IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

AVENTIS PHARMACEUTICALS INC., AVENTIS INC., and CARDERM CAPITAL L.P.,	)	
Plaintiffs,	)	Civ. Action No. _____
v.	)	COMPLAINT
SUN PHARMA GLOBAL INC., SUN PHARMACEUTICAL INDUSTRIES INC., and SUN PHARMACEUTICAL INDUSTRIES LTD.	)	**JURY TRIAL REQUESTED**
Defendants.	)	

COMPLAINT FOR
PATENT INFRINGEMENT

Plaintiffs Aventis Pharmaceuticals Inc. ("Aventis"), Aventis Inc. ("Aventis Inc."), and Carderm Capital L.P. ("Carderm"), by their attorneys, for their Complaint against Sun Pharmaceutical Industries Inc., Sun Pharmaceutical Industries Ltd., and Sun Pharma Global Inc. (collectively, Sun) allege as follows:

Nature of the Action

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 100 *et seq*. This action relates to the Abbreviated New Drug Application No. 90-818 ("Sun's ANDA") filed or caused to be filed by Sun Pharmaceutical Industries Inc., Sun Pharmaceutical Industries Ltd., and Sun Pharma Global Inc., with the United States Food and Drug Administration ("FDA") for approval to market a generic version of Aventis' ALLEGRA®-D 12 Hour drug product, extended-release tablets containing 60 mg fexofenadine hydrochloride and 120 mg pseudoephedrine hydrochloride ("Sun's ANDA Tablets").

The Parties

2. Aventis is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807. Aventis sells drug products containing fexofenadine hydrochloride in the United States under the trademarks ALLEGRA® 30 mg, 60 mg and 180 mg tablets, ALLEGRA® Oral Suspension 30 mg/5 mL, ALLEGRA®-D 12 Hour fexofenadine hydrochloride/pseudoephedrine hydrochloride 60 mg/120 mg extended release tablets, and ALLEGRA®-D 24 Hour fexofenadine hydrochloride/pseudoephedrine hydrochloride 180 mg/240 mg extended release tablets.

3. Aventis Inc. is a corporation organized and existing under the laws of Pennsylvania, having its principal place of business at 3711 Kennett Pike, Suite 200, Greenville, Delaware 19807.

4. Carderm is a limited partnership organized and existing under the laws of Delaware, having its principal place of business at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

5. Upon information and belief, Sun Pharmaceutical Industries Inc. is a corporation organized and existing under the laws of the State of Michigan, with headquarters at 29714 Orion Ct., Farmington Hills, MI 48334, and a principal place of business at 270 Prospect Plains Rd., Cranbury, New Jersey 08512. Upon information and belief, Sun Pharmaceutical Industries Inc. is a wholly-owned subsidiary of, and is an agent of, Sun Pharmaceutical Industries Ltd. Upon information and belief, Sun Pharmaceutical Industries Inc. on behalf of and as an agent of Sun Pharmaceutical Industries Ltd., manufactures, sells, and/or markets pharmaceutical products for sale and use in this judicial district and throughout the United States.

6. Upon information and belief, Sun Pharmaceutical Industries Ltd. is an Indian corporation with its principal place of business at Acme Plaza, Andheri - Kurla Rd., Andheri (E), Mumbai - 400, 059. Upon information and belief, Sun Pharmaceutical Industries Ltd. is a generic pharmaceutical company that manufactures, sells, and/or markets generic drugs for sale and use in this judicial district and throughout the United States, including through Sun Pharmaceutical Industries Inc., its wholly-owned subsidiary and agent.

7. Upon information and belief, Sun Pharma Global Inc. is a corporation organized and existing under the laws of the British Virgin Islands and maintains a post office box at International Trust Building, P.O. Box No. 659, Road Town, Tortola, British Virgin Islands. Upon information and belief, Sun Pharma Global Inc. is a wholly-owned subsidiary of Sun Pharmaceutical Industries Ltd. Upon information and belief, Sun Pharma Global Inc. is an agent of Sun Pharmaceutical Industries Ltd. and/or Sun Pharmaceutical Industries Inc. Upon information and belief, Sun Pharma Global Inc., files Abbreviated New Drug Applications ("ANDAs") on behalf of Sun Pharmaceutical Industries Ltd. and/or Sun Pharmaceutical Industries Inc. Upon information and belief, Sun Pharma Global Inc. acts in concert with and/or supports the sales and marketing of pharmaceutical products by Sun Pharmaceutical Industries Ltd. and/or Sun Pharmaceutical Industries Inc., in this judicial district and throughout the United States.

8. Sun Pharma Global Inc., upon information and belief, acting as the agent of Sun Pharmaceutical Industries Ltd. and/or Sun Pharmaceutical Industries Inc., submitted ANDA No. 90-818 for approval by the FDA.

9. Upon information and belief, Sun's ANDA Tablets, if approved for marketing by the FDA, will be distributed throughout the United States including in this judicial district, by Sun. Upon information and belief, Sun Pharma Global Inc. will act in concert with and/or

support the sales and marketing of Sun's ANDA Tablets by Sun Pharmaceutical Industries Ltd. and/or Sun Pharmaceutical Industries Inc., in this judicial district and throughout the United States.

Jurisdiction and Venue

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1400(b), 2201 and 2202.

11. This Court has personal jurisdiction over Sun Pharma Global Inc. because, *inter alia*, of its presence in this judicial district through its agent, James F. Hurst, Esq. of Winston & Strawn LLP, 35 West Wacker Dr., Chicago, IL 60601, who was designated by Sun Pharma Global Inc. as its agent for service of process with respect to the acts complained of herein pursuant to 21 C.F.R. § 314.95(c)(7).

12. This Court also has personal jurisdiction over each of the Defendants because, upon information and belief, each Defendant has maintained continuous and systematic contacts with this judicial district, and has purposefully availed itself of the benefits and protections of the laws of this judicial district, including by the sale and distribution of products in this district.

13. Sun Pharmaceutical Industries Ltd. has previously admitted that venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b) in civil actions in this judicial district, including: (a) *Novartis Pharma. Corp. v. Sun Pharma. Indus.*, *Ltd.*, 1:04-CV-05477 (N.D. Ill.) and; (b) *Pfizer, Inc. v. Sun Pharma. Indus.*, *Ltd.*, 1:04-CV-08025 (N.D. Ill.).

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

The Patents in Suit

15. United States Patent No. 7,135,571 (the "'571 patent"), entitled "Processes For Preparing Anhydrous and Hydrate Forms of Antihistaminic Piperidine Derivatives, Polymorphs

and Pseudomorphs Thereof," was duly and legally issued on November 14, 2006. Aventis is the owner by assignment of all right, title and interest in and to the '571 patent.

16. The '571 patent claims Form II hydrated 4-[4-[4-(Hydroxydiphenylmethyl)-1-piperidinyl]-l-hydroxybutyl]-∝,∝-dimethylbenzeneacetic acid hydrochloride, also known as Form II hydrated fexofenadine hydrochloride.

17. United States Patent No. 6,399,632 (the "'632 Patent"), entitled "Method of Providing an Antihistaminic Effect in a Hepatically Impaired Patient," was duly and legally issued on June 4, 2002 to inventors James K. Woodward *et al*. The '632 patent was assigned to Merrell Pharmaceuticals, Inc. ("Merrell"), and subsequently assigned to Aventis Inc. At all times from the issuance of the '632 patent to the present, Aventis Inc. or one of its predecessors in interest has been the owner of the '632 patent.

18. United States Patent No. 6,187,791 (the "'791 Patent"), entitled "Method of Providing an Antihistaminic Effect in a Hepatically Impaired Patient," was duly and legally issued on February 13, 2001, to inventors James K. Woodward *et al*. The '791 patent was assigned to Merrell, and subsequently assigned to Carderm. At all times from the issuance of the '791 patent to the present, Carderm or one of its predecessors in interest has been the owner of the '791 patent.

19. United States Patent No. 6,037,353 (the "'353 Patent"), entitled "Method of Providing an Antihistaminic Effect in a Hepatically Impaired Patient," was duly and legally issued on March 14, 2000, to inventors James K. Woodward *et al*. The '353 patent was assigned to Merrell, and subsequently assigned to Aventis. At all times from the issuance of the '353 patent to the present, Aventis or one of its predecessors in interest has been the owner of the '353 patent.

20. United States Patent No. 6,039,974 (the "'974 Patent"), entitled "Pharmaceutical Composition for Combination of Piperidinoalkanol-Decongestant," was duly issued on March 21, 2000 to inventors David D. MacLaren *et al*. The '974 patent was assigned to Hoescht Marion Roussel, Inc., a predecessor in interest of Aventis. At all times from the issuance of the '974 patent to present, Aventis or one of its predecessors in interest has been the owner of the '974 patent.

21. United States Patent No. 5,855,912 (the "'912 Patent"), entitled "Pharmaceutical Compositions for Piperidinalkanol Compounds," was duly and legally issued on January 5, 1999 to inventors Thomas Ortyl, *et al*. The '912 patent was assigned to Hoescht Marion Roussel, Inc., a predecessor in interest of Aventis. At all times from the issuance of the '912 patent to the present, Aventis or one of its predecessors in interest has been the owner of the '912 patent.

22. United States Patent No. 6,113,942 (the "'942 Patent"), entitled "Pharmaceutical Composition for Piperidinoalkanol Compounds," was duly and legally issued on September 5, 2000 to inventors Thomas Ortyl, *et al*. The '942 patent was assigned to Hoescht Marion Roussel, Inc., a predecessor in interest of Aventis. At all times from the issuance of the '942 patent to the present, Aventis or one of its predecessors in interest has been the owner of the '942 patent.

23. United States Patent No. 5,738,872 (the "'872 Patent"), entitled "Pharmaceutical Composition for Piperidinoalkanol Compounds," was duly and legally issued on April 14, 1998 to inventors Thomas Ortyl, *et al*. The '872 patent was assigned to Hoescht Marion Roussel, Inc., a predecessor in interest of Aventis. At all times from the issuance of the '872 patent to the present, Aventis or one of its predecessors in interest has been the owner of the '872 patent.

24. In an Opinion dated May 31, 2005, in Civil Action No. 01-3627 and published at 372 F. Supp. 2d 430, the District Court for the District of New Jersey granted summary judgment

that claims 1 and 2 of the '872 patent are invalid. For this reason, Plaintiffs will not oppose the entry of summary judgment in this action on the '872 patent, and are asserting that patent herein solely to preserve their rights under the Hatch-Waxman Act and for appeal.

Acts Giving Rise to This Action

25. Upon information and belief, Sun filed or caused to be filed with the FDA, ANDA No. 90-818 under section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use and sale of Sun's ANDA Tablets. Upon information and belief, Sun has represented that Sun's ANDA Tablets are bioequivalent to Aventis's 60 mg fexofenadine hydrochloride/120 mg pseudoephedrine hydrochloride Allegra®-D 12 Hour extended-release tablets.

26. Upon information and belief, when filed, ANDA No. 90-818 contained a "paragraph IV" certification pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV). Upon information and belief, the paragraph IV certification states in Sun's opinion that, *inter alia*, the commercial manufacture, use and sale or offer for sale of Sun's ANDA Tablets would not infringe the '912, '353, '974, '942, '791, '632, or '571 patents, and that the '353, '791, and '632 patents are invalid.

27. Sun sent or caused to be sent, a letter dated December 12, 2008, notifying Aventis that ANDA No. 90-818 had been submitted to the FDA ("Notice Letter"). The Notice Letter alleges non-infringement of the '912, '353, '974, '942, '791, '632, or '571 patents. The Notice Letter also alleges that claims of the '353, '791, and '632 patents are invalid.

28. Sun's submission of ANDA No. 90-818 to obtain approval to engage in the commercial manufacture, use, sale or offer for sale of Sun's ANDA Tablets prior to the expiration of the '912, '353, '974, '942, '791, '632, or '571 patents, and the '872 patent

(collectively, the "Aventis Patents") constituted infringement of one or more claims of each of those patents under 35 U.S.C. § 271(e)(2).

29. Upon information and belief, Sun intends to engage in the commercial manufacture, use, sale or offer for sale of Sun's ANDA Tablets immediately upon receiving FDA approval to do so.

30. Actual commercial manufacture, use, sale or offer for sale of Sun's ANDA Tablets prior to the expiration of the Aventis Patents would constitute infringement of such patents under 35 U.S.C. § 271. ANDA No. 90-818 and Sun's intention to engage in the commercial manufacture, use, sale or offer for sale of Sun's ANDA Tablets upon receiving FDA approval create an actual case or controversy with respect to infringement of the Aventis Patents.

31. Upon FDA approval of ANDA No. 90-818, Sun will infringe, will actively induce infringement of, and will contribute to infringement by others of the Aventis Patents, by making, using, selling, offering for sale Sun's ANDA Tablets in the United States, unless enjoined by this Court.

32. Sun had notice of the Aventis Patents at the time of its infringement. Sun's infringement has been and continues to be willful and deliberate.

33. Plaintiffs will be substantially and irreparably harmed by Sun's infringement if not enjoined. Plaintiffs do not have an adequate remedy at law.

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that Sun's manufacture, use, sale, offers for sale, marketing or distribution of Sun's ANDA Tablets, have infringed and will infringe the Aventis Patents;

(b) A judgment providing that the effective date of any FDA approval for Sun to make, use or sell Sun's ANDA Tablets be no earlier than the date on which each of the Aventis Patents expire, as extended by any applicable period of exclusivity;

(c) A judgment permanently enjoining Sun from making, using, selling, offering to sell, marketing or distributing Sun's ANDA Tablets until after expiration of the Aventis Patents;

(d) If Sun engages in the commercial manufacture, use, offer for sale, sale or importation of Sun's ANDA Tablets prior to the expiration of the Aventis Patents, as extended by any applicable period of exclusivity, a judgment awarding Plaintiffs damages resulting from such infringement, increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

(e) A judgment that this is an exceptional case and an award of reasonable attorneys' fees in this action to Plaintiffs pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further relief as this Court may deem just and proper.

JURY TRIAL DEMAND

Pursuant to Fed. R. Civ. P.38(b), Plaintiffs hereby demand a trial by jury of all issues so triable.

DATED: January 26, 2009

By: s/ Paul A. Kafadar

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