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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, AVENTISUB II INC. and CARDERM CAPITAL L.P., Plaintiffs, v. ACTAVIS INC. and ACTAVIS MID ATLANTIC LLC Defendants.	Civil Action No. _____ **COMPLAINT** **JURY TRIAL REQUESTED**

Plaintiffs sanofi-aventis U.S. LLC, Aventisub II Inc., and Carderm Capital L.P. (collectively, "Aventis"), by their attorneys, for their Complaint against Actavis Inc. and Actavis Mid Atlantic LLC (collectively, "Actavis" or "Defendants") 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 an Abbreviated New Drug Application ("ANDA") filed with the United States Food and Drug Administration ("FDA") for the approval necessary for Actavis to manufacture and market a generic version of Aventis's ALLEGRA® Oral Suspension 30 mg/5 mL drug product.

The Parties

2. Sanofi-aventis U.S. LLC is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 300 Somerset Corporate Drive, Bridgewater, New Jersey 08807-1265. sanofi-aventis U.S. LLC 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. Aventisub II Inc. is a corporation organized and existing under the laws of Delaware having its principal place of business at 3711 Kennett Pike, Suite 200, Greenville, Delaware 19807.

4. Carderm Capital L.P. 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, Actavis Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 60 Columbia Road, Morristown, New Jersey 07960-4535. Upon information and belief, Actavis Inc. manufactures, sells and/or markets generic pharmaceutical products in the United States.

6. Upon information and belief, Actavis Mid Atlantic LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 60 Columbia Road, Morristown, New Jersey 07960-4535. Upon information and belief, Actavis Mid Atlantic LLC also has regular and established places of business at 990 Riverview Drive, Totowa, New Jersey 07512-1129 and 200 Elmora Avenue, Elizabeth, NJ

07207. Upon information and belief, Actavis Mid Atlantic LLC is a wholly owned subsidiary of Actavis Inc., and acts in concert with and/or supports Actavis Inc. in the manufacture, sale and/or marketing of generic pharmaceutical products.

7. Upon information and belief, Actavis' ANDA oral suspension, if approved for marketing by the FDA, will be manufactured in New Jersey and will be distributed throughout the United States including in New Jersey, by Actavis.

Jurisdiction and Venue

8. 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.

9. This Court has personal jurisdiction over each of the Defendants by virtue of their presence in New Jersey, including having principal and/or regular and established places of business in Morristown, Totowa and Elizabeth, New Jersey.

10. 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.

11. This Court also has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, on information and belief each Actavis entity 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 sanofi-aventis U.S. LLC, Aventisub II Inc., and Carderm Capital L.P. in New Jersey.

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

The Patents in Suit

13. 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*. Aventisub II Inc. is the owner by assignment of all right, title and interest in and to the '632 patent. At all times from the issuance of the '632 patent to the present, Aventisub II Inc. or one of its predecessors in interest has been the owner of the '632 patent. Sanofi-aventis U.S. LLC holds an exclusive license to the '632 patent. A copy of the '632 patent is attached hereto as Exhibit A.

14. 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*. Carderm Capital L.P. is the owner by assignment of all right, title and interest in and to the '791 patent. 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. Sanofi-aventis U.S. LLC holds an exclusive license to the '791 patent. A copy of the '791 patent is attached hereto as Exhibit B.

15. 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*. Aventisub II Inc. is the owner by assignment of all right, title and interest in and to the '353 patent. At all times from the issuance of the '353 patent to the present, Aventisub II Inc. or one of its predecessors in interest has been the owner of the '353 patent. Sanofi-aventis U.S. LLC holds an exclusive license to the '353 patent. A copy of the '353 patent is attached hereto as Exhibit C.

Acts Giving Rise to this Action

Actavis' ANDA No. 79-112

16. Aventis sells drug products in the United States containing 30 mg fexofenadine hydrochloride in an oral suspension under the proprietary name ALLEGRA® Oral Suspension 30 mg/5 mL.

17. By letter dated April 9, 2010, Actavis, through Actavis Mid Atlantic LLC, notified Aventis that ANDA No. 201311 had been submitted 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 an oral suspension containing 30 mg of fexofenadine hydrochloride (the "ANDA 201311 oral suspension"). On information and belief, ANDA 201311 contains a statement that the ANDA 201311 oral suspension is bioequivalent to Aventis' ALLEGRA® Oral Suspension 30 mg/5 mL.

18. In its April 9, 2010 notification letter, Actavis also notified Aventis that ANDA 201311 contained "paragraph IV" certifications that in Actavis' opinion, the '353, '791 and '632 Patents are invalid or would not be infringed by the commercial manufacture, use or sale of Actavis' ANDA 201311 oral suspension.

19. ANDA 201311 was submitted to obtain FDA approval to engage in the commercial manufacture, use and sale of Actavis' ANDA 201311 oral suspension prior to the expiration of the '353, '791 and '632 Patents, each of which is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book") as being applicable to Aventis' ALLEGRA® Oral Suspension 30 mg/5 mL.

20. The submission of ANDA 201311 to obtain approval to engage in the commercial manufacture, use, offer for sale or sale of its ANDA 201311 oral suspension prior to the

expiration of the '353, '791 and '632 Patents, constitutes infringement of one or more of the claims of each of those patents under 35 U.S.C. § 271(e)(2).

21. Upon information and belief, Actavis intends to engage in the commercial manufacture, use, offer for sale and sale of its ANDA 201311 oral suspension promptly upon receiving FDA approval to do so.

22. Actavis' actual commercial manufacture, use, offer for sale or sale of its ANDA 201311 oral suspension, prior to the expiration of the '353, '791 and '632 Patents, will constitute infringement of those patents under 35 U.S.C. § 271. Actavis' ANDA 201311 and Actavis' intention to engage in the commercial manufacture, use, offer for sale or sale of its ANDA 201311 oral suspension upon receiving FDA approval create an actual case or controversy with respect to infringement of those patents.

23. Upon FDA approval of ANDA 201311, Actavis will infringe, will actively induce infringement of, and will contribute to infringement by others of, the '353, '791 and '632 Patents by making, using, offering for sale, and selling its ANDA 201311 oral suspension in the United States, unless enjoined by this Court.

24. Actavis had notice of the '353, '791 and '632 Patents at the time of its infringement, and, on information and belief, had notice that its actual commercial manufacture, use, offer for sale or sale of its ANDA 201311 oral suspension, prior to the expiration of those patents, would constitute infringement of such patents under 35 U.S.C. § 271.

25. Actavis' infringement has been, and continues to be, willful and deliberate.

26. Aventis will be substantially and irreparably damaged and harmed if Actavis' infringement is not enjoined. Aventis does not have an adequate remedy at law.

Requested Relief

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that Actavis has infringed each of the ’353, ’791 and ’632 Patents;

(b) A judgment declaring that Actavis’ making, using, offering for sale, selling, or importing the ANDA 201311 oral suspension will infringe each of the ’353, ’791 and ’632 Patents;

(c) A judgment providing that the effective date of any FDA approval for Actavis to make, use or sell the ANDA 79-112 Tablets be no earlier than the date on which each of the ’353, ’791 and ’632 Patents expires;

(d) A judgment permanently enjoining Actavis from making, using, offering for sale, selling or importing the ANDA 201311 oral suspension until after expiration of each of the ’353, ’791 and ’632 Patents;

(e) If Actavis engages in the commercial manufacture, use, offer for sale or sale of its ANDA 201311 oral suspension prior to the expiration of any of the ’353, ’791 and ’632 Patents, a judgment awarding Plaintiffs damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(f) Attorneys’ fees in this action pursuant to 35 U.S.C. § 285;

(g) Costs and expenses in this action; and

(h) Such further and other 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: May 24, 2010

By: S/William J. Heller

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