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

AVENTIS PHARMACEUTICALS INC. and AMR TECHNOLOGY, INC., Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD., and DR. REDDY'S LABORATORIES, INC., Defendant.	Civil Action No. **COMPLAINT**

Plaintiffs Aventis Pharmaceuticals Inc. ("Aventis") and AMR Technology, Inc. ("AMR"), by their attorneys, for their Complaint against Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "Reddy") 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® drug products for which Reddy has

sought marketing approval from the U.S. Food and Drug Administration ("FDA") and which Reddy 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. Aventis sells drug products containing fexofenadine hydrochloride in the United States under the trademarks ALLEGRA® and ALLEGRA-D®.

3. AMR is a corporation organized and existing under the laws of Vermont, having its principal place of business at 5429 Main Street, Manchester, Vermont 05255. AMR is a wholly owned subsidiary of Albany Molecular Research, Inc., a Delaware corporation.

4. Upon information and belief, Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of New Jersey, has its principal place of business at 1 Park Way, Upper Saddle River, New Jersey, and has a regular and established place of business at 1 Park Way, Upper Saddle River, New Jersey 07458.

5. Upon information and belief, Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India, has its principal place of business at 7-1-27 Ameerpet, Hyderabad 500016, Andhra Pradesh, India, and has a regular and established place of business at 1 Park Way, Upper Saddle River, New Jersey 07458.

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 defendants by virtue of their presence in New Jersey, and their continuous and systematic contacts with New Jersey.

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. 5,581,011 (the " '011 patent") duly and legally issued on December 3, 1996 to inventor Thomas E. D'Ambra. The '011 patent was assigned to Albany Molecular Research, Inc., a New York corporation, which subsequently assigned its rights to Albany Molecular Research, Inc., a Delaware corporation, which later assigned its rights to AMR. At all times from the issuance of the '011 patent to the present, AMR or one of its predecessors in interest has been the owner of the '011 patent, and Aventis or one of its predecessors in interest has been the exclusive licensee of the '011 patent.

10. United States Patent No. 5,750,703 (the " '703 patent") duly and legally issued on May 12, 1998 to inventor Thomas E. D'Ambra. The '703 patent was assigned to Albany Molecular Research, Inc., which subsequently assigned its rights to Albany Molecular Research, Inc., a Delaware corporation, which later assigned its rights to AMR. At all times from the issuance of the '703 patent to the present, AMR or one of its predecessors in interest has been the owner of the '703 patent, and Aventis or one of its predecessors in interest has been the exclusive licensee of the '703 patent.

Acts Giving Rise to this Action

11. Reddy has submitted to the FDA Abbreviated New Drug Applications ("ANDAs") 76-502 and 76-667 under Section 505(j)(1) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)(1)) and New Drug Application ("NDA") 21-581 under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)), seeking approval to engage in the commercial manufacture, use and sale of 30 mg, 60 mg and 180 mg fexofenadine

hydrochloride tablets, and 60 mg fexofenadine hydrochloride/120 mg pseudoephedrine hydrochloride tablets (collectively, the "ANDA and NDA Products").

12. On information and belief, Reddy intends to engage in the commercial manufacture, use and sale of its ANDA and NDA Products promptly upon receiving FDA approval to do so.

13. The '011 and '703 patents claim fexofenadine intermediates and processes for making fexofenadine. On information and belief, Reddy's commercial manufacture, importation, use or sale of its fexofenadine hydrochloride drug substance, and Reddy's commercial manufacture, importation, use or sale of its ANDA and NDA Products, will infringe one or more claims of the '011 and '703 patents under 35 U.S.C. §271(a) and (g).

14. Aventis notified Reddy that its manufacture, importation, use or sale of its fexofendine products may infringe the '011 and '703 patents. On information and belief, despite this knowledge, Reddy has not altered its conduct to avoid infringement.

15. On information and belief, Reddy has submitted all information to the FDA necessary to obtain marketing approval for its ANDA and NDA Products. On information and belief, marketing approvals for Reddy's ANDA and NDA Products are imminent, subject only to statutory stays arising from the pendency of related patent litigation against Reddy in this Court. The advanced stage of Reddy's ANDAs and NDA, and its intention to engage in the commercial manufacture, use, offer to sell or sale of its ANDA and NDA Products promptly upon receiving final FDA approval, create an actual case or controversy with respect to infringement of the '011 and '703 patents.

16. Reddy's infringement has been, and continues to be, willful and deliberate.

17. Plaintiffs will be substantially and irreparably damaged and harmed if Reddy'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 Reddy has infringed, and that Reddy's commercial making, using, selling, offering to sell or importing the ANDA and NDA Products will infringe, each of the '011 and '703 patents;

(b) A judgment permanently enjoining Reddy from making, using, selling, offering to sell, or importing fexofenadine hydrochloride or the ANDA and NDA Products until after expiration of each of the '011 and '703 patents;

(c) If Reddy engages in the commercial manufacture, use, offer to sell or sale of its ANDA and NDA Products prior to the expiration of either of the '011 and '703 patents, a judgment awarding plaintiffs damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

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

(e) Costs and expenses in this action; and

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

Dated: March 5, 2004

CONNELL FOLEY LLP

By: Liza M. Walsh (LW4095)

DECOTIIS, FITZPATRICK, COLE & WISLER, LLP

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RULE 11.2 CERTIFICATION

We hereby certify that the matter in controversy is related to the following actions pending before the Honorable Joseph A. Greenaway, Jr., U.S.D.J., captioned *Aventis v. Barr,* No. 01-3627 (JAG)(D.N.J.) (**Consolidated**), *Aventis v. Impax,* No. 02-1322 (JAG)(D.N.J.), *Aventis v. Teva,* No. 03-487 (JAG)(D.N.J.), *Aventis v. Dr. Reddy's,* No. 03-1180 (JAG)(D.N.J.), *Aventis v. Mylan,* No. 03-1179 (JAG)(D.N.J.), *Aventis v. Dr. Reddy's*, No. 03-5108(JAG)(D.N.J.) and *Aventis v. Sandoz, Inc*. 04-222(JAG)(D.N.J.).

Liza M. Walsh

Gregory J. Bevelock

Dated: March 5, 2004

RULE 201.1 CERTIFICATION

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

Dated: March 5, 2004

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By: Liza M. Walsh (LW4095)

Attorneys for Plaintiff
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