IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC., Plaintiff, v. ALEMBIC PHARMACEUTICALS LIMITED and ALEMBIC PHARMACEUTICALS, INC., Defendants.	C.A. No. _____ **ANDA CASE**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Vanda Pharmaceuticals Inc. (Vanda) brings this Complaint for Patent Infringement of U.S. Patent No. 8,586,610 (the '610 patent or the Asserted Patent) against Defendants Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. (collectively, Alembic) related to Alembic's filing of Abbreviated New Drug Application No. 207409 (Alembic's ANDA) for approval of a generic version of Vanda's FANAPT® (iloperidone) oral tablets (Alembic's ANDA Product), as well as the anticipated future commercial manufacture, use, importation, marketing, sale, and offer for sale of Alembic's ANDA Product. Vanda alleges as follows:

THE PARTIES

1. Plaintiff Vanda Pharmaceuticals Inc. is a global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high-priority unmet medical needs and to improve the lives of patients. Vanda is incorporated in Delaware and maintains its principal place of business in Washington, D.C.

2. On information and belief, Defendant Alembic Pharmaceuticals Limited (APL) is an entity organized and existing under the laws of India, having a principal place of business at

Alembic Road, Vadodara 390 003, Gujarat, India.

3. On information and belief, Defendant Alembic Pharmaceuticals, Inc. (API) is incorporated in Delaware, having its principal place of business at 550 Hills Drive, Suite 104B, Bedminster, New Jersey 07921.

4. On information and belief, API is a wholly owned subsidiary of APL.

5. On information and belief, APL and API are generic pharmaceutical companies that distribute and sell generic pharmaceutical products in the State of Delaware and throughout the United States that are manufactured by APL.

6. On information and belief, APL and API acted in concert with one another in preparing and submitting Alembic's ANDA.

7. On information and belief, APL and API will work, in concert with one another to make, use, offer for sale, import, and/or sell Alembic's ANDA Product in the United States, including in this District.

JURISDICTION AND VENUE

8. The Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), at least because this action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, including at least 35 U.S.C. § 271(e)(2)(A).

9. The Court has personal jurisdiction over API by virtue of that entity's incorporation in the State of Delaware.

10. API's affiliations with the State of Delaware are so continuous and systematic as to render API essentially at home in this forum.

11. APL is a foreign defendant that is not subject to jurisdiction in any state's courts of general jurisdiction, making this Court a proper venue for personal jurisdiction under Federal Rule of Civil Procedure 4(k)(2).

12. The Court also has personal jurisdiction over each Defendant because, among other things: (1) each Defendant, by acting in concert to prepare and file Alembic's ANDA, has sought approval to market and sell a generic version of Vanda's FANAPT® in this District, and (2) each Defendant will imminently commit, aid, abet, contribute to, or participate in the commission of a tortious act of patent infringement by making, using, offering to sell, or selling Alembic's ANDA Product throughout the United States and in this District.

13. The Court also has personal jurisdiction over each Defendant because, among other things, each Defendant has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware.

14. On information and belief, each Defendant regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware, either on its own or through its affiliates.

15. On information and belief, each Defendant derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business in Delaware.

16. The Court also has personal jurisdiction over each Defendant because each Defendant has frequently availed itself of the legal protections of the State of Delaware, by, among other things, filing suit in and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Alembic Pharms. Ltd. et al. v. Glaxosmithkline LLC et al.*, C.A. No. 18-1513-RGA (D. Del.), D.I. 1; *Bow River LLC v. Alembic Pharms. Ltd. et al.*, C.A. No. 25-1017-CFC (D. Del.), D.I. 13; *Orion Corp. et al. v. Alembic Pharms. Ltd. et al.*, C.A. No. 25-825-JLH (D. Del.), D.I. 12.

17. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over each Defendant.

18. Venue is appropriate in this District with regard to Vanda's claims against API under 28 U.S.C. §§ 1391 and 1400(b), at least because API is incorporated in Delaware and thus resides in this District.

19. In addition, venue is appropriate in this District with regard to Vanda's claims against APL under 28 U.S.C. § 1391(b)(3), at least because APL (1) is a foreign defendant that may be sued in any judicial district; (2) has previously consented to venue in this district, *e.g.*, *Alembic Pharms. Ltd. et al. v. Glaxosmithkline LLC et al.*, C.A. No. 18-1513-RGA (D. Del.), D.I. 1; *Bow River LLC v. Alembic Pharms. Ltd. et al.*, C.A. No. 25-1017-CFC (D. Del.), D.I. 13; *Orion Corp. et al. v. Alembic Pharms. Ltd. et al.*, C.A. No. 25-825-JLH (D. Del.), D.I. 12; and (3) on information and belief, is preparing to directly or indirectly market and sell Alembic's ANDA Product in this District.

BACKGROUND

A. Vanda and FANAPT®

20. Vanda holds approved New Drug Application (NDA) No. 022192 for FANAPT® (iloperidone) oral tablets, approved by the FDA on May 6, 2009, for the treatment of schizophrenia in adults.

21. On April 2, 2024, the FDA approved a supplemental indication for NDA No. 022192 such that FANAPT® is also approved for acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.

22. A copy of the FANAPT® Prescribing Information, Revised January 2025 is attached as **Exhibit A** (FANAPT® Label).

23. FANAPT® contains the active compound iloperidone and is available in 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths.

24. The ’610 patent is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) in connection with NDA No. 022192 as covering FANAPT®.

25. FANAPT® is covered by one or more claims of the ’610 patent.

B. Alembic’s ANDA and Notice Letter

26. On or around June 11, 2026, Vanda received a letter sent on behalf of Alembic informing Vanda that the FDA received Alembic’s ANDA along with a paragraph IV certification for two of the patents listed in the Orange Book in connection with NDA No. 022192 (the “Notice Letter”).

27. Alembic attached to the Notice Letter what it purports to be a statement of detailed factual and legal bases for its paragraph IV certification that two of the Orange Book-listed patents are invalid, unenforceable, and/or not infringed.

28. On information and belief, Alembic submitted Alembic’s ANDA to obtain FDA approval to market Alembic’s ANDA Product.

29. On information and belief, Alembic has represented to the FDA that Alembic’s ANDA Product is bioequivalent to FANAPT®.

30. On information and belief, Alembic’s ANDA Product will comprise iloperidone oral tablets, in 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths.

THE ASSERTED PATENT AND ALEMBIC’S INFRINGEMENT

31. On November 19, 2013, the ’610 patent, titled “Methods for the Administration of Iloperidone,” was duly and legally issued by the United States Patent & Trademark Office (USPTO). A copy of the ’610 patent is attached as **Exhibit B**.

32. Vanda is the assignee of, and owns all rights, title, and interest in, the '610 patent.

33. The '610 patent names Curt D. Wolfgang and Mihael H. Polymeropoulos as inventors.

34. The '610 patent expires on November 2, 2027.

35. The '610 patent generally relates to methods of treating patients suffering from certain disorders, including schizophrenia, by administering iloperidone in different dosage amounts depending on whether a patient is a CYP2D6 poor metabolizer.

36. For example, claim 1 of the '610 patent recites the steps of determining whether a patient is a CYP2D6 poor metabolizer by obtaining or having obtained a biological sample from the patient and performing or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype. If the patient has a CYP2D6 poor metabolizer genotype, then claim 1 of the '610 patent provides for a specific dose reduction—the maximum dosage amount of iloperidone is reduced by half in such patients (from 24 mg per day to 12 mg per day).

37. Under Section 505(j)(2)(A)(v) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(v), the proposed prescribing information of Alembic's ANDA Product (Alembic's Label) is required to substantively copy the FANAPT® Label.

38. The FANAPT® Label provides that FANAPT® is indicated for the treatment of schizophrenia and the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.

39. The FANAPT® Label actively encourages physicians to determine whether the patient is a poor CYP2D6 metabolizer by obtaining or having obtained a biological sample from the patient and performing or having performed a genotyping assay on the biological sample to

determine if the patient has a CYP2D6 poor metabolizer genotype.

40. Upon determining whether a patient has a CYP2D6 poor metabolizer genotype, the FANAPT® Label actively encourages physicians to administer either the target dosage amount if the patient is a normal CYP2D6 metabolizer or a halved dosage amount if the patient is a poor CYP2D6 metabolizer. If a patient is a CYP2D6 poor metabolizer, the maximum target dosage amount is reduced by half (from 24 mg per day to 12 mg per day).

41. On information and belief, Alembic's Label will be substantially similar to the FANAPT® Label.

42. On information and belief, Alembic's Label will indicate Alembic's ANDA Product for the treatment of schizophrenia and the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.

43. On information and belief, the relevant sections of Alembic's Label will be substantially similar to the corresponding sections of the FANAPT® Label that encourage physicians to perform the method covered by at least claim 1 of the '610 patent.

44. On information and belief, by marketing, selling, or offering for sale Alembic's ANDA Product with Alembic's Label, Alembic will indirectly infringe at least claim 1 of the '610 patent and/or an equivalent method.

CLAIMS FOR RELIEF
COUNT I
(Infringement of U.S. Patent No. 8,586,610)

45. Vanda realleges and incorporates by reference the allegations contained in the preceding paragraphs as though set forth fully herein.

46. On information and belief, Alembic has infringed the '610 patent, pursuant to 35 U.S.C. § 271(e)(2), including at least claim 1, by submitting Alembic's ANDA, by which Alembic seeks approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale,

or importation in the United States of Alembic's ANDA Product prior to the expiration of the '610 patent.

47. On information and belief, if Alembic markets its ANDA Product, Alembic will, through the manufacture, use, importation, offer for sale, and/or sale of Alembic's ANDA Product, contributorily infringe and/or induce infringement of at least one claim of the '610 patent, under 35 U.S.C. § 271, either literally or under the doctrine of equivalents.

48. On information and belief, Alembic's Label will instruct and encourage prescribers to practice the claimed methods of the '610 patent.

49. On information and belief, if Alembic's ANDA Product is sold, marketed, distributed, and/or imported in the United States, Alembic knows and intends that prescribers, physicians, healthcare professionals, and/or patients will prescribe, administer, and/or use Alembic's ANDA Product according to Alembic's instructions and/or Alembic's Label in an infringing manner, and will therefore induce infringement of one or more claims of the '610 patent with the requisite intent under 35 U.S.C. § 271(b).

50. On information and belief, if Alembic's ANDA Product is sold, marketed, distributed, and/or imported in the United States, Alembic will sell or offer to sell generic iloperidone oral tablets with accompanying instructions and/or Alembic's Label in an infringing manner because Alembic's ANDA Product is a material part of the claimed invention, and Alembic knows that physicians will prescribe, healthcare providers will administer, and/or patients will use Alembic's ANDA Product in accordance with the accompanying instructions and/or Alembic's Label, and such use will directly infringe one or more claims of the '610 patent. Moreover, iloperidone oral tablets are not a staple article or commodity of commerce suitable for substantial non-

infringing use. On information and belief, Alembic will thus contribute to the infringement of one or more claims of the ’610 patent under 35 U.S.C. § 271(c).

51. If Alembic’s marketing and sale of Alembic’s ANDA Product prior to the expiration of the ’610 patent is not enjoined, Vanda will suffer substantial and irreparable harm for which there is no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Vanda respectfully requests that the Court enter judgment in its favor against Alembic on the patent infringement claims set forth above and respectfully requests that the Court:

a. enter judgment that, under 35 U.S.C. § 271(e)(2), Alembic has infringed at least one claim of the ’610 patent by submitting or causing to be submitted Alembic’s ANDA to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Alembic’s ANDA Product before the expiration of the ’610 patent;

b. enter judgment that, under 35 U.S.C. § 271(b) Alembic has induced or will induce the infringement of at least one claim of the ’610 patent by promoting Alembic’s ANDA Product for others’ use or by offering to sell or selling Alembic’s ANDA Product in the United States before the expiration of the ’610 patent;

c. enter judgment that, under 35 U.S.C. § 271(c) Alembic has contributed to or will contribute to the infringement of at least one claim of the ’610 patent by promoting Alembic’s ANDA Product for others’ use or by offering to sell or selling Alembic’s ANDA Product in the United States before the expiration of the ’610 patent;

d. order that the effective date of any approval by the FDA of Alembic's ANDA Product be a date that is not earlier than the expiration of the '610 patent, or such later date as the Court may determine consistent with 35 U.S.C. § 271(e)(4)(A);

e. enjoin Alembic and all persons acting in concert with Alembic from maintaining approval of Alembic's ANDA, or contributing to or inducing anyone to do the same, until expiration of the '610 patent;

f. enjoin Alembic and all persons acting in concert with Alembic from the commercial manufacture, use, import, offer for sale, and/or sale of Alembic's ANDA Product, or contributing to or inducing anyone to do the same, until expiration of the '610 patent or such later date as the Court may determine;

g. enjoin Alembic and all persons acting in concert with Alembic from infringing the '610 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer for sale, sale, distribution, or importation of any current or future versions of the product described in Alembic's ANDA while the litigation is pending;

h. award monetary damages under 35 U.S.C. §§ 271(e)(4)(C) and 284, to the extent applicable;

i. assess pre-judgment and post-judgment interest and costs against Alembic, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284; and

j. award Vanda such further and additional relief as this Court deems just and proper.

Dated: July 24, 2026

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