James E. Cecchi
Lindsey H. Taylor
CARELLA, BYRNE, BAIN, GILFILLAN,
CECCHI, STEWART & OLSTEIN, PC
5 Becker Farm Road
Roseland, New Jersey 07068-1739
(973) 994-1700

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AVENTIS PHARMACEUTICALS INC., AVENTIS INC. and CARDERM CAPITAL L.P., Plaintiffs, v. SANDOZ INC., Defendant.	Civil Action No. **COMPLAINT**

Plaintiffs, Aventis Pharmaceuticals Inc. ("Aventis"), Aventis Inc. ("Aventis Inc."), and Carderm Capital L.P. ("Carderm"), by way of Complaint against Defendant Sandoz Inc. ("Sandoz"), 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 generic versions of Aventis's ALLEGRA® and ALLEGRA-D® 12-Hour drug products for which Sandoz has sought marketing approval from the U.S. Food and Drug Administration ("FDA") and which Sandoz intends to market in the United States immediately upon FDA approval.

The Parties

2. Aventis is a corporation organized and existing under the laws of Delaware, having its principal place of business at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

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. Aventis is the principal shareholder of Carderm.

5. On information and belief, Sandoz is a corporation organized and existing under the laws of Colorado, having principal places of business in this judicial district at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540 and 2400 Route 130 North, Dayton, New Jersey 08810. Sandoz is in the business of marketing pharmaceutical products, including generic pharmaceutical products.

Jurisdiction and Venue

6. 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.

7. This Court has personal jurisdiction over Sandoz by virtue of its presence in New Jersey and its continuous and systematic contacts with New Jersey. On information and belief, the corporate headquarters of Sandoz's generic drug business is located at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540. Additionally, on information and belief, Sandoz maintains a large research and development operation directed to its generic drug operations at 2400 Route 130

North, Dayton, New Jersey 08810. Accordingly, Sandoz is subject to personal jurisdiction in this judicial district.

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

The Patents

9. United States Patent No. 6,399,632 (the "'632 patent") 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.

10. United States Patent No. 6,187,791 (the "'791 patent") 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.

11. United States Patent No. 6,037,353 (the "'353 patent") 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.

Acts Giving Rise to this Action

12. By letter dated December 9, 2003, Sandoz notified Aventis that Sandoz had submitted ANDA No. 76-707 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 fexofenadine hydrochloride (the "Fexofenadine ANDA

Tablets"). Sandoz stated in its ANDA No. 76-707 that its Fexofenadine ANDA Tablets are bioequivalent to Aventis's 30 mg, 60 mg and 180 mg ALLEGRA® tablets.

13. When filed, Sandoz's ANDA No. 76-707 contained a "paragraph IV" certification pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV). In its paragraph IV certification, Sandoz stated, *inter alia*, that in Sandoz's opinion the commercial manufacture, use, sale or offer for sale of Sandoz's Fexofenadine ANDA Tablets would not infringe U.S. Patent Nos. 6,113,942; 5,855,912; and 5,932,247.

14. Sandoz's submission of its ANDA No. 76-707 to obtain approval to engage in the commercial manufacture, use, offer for sale of Sandoz's Fexofenadine ANDA Tablets prior to the expiration of the '942, '912, and '247 patents constituted infringement of one or more claims of each of those patents under 35 U.S.C. § 271(e)(2).

15. In response to Sandoz's submission of its ANDA No. 76-707 with a paragraph IV certification, Aventis Pharmaceuticals Inc. filed a patent infringement action against Sandoz in this Court on January 20, 2004 (Civil Action No. 04-222), alleging infringement of U.S. Patent Nos. 6,113,942; 5,855,912; and 5,932,247; and seeking a declaratory judgment of infringement of U.S. Patent No. 5,738,872. The action set forth in the instant complaint is a related action to No. 04-222.

16. When filed, Sandoz's ANDA No. 76-707 also contained a "paragraph III" certification pursuant to 21 U.S.C. § 355(j)(2)(vii)(III). In its paragraph III certification, Sandoz stated it would not market its Fexofenadine ANDA Tablets prior to the expiration of the '632, '791 and '353 patents.

17. By letter dated April 11, 2007, Sandoz notified Plaintiffs that it had amended its ANDA No. 76-707 to change its paragraph III certification with respect to the '632, '791 and '353

patents to a paragraph IV certification. In its new paragraph IV certification, Sandoz asserts that the claims of the '632, '791 and '353 patents are invalid.

18. Sandoz's ANDA No. 76-707, as amended, was submitted to obtain FDA approval to engage in the commercial manufacture, use and sale of Sandoz's Fexofenadine ANDA Tablets prior to the expiration of the '632, '791 and '353 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's ALLEGRA® tablets.

19. Sandoz's submission of its ANDA to obtain approval to engage in the commercial manufacture, use and sale of its Fexofenadine ANDA Tablets prior to the expiration of the '632, '791 and '353 patents constitutes infringement of one or more claims of each of those patents under 35 U.S.C. § 271(e)(2).

20. On information and belief, Sandoz intends to engage in the commercial manufacture, use, offer for sale and sale of its Fexofenadine ANDA Tablets promptly upon receiving FDA approval to do so.

21. Actual commercial manufacture, use, offer for sale or sale of Sandoz's Fexofenadine ANDA Tablets prior to the expiration of the '632, '791 and '353 patents would constitute infringement of such patents under 35 U.S.C. § 271. Sandoz's ANDA No. 76-707 and Sandoz's intention to engage in the commercial manufacture, use, offer for sale or sale of its Fexofenadine ANDA Tablets upon receiving FDA approval create an actual case or controversy with respect to infringement of the '632, '791 and '353 patents.

22. Upon FDA approval of Sandoz's ANDA No. 76-707, Sandoz will infringe, will actively induce infringement of, and will contribute to infringement by others of, the '632, 791 and

'353 patents by making, using, offering for sale and selling its Fexofenadine ANDA Tablets in the United States, unless enjoined by this Court.

23. By letter dated February 1, 2006, Sandoz notified Aventis Pharmaceuticals Inc. that Sandoz had submitted ANDA No. 77-999 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 fexofenadine hydrochloride and 120 mg pseudoephedrine hydrochloride (the "Fexofenadine/Pseudoephedrine ANDA Tablets"). Sandoz stated in its ANDA No. 77-999 that its Fexofenadine/Pseudoephedrine ANDA Tablets are bioequivalent to Aventis's ALLEGRA-D® 12-Hour tablets.

24. When filed, Sandoz's ANDA No. 77-999 contained a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV). In its paragraph IV certification, Sandoz stated, *inter alia*, that in Sandoz's opinion the commercial manufacture, use, sale or offer for sale of Sandoz's Fexofenadine/Pseudoephedrine ANDA Tablets would not infringe U.S. Patent Nos. 6,039,974; 6,113,942; and 5,855,912.

25. Sandoz's submission of its ANDA No. 77-999 to obtain approval to engage in the commercial manufacture, use, offer for sale of Sandoz's Fexofenadine/Pseudoephedrine ANDA Tablets prior to the expiration of the '974, '942, and '912 patents constituted infringement of one or more claims of each of those patents under 35 U.S.C. § 271(e)(2).

26. In response to Sandoz's submission of its ANDA No. 77-999 with a paragraph IV certification, Aventis Pharmaceuticals Inc. filed a patent infringement action against Sandoz in this Court on March 17, 2006 (Civil Action No. 06-1277), alleging infringement of U.S. Patent Nos. 6,039,974; 6,113,942; and 5,855,912; and seeking a declaratory judgment of infringement of U.S.

Patent No. 5,738,872. The action set forth in the instant complaint is a related action to No. 06-1277.

27. When filed, Sandoz's ANDA No. 77-999 also contained a paragraph III certification pursuant to 21 U.S.C. § 355(j)(2)(vii)(III). In its paragraph III certification, Sandoz stated it would not market its Fexofenadine/Pseudoephedrine ANDA Tablets prior to the expiration of the '632, '791 and '353 patents.

28. By letter dated April 11, 2007, Sandoz notified Plaintiffs that it had amended its ANDA No. 77-999 to change its paragraph III certification with respect to the '632, '791 and '353 patents to a paragraph IV certification. In its new paragraph IV certification, Sandoz asserts that the claims of the '632, '791 and '353 patents are invalid.

29. Sandoz's ANDA No. 77-999, as amended, was submitted to obtain FDA approval to engage in the commercial manufacture, use and sale of Sandoz's Fexofenadine/Pseudoephedrine ANDA Tablets prior to the expiration of the '632, '791 and '353 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's ALLEGRA-D® 12-Hour tablets.

30. Sandoz's submission of its ANDA to obtain approval to engage in the commercial manufacture, use and sale of its Fexofenadine/Pseudoephedrine ANDA Tablets prior to the expiration of the '632, '791 and '353 patents constitutes infringement of one or more claims of each of those patents under 35 U.S.C. § 271(e)(2).

31. On information and belief, Sandoz intends to engage in the commercial manufacture, use, offer for sale and sale of its Fexofenadine/Pseudoephedrine ANDA Tablets promptly upon receiving FDA approval to do so.

32. Actual commercial manufacture, use, offer for sale or sale of Sandoz's Fexofenadine/Pseudoephedrine ANDA Tablets prior to the expiration of the '632, '791 and '353 patents would constitute infringement of such patents under 35 U.S.C. § 271. Sandoz's ANDA No. 77-999 and Sandoz's intention to engage in the commercial manufacture, use, offer for sale or sale of its Fexofenadine/Pseudoephedrine ANDA Tablets upon receiving FDA approval create an actual case or controversy with respect to infringement of the '632, '791 and '353 patents.

33. Upon FDA approval of Sandoz's ANDA No. 77-999, Sandoz will infringe, will actively induce infringement of, and will contribute to infringement by others of, the '632, 791 and '353 patents by making, using, offering for sale and selling its Fexofenadine/Pseudoephedrine ANDA Tablets in the United States, unless enjoined by this Court.

34. On January 30, 2006, the United States District Court for the District of New Jersey denied a motion for preliminary injunction in Civil Action Nos. 01-3627(JAG) and 03-487(JAG). The motion for preliminary injunction was based in part on the '632, '791 and '353 patents. Subsequently, the Court of Appeals for the Federal Circuit affirmed the district court decision pursuant to Fed. R. App. P. 36. Summary judgment has not been granted and no motion for summary judgment has been filed with respect to the '632, '791 and '353 patents.

35. Sandoz had notice of the '632, '791 and '353 patents at the time of its infringement. Sandoz's infringement has been, and continues to be, willful and deliberate.

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

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that Sandoz has infringed, and that Sandoz's making, using, selling, offering to sell, or importing its Fexofenadine and Fexofenadine/Pseudoephedrine Tablets will infringe each of the '632, '791 and '353 patents;

(b) A judgment providing that the effective date of any FDA approval for Sandoz to make, use or sell its Fexofenadine or Fexofenadine/Pseudoephedrine Tablets be no earlier than the date on which each of the '632, '791 and '353 patents expires, as extended by any applicable period of pediatric exclusivity;

(c) A judgment permanently enjoining Sandoz from making, using, selling, offering to sell, or importing its Fexofenadine or Fexofenadine/Pseudoephedrine Tablets until after expiration of each of the '632, '791 and '353 patents, as extended by any applicable period of pediatric exclusivity;

(d) If Sandoz engages in the commercial manufacture, use, sale, offer for sale or importation of its Fexofenadine or Fexofenadine/Pseudoephedrine Tablets prior to the expiration of the '632, '791 and '353 patents, as extended by any applicable period of pediatric exclusivity, a judgment awarding Plaintiffs damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(e) Attorney's fees in this action 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.

CARELLA, BYRNE, BAIN, GILFILLAN,
CECCHI, STEWART & OLSTEIN
Attorneys for Plaintiffs

Date: May 24, 2007

By: /s/ James E. Cecchi
JAMES E. CECCHI

OF COUNSEL:
Paul H. Berghoff
James C. Gumina
Aaron F. Barkoff
McDONNELL BOEHNEN HULBERT &
BERGHOFF LLP
300 South Wacker Drive, Suite 3200
Chicago, Illinois 60606
(312) 913-0001

RULE 11.2 CERTIFICATION

We hereby certify that the matter in controversy is related to the following actions, among others, pending before the Honorable Joseph A. Greenaway, Jr., U.S.D.J., captioned *Aventis v. Barr,* No. 01-3627 (JAG) (Consolidated), *Aventis v. Impax,* No. 02-1322 (JAG), *Aventis v. Teva,* No. 03-487 (JAG), *Aventis v. Dr. Reddy's, No*, 03-1180 (JAG)(D.N.J.), *Aventis v. Mylan,* No. 03-1179 (JAG), *Aventis v. Dr. Reddy's*, No. 03-5108 (JAG), *Aventis v, Sandoz, Inc.* No. 04-222 (JAG), *Aventis and AMR v. Barr and Ranbaxy,*, No. 04-1064(JAG), *Aventis and AMR v. Dr. Reddy*, 04-1076(JAG), *Aventis and AMR v. Mylan and Amino*, 04-1077(JAG), *Aventis and AMR v. Teva and Amino*, No. 04-1078(JAG), *Aventis v. Ranbaxy*, No. 04-1731(JAG), *Aventis v. Mylan*, No. 04-2305, *Aventis v. Dr. Reddy*, No. 04-3194 (JAG), *Aventis v. Sandoz*, 04-3944 (JAG), *Aventis v. Mylan*, 05-4255 (JAG), *Sanofi-Aventis v. Ranbaxy*, No. 06-846(JAG), and *Aventis v. Sandoz*, 06-1277(JAG)

CARELLA, BYRNE, BAIN, GILFILLAN,
CECCHI, STEWART & OLSTEIN
Attorneys for Plaintiffs

By: /s/ James E. Cecchi
JAMES E. CECCHI

Dated: May 24, 2007

RULE 201.1 CERTIFICATION

We hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

CARELLA, BYRNE, BAIN, GILFILLAN,
CECCHI, STEWART & OLSTEIN
Attorneys for Plaintiff
AVENTIS PHARMACEUTICALS INC.

By: /s/ James E. Cecchi
JAMES E. CECCHI

Dated: May 24, 2007