IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
AUROBINDO PHARMA USA, INC. and AUROBINDO PHARMA LTD.,	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff AbbVie Inc. ("AbbVie"), by its undersigned attorneys, brings this action against Defendants Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. (collectively, "Aurobindo"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. § 271. This action arises from Aurobindo's submission of Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to market generic versions of AbbVie's highly successful pharmaceutical product RINVOQ®, prior to the expiration of United States Patent No. RE47,221 ("the RE'221 Patent") (collectively, "the Patent-in-Suit").

2. In November 2023, Plaintiff filed related action *AbbVie Inc. v. Hetero USA, Inc. et al.*, C.A. No. 23-1332 (MN) (D. Del.) against, inter alia, Hetero, Aurobindo, Sandoz, and Sun for patent infringement arising from their respective ANDA submissions. In August 2024, Plaintiff filed related action *AbbVie Inc. v. Hetero USA, Inc. et al.*, C.A. No. 24-0924 (MN) (D. Del.) against Hetero, Aurobindo, and Sun. In November 2024, Plaintiff filed related action *AbbVie Inc. v. Hetero USA, Inc. et al.*, C.A. No. 24-1254 (MN) (D. Del.) against, Hetero, Aurobindo, Sandoz, and Sun.

These actions have all been consolidated for all purposes, including trial. *See* C.A. No. 23-1332 (MN) (D. Del.) (D.I. 114). Subsequently, Aurobindo sent AbbVie a new Notice Letter dated February 19, 2025 with new purported Paragraph IV certification to the RE'221 Patent. Plaintiff has timely filed suit within 45 days of receipt of Aurobindo's newest Notice Letter.

RINVOQ®

3. RINVOQ® (upadacitinib) is a ground-breaking, once-daily oral Janus kinase (JAK) inhibitor that has gained widespread medical acceptance. In less than five years since its first FDA approval on August 16, 2019, RINVOQ® has been approved to treat patients with a number of different immune-mediated diseases, including rheumatoid arthritis, psoriatic arthritis and ulcerative colitis. It has been used to treat more than 160,000 patients in the United States alone.

4. Janus kinases (JAKs), including JAK1, JAK2, JAK3 and Tyrosine kinase 2 (Tyk2), are intracellular enzymes that play a pivotal role in signaling pathways arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. Within the signaling pathway, JAKs phosphorylate and activate signal transducers and activators of transcription (STATs) which modulate intracellular activity including gene expression. RINVOQ®'s active ingredient, upadacitinib, modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs. Upadacitinib has surprising selectivity for JAK1.

5. AbbVie invested more than 3.5 billion dollars in the development of RINVOQ® and in its extensive clinical development program, which includes more than 45 completed or ongoing company-sponsored clinical trials and has resulted in approvals for an unexpected array of onerous diseases of the immune system. AbbVie continues to invest in the clinical development of RINVOQ®.

6. AbbVie's development of RINVOQ® is part of its long legacy of research in immunology and its track record to making life better for people living with immune-mediated diseases.

7. RINVOQ® is currently approved for treatment of:

a. adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more tumor necrosis factor ("TNF") blockers;

b. adults and pediatric patients 2 years of age and older with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers;

c. adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable;

d. adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers;

e. adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers;

f. adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers;

g. adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy;

h. Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.

8. RINVOQ® represents an important advance for patients with these conditions. RINVOQ® was designated as a "Breakthrough Therapy" by FDA for treatment of adult patients with moderate to severe atopic dermatitis who are candidates for systemic therapy, based on FDA's determination that RINVOQ® may offer substantial treatment advantages over existing options for patients with serious or life-threatening diseases. RINVOQ® is the first and only JAK inhibitor that is approved for both non-radiographic axial spondyloarthritis (nr-axSpA) and active ankylosing spondylitis (AS). RINVOQ® was also the first oral therapy to receive FDA approval for moderate to severe Crohn's disease.

9. As a result of the inventive work of the AbbVie scientists responsible for development and formulation, RINVOQ® is available in 15 mg, 30 mg, and 45 mg extended-release tablets, which allow for convenient once daily oral dosing.

THE PARTIES

10. Plaintiff AbbVie is a corporation organized and existing under the laws of the State of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is a global research and development-based biopharmaceutical company committed to developing innovative therapies for some of the world's most complex and critical conditions. AbbVie's mission is to use its expertise, dedicated people, and unique approach to innovation to markedly improve treatments across therapeutic areas.

11. AbbVie is the assignee and owner of the Patent-in-Suit.

12. AbbVie holds NDA No. 211675 for RINVOQ®.

13. Defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ 08520. On information and belief, Aurobindo Pharma USA, Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd.

14. Defendant Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 11, Survey No. 9, Water Mark Building, Kondapur, Hitech City, Hyderabad 500 084, Telangana, India.

15. On information and belief, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. are agents of one another and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

16. Aurobindo caused ANDA No. 218866 to be submitted to FDA and seeks FDA approval of ANDA No. 218866.

17. On information and belief, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. acted collaboratively in the preparation of ANDA No. 218866 and continue to act collaboratively in pursuing FDA approval of ANDA No. 218866 and seeking to market the Aurobindo ANDA Products.

18. On information and belief, Aurobindo intends to commercially manufacture, market, offer for sale, and sell the Aurobindo ANDA Products throughout the United States, including in the State of Delaware, in the event FDA approves ANDA No. 218866.

19. On information and belief, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. rely on material assistance from one another to market, distribute, offer for sale, and/or sell generic drugs in the U.S. market, including in the State of Delaware. On information and belief, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell Aurobindo's ANDA Products, in the event FDA approves ANDA No. 218866.

JURISDICTION AND VENUE

20. This is a civil action for patent infringement arising under the patent laws of the United States, including 35 U.S.C. § 271 and 28 U.S.C. §§ 1338(a), 2201, 2202.

21. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

22. This Court has personal jurisdiction over Aurobindo Pharma USA, Inc. because Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of Delaware. On information and belief, Aurobindo Pharma USA, Inc. is registered to do business as a domestic corporation in Delaware (File Number 3769913).

23. Additionally, this Court has personal jurisdiction over Aurobindo Pharma Ltd. because, on information and belief, Aurobindo Pharma Ltd., *inter alia*, has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Aurobindo's ANDA Products in the State of Delaware upon approval of ANDA No. 218866.

24. On information and belief, Aurobindo is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic

drug products, either directly or through subsidiaries, agents, and/or alter egos, which Aurobindo manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

25. On information and belief, Aurobindo is licensed to sell generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

26. Aurobindo has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to AbbVie, which manufactures and markets RINVOQ® for sale and use throughout the United States, including in this judicial district. On information and belief and as indicated by letters dated October 13, 2023; January 23, 2024; August 7, 2024; October 23, 2024; November 4, 2024; November 26, 2024; and February 19, 2025 sent by Aurobindo to AbbVie pursuant to 21 U.S.C. § 355(j)(2)(B), Aurobindo prepared and filed its ANDA with the intention of seeking to market Aurobindo's ANDA Products nationwide, including within this judicial district.

27. On information and belief, Aurobindo plans to sell the Aurobindo ANDA Products in the State of Delaware, list the Aurobindo ANDA Products on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the Aurobindo ANDA Products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

28. On information and belief, Aurobindo knows and intends that the Aurobindo ANDA Products will be distributed and sold in Delaware and will thereby displace sales of RINVOQ®, causing injury to AbbVie. Aurobindo intends to take advantage of its established channels of distribution in Delaware for the sale of the Aurobindo ANDA Products.

29. Aurobindo Pharma Ltd. regularly invokes the jurisdiction of the courts of this judicial district by pleading claims and counterclaims in pharmaceutical patent infringement actions in this judicial district. *See, e.g., Taiho Pharmaceutical Co., Ltd. et al. v. Eugia Pharma Specialities Limited et al.*, C.A. No. 23-1193-CFC, D.I. 10 (D. Del. Oct. 30, 2023); *Taiho Pharmaceutical Co., Ltd. et al. v. Eugia Pharma Specialities Limited et al.*, C.A. No. 22-1611-CFC, D.I. 9 (D. Del. Jan. 3, 2023); *Acadia Pharmaceuticals Inc. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 20-985-RGA, D.I. 215 (D. Del. June 15, 2022). Aurobindo Pharma Ltd. has also not contested personal jurisdiction or venue in pharmaceutical patent litigation in this judicial district. *See, e.g., Taiho Pharmaceutical Co., Ltd. et al. v. Eugia Pharma Specialities Limited et al.*, C.A. No. 23-1193-CFC, D.I. 10 (D. Del. Oct. 30, 2023); *Taiho Pharmaceutical Co., Ltd. et al. v. Eugia Pharma Specialities Limited et al.*, C.A. No. 22-01611-CFC, D.I. 9 (D. Del. Jan. 3, 2023); *Acadia Pharmaceuticals Inc. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 20-985-RGA, D.I. 215 (D. Del. June 15, 2022).

30. In the alternative, this Court has personal jurisdiction over Aurobindo Pharma Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) AbbVie's claims arise under federal law; (b) Aurobindo Pharma Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Aurobindo Pharma Ltd. has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Aurobindo's ANDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Aurobindo Pharma Ltd. satisfies due process.

31. Venue is proper in this district for Aurobindo Pharma USA, Inc. pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware.

32. Venue is proper in this district for Aurobindo Pharma Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India and may be sued in any judicial district.

33. Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. did not contest personal jurisdiction or venue in this judicial district in response to the complaints Plaintiff filed in *AbbVie Inc. v. Hetero USA, Inc. et al*, C.A. No. 23-1332 (MN) (D. Del.); *AbbVie Inc. v. Hetero USA, Inc. et al*, C.A. No. 24-0924 (MN) (D. Del.); and *AbbVie Inc. v. Hetero USA, Inc. et al*, C.A. No. 24-1254 (MN) (D. Del.), now collectively *AbbVie Inc. v. Hetero USA, Inc. et al*, C.A. No. 23-1332 (MN) (D. Del.) (consolidated). Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. asserted counterclaims invoking this Court's jurisdiction in their answers to each complaint.

THE ASSERTED PATENT

34. The RE'221 Patent, entitled "Tricyclic compounds," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO") on February 5, 2019. The RE'221 Patent is a reissue of U.S. Patent No. 8,426,411, which originally issued on April 23, 2013. A true and correct copy of the RE'221 Patent is attached hereto as Exhibit A. The RE'221 Patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for RINVOQ® 15 mg, 30 mg, and 45 mg tablets.

AUROBINDO'S ANDA NO. 218866

35. Aurobindo has submitted ANDA No. 218866 ("Aurobindo's ANDA") which seeks approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of purported generic versions of RINVOQ® 15 mg and 30 mg tablets

("Aurobindo's ANDA Products" or "the Aurobindo ANDA Products") prior to the expiration of the RE'221 Patent.

36. On information and belief, FDA tentatively approved Aurobindo's ANDA on January 3, 2025.

37. Aurobindo sent AbbVie a new Notice Letter dated February 19, 2025. Aurobindo's Notice Letter represented that Aurobindo had submitted new a purported Paragraph IV certification with respect to the RE'221 Patent, which is listed in the Orange Book for RINVOQ®.

38. According to applicable regulations, Notice Letters such as Aurobindo's must contain a detailed statement of the factual and legal basis for the applicant's opinion that the patent is invalid, unenforceable, or not infringed which includes a claim-by-claim analysis, describing "for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

39. For the claims of the RE'221 Patent, Aurobindo's Notice Letter failed to allege that its ANDA Products or the proposed administration of those Products would not meet the limitations of that claim.

40. On information and belief, if FDA grants final approval of Aurobindo's ANDA, Aurobindo will manufacture, offer for sale, or sell its ANDA Products, within the United States, including within the State of Delaware, or will import its ANDA Products into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Aurobindo's ANDA Products will directly infringe the RE'221 Patent, either literally or under the

doctrine of equivalents, and Aurobindo will actively induce and/or contribute to the infringement of those patents.

COUNT 1 — INFRINGEMENT OF THE RE'221 PATENT BY AUROBINDO

41. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

42. On information and belief, Aurobindo has submitted or caused the submission of Aurobindo's ANDA to FDA, and thereby seeks FDA approval of Aurobindo's ANDA Products.

43. AbbVie owns all rights, title, and interest in and to the RE'221 Patent.

44. Aurobindo's ANDA Products infringe one or more claims of the RE'221 Patent.

45. Aurobindo did not contest infringement of claims 13–14 of the RE'221 Patent in Aurobindo's February 19, 2025 Notice Letter. If Aurobindo had a factual or legal basis to contest infringement of the claims of the RE'221 Patent, it was required by applicable regulations to state such a basis in the Notice Letter. *See* 21 C.F.R. § 314.95(c)(7); 21 C.F.R. § 314.52.

46. Aurobindo has infringed one or more claims of the RE'221 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Aurobindo's ANDA with a Paragraph IV certification and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the RE'221 Patent.

47. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Products prior to the expiration of the RE'221 Patent would infringe one or more claims of the RE'221 Patent under 35 U.S.C. § 271(a), and/or Aurobindo would induce the infringement of and/or contribute to the infringement of one or more claims of the RE'221 Patent under 35 U.S.C. § 271(b) and/or (c).

48. Aurobindo had actual and constructive notice of the RE'221 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with

the request for FDA approval prior to the expiration of the RE'221 Patent would constitute an act of infringement of the RE'221 Patent.

49. Aurobindo filed its ANDA without adequate justification for asserting that the RE'221 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Products. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the RE'221 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles AbbVie to recovery of its attorneys' fees and such other relief as this Court deems proper.

50. AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing and from actively inducing or contributing to the infringement of the RE'221 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Aurobindo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

REQUEST FOR RELIEF

WHEREFORE, AbbVie respectfully requests the following relief:

(A) A judgment that Aurobindo has infringed the RE'221 Patent under 35 U.S.C. § 271(e)(2)(A);

(B) A judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the last expiration date of the RE'221 Patent, or any later expiration of exclusivity for any of the RE'221 Patent, including any extensions or regulatory exclusivities;

(C) A judgment that making, using, selling, offering to sell, or importing Aurobindo's accused ANDA Products, or inducing or contributing to such conduct, would constitute infringement of the RE'221 Patent pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(D) Entry of a permanent injunction enjoining Aurobindo, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Aurobindo or on its behalf from commercially manufacturing, using, offering for sale, or selling its accused ANDA Products within the United States, or importing its accused ANDA Products into the United States, until the day after the expiration of the RE'221 Patent, including any additional exclusivity period applicable to that patents, and from otherwise infringing the claims of the RE'221 Patent;

(E) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Aurobindo engages in the commercial manufacture, use, offer for sale, sale, and/or importation of its accused ANDA Products, or any product that infringes the RE'221 Patent, or induces or contributes to such conduct, prior to the expiration of the patents including any additional exclusivity period applicable to that patent;

(F) A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(G) Costs and expenses in this action; and

(H) Such other and further relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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