**

39. ACADIA restates and incorporates herein its answers to each allegation of paragraphs 1 through 38.

40. ACADIA admits it has asserted the '480 patent against Hetero USA based on the filing of ANDA No. 214828 and admits that it alleges that the claims of the '480 patent cover the ANDA product. Except as admitted, ACADIA denies the remaining allegations of paragraph 40.

41. ACADIA denies the allegations of paragraph 41.

42. Paragraph 42 contains legal conclusions for which no response is required.

Except as admitted, ACADIA denies the remaining allegations of paragraph 42.

43. ACADIA denies the allegations of paragraph 43.

**SIXTH COUNTERCLAIM**  
**(Declaration of Invalidity of U.S. Patent No. 10,646,480)**

44. ACADIA restates and incorporates herein its answers to each allegation of paragraphs 1 through 43.

45. ACADIA admits it alleges that the '480 patent is valid. Except as admitted, ACADIA denies the remaining allegations of paragraph 45.

46. ACADIA denies the allegations of paragraph 46.

47. Paragraph 47 contains legal conclusions for which no response is required. Except as admitted, ACADIA denies the remaining allegations of paragraph 47.

48. ACADIA denies the allegations of paragraph 48.

**PRAYER FOR RELIEF**

ACADIA denies that Hetero USA is entitled to any of the relief requested in its Prayer for Relief or any remedy or relief whatsoever.

\* \* \*

ACADIA denies each and every allegation of Hetero USA's Counterclaims not expressly admitted or otherwise responded to above.

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