IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ANCHEN PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
LABOPHARM INC., LABOPHARM EUROPE, LTD., and LABOPHARM (BARBADOS), LTD.	)	Case No.
	)	
Defendants,	)	
	)	

Plaintiff Anchen Pharmaceuticals, Inc, ("Anchen"), by and through its attorneys, for its complaint against defendants Labopharm Inc., Labopharm Europe, Ltd., and Labopharm (Barbados), Ltd., (collectively "Defendants" or "Labopharm") alleges the following:

NATURE OF THE ACTION

1. Anchen seeks a declaratory judgment of invalidity and non-infringement of United States Patent No. 6,607,748, (the "'748 patent") pursuant to the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq., the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(5)(C)(i) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 et seq.

PARTIES

2. Anchen is a corporation organized and existing under the laws of the state of California, with its principal place of business located at 9601 Jeronimo Road, Irvine, California 92618-2025.

3. Upon information and belief, Labopharm Inc., is a corporation incorporated and existing under the laws of Canada, having its principal place of business at 480 Armand-Frappier Blvd., Laval, Quebec, H7V 4B4, Canada.

4. Upon information and belief, Labopharm Europe, Ltd., is a wholly owned subsidiary of Labopharm Inc., incorporated and existing under the laws of Ireland, having its principal place of business at 5, The Seapoint Building, 44 Clontarf Road, Dublin 3, Ireland.

5. Upon information and belief, Labopharm (Barbados), Ltd., is wholly owned of subsidiary of Labopharm Inc., incorporated and existing under the laws of Barbados, having its principal place of business at Alphonzo House, Cnr 2nd Avenue and George Street, Belleville, St. Michael, Barbados.

6. On or about August 19, 2003, the United States Patent and Trademark Office issued the '748 patent entitled "Cross Linked High Amylose Starch For Use In Controlled Release Pharmaceutical Formulations And Process For Its Manufacture." The listed inventors on the '748 patent are Vincent Lenaerts, Roland Herwig Friedrich Beck, Elsie Van Bogaert, Francois Chouinard, Reiner Höpcke, and Cyril Désévaux. (*See* http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=6607748.PN.&OS=PN/6607748&RS=PN/6607748).

7. Upon information and belief Labopharm Inc., Labopharm Europe, Ltd., and Labopharm (Barbados), Ltd., each have an ownership interest in the '748 patent.

PERSONAL JURISDICTION AND VENUE

8. Upon information and belief, none of the Defendants reside within the United States.

9. Upon information and belief, none of the Defendants have filed in the United States Patent and Trademark Office a written designation stating the name and address of a person residing within the United States on whom may be served process or notice of proceedings affecting the '748 patent or rights thereunder.

10. Because all Defendants reside outside of the United States, and because no person has been designated to receive process or notice of proceedings affecting the '748 patent, the United States District Court for the District of Columbia has personal jurisdiction over the Defendants pursuant to 35 U.S.C. § 293.

11. Venue is appropriate in the District of Columbia pursuant to 35 U.S.C. § 293 and 28 U.S.C. §§ 1391(a), 1391(c) and 1391(d).

SUBJECT MATTER JURISDICTION

12. This Complaint arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (hereinafter "Hatch-Waxman Amendments"), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003) (hereinafter "MMA"); and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

13. This Court has subject matter jurisdiction over this Complaint pursuant to 28 U.S.C. §§ 1331, and 1338(a).

FACTUAL ALLEGATIONS

14. Upon information and belief, Labopharm holds New Drug Application 21-475 ("NDA 21-745") for 100 mg, 200 mg, and 300 mg tramadol hydrochloride extended release tablets, marketed under the brand name RYZOLT™.

15. In connection with NDA 21-745, Labopharm caused the Food and Drug Administration ("FDA") to list the '748 patent in the "Approved Drug Products with Therapeutic Equivalence Evaluations", or the "Orange Book," as a patent that would be infringed by a generic equivalent to is NDA product. 21 U.S.C. § 355(j)(7)(A)(iii).

16. Anchen submitted Abbreviated New Drug Application ("ANDA") No. 20-491 to FDA, which seeks approval to engage in the commercial manufacture, use or sale of tramadol hydrochloride extended release tablets in the 100 mg, 200 mg, and 300 mg dosage forms, before the expiration of the patents listed in the Orange Book. As part of its ANDA, Anchen made a certification pursuant to the 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") that the '748 patent was not infringed by Anchen's ANDA product.

17. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), on or about December 14, 2009, Anchen provided Labopharm notice of the Paragraph IV certification that it filed with ANDA No. 20-491.

18. After receiving Anchen's Paragraph IV notification and offer of confidential access to information regarding Anchen's ANDA, Labopharm declined to file suit against Anchen regarding the '748 patent.

19. If a patent holder who received a Paragraph IV certification decides not to bring suit, the Hatch-Waxman Act provides for civil actions brought by the ANDA filer to obtain patent certainty through the Declaratory Judgment Act. 21 U.S.C. § 355(j)(5)(C); 35 U.S.C. § 271(e)(5).

COUNT ONE

Declaratory Judgment Regarding The '748 Patent

20. Anchen reasserts and reallages paragraphs 1-18 as if fully set forth herein.

21. The submission of ANDA No. 20-491 does not infringe any claim of the '748 patent.

22. The commercial manufacture, use, offer for sale, sale, or importation of Anchen's tramadol hydrochloride extended release product, which are the subject of ANDA 20-491 would not infringe any claim of the '748 patent.

23. An actual and justiciable controversy exists between the parties with respect to the '748 patent, and Anchen is entitled to declaratory judgment that the '748 patent is not infringed.

24. Anchen is entitled to a judicial determination that the Anchen extended-release tramadol tablets, which are the subject of ANDA No. 20-491, have not infringed, do not infringe, and would not, if marketed, infringe any valid claim of the '748 patent.

PRAYER FOR RELIEF

WHEREFORE. Anchen respectfully requests that this Court enter judgment in its favor and against Defendants and grant the following relief:

A. Declare that the manufacture, use, offer for sale, sale, or importation of Anchen's tramadol hydrochloride extended release products, which are the subject of ANDA No. 20-491, would not infringe the claims of the '748 patent;

B. Award Anchen its costs and attorney fees; and

C. Award Anchen such other and further relief as the Court deems just and proper.

Dated: September 27, 2010

ANCHEN PHARMACEUTICALS, INC.

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