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

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| SANOFI-AVENTIS U.S. LLC, AVENTISUB II INC. and CARDERM CAPITAL L.P.,<br><br>Plaintiffs,<br><br>v.<br><br>WOCKHARDT LTD, WOCKHARDT USA LLC and WOCKHARDT USA INC.,<br><br>Defendants. | Civil Action No. _____<br><br>**COMPLAINT**<br><br>**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 Wockhardt Ltd, Wockhardt USA LLC and Wockhardt USA, Inc. (collectively, "Wockhardt") 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 Abbreviated New Drug Applications ("ANDAs") filed by Wockhardt with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Aventis's ALLEGRA® drug product and Aventis' ALLEGRA-D® 12 HOUR 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 mg, 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, Wockhardt Limited is a corporation organized and existing under the laws of India, having its principal place of business at Wockhardt Towers, Bandra-Kurla Complex, Bandra (East), Mumbai - 400 051, Maharashtra, India and has a regular and established place of business at 135 Route 202/206, Bedminster, New Jersey 07921.

6. Upon information and belief, Wockhardt USA Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 135 Route 202/206, Bedminster, New Jersey 07921. Upon information and belief, Wockhardt USA Inc. markets and sells products for Wockhardt Ltd and Wockhardt USA LLC.

7. Upon information and belief, Wockhardt USA LLC is a corporation organized and existing under the laws of Delaware, having its principal place of business at 20 Waterview

Boulevard, 3rd Floor, Parsippany, NJ 07054, USA and a regular and established place of business at 135 Route 202/206, Bedminster, New Jersey 07921.

**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 each Defendant's presence in New Jersey, including having principal and/or regular and established places of business in Bedminster and Parsippany, 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 Wockhardt 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. In addition, Wockhardt is a party to a related action filed in this Court, *Aventis et al. v. Wockhardt et al.*, No. 2:07-CV-05647 (D.N.J.), which alleges infringement of certain Aventis patents based on the same ANDA filings by Wockhardt at issue in this complaint.

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

**The Patents in Suit**

14. United States Patent No. 7,138,524 (the "'524 patent"), entitled "Processes For Preparing Anhydrous and Hydrate Forms of Antihistaminic Piperidine Derivatives, Polymorphs and Pseudomorphs Thereof," was duly and legally issued on November 21, 2006. Aventisub II Inc. is the owner by assignment of all right, title and interest in and to the '524 patent. At all times from the issuance of the '524 patent to the present, Aventisub II Inc. or one of its predecessors in interest has been the owner of the '524 patent. Sanofi-aventis U.S. LLC holds an exclusive license to the '524 patent.

15. The '524 patent claims Form I anhydrous 4-[4-[4-(Hydroxydiphenylmethyl)-1-piperidinyl]-1-hydroxybutyl]-∝,∝-dimethylbenzeneacetic acid hydrochloride, also known as Form I anhydrous fexofenadine hydrochloride.

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. Aventisub II Inc. is the owner by assignment of all right, title and interest in and to the '571 patent. At all times from the issuance of the '571 patent to the present, Aventisub II Inc. or one of its predecessors in interest has been the owner of the '571 patent. Sanofi-aventis U.S. LLC holds an exclusive license to the '571 patent.

17. 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.

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.* 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.

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.* 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.

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.* 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.

**Acts Giving Rise to this Action**

**Wockhardt's ANDA No. 79-112**

21. Aventis sells drug products containing 30 mg, 60 mg and 180 mg fexofenadine hydrochloride in the United States under the proprietary name ALLEGRA®.

22. By letter dated October 12, 2007, Wockhardt, through Wockhardt Ltd, notified Aventis that Wockhardt had submitted ANDA No. 79-112 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 tablets containing 30 mg, 60 mg and 180 mg of fexofenadine hydrochloride (the "ANDA 79-112 Tablets"). On information and belief, Wockhardt stated in its ANDA No. 79-112 that its ANDA 79-112 Tablets are bioequivalent to Aventis' 30 mg, 60 mg and 180 mg fexofenadine hydrochloride ALLEGRA® tablets.

23. In its October 12, 2007, notification letter, Wockhardt notified Aventis that its ANDA No. 79-112 contained "paragraph IV" certifications that in Wockhardt's opinion, Aventis's United States Patent Nos. 5,855,912 (the "'912 Patent") and 6,113,942 (the "'942 Patent") are invalid or would not be infringed by the commercial manufacture, use or sale of Wockhardt's ANDA 79-112 Tablets. Wockhardt also notified Aventis that its ANDA No. 79-112 contained "paragraph III" certifications with respect to the '353, '791, '632, '571 and '524 patents, stating that it would not seek to market its ANDA 79-112 Tablets before the expiration of those patents.

24. Wockhardt submitted its ANDA No. 79-112 to obtain FDA approval to engage in the commercial manufacture, use and sale of Wockhardt's ANDA 79-112 Tablets prior to the expiration of the '912 and '942 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® tablets.

25. On November 26, 2007, on the basis of Wockhardt's ANDA No. 79-112 "paragraph IV" certifications, Aventis filed suit against Wockhardt for infringement of the '912 and '942 patents. Aventis also asserted that the product described in Wockhardt's ANDA No.

79-112 would infringe Aventis's U.S. Patent No. 5,738,872 (the "'872 Patent"). By stipulation dated March 31, 2008, that action, Civil Action No. 07-5647, was stayed. By Order dated March 21, 2009, Civil Action No. 07-5647 was administratively terminated without prejudice to the right of the parties to reopen the proceedings for good cause shown.

26. In a letter dated February 2, 2010, Wockhardt, through Wockhardt Ltd and Wockhardt USA LLC, notified Aventis that it had amended its paragraph III certifications relating to the '353, '791, '632, '571 and '524 patents, to paragraph IV certifications stating that, in Wockhardt's opinion, the '353, '791, '632, '571 and '524 patents are invalid or will not be infringed by the commercial manufacture, use or sale of Wockhardt's ANDA 79-112 Tablets.

27. In light of its amended certifications, Wockhardt now submits its ANDA No. 79-112 to obtain FDA approval to engage in the commercial manufacture, use and sale of Wockhardt's ANDA 79-112 Tablets prior to the expiration of the '353, '791, '632, '571 and '524 patents, each of which is listed in the Orange Book as being applicable to Aventis' ALLEGRA® tablets.

28. Wockhardt's submission of its ANDA No. 79-112 to obtain approval to engage in the commercial manufacture, use, offer for sale or sale of its ANDA 79-112 Tablets, prior to the expiration of the '353, '791, '632, '571 and '524 patents, constitutes infringement of one or more of the claims of each of those patents under 35 U.S.C. § 271(e)(2).

29. Upon information and belief, Wockhardt intends to engage in the commercial manufacture, use, offer for sale and sale of its ANDA 79-112 Tablets promptly upon receiving FDA approval to do so.

30. Wockhardt's actual commercial manufacture, use, offer for sale or sale of its ANDA 79-112 Tablets, prior to the expiration of the '353, '791, '632, '571 and '524 patents, will

constitute infringement of those patents under 35 U.S.C. § 271. Wockhardt's ANDA No. 79-112 and Wockhardt's intention to engage in the commercial manufacture, use, offer for sale or sale of its ANDA 79-112 Tablets upon receiving FDA approval create an actual case or controversy with respect to infringement of those patents.

31. Upon FDA approval of Wockhardt ANDA No. 79-112, Wockhardt will infringe, will actively induce infringement of, and will contribute to infringement by others of, the '353, '791, '632, '571 and '524 patents by making, using, offering for sale, and selling its ANDA 79-112 Tablets in the United States, unless enjoined by this Court.

32. Wockhardt had notice of the '353, '791, '632, '571 and '524 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 79-112 Tablets, prior to the expiration of those patents, would constitute infringement of such patents under 35 U.S.C. § 271.

33. Wockhardt's infringement has been, and continues to be, willful and deliberate.

34. Plaintiffs will be substantially and irreparably damaged and harmed if Wockhardt's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

**Wockhardt's ANDA No. 79-115**

35. Aventis also sells a drug product containing 60 mg of fexofenadine hydrochloride and 120 mg of pseudoephedrine hydrochloride in the United States under the proprietary name ALLEGRA-D® 12 HOUR.

36. By letters dated October 12, 2007, and November 19, 2007, Wockhardt notified Aventis that Wockhardt had submitted ANDA No. 79-115 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 tablets containing 60 mg of fexofenadine hydrochloride

and 120 mg of pseudoephedrine hydrochloride (the "ANDA 79-115 Tablets"). On information and belief, Wockhardt stated in its ANDA No. 79-115 that its ANDA 79-115 Tablets are bioequivalent to Aventis' 60 mg of fexofenadine hydrochloride/120 mg of pseudoephedrine hydrochloride ALLEGRA-D® 12 HOUR tablets.

37. In its October 12, 2007, and November 19, 2007 notification letters, Wockhardt notified Aventis that its ANDA No. 79-115 contained paragraph IV certifications that in Wockhardt's opinion, the '942 and '912 patents are invalid or would not be infringed by the commercial manufacture, use or sale of Wockhardt's ANDA 79-115 Tablets. Wockhardt also notified Aventis that its ANDA No. 79-115 contained paragraph III certifications with respect to the '353, '791, '632 and '524 patents.

38. Wockhardt submitted its ANDA No. 79-115 to obtain FDA approval to engage in the commercial manufacture, use and sale of Wockhardt's ANDA 79-115 Tablets prior to the expiration of the '942 and '912 patents, each of which is listed in the Orange Book as being applicable to Aventis' ALLEGRA-D® 12 HOUR tablets.

39. On November 26, 2007, on the basis of Wockhardt's ANDA No. 79-115 paragraph IV certifications, Aventis filed suit against Wockhardt for infringement of the '912 and '942 patents. Aventis also asserted that the product described in Wockhardt's ANDA No. 79-115 would infringe the '872 patent. By stipulation dated March 31, 2008, that action, Civil Action No. 07-5647, was stayed. By Order dated March 21, 2009, Civil Action No. 07-5647 was administratively terminated without prejudice to the right of the parties to reopen the proceedings for good cause shown.

40. In a letter dated February 2, 2010, Wockhardt notified Aventis that it had amended its paragraph III certifications relating to the '353, '791, '632, and '524 patents, to

paragraph IV certifications stating that in Wockhardt's opinion, the '353, '791, '632, and '524 patents are invalid or would not be infringed by the commercial manufacture, use or sale of Wockhardt's ANDA 79-115 Tablets.

41. In light of its amended certifications, Wockhardt now submits its ANDA No. 79-115 to obtain FDA approval to engage in the commercial manufacture, use and sale of Wockhardt's ANDA 79-115 Tablets prior to the expiration of the '353, '791, '632 and '524 patents, each of which is listed in the Orange Book as being applicable to Aventis' ALLEGRA-D® 12 HOUR tablets.

42. Wockhardt's submission of its ANDA No. 79-115 to obtain approval to engage in the commercial manufacture, use, offer for sale or sale of its ANDA 79-115 Tablets, prior to the expiration of the '353, '791, '632 and '524 patents, constitutes infringement of one or more of the claims of each of those patents under 35 U.S.C. § 271(e)(2).

43. Upon information and belief, Wockhardt intends to engage in the commercial manufacture, use, offer for sale and sale of its ANDA 79-115 Tablets promptly upon receiving FDA approval to do so.

44. Wockhardt's actual commercial manufacture, use, offer for sale or sale of its ANDA 79-115 Tablets, prior to the expiration of the '353, '791, '632 and '524 patents, will constitute infringement of those patents under 35 U.S.C. § 271. Wockhardt's ANDA No. 79-115 and Wockhardt's intention to engage in the commercial manufacture, use, offer for sale or sale of its ANDA 79-115 Tablets upon receiving FDA approval create an actual case or controversy with respect to infringement of the those patents.

45. Upon FDA approval of Wockhardt ANDA No. 79-115, Wockhardt will infringe, will actively induce infringement of, and will contribute to infringement by others of, the '353,

'791, '632 and '524 patents by making, using, offering for sale, and selling its ANDA 79-112 Tablets in the United States, unless enjoined by this Court.

46. Wockhardt had notice of all of the '353, '791, '632, and '524 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 79-115 Tablets, prior to the expiration of the '353, '791, '632 and '524 patents, would constitute infringement of those patents under 35 U.S.C. § 271.

47. Wockhardt's infringement has been, and continues to be, willful and deliberate.

48. Plaintiffs will be substantially and irreparably damaged and harmed if Wockhardt's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

**Requested Relief**

**WHEREFORE**, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that Wockhardt has infringed each of the '353, '791, '632, '571, and '524 patents;

(b) A judgment declaring that Wockhardt's making, using, offering for sale, selling, or importing the ANDA 79-112 Tablets will infringe each of the '353, '791, '632, '571, and '524 patents;

(c) A judgment declaring that Wockhardt's making, using, offering for sale, selling, or importing the ANDA 79-115 Tablets will infringe each of the '353, '791, '632 and '524 patents;

(d) A judgment providing that the effective date of any FDA approval for Wockhardt to make, use or sell the ANDA 79-112 Tablets be no earlier than the date on which each of the '353, '791, '632, '571, and '524 patents expires;

(e) A judgment providing that the effective date of any FDA approval for Wockhardt to make, use or sell the ANDA 79-115 Tablets be no earlier than the date on which each of the '353, '791, '632 and '524 patents expires;

(f) A judgment permanently enjoining Wockhardt from making, using, offering for sale, selling or importing the ANDA 79-112 Tablets until after expiration of each of the '353, '791, '632, '571, and '524 patents;

(g) A judgment permanently enjoining Wockhardt from making, using, offering for sale, selling, or importing the ANDA 79-115 Tablets until after expiration of each of the '353, '791, '632 and '524 patents;

(h) If Wockhardt engages in the commercial manufacture, use, offer for sale or sale of its ANDA 79-112 Tablets prior to the expiration of any of the '353, '791, '632, '571, and '524 patents, a judgment awarding Plaintiffs damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(i) If Wockhardt engages in the commercial manufacture, use, offer for sale or sale of its ANDA 79-115 Tablets prior to the expiration of any of the '353, '791, '632 and '524 patents, a judgment awarding Plaintiffs damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

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

(k) Costs and expenses in this action; and

(l) 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: March 18, 2010

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