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*Attorneys for Plaintiffs  
Aventis Pharmaceuticals Inc.,  
Aventis Inc., and Carderm Capital L.P.*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

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AVENTIS PHARMACEUTICALS INC., )  
AVENTIS INC. and CARDERM CAPITAL L.P., )  
 )  
 ) Plaintiffs, )  
 )  
 ) v. )  
 )  
 ) SUN PHARMACEUTICAL INDUSTRIES LTD., )  
 ) SUN PHARMACEUTICAL INDUSTRIES INC., )  
 ) and SUN PHARMA GLOBAL INC., )  
 )  
 ) Defendants. )

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Civ. Action No. \_\_\_\_\_

**COMPLAINT**

**JURY TRIAL REQUESTED**

**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 Ltd., Sun Pharmaceutical Industries Inc., 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. 91-567 (“Sun’s ANDA”) filed or caused to be filed by Sun Pharmaceutical Industries Ltd., with the United States Food and Drug Administration

("FDA") for approval to market a generic version of Aventis' ALLEGRA® drug products containing 30 mg, 60 mg, and 180 mg fexofenadine 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 Ltd. is an Indian corporation with its principal place of business at Acme Plaza, Andheri - Kurla Rd., Andheri (E), Mumbai - 400059, Republic of India. 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 New Jersey and throughout the United States, including through Sun Pharmaceutical Industries Inc., its wholly-owned subsidiary and agent. Sun Pharmaceutical

Industries Ltd. sent and/or caused to be sent, through its New Jersey agent, a letter dated August 27, 2009 notifying Aventis that Sun's ANDA had been submitted to the FDA.

6. 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. on behalf of and as an agent of Sun Pharmaceutical Industries Ltd., manufactures, sells, and/or markets pharmaceutical products for sale and use in New Jersey and throughout the United States. A letter dated August 27, 2009 notifying Aventis that Sun's ANDA had been submitted to the FDA was sent to Plaintiffs by John Dauer, Chief Patent Counsel of Sun Pharmaceutical Industries, Inc., as agent for Sun Pharmaceuticals Industries Ltd.

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. 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 New Jersey and throughout the United States.

8. Upon information and belief, Sun's ANDA Tablets, if approved for marketing by the FDA, will be distributed throughout the United States including in New Jersey, by Sun. Upon information and belief, Sun Pharma Global Inc. and Sun Pharmaceutical Industries Inc.

will act in concert with and/or support the sales and marketing of Sun's ANDA Tablets by Sun Pharmaceutical Industries Ltd. in New Jersey and throughout the United States.

**Jurisdiction and Venue**

9. 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.

10. This Court has personal jurisdiction over Sun Pharmaceutical Industries Inc. because, *inter alia*, of its presence in this judicial district, including at its Cranbury, New Jersey place of business.

11. This Court has personal jurisdiction over Sun Pharmaceutical Industries Ltd. because, *inter alia*, it is present in this judicial district through its New Jersey agent, John Dauer, Chief Patent Counsel of Sun Pharmaceutical Industries, Inc., whose business address is the Sun Pharmaceutical Industries, Inc. place of business in Cranbury, New Jersey. Mr. Dauer was designated by Sun Pharmaceutical Industries Ltd. 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 has personal jurisdiction over each of the Defendants because, upon information and belief, each Defendant has maintained continuous and systematic contacts with the State of New Jersey, and has purposefully availed itself of the benefits and protections of the laws of the State of New Jersey, including by the sale and distribution of products in this district.

13. This Court also has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement alleged herein that has led to foreseeable harm and injury to plaintiffs Aventis and Carderm, each of which has a principal place of business in New Jersey.

14. In addition, each of the Defendants in prior actions has consented to jurisdiction in New Jersey, and/or has availed itself of this judicial district by asserting counterclaims in civil actions in this jurisdiction, including in the following actions: (a) *Schering Corp. v. Caraco Pharm. Labs. Ltd. et al.*, No. 3:08-CV-05623 (D.N.J.); (b) *Orion Corp. v. Sun Pharm. Indus. Inc. et al.*, No. 3:07-CV-05436 (D.N.J.); (c) *Otsuka Pharm. Co., Ltd. v. Sun Pharm. Indus. Ltd.*, No. 3:07-CV-01516 (D.N.J.); (d) *Altana Pharma AG. et al. v. Sun Pharm. Indus. Ltd. et al.*, No. 2:05-CV-01966 (D.N.J.); and (e) *PDL Biopharma, Inc. v. Sun Pharm. Indus. Ltd.*, No. 2:07-CV-01788 (D.N.J.); *Sepracor Inc. v. Sun Pharm. Indus. Ltd.*, No. 3:07-CV-04213 (D.N.J.); *Aventis et al. v. Sun Pharm. Indus. Ltd. et al.*, No. 09-325 (D.N.J.).

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

#### **The Patents in Suit**

16. 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.

17. The ’571 patent claims Form II hydrated 4-[4-[4-(Hydroxydiphenylmethyl)-1-piperidinyl]-1-hydroxybutyl]- $\alpha,\alpha$ -dimethylbenzeneacetic acid hydrochloride, also known as Form II hydrated fexofenadine hydrochloride.

18. 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.

19. 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.

20. 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.

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 Order and Opinion dated May 31, 2005, in Civil Action Nos. 01-3627, 02-1322, 03-1179, and 03-1180 and published at 372 F. Supp. 2d 430, the Court granted summary judgment that claims 1 and 2 of the '872 patent are invalid. In an August 14, 2008 Order in Civil Action No. 07-5180, and based on the May 31, 2008 Opinion and Order, the Court granted summary judgment that claims 1 and 2 of the '872 patent are invalid. Plaintiffs have filed a motion to vacate this grant of summary judgment in Civil Action Nos. 02-1322, 03-1179, 03-1180 and 07-5180, and that motion is fully briefed and pending. Should the motion to vacate be denied, Plaintiffs will not oppose the entry of an order granting partial summary judgment that claims 1 and 2 of the '872 patent are invalid in this action, in a manner that preserves their rights under the Hatch-Waxman Act and on appeal.

#### **Acts Giving Rise to This Action**

25. Upon information and belief, Sun filed or caused to be filed with the FDA, ANDA No. 91-567 to the FDA 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 30 mg, 60 mg and 180 mg fexofenadine hydrochloride Allegra® tablets.

26. Upon information and belief, when filed, ANDA No. 91-567 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, ’942, ’571, ’353, ’791, and ’632 patents, and/or that these patents are invalid.

27. Sun sent or caused to be sent, a letter dated August 27, 2009, notifying Aventis that ANDA No. 91-567 had been submitted to the FDA (“Notice Letter”). The Notice Letter alleges, *inter alia*, non-infringement of the ’912, ’942, and ’571 patents. The Notice Letter also alleges that claims of the ’353, ’791, and ’632 patents are invalid.

28. By letter dated December 12, 2008, Sun previously notified Plaintiffs that Sun had submitted ANDA No. 90-818 to obtain approval to engage in the commercial manufacture, use, sale or offer for sale of fexofenadine hydrochloride/pseudoephedrine hydrochloride 60 mg/120 mg extended release tablets. Plaintiffs filed a related patent infringement action against Sun in this Court on January 23, 2009.

29. Sun’s submission of ANDA No. 91-567 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, ’942, ’791, ’632, or ’571 patents, and prior to the expiration of 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).

30. 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.

31. 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. 91-567 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.

32. Upon FDA approval of ANDA No. 91-567, 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.

33. 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.

34. 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 requests 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 expires, 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: October 9, 2009

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