

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC., )  
)  
Plaintiff, )  
)  
v. ) C.A. No.  
)  
TARO PHARMACEUTICALS USA, INC. and )  
TARO PHARMACEUTICAL INDUSTRIES, )  
LTD., )  
)  
Defendants. )

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Vanda Pharmaceuticals Inc. (“Vanda”) for its Complaint against Defendants Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (collectively “Taro”) alleges as follows:

**I. THE PARTIES**

1. Plaintiff 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, Defendant Taro Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 3 Skyline Drive, Hawthorne, New York 10532.

3. On information and belief, Defendant Taro Pharmaceutical Industries, Ltd. is a corporation organized and existing under the laws of Israel with its principal place of business at 14 Hakitor Street, Haifa Bay 2624761, Israel.

4. On information and belief Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. collaborate to manufacture, import, market, distribute, and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved abbreviated new drug applications) in the State of Delaware and the United States.

5. On information and belief, Taro 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**

6. This is an action arising under the patent laws of the United States (Title 35, United States Code, § 100, *et seq.*) based upon Taro's infringement of one or more claims of Vanda's U.S. Patent No. 8,586,610 ("the '610 patent") and Taro's infringement of claim 1 of Vanda's U.S. Patent No. 9,138,432 ("the '432 patent"), which relate to the field of schizophrenia treatment.

7. On information and belief, Taro Pharmaceuticals USA, Inc., by and with Taro Pharmaceutical Industries, Ltd., filed an Abbreviated New Drug Application No. 207098 (the "Taro 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, 8 mg, 10 mg, and 12 mg strengths for the treatment of schizophrenia.

8. Taro has infringed one or more claims of the '610 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the Taro 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. Taro 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 patents, or any extensions thereof.

9. Taro has infringed claim 1 of the '432 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the Taro ANDA, including its filing of any amendments or supplements thereto, 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 '432 patent, or any extensions thereof. Taro will infringe claim 1 of the '432 patent under 35 U.S.C. § 271(a), (b), or (c) should it engage in, induce, or contribute to the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic iloperidone for the treatment of schizophrenia according to the methods of the '432 patent prior to the expiration of that patent, or any extensions thereof.

### **III. JURISDICTION AND VENUE**

10. This Court has subject matter jurisdiction over Vanda's patent infringement claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. This Court has personal jurisdiction over Taro by virtue of the fact that, *inter alia*, both Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. have 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 Taro for the additional reasons set forth below.

12. This Court has personal jurisdiction over Taro, by virtue of, *inter alia*, its activities (*e.g.*, filing the Taro ANDA seeking approval to market generic iloperidone prior to the

expiration of the '610 and '432 patents along with a Paragraph IV certification regarding its intent to market generic iloperidone 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 Taro's actions were (and will be) suffered in Delaware. Taro knew or should have known that Vanda is a Delaware corporation and thus Taro knew or should have known that the consequences of its actions were (and will be) suffered in Delaware.

13. This Court also has personal jurisdiction over Taro because at the time Taro sent notice of a Paragraph IV certification, it was reasonably foreseeable that Taro 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); C.A. No. 15-362 (GMS)). Taro knew or should have known that Vanda is a Delaware corporation and Taro 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.

14. This Court also has personal jurisdiction over Taro because this suit arises out of and relates to Taro's activities that are, and will be, directed to Delaware. On information and belief, Taro 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, Taro 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 Taro.

15. This Court also has personal jurisdiction over Taro because, on information and belief, Taro has previously availed itself of this forum for purposes of litigating its patent disputes. For example, Taro brought a patent infringement lawsuit in this district to protect two patents on July 28, 2014 (C.A. No. 14-989 (RGA)). Taro Pharmaceuticals USA, Inc. was listed as a Plaintiff, and Taro Pharmaceutical Industries, Ltd. states that it had filed the lawsuit in its most recent Securities and Exchange Commission Form 20-F, for the fiscal year ended March 31, 2015. Additionally, Taro Pharmaceuticals USA, Inc. brought another patent infringement lawsuit in this district on September 22, 2015 (C.A. No. 15-859 (RGA)).

16. On information and belief, Taro, following any FDA approval of the Taro 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.

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

#### **IV. THE PATENTS-IN-SUIT – U.S. PATENT NOS. 8,586,610 AND 9,138,432**

18. The allegations of ¶¶ 1-17 are incorporated herein by reference.

19. 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, 8 mg, 10 mg, and 12 mg strengths under § 505(b) of the FDCA, 21 U.S.C. § 355(b), for the treatment of schizophrenia ("FANAPT® NDA").

20. 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.

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