

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 23-1332 (MN)
)	(Consolidated)
HETERO USA, INC.,)	
HETERO LABS LIMITED,)	
HETERO LABS LIMITED UNIT-V,)	
AUROBINDO PHARMA USA, INC., and)	
AUROBINDO PHARMA LTD.,)	
)	
Defendants.)	
)	
)	

**PLAINTIFF'S ANSWER TO AUROBINDO PHARMA USA, INC.
AND AUROBINDO PHARMA LTD.'S COUNTERCLAIMS**

Plaintiff/Counterclaim Defendant AbbVie Inc. (“AbbVie” or “Plaintiff”), by its undersigned attorneys, hereby answers the Counterclaims filed on June 16, 2025 (D.I. 258) by Defendants/Counterclaim Plaintiffs Aurobindo Pharma USA, Inc. (“Aurobindo Pharma USA”) and Aurobindo Pharma Ltd. (collectively, “Aurobindo”) as follows:

AUROBINDO'S ANSWER AND AFFIRMATIVE DEFENSES

Paragraphs 1–50, the “Response to ‘Request for Relief,’” and the “Separate Defenses” of Aurobindo’s Answer, Defenses, and Counterclaims (D.I. 258) are not part of the Counterclaims and require no response by AbbVie.

ANSWER TO AUROBINDO'S COUNTERCLAIMS

Plaintiff denies all allegations in Aurobindo’s Counterclaims except as expressly admitted below.

THE PARTIES

1. Counterclaim-Plaintiff Aurobindo Pharma Limited is a corporation organized and existing under the laws of the Republic of India with its principal place of business at Plot No. 11, Survey No. 9, Water Mark Building, Kondapur, Hitech City, Hyderabad 500 084, Telangana, India.

ANSWER: Upon information and belief, admitted.

2. Counterclaim-Plaintiff Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ 08520.

ANSWER: Upon information and belief, admitted.

3. AbbVie Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1 North Waukegan Road, North Chicago, Illinois 60064.

ANSWER: Admitted.

BACKGROUND

4. Aurobindo filed ANDA No. 218866 with the FDA seeking approval to market upadacitinib extended-release tablets, 15 mg and 30 mg, referencing the approved New Drug Application (“NDA”) for RINVOQ®, NDA No. 211675.

ANSWER: Upon information and belief, admitted.

5. The United States Patent and Trademark Office (“USPTO”) issued U.S. Patent No. RE47,221 (“RE’221”) titled “Tricyclic Compounds”, naming Plaintiff/Counterclaim-Defendant AbbVie Inc. as the assignee on the face of the patent, and listing an issue date of February 5, 2019. The patent states that it is a reissue of U.S. Patent No. 8,426,411, issued on April 23, 2013.

ANSWER: Admitted.

6. AbbVie is the current holder of NDA No. 211675.

ANSWER: Admitted.

7. The United States Food and Drug Administration’s “Approved Drug Products with Therapeutic Equivalence Evaluation,” also known as the “Orange Book,” lists U.S. Patent No. RE’221 as covering RINVOQ® as manufactured under NDA No. 211675.

ANSWER: Admitted.

8. Aurobindo filed ANDA No. 218866 with the FDA seeking approval to market upadacitinib extended-release tablets, 15 mg and 30 mg, referencing the approved New Drug Application (“NDA”) for RINVOQ®, NDA No. 211675.

ANSWER: Upon information and belief, admitted.

9. As part of its ANDA, Aurobindo submitted to the FDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) (“Paragraph IV Certification”) that RE’221 is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the drug product described by Aurobindo’s ANDA.

ANSWER: On information and belief, admitted that Aurobindo’s ANDA included a purported Paragraph IV Certification for the RE’221 Patent for Aurobindo’s ANDA Products. Plaintiff denies the remaining allegations of Paragraph 9.

10. On or about February 19, 2025, Aurobindo sent by FedEx and by email to Counterclaim-Defendant’s counsel a letter concerning its Paragraph IV certification regarding RE’221 (the “February 2025 Notice Letter”) to AbbVie Inc.

ANSWER: Plaintiff admits that it received a letter, dated February 19, 2025, sent on behalf of Aurobindo (the “February 2025 Notice Letter”), stating Aurobindo had filed a purported Paragraph IV Certification for the RE’221 Patent for Aurobindo’s ANDA Products. Plaintiff denies any remaining allegations of Paragraph 10.

11. The February 2025 Notice Letter included a detailed statement of the factual and legal bases for Aurobindo’s opinion that RE’221 is invalid, unenforceable, and/or not infringed by Aurobindo’s Proposed ANDA Product.

ANSWER: Paragraph 11 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiff admits that the February 2025 Notice Letter purports to include detailed statements. Plaintiff denies any remaining allegations of Paragraph 11 and denies that any of the allegations in the purported detailed statements have merit.

12. Counterclaim-Defendant has actual knowledge of the contents of the February 2025 Notice Letter.

ANSWER: Upon information and belief, admitted that Plaintiff received the February 2025 Notice Letter. Plaintiff denies the remaining allegations of Paragraph 12.

13. Aurobindo produced ANDA No. 218866 and DMF No. 38095 to Counterclaim-Defendant in *AbbVie Inc. v. Hetero USA, Inc. et al.*, C.A. No. 23-1332 (MN) (D. Del.) in a case regarding other patents also listed in the Orange Book for Rinvvoq®.

ANSWER: Upon information and belief, admitted that Aurobindo has stated its production of ANDA No. 218866 and DMF No. 38095 to AbbVie in *AbbVie Inc. v. Hetero USA, Inc. et al.*, C.A. No. 23-1332 (MN) (D. Del.) was current as of June 16, 2025. Plaintiff denies any remaining allegations of Paragraph 13.

14. AbbVie filed the Complaint in this action on April 4, 2025.

ANSWER: Admitted.

15. On information and belief, Aurobindo's February 2025 Notice Letter was received by AbbVie on or about February 19, 2025.

ANSWER: Admitted that Aurobindo's purported February 2025 Notice Letter, dated February 19, 2025, was received by AbbVie on February 20, 2025.

16. WO 2009/152133 ("WO '133") was published on December 17, 2009, and is prior art to RE'221 under 35 U.S.C. § 102(a)(1).

ANSWER: Paragraph 16 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiff denies the allegations of Paragraph 16.

17. WO 2010/119284 ("WO '284") was published on October 21, 2010, and is prior art to RE'221 under 35 U.S.C. § 102(a)(1).

ANSWER: Paragraph 17 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiff denies the allegations of Paragraph 17.

18. WO 2010/119285 ("WO '285") was published on October 21, 2010, and is prior art to RE'221 under 35 U.S.C. § 102(a)(1).

ANSWER: Paragraph 18 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiff denies the allegations of Paragraph 18.

19. WO 2009/150240 ("WO '240") was published on December 17, 2009, and is prior art to RE'221 under 35 U.S.C. § 102(a)(1).

ANSWER: Paragraph 19 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiff denies the allegations of Paragraph 19.

20. WO 2009/047506 (“WO ’506”) was published on April 16, 2009, and is prior art to RE’221 under 35 U.S.C. § 102(a)(1).

ANSWER: Paragraph 20 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiff denies the allegations of Paragraph 20.

21. WO 2008/119792 (“WO ’792”) was published on October 9, 2008, and is prior art to RE’221 under 35 U.S.C. § 102(a)(1).

ANSWER: Paragraph 21 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiff denies the allegations of Paragraph 21.

22. WO 2008/078091 (“WO ’091”) was published on July 3, 2008, and is prior art to RE’221 under 35 U.S.C. § 102(a)(1).

ANSWER: Paragraph 22 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiff denies the allegations of Paragraph 22.

JURISDICTION AND VENUE

23. This Court has subject matter jurisdiction over the counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 1331, 1338(a), based on actual controversy between Aurobindo and Counter-Defendant arising under the patent laws of the United States, 35 U.S.C. §§ 100 et seq.

ANSWER: Paragraph 23 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiff admits that Aurobindo purports to assert declaratory judgment counterclaims. Plaintiff denies the remaining allegations of Paragraph 23 and further denies that Aurobindo’s Counterclaims have any merit.

24. This Court has personal jurisdiction over Counterclaim-Defendant because Counterclaim-Defendant has voluntarily subjected itself to the Court’s jurisdiction by filing the Complaint, and for other reasons.

ANSWER: Paragraph 24 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiff admits that it has sued Aurobindo in this judicial district in this action. For the purposes of this action only, Plaintiff does not contest personal jurisdiction in this judicial district. Plaintiff denies the remaining allegations of Paragraph 24.

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

ANSWER: Paragraph 25 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiff admits that it has sued Aurobindo in this judicial district in this action. For the purposes of this action only, Plaintiff does not contest venue in this judicial district. Plaintiff denies the remaining allegations of Paragraph 25.

FIRST COUNTERCLAIM
(Declaration of Non-infringement of RE'221)

26. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1-25 of the Counterclaims as if fully set forth herein.

ANSWER: Plaintiff incorporates its answers to Paragraphs 1 through 25 above, and each paragraph in its Complaint, as if fully set forth herein.

27. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of RE'221 will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's Proposed ANDA Product described by ANDA No. 218866.

ANSWER: Paragraph 27 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiff admits that Aurobindo purports to assert declaratory judgment counterclaims. Plaintiff denies the remaining allegations of Paragraph 27 and further denies that Aurobindo's Counterclaims have any merit.

28. The commercial manufacture, use, offer for sale, sale, or import of Aurobindo's Proposed ANDA Product has not infringed, does not infringe, and would not directly infringe or indirectly infringe any valid claim of RE'221, either literally or under the doctrine of equivalents, for at least the reasons Aurobindo presented in the February 2025 Notice Letter, which is incorporated herein by reference.

ANSWER: Denied.

29. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of RE'221, and will not be liable for such infringement, for at least the reasons Aurobindo presented in the February 2025 Notice Letter, which is incorporated herein by reference.

ANSWER: Denied.

30. By way of example and not limitation, Aurobindo will not infringe the claims of RE'221 because the Aurobindo ANDA Product will not meet all claim limitations.

ANSWER: Denied.

31. Counterclaim-Defendant bears the burden of proving infringement and will not be able to meet that burden.

ANSWER: Denied.

32. There is an actual and justiciable controversy between the parties concerning whether the manufacturing, use, sale, offering for sale, or importation of Aurobindo's ANDA Product described by ANDA No. 218866 will infringe any valid and enforceable claim of RE'221.

ANSWER: Paragraph 32 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiff admits that its Complaint includes claims that Aurobindo infringed the RE'221 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 218866 with a purported Paragraph IV Certification; and that Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Products would actively infringe, induce the infringement of, and/or contribute to the infringement of the RE'221 Patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (c). Plaintiff denies the remaining allegations of Paragraph 32.

33. Aurobindo is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of Aurobindo's ANDA Product described by ANDA No. 218866 will not infringe, directly or indirectly, any valid claim of RE'221.

ANSWER: Denied.

SECOND COUNTERCLAIM
(Declaration of Invalidity of RE'221)

34. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1-33 of the Counterclaims as if fully set forth herein.

ANSWER: Plaintiff incorporates its answers to Paragraphs 1 through 33 above, and each paragraph in its Complaint, as if fully set forth herein.

35. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of RE'221 are invalid for failure to comply with the statutory prerequisites of 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases of invalidation and unenforceability.

ANSWER: Paragraph 35 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiff admits that Aurobindo purports to assert declaratory judgment counterclaims. Plaintiff denies the remaining allegations of Paragraph 35 and further denies that Aurobindo's Counterclaims have any merit.

36. In the February 2025 Notice Letter, Aurobindo explained reasons sufficient to show that the claims of RE'221 are invalid, yet Counterclaim-Defendant brought this case anyway.

ANSWER: Denied.

37. All claims of RE'221 are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, the defenses recognized in 25 U.S.C. § 282(b), double patenting, and/or other judicially-created bases for invalidation, at least for the reasons stated in the February 2025 Notice Letter, which is incorporated herein by reference.

ANSWER: Denied.

38. By way of example and not limitation, as described in the February 2025 Notice Letter, each claim of RE'221 is invalid under 35 U.S.C. § 103 in light of at least WO '133, WO '284, WO '285, WO '240, WO '506, WO '792, and/or WO '091.

ANSWER: Denied.

39. There is no substantial difference between the claims of RE'221 and the disclosures of WO '133, WO '284, WO '240, WO '506, WO '792, and/or WO '091.

ANSWER: Denied.

40. There are no secondary indicia of nonobviousness that have a nexus to the claims of RE'221.

ANSWER: Denied.

41. By way of example and not limitation, as described in the February 2025 Notice Letter, each claim of RE'221 lacks utility under 35 U.S.C. § 101, and enablement and written description under 35 U.S.C. § 112.

ANSWER: Denied.

42. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, offering for sale, or importation of Aurobindo's ANDA Product described by ANDA No. 218866 will infringe any valid and enforceable claim of RE'221.

ANSWER: Paragraph 42 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiff admits that its Complaint includes claims that Aurobindo infringed the RE'221 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 218866 with a purported Paragraph IV Certification; and that Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Products would actively infringe, induce the infringement of, and/or contribute to the infringement of the RE'221 Patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (c). Plaintiff denies the remaining allegations of Paragraph 42.

43. Aurobindo is entitled to a judicial declaration that the claims of RE'221 are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112 or other judicially created bases or invalidation and unenforceability.

ANSWER: Denied.

AUROBINDO'S PRAYER FOR RELIEF

Plaintiff denies that Aurobindo is entitled to any of the relief it has requested or to any other relief.

AFFIRMATIVE AND OTHER DEFENSES

In response to Aurobindo's Counterclaims, Plaintiff asserts the following affirmative and other defenses. In asserting these defenses, Plaintiff does not assume the burden of proof with respect to any issue upon which applicable law puts the burden of proof upon Aurobindo.

First Defense

Aurobindo's Counterclaims, in whole or in part, are barred because they fail to state claims upon which relief may be granted.

Second Defense

Plaintiff 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. Plaintiff further reserves the right to amend this Answer and/or affirmative defenses accordingly.

PLAINTIFF'S PRAYER FOR RELIEF ON AUROBINDO'S COUNTERCLAIMS

WHEREFORE, Plaintiff respectfully requests the following relief:

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

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/s/ Jeremy A. Tigan

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July 7, 2025

CERTIFICATE OF SERVICE

I hereby certify that on July 7, 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 July 7, 2025, upon the following in the manner indicated:

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