IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| VANDA PHARMACEUTICALS INC., | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | C.A. No. 15-_____ |
| | ) | |
| INVENTIA HEALTHCARE PVT. LTD., | ) | |
| | ) | |
| Defendant. | ) | |

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Vanda Pharmaceuticals Inc. ("Vanda") for its Complaint against Defendant Inventia Healthcare Pvt. Ltd. ("Inventia") alleges as follows:

## I. THE PARTIES

1. Vanda is a Delaware corporation with its principal place of business at 2200 Pennsylvania Ave NW, Washington, DC 20037. Vanda is a pharmaceutical company that focuses on the development and commercialization of new medicines to address unmet medical needs, including FANAPT® (iloperidone oral tablets), for the treatment of schizophrenia.

2. On information and belief, Inventia is a corporation organized and existing under the laws of India, with a principal place of business at Unit 703 and 704, 7th Floor, Hubtown Solaris, N S Phadke Marg, Andheri (East), Mumbai – 400 069, Maharashtra, India. On information and belief, Inventia is in the business of manufacturing generic pharmaceutical drugs that it distributes and sells in the State of Delaware and throughout the United States.

## II. NATURE OF THE ACTION

3. This is an action arising under the patent laws of the United States (Title 35, United States Code, § 100, *et seq*.) based upon Inventia's infringement of one or more claims

of Vanda's U.S. Patent No. 8,586,610 ("the '610 patent"), which relates to the field of schizophrenia treatment.

4. On information and belief, Inventia filed an Abbreviated New Drug Application No. 207231 (the "Inventia ANDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), to obtain approval to commercially manufacture and sell generic iloperidone tablets in their 1 mg, 2 mg, 4 mg, 6 mg, 8mg, 10 mg, and 12 mg strengths for the treatment of schizophrenia.

5. Inventia has infringed one or more claims of the '610 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing the Inventia ANDA with a Paragraph IV certification and seeking FDA approval of the Inventia ANDA prior to the expiration of the '610 patent, or any extensions thereof.

6. Inventia has infringed one or more claims of the '610 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of the Inventia ANDA seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States generic iloperidone for the treatment of schizophrenia prior to the expiration of the '610 patent, or any extensions thereof. Inventia will infringe one or more claims of the '610 patent under 35 U.S.C. § 271(a), (b), or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic iloperidone for the treatment of schizophrenia prior to the expiration of the '610 patent, or any extensions thereof.

## III. JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over Vanda's patent infringement claims under 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Inventia by virtue of the fact that, *inter alia*, Inventia has committed, induced, contributed to, aided, abetted, or participated in

in the commission of the tortious act of patent infringement that has led to foreseeable harm and injury to Vanda, a Delaware corporation. This Court has personal jurisdiction over Inventia for the additional reasons set forth below.

9. This Court has personal jurisdiction over Inventia, by virtue of, *inter alia*, its activities (*e.g.*, filing the Inventia ANDA with a Paragraph IV certification and sending notice of that Paragraph IV certification), which were purposefully directed to the State of Delaware, where Vanda is organized. As a result, the consequences of Inventia's actions were (and will be) suffered in Delaware. Inventia knew or should have known that Vanda is a Delaware corporation and thus Inventia knew or should have known that the consequences of its actions were (and will be) suffered in Delaware.

10. This Court also has personal jurisdiction over Inventia because at the time Inventia sent notice of a Paragraph IV certification, it was reasonably foreseeable that Inventia would be sued within 45 days in this District, where Vanda is organized and where related ANDA litigation over generic iloperidone, including litigation based on infringement of the '610 patent, had already been filed (C.A. Nos. 13-1973 (GMS); 14-757 (GMS) (consolidated)). Inventia knew or should have known that Vanda is a Delaware corporation and Inventia knew or should have known that there is related ANDA litigation over generic iloperidone, including litigation based on infringement of the '610 patent, pending in Delaware.

11. This Court also has personal jurisdiction over Inventia because this suit arises out of and relates to Inventia's activities that are, and will be, directed to Delaware. On information and belief, Inventia develops, manufactures, seeks approval for, and sells FDA-approved generic pharmaceutical drugs, which are being marketed, distributed, and sold in Delaware and throughout the United States. Thus, on information and belief, Inventia does

substantial business in Delaware, derives substantial revenue from Delaware, and engages in other persistent courses of conduct in Delaware. These continuous and systematic contacts, including, but not limited, to those described above and below, are more than sufficient for this Court to exercise personal jurisdiction over Inventia.

12. On information and belief, Inventia, following any FDA approval of the Inventia ANDA, will sell the generic product that is the subject of the infringement claims in this action in the State of Delaware and throughout the United States.

13. In the alternative, should Inventia contest jurisdiction in this forum, this Court has personal jurisdiction over Inventia under Fed. R. Civ. P. 4(k)(2) because, on information and belief, Inventia is not subject to jurisdiction in any state's courts of general jurisdiction, and because exercising jurisdiction is nevertheless consistent with the United States Constitution given that Inventia has sufficient contacts with the United States that relate to the claims in this case.

14. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

## IV. THE PATENT-IN-SUIT (U.S. PATENT NO. 8,586,610)

15. The allegations of ¶¶ 1-14 are incorporated herein by reference.

16. Vanda is the owner of all rights, title and interest in the '610 patent, entitled "Methods for the Administration of Iloperidone." The United States Patent and Trademark Office ("USPTO") duly and legally issued the '610 patent on November 19, 2013, to Curt D. Wolfgang and Mihael H. Polymeropoulos, which was assigned to Vanda. A true and correct copy of the '610 patent is attached to this Complaint as Exhibit A.

17. The ’610 patent covers methods of using FANAPT® (iloperidone oral tablets) for the treatment of schizophrenia in certain patients based on whether the patients are poor metabolizers of FANAPT®. The patients that are poor metabolizers of FANAPT® have certain mutations of a gene known as CYP2D6. The ’610 patent covers the identification of patients that are poor metabolizers by genotyping and making a specific dose reduction—the dosage must be halved—in those patients to avoid prolonged QTc as measured by an electrocardiogram (“EKG”). Various studies have shown that patients with QTc prolongation may have an increased risk of cardiovascular side effects, including serious arrhythmias, such as ventricular tachycardia, ventricular fibrillation, and irregular heartbeats (torsades de pointes or TDP), which could lead to cardiac death.

18. On May 6, 2009, FDA approved Vanda’s new drug application 22-192 for FANAPT® (iloperidone oral tablets) in their 1 mg, 2 mg, 4 mg, 6 mg, 8mg, 10 mg, and 12 mg strengths under § 505(b) of the FFDCA, 21 U.S.C. § 355(b), for the treatment of schizophrenia (“FANAPT® NDA”).

19. The prescribing information for FANAPT® (“FANAPT® Label”), instructs physicians to (1) determine whether the patient is a poor CYP2D6 metabolizer using available laboratory tests,[1] and (2) administer either the target dose if the patient is a normal CYP2D6 metabolizer or a halved dosage if the patient is a poor CYP2D6 metabolizer.

20. Thus, the use of FANAPT® (iloperidone oral tablets) and any generic iloperidone for the treatment of schizophrenia is covered by the ’610 patent, and Vanda has the right to enforce the ’610 patent.

[1] There are numerous commercially available genotyping assays (offered by Laboratory Corporation of America, Roche Molecular Systems, Illumina, Quest Diagnostics, AutoGenomics, etc.).

21. FDA listed the ’610 patent in the Orange Book for FANAPT® in its 1 mg, 2 mg, 4 mg, 6 mg, 8mg, 10 mg, and 12 mg strengths on January 15, 2015.

22. Inventia has refused to disclose to Vanda the date on which Inventia submitted the Inventia ANDA to FDA. Based on Inventia’s refusal to disclose the filing date, and the totality of the circumstances described herein, it is reasonable to infer that Inventia submitted the Inventia ANDA to FDA after the ’610 patent was listed in the Orange Book.

**COUNT I**
**(INFRINGEMENT OF THE ’610 PATENT)**

23. The allegations of ¶¶ 1-22 are incorporated herein by reference.

24. On information and belief, Inventia filed the Inventia ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell a generic version of FANAPT® (iloperidone oral tablets) for the treatment of schizophrenia before the expiration of the ’610 patent, and any extensions thereof.

25. On or about April 3, 2015, Vanda received a letter (“Inventia Notice Letter”) dated April 2, 2015, stating that Inventia had filed the Inventia ANDA seeking approval to manufacture, use, offer to sell, and sell a generic version of FANAPT® (iloperidone oral tablets) in their 1 mg, 2 mg, 4 mg, 6 mg, 8mg, 10 mg, and 12 mg strengths for the treatment of schizophrenia before the expiration of the ’610 patent. The letter notifies Vanda that the Inventia ANDA was submitted with a Paragraph IV certification that the ’610 patent purportedly is noninfringed and invalid.

26. On information and belief, the Inventia ANDA essentially copies the FANAPT® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs physicians to (1) determine whether the patient is a poor CYP2D6 metabolizer using available

laboratory tests, and (2) administer either the target dose if the patient is a normal CYP2D6 metabolizer or a halved dosage if the patient is a poor CYP2D6 metabolizer.

27. Inventia has infringed the ’610 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Inventia ANDA to FDA for generic iloperidone tablets in their 1 mg, 2 mg, 4 mg, 6 mg, 8mg, 10 mg, and 12 mg strengths, for the treatment of schizophrenia, which are covered by one or more claims of the ’610 patent.

28. Inventia’s participation in, contribution to, inducement of, aiding or abetting the submission of the Inventia ANDA to FDA constitutes direct, contributory, or induced infringement of one or more claims of the ’610 patent under 35 U.S.C. § 271(e)(2)(A).

29. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Inventia ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the ’610 patent.

30. Vanda seeks entry of an order requiring that Inventia amend its Paragraph IV certification in the Inventia ANDA to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) (“Paragraph III certification”) as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

31. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Inventia ANDA be a date that is not earlier than the expiration of the ’610 patent, or any later expiration of exclusivity for the ’610 patent to which Vanda becomes entitled.

32. Vanda will be irreparably harmed if Inventia is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the ’610

patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

33. On information and belief, Inventia was aware of the existence of the '610 patent and the listing of the '610 patent in the Orange Book as demonstrated by Inventia's reference to that patent in the Inventia Notice Letter and its refusal to disclose when the Inventia ANDA was filed and accepted by FDA. On information and belief, Inventia's statement of the factual and legal basis for its opinion regarding the validity of the '610 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

34. To the extent Inventia commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

**PRAYER FOR RELIEF**

WHEREFORE, Vanda respectfully requests that this Court enter judgment in its favor against Inventia and grant the following relief:

A. an adjudication that Inventia has infringed directly, contributed to, or induced the infringement of one or more claims of the '610 patent under 35 U.S.C. § 271(e)(2)(A), by submitting to FDA the Inventia ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic iloperidone for the treatment of schizophrenia before the expiration of the '610 patent;

B. an order requiring that Inventia amend its Paragraph IV certification to a Paragraph III certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

C. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Inventia ANDA for generic iloperidone be a date that is not

earlier than the date of the expiration of the ’610 patent or any later period of exclusivity to which Vanda is or may become entitled;

D. a permanent injunction enjoining Inventia, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’610 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Inventia ANDA;

E. an order enjoining Inventia, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’610 patent, contributing to, or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Inventia ANDA while the litigation is pending;

F. a judgment declaring that the manufacture, use, offer to sell, sale, distribution, or importation of the products described in the Inventia ANDA would constitute infringement of one or more claims of the ’610 patent, or inducement of or contribution to such conduct, by Inventia pursuant to 35 U.S.C. § 271 (a), (b), or (c);

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

H. an award to Vanda of its attorneys’ fees incurred in connection with this lawsuit pursuant to 35 U.S.C. § 285; and

I. such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Karen Jacobs*

_____

Jack B. Blumenfeld (#1014)
Karen Jacobs (#2881)
Ethan H. Townsend (#5813)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
kjacobs@mnat.com
etownsend@mnat.com

*Attorneys for Plaintiff*
*Vanda Pharmaceuticals Inc.*

OF COUNSEL:

Nicholas Groombridge
Eric Alan Stone
Kira A. Davis
Josephine Young
PAUL, WEISS, RIFKIND, WHARTON
& GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

May 5, 2015

9118486