IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS PHARMA AG and AVENTISUB II INC.,	:	
Plaintiffs,	:	C.A. No. _____
v.	:	
ROXANE LABORATORIES, INC.,	:	
Defendant.	:	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis Pharma AG, and Aventisub II Inc. (hereinafter "Plaintiffs"), for their Complaint against defendant Roxane Laboratories, Inc. allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Plaintiff Novartis Pharma AG ("Pharma AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

4. Plaintiff Aventisub II Inc. ("Aventisub II") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 3711 Kennett Pike, Suite 200, Greenville, Delaware 19807.

5. On information and belief, defendant Roxane Laboratories, Inc. ("Roxane") is a corporation organized and existing under the laws of the State of Nevada, having a place of business at 1809 Wilson Road, Columbus, Ohio 43228. Upon information and belief, defendant Roxane manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

7. This Court has personal jurisdiction over Roxane by virtue of, *inter alia*, the fact that it has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to plaintiffs, including NPC and Aventisub II, Delaware corporations. This Court has personal jurisdiction over Roxane for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

8. This Court has personal jurisdiction over Roxane because it has previously been sued in this district and has not challenged personal jurisdiction, and has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *Eisai Co. Ltd., et al. v. Roxane Laboratories, Inc.*, 13-cv-01284 (D. Del.); *Glaxo SmithKline LLC*

v. Roxane Laboratories, Inc., et al., 11-cv-00542 (D. Del.); and *Abbott Laboratories and Wisconsin Alumni Research Foundation v. Roxane Laboratories, Inc.*, 10-cv-00998 (D. Del.).

9. Upon information and belief, Roxane has received at least 94 approvals from the FDA for drug products since 2006 and sells drug products throughout the United States, including this judicial district.

10. This Court has personal jurisdiction over Roxane by virtue of, *inter alia*, the fact that it has availed itself of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware.

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

CLAIM FOR RELIEF – PATENT INFRINGEMENT

12. Plaintiff NPC holds an approved new drug application ("NDA") No. 22-192 for FANAPT® (iloperidone oral tablets) (1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg dosage strengths), which contains the active ingredient iloperidone. FANAPT® tablets were approved by the United States Food and Drug Administration ("FDA") on May 6, 2009. FANAPT® is indicated for the acute treatment of adults with schizophrenia. FANAPT® tablets (1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg dosage strengths) are sold in the United States by Plaintiff NPC.

13. Iloperidone is known chemically as 4'-[3-[4-(6-Fluoro-1,2-benzisoxazol-3-yl)piperidino]propoxy]-3'-methoxyacetophenone or 1-[4-[3-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]-propoxy]-3-methoxyphenyl]ethanone.

14. Plaintiff Aventisub II is the owner of reissued United States Letters Patent No. 39,198E ("the RE198 patent"), duly and legally issued on July 18, 2006. The RE198 patent

is a reissue of United States Letters Patent No. 5,364,866 ("the '866 patent") duly and legally issued on November 15, 1994. At all times from the issuance of the '866 patent to the present, Aventisub II or one of its predecessors in interest has been the owner of the RE198 and '866 patents.

15. Plaintiff Pharma AG holds an exclusive license to the RE198 patent.

16. The RE198 patent claims compounds and pharmaceutical compositions comprising, *inter alia*, iloperidone, and methods of treating psychoses by, *inter alia*, administering iloperidone. A true copy of the RE198 patent is attached hereto as Exhibit A.

17. On information and belief, Roxane submitted to the FDA an abbreviated new drug application ("ANDA") under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, and sale of iloperidone tablets, 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg dosage strengths ("Roxane's ANDA Products") before the expiration of the RE198 patent.

18. On information and belief, Roxane made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the RE198 patent claims are invalid and/or that certain claims will not be infringed. Roxane did not, however, allege that the RE198 patent claims covering iloperidone will not be infringed.

19. Plaintiffs received written notification of Roxane's ANDA and its accompanying § 505(j)(2)(4)(vii)(IV) certification by a letter dated October 17, 2013 ("Notice Letter").

20. This action was commenced within 45 days of receipt of the Roxane Notice Letter.

21. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Roxane's ANDA Products before the expiration of the RE198 patent, Roxane has committed an act of infringement under 35 U.S.C. § 271(e)(2).

22. On information and belief, when Roxane filed its ANDA, it was aware of the RE198 patent and that the filing of its ANDA with the request for its approval prior to the expiration of the RE198 patent was an act of infringement of that patent.

23. On information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Roxane's ANDA Products will infringe one or more claims of the RE198 patent.

24. On information and belief, Roxane's ANDA Products, if approved, will be administered to human patients for the treatment of psychoses, which administration constitutes direct infringement of the RE198 patent. On information and belief, this will occur at Roxane's active behest, and with Roxane's intent, knowledge and encouragement. On information and belief, Roxane will actively induce, encourage and abet this administration with knowledge that it is in contravention of the rights under the RE198 patent.

25. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned ANDA relating to Roxane's ANDA Products be a date that is not earlier than November 15, 2016, the expiration date of the RE198 patent, and an award of damages for any commercial sale or use of Roxane's ANDA Products and any act committed by Roxane with respect to the subject matter claimed in the RE198 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

26. On information and belief, Roxane has taken and continues to take active steps towards the commercial manufacture, use, offer for sale, sale and/or importation of Roxane's ANDA Products, including seeking approval of those products under Roxane's ANDA.

27. There is a substantial and immediate controversy between Plaintiffs and Roxane concerning the RE198 patent. Plaintiffs are entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Roxane will infringe and/or induce infringement of one or more claims of the RE198 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Roxane has infringed and induced infringement of one or more claims of the RE198 patent by filing the aforesaid ANDA relating to Roxane's iloperidone tablets, 1 mg, 2 mg, 4 mg, 6 mg, 8 mg,10 mg and 12 mg dosage strengths;

B. A permanent injunction restraining and enjoining Roxane and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Roxane's iloperidone tablets, 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg dosage strengths, as claimed in the RE198 patent;

C. An order that the effective date of any approval of the aforementioned ANDA relating to Roxane's iloperidone tablets, 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg dosage strengths, be a date that is not earlier than the expiration of the right of exclusivity under the RE198 patent;

D. Declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of Roxane's iloperidone tablets, 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg dosage strengths, will infringe one or more claims of the RE198 patent and that Roxane will induce infringement of one or more claims of the RE198 patent;

E. Damages from Roxane for the infringement and inducement of infringement of the RE198 patent;

F. The costs and reasonable attorney fees of Plaintiffs in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: November 25, 2013

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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