

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VERTEX PHARMACEUTICALS)	
INCORPORATED,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 22-966 (RGA)
)	CONSOLIDATED
LUPIN LIMITED and)	
LUPIN PHARMACEUTICALS, INC.,)	
)	
Defendants.)	

**VERTEX PHARMACEUTICALS INCORPORATED'S
ANSWER TO LUPIN LIMITED'S COUNTERCLAIMS**

Vertex Pharmaceuticals Incorporated (“Vertex”), by its attorneys, answers Lupin Limited’s (“Lupin Ltd.” or “Defendant”) counterclaims as follows.

ANSWER TO LUPIN'S COUNTERCLAIMS

Each of the paragraphs below corresponds to the same-numbered paragraphs (each a “Paragraph”) in the counterclaims. Vertex denies all allegations in Defendant’s counterclaims, whether express or implied, except those admitted specifically below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that Defendant may argue follow from the admitted facts. Moreover, to the extent that any of Defendant’s allegations are vague and/or ambiguous, Vertex denies said allegations. To the extent that any of the counterclaims’ headings and/or footnotes constitute allegations, Vertex specifically denies each and every one of them. To the extent that Defendant improperly attaches exhibits to its counterclaims, Vertex objects to such exhibits as improperly included in the counterclaims at least because they violate Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing that the pleader is entitled to relief, and therefore Vertex denies that such exhibits are incorporated by reference into the counterclaims.

Vertex reserves the right to amend this Answer or to assert other defenses as this action proceeds. Vertex denies that Defendant is entitled to the relief requested or any other relief.

Vertex responds to the counterclaims as follows:

THE PARTIES

1. Upon information and belief, admitted.
2. Admitted.

JURISDICTION AND VENUE

3. Paragraph 3 states a legal conclusion for which no response is required. To the extent that a response is required, Vertex admits that by Defendant's counterclaims, Defendant purports to seek a declaratory judgment under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, 35 U.S.C. § 1 et seq., and 35 U.S.C. § 271(e)(5). Vertex denies that Defendant's counterclaims have any merit. Vertex does not contest that this Court has subject matter jurisdiction for purposes of this action.

4. Paragraph 4 states a legal conclusion for which no response is required. To the extent that a response is required, Vertex does not contest that this Court has personal jurisdiction for purposes of this action.

5. Paragraph 5 states a legal conclusion for which no response is required. To the extent that a response is required, Vertex does not contest that venue is proper in this judicial district for purposes of this action.

REGULATORY FRAMEWORK

6. Paragraph 6 contains Defendant's characterization of applicable law and regulations and/or legal conclusions for which no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 6.

7. Paragraph 7 contains Defendant's characterization of applicable law and regulations and/or legal conclusions for which no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 7.

8. Paragraph 8 contains Defendant's characterization of applicable law and regulations and/or legal conclusions for which no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 8.

9. Paragraph 9 contains Defendant's characterization of applicable law and regulations and/or legal conclusions for which no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 9.

ORANGE BOOK-LISTED PATENTS FOR KALYDECO®

10. Vertex admits that it holds approved NDA No. 207925 for KALYDECO® (ivacaftor) oral granules in 5.8, 13.4, 25, 50, and 75 mg packets.

11. Admitted.

12. Admitted.

13. Admitted.

'083 PATENT

14. Paragraph 14 states legal conclusions for which no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 14.

15. To the extent that Paragraph 15 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or

description and notes that such documents speak for themselves and no response is required.

To the extent that a response is required, Vertex denies the allegations in Paragraph 15.

16. To the extent that Paragraph 16 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 16. Vertex also objects to Exhibits 1 and 2 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing that the pleader is entitled to relief, and therefore Vertex denies that such exhibits are incorporated by reference into the counterclaims.

17. To the extent that Paragraph 17 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 17. Vertex also objects to Exhibit 3 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing that the pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

18. To the extent that Paragraph 18 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 18. Vertex also objects to Exhibit 4 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing that the

pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

19. To the extent that Paragraph 19 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 19. Vertex also objects to Exhibit 4 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing that the pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

20. To the extent that Paragraph 20 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 20. Vertex also objects to Exhibit 5 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing that the pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

21. To the extent that Paragraph 21 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 21. Vertex also objects to Exhibit 6 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing that the

pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

22. To the extent that Paragraph 22 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 22. Vertex also objects to Exhibit 7 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing that the pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

23. To the extent that Paragraph 23 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 23. Vertex also objects to Exhibit 8 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing that the pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

24. To the extent that Paragraph 24 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 24. Vertex also objects to Exhibit 9 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing that the

pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

25. To the extent that Paragraph 25 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 25. Vertex also objects to Exhibit 10 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing that the pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

26. To the extent that Paragraph 26 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 26. Vertex also objects to Exhibit 11 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing that the pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

27. To the extent that Paragraph 27 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 27. Vertex also objects to Exhibit 12 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing

that the pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

28. To the extent that Paragraph 28 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 28. Vertex also objects to Exhibit 13 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing that the pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

29. To the extent that Paragraph 29 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 29. Vertex also objects to Exhibit 14 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing that the pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

30. To the extent that Paragraph 30 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 30. Vertex also objects to Exhibit 15 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing

that the pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

31. To the extent that Paragraph 31 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 31. Vertex also objects to Exhibit 16 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing that the pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

32. To the extent that Paragraph 32 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 32. Vertex also objects to Exhibit 17 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing that the pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

33. To the extent that Paragraph 33 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 33. Vertex also objects to Exhibit 18 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing

that the pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

34. To the extent that Paragraph 34 contains Defendant's characterization or description of publicly available documents, Vertex objects to such characterization or description and notes that such documents speak for themselves and no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 34. Vertex also objects to Exhibit 19 as improperly included in the counterclaims at least because it violates Fed. R. Civ. P. 8(a), which requires a short and plain statement of the claim showing that the pleader is entitled to relief, and therefore Vertex denies that such exhibit is incorporated by reference into the counterclaims.

LUPIN'S ANDA

35. Upon information and belief, Vertex admits that Lupin Ltd. filed ANDA No. 217431 with the FDA. Vertex otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 35 and, therefore, denies the same.

36. Because Paragraph 36 contains Defendant's characterization of applicable law and regulations and/or legal conclusions for which no response is required. To the extent that a response is required, upon information and belief, Vertex admits that Lupin Ltd.'s ANDA No. 217431 includes a Paragraph IV certification as to the '083 patent. Vertex otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 36 and, therefore, denies the same.

37. Vertex admits that in a letter dated June 9, 2022 ("First Notice Letter"), Lupin Ltd. stated that its ANDA No. 217431 contained Paragraph IV certifications with respect to U.S. Patent Nos. 8,883,206 ("the '206 patent"), 10,272,046 ("the '046 patent"), and 10,646,481 ("the '481 patent"), and further stated that Lupin Ltd. had certified that no valid claim of the '206, '046, and '481 patents would be infringed by the manufacture, importation, use, or sale

of its proposed ANDA products. Vertex admits that Lupin Ltd. attached exhibits to its First Notice Letter, in which Lupin Ltd. purports to allege the factual and legal bases for its Paragraph IV certifications and to extend an offer of confidential access to Lupin Ltd.'s ANDA No. 217431. Vertex otherwise denies the allegations in Paragraph 37, and specifically denies that the '206, '046, and '481 patents are invalid and/or would not be infringed by the manufacture, importation, use, sale, or offer to sell in the United States of Lupin Ltd.'s proposed ANDA products.

38. Paragraph 38 contains Defendant's characterization of its legal claims for which no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 38, and specifically denies that Vertex is estopped from asserting infringement of claim 1 of the '046 patent due to the doctrine of prosecution history estoppel.

39. Vertex admits that on July 22, 2022, it filed its Complaint alleging infringement of the '206, '046, and '481 patents, and U.S. Patent No. 11,147,770 ("the '770 patent") by Lupin Ltd. and Lupin Pharmaceuticals, Inc. Vertex admits that its Complaint alleges, among other things, that: (i) by submitting and maintaining ANDA No. 217431 containing Paragraph IV certifications and by which Lupin Ltd. seeks approval prior to the expiration of the '206, '046, '481, and '770 patents, Lupin Ltd. has infringed the '206, '046, '481, and '770 patents; and (ii) Lupin Ltd. and Lupin Pharmaceuticals, Inc.'s intended commercial manufacture, use, sale, offer for sale, or importation for sale of Lupin Ltd.'s proposed ANDA products will infringe the '206, '046, '481, and '770 patents. Vertex otherwise denies the allegations in Paragraph 39.

40. Upon information and belief, Vertex admits that Lupin Ltd. made a production to Vertex on December 16, 2022. Vertex otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 40 and, therefore, denies the same.

41. Paragraph 41 contains Defendant's characterization of its legal claims and/or states a legal conclusion for which no response is required. To the extent that a response is required, Vertex denies that Lupin Ltd.'s proposed ANDA products do not meet the limitations of the '206, '046, '481, and '770 patents either literally or equivalently.

42. Vertex admits that in a letter dated March 19, 2025 ("Fourth Notice Letter"), Lupin Ltd. stated that Lupin Ltd.'s ANDA No. 217431 contained a Paragraph IV certification with respect to the '083 patent and further stated that Lupin Ltd. had certified that no valid claim of the '083 patent would be infringed by the manufacture, importation, use, or sale of Lupin Ltd.'s proposed ANDA products. Vertex admits that Lupin Ltd. attached exhibits to its Fourth Notice Letter, in which Lupin Ltd. purports to allege the factual and legal bases for its Paragraph IV certification and to extend an offer of confidential access to Lupin Ltd.'s ANDA No. 217431. Vertex otherwise denies the allegations in Paragraph 42, and specifically denies that the '083 patent is invalid and/or will not be infringed by the manufacture, importation, use, sale, or offer to sell in the United States of Lupin Ltd.'s proposed ANDA products.

43. Paragraph 43 contains Defendant's characterization of its legal claims for which no response is required. To the extent that a response is required, Vertex denies the allegations in Paragraph 43, and specifically denies that Vertex is estopped from asserting infringement of claim 1 of the '083 patent due to the doctrine of prosecution history estoppel.

44. Vertex admits that on April 11, 2025, it filed its Complaint alleging infringement of the '083 patent by Lupin Ltd. and Lupin Pharmaceuticals, Inc. Vertex admits that its Complaint alleges, among other things, that: (i) by submitting and maintaining ANDA No. 217431 containing a Paragraph IV certification and by which Lupin Ltd. seeks approval prior to the expiration of the '083 patent, Lupin Ltd. has infringed the '083 patent; and (ii) Lupin Ltd. and Lupin Pharmaceuticals, Inc.'s intended commercial manufacture, use, sale,

offer for sale, or importation for sale of Lupin Ltd.'s proposed ANDA products will infringe the '083 patent. Vertex otherwise denies the allegations in Paragraph 44.

45. Paragraph 45 contains Defendant's characterization of its legal claims and/or states a legal conclusion for which no response is required. To the extent that a response is required, Vertex denies that Lupin Ltd.'s proposed ANDA products do not meet the limitations of the '083 patent either literally or equivalently.

46. Paragraph 46 states a legal conclusion for which no response is required. To the extent that a response is required, Vertex denies that Defendant's counterclaims have any merit.

47. Paragraph 47 contains Defendant's characterization of applicable law and regulations and/or legal conclusions for which no response is required. To the extent that a response is required, Vertex admits that the '083 patent is properly listed in the Orange Book pursuant to 21 U.S.C. § 355(b)(1) and/or 21 U.S.C. § 355(c)(2) and/or attendant FDA regulations. Vertex otherwise denies the allegations in Paragraph 47.

48. Paragraph 48 contains Defendant's characterization of applicable law and regulations and/or legal conclusions for which no response is required. To the extent that a response is required, Vertex admits that it brought an infringement suit based on the Orange Book-listed '083 patent against Defendant. Vertex otherwise denies the allegations in Paragraph 48.

49. Paragraph 49 contains Defendant's characterization of applicable law and regulations and/or legal conclusions for which no response is required. To the extent that a response is required, Vertex admits that Defendant faces infringement liability if it commences marketing its proposed ANDA products prior to the expiration of the '083 patent. Vertex otherwise denies the allegations in Paragraph 49.

50. Paragraph 50 contains Defendant's characterization of applicable law and regulations and/or legal conclusions for which no response is required. To the extent that a response is required, Vertex does not contest that this Court has personal and subject matter jurisdiction for purposes of this action. Vertex otherwise denies the allegations in Paragraph 50.

COUNT I
(Declaratory Judgment of Noninfringement of the '083 Patent)

51. Vertex hereby repeats and incorporates by reference its answers to Paragraphs 1-50 of the Counterclaims as if fully set forth in response to Paragraph 51.

52. Denied.

53. Denied.

54. Denied.

COUNT II
(Declaratory Judgment of Invalidity of the '083 Patent)

55. Vertex hereby repeats and incorporates by reference its answers to Paragraphs 1-54 of the Counterclaims as if fully set forth in response to Paragraph 55.

56. Denied.

57. Vertex admits that in its Fourth Notice Letter, Lupin Ltd. purports to allege the factual and legal bases for its Paragraph IV certification for the '083 patent. Vertex otherwise denies the allegations in Paragraph 57, and specifically denies that the contents of Lupin Ltd.'s Fourth Notice Letter have been incorporated by reference into Defendant's counterclaims. Vertex also specifically denies that the claims of the '083 patent are invalid.

58. Paragraph 58 contains Defendant's characterization of applicable law and regulations and/or legal conclusions for which no response is required. To the extent that a response is required, Vertex denies that Defendant's counterclaim has any merit.

PRAYER FOR RELIEF

Vertex denies that Defendant is entitled to any relief.

AFFIRMATIVE DEFENSES

In response to Defendant's counterclaims, Vertex hereby realleges and incorporates by reference the allegations set forth in the Complaint in this action. Vertex also asserts the following affirmative and other defenses. By characterizing these as "Affirmative Defenses," Vertex is not taking on any burden of proof beyond that which the law applies to it. Thus, without admitting or implying that Vertex bears the burden of proof as to any of them, Vertex, on information and belief, asserts the following affirmative defenses:

First Affirmative Defense

The '083 patent is valid.

Second Affirmative Defense

The sale, offer for sale, use, or commercial manufacture within the United States, or importation into the United States, of the products that are the subject of Lupin Ltd.'s ANDA No. 217431 will infringe the '083 patent.

Third Affirmative Defense

Defendant's counterclaims, in whole or in part, are barred because they fail to state a cause of action upon which relief may be granted.

Fourth Affirmative Defense

Vertex has not knowingly or intentionally waived any applicable affirmative or other defenses and reserves the right to assert and rely upon such other affirmative and other defenses as may become available or apparent during discovery proceedings. Vertex further reserves the right to amend this Answer and/or affirmative defenses accordingly.

**COUNTER-DEFENDANT'S PRAYER FOR RELIEF
ON DEFENDANT'S COUNTERCLAIMS**

WHEREFORE, Vertex respectfully requests the following relief:

- A. A judgment denying all relief sought by Defendant;
- B. An order dismissing Defendant's counterclaims with prejudice;
- C. A judgment, order, and/or injunction granting each and every form of relief sought by Vertex in its Complaint;
- D. An award to Vertex of its costs and expenses in this action;
- E. A finding in Vertex's favor that this case is exceptional, and an award of Vertex's attorneys' fees pursuant to 35 U.S.C. § 285;
- F. An award of costs and expenses to Vertex for defending against Defendant's counterclaims; and
- G. Such further and other relief as this Court deems to be just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

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May 23, 2025

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CERTIFICATE OF SERVICE

I hereby certify that on May 23, 2025, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on May 23, 2025, upon the following in the manner indicated:

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