IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 14-___
	)	
ROXANE LABORATORIES, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Vanda Pharmaceuticals Inc. ("Vanda") for its Complaint against Defendant Roxane Laboratories, Inc. ("Roxane") 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, Roxane is a Nevada corporation, with a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228. On information and belief, Roxane 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 Roxane's infringement of one or more of 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, Roxane filed an Abbreviated New Drug Application (the "Roxane 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. Roxane 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 Roxane ANDA seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States generic FANAPT® (iloperidone oral tablets) for the treatment of schizophrenia prior to the expiration of the '610 patent, or any extensions thereof. Roxane 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 FANAPT® (iloperidone oral tablets) for the treatment of schizophrenia prior to the expiration of the '610 patent, or any extensions thereof.

III. JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over Roxane by virtue of the fact that, *inter alia*, Roxane 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 Roxane for the additional reasons set forth below.

8. This Court has personal jurisdiction over Roxane, by virtue of, *inter alia*, its having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State.

9. On information and belief, Roxane develops, manufactures, seeks approval for, and sells FDA-approved generic pharmaceutical drugs, which are being marketed, distributed, and sold in Delaware and in the United States. Thus, on information and belief, Roxane 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 general personal jurisdiction over Roxane.

10. On information and belief, Roxane, following any FDA approval of the Roxane 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.

11. On information and belief, Roxane has previously availed itself of this forum for purposes of litigating its patent disputes. For example, Roxane has submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Specifically, Roxane admitted jurisdiction (for purposes of the litigation) and filed counterclaims in at least the following actions in this Court: *Novartis Pharm. Corp. v. Roxane Labs., Inc.*, 13-cv-1973 (D. Del.); *Eisai Co. v. Roxane Labs., Inc.*, 13-cv-1284 (D. Del.); *Glaxo SmithKline LLC v. Roxane Labs., Inc.*, 11-cv-542 (D. Del.); *Abbott Labs. v. Roxane Labs., Inc.*, 10-cv-998 (D. Del.).

12. 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

13. The allegations of ¶¶ 1-12 are incorporated herein by reference.

14. 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.

15. The ’610 patent covers methods of using iloperidone 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.

16. 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”). Novartis Pharmaceutical Corp. (“Novartis”) now owns the FANAPT® NDA.

17. 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.

18. 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.

COUNT I
(INFRINGEMENT OF THE '610 PATENT)

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

20. On information and belief, Roxane filed the Roxane 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.

21. On information and belief, Novartis received a letter ("Roxane Notice Letter") dated October 17, 2013, stating that Roxane had filed the Roxane 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 RE198, and therefore necessarily before the expiration of the '610 patent.

22. On information and belief, the Roxane ANDA essentially copies the FANAPT® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs

[1] There are numerous commercially available genotyping assays (offered by Roche, Illumina, etc.).

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.

23. Roxane has infringed the ’610 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Roxane ANDA to FDA for generic 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, which are covered by one or more claims of the ’610 patent.

24. Roxane’s participation in, contribution to, inducement of, aiding or abetting the submission of the Roxane 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).

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

26. 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 Roxane 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.

27. Vanda will be irreparably harmed if Roxane 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.

28. To the extent Roxane 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 Roxane and grant the following relief:

A. an adjudication that Roxane 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 Roxane ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic FANAPT® (iloperidone oral tablets) for the treatment of schizophrenia before the expiration of the '610 patent;

B. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Roxane ANDA for generic FANAPT® (iloperidone oral tablets) 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;

C. a permanent injunction enjoining Roxane, 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 Roxane ANDA;

D. an order enjoining Roxane, 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 Roxane ANDA while the litigation is pending;

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

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

G. 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)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
kjacobs@mnat.com
Attorneys for Plaintiff
Vanda Pharmaceuticals Inc.

OF COUNSEL:

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

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