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

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| AVENTIS PHARMACEUTICALS INC. and AMR TECHNOLOGY, INC.,<br><br>Plaintiffs,<br><br>v.<br><br>MYLAN PHARMACEUTICALS, INC., AMINO CHEMICALS LTD., and DIPHARMA S.P.A., and DIPHARMA FRANCIS, Sr.l.,<br><br>Defendants. | Civil Action No. 04-1077 (JAG)<br><br>**THIRD AMENDED AND SUPPLEMENTAL COMPLAINT** |

Plaintiffs Aventis Pharmaceuticals Inc. ("Aventis") and AMR Technology, Inc. ("AMR"), by their attorneys, for their Third Amended and Supplemental Complaint against Mylan Pharmaceuticals, Inc. ("Mylan"), Amino Chemicals Ltd. ("Amino"), and DiPharma S.P.A. and DiPharma Francis Sr.l. (collectively "DiPharma") 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 Mylan has sought marketing approval from the U.S. Food and Drug Administration ("FDA") and which Mylan 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. On information and belief, Mylan is a corporation organized and existing under the laws of West Virginia, and has its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26504.

5. On information and belief, Amino is a corporation organized and existing under the laws of Malta, having its principal place of business at A 61, Industrial Estate, Marsa, LQA 06, Malta and having an office and agent at c/o Gyma Laboratories of America, Inc., 135 Cantiague Rock Road, Westbury, New York 11590.

6. On information and belief, Amino is a wholly-owned subsidiary of Dibulux, which is a wholly-owned subsidiary of DiPharma.

7. On information and belief, DiPharma S.P.A. is a corporation organized and existing under the laws of Italy, having its principal place of business at Via XXIV Maggio 40, Mereto Di Tomba, UD 33036 Italy.

8. On information and belief, DiPharma Francis Sr.l. is a subsidiary of DiPharma S.P.A. and is a corporation organized and existing under the laws of Italy, having its principal place of business at Via Bissone 5, 20021 Baranzate di Bollate, Milan Italy.

**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 Mylan by virtue of, *inter alia*, Mylan's continuous and systematic contacts with New Jersey, its sale of prescription drugs in New Jersey, its registration of prescription drug products in the *New Jersey Generic Formulary* of the New Jersey Department of Health and Senior Services, its consent to being sued in New Jersey, as evidenced by its registration to do business in New Jersey and its appointment of a registered agent in New Jersey, and its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in New Jersey.

11. This Court has personal jurisdiction over Amino by virtue of, *inter alia*, its continuous and systematic contacts with New Jersey and its contacts with New Jersey relating to the subject matter of this action.

12. This Court has personal jurisdiction over DiPharma by virtue of, *inter alia*, its continuous and systematic contacts with New Jersey relating to the subject matter of this action, including the submission of evidence to the Court in this proceeding, its designation in submissions to the FDA as an alternative site for fexofenadine production under Amino's Drug Master File ("DMF"), and its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in New Jersey..

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

**The Patents**

14. 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.

15. 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**

16. Mylan has submitted Abbreviated New Drug Applications ("ANDA") 76-538 and 77-081 to the FDA under Section 505(j)(1) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)(1)), seeking approval to engage in the commercial manufacture, use and sale of tablets containing 60 mg fexofenadine hydrochloride and 120 mg pseudoephedrine hydrochloride and tablets containing 180 mg of fexofenadine hydrochloride (collectively "ANDA Tablets").

17. On information and belief, the fexofenadine hydrochloride contained in Mylan's ANDA Tablets is manufactured by Amino and DiPharma. Amino and DiPharma manufacture

the product with knowledge and intent that it will be imported into the United States. On information and belief, Amino and DiPharma direct and control such importation.

18. On information and belief, Defendants intend to engage in the commercial manufacture, use and sale of the fexofenadine hydrochloride drug substance and the ANDA Tablets promptly upon receiving FDA approval to do so.

19. The '011 and '703 patents claim fexofenadine intermediates and processes for making fexofenadine. On information and belief, Defendants Mylan, Amino and DiPharma's commercial manufacture, importation, use or sale of the fexofenadine hydrochloride drug substance, and Mylan's commercial manufacture, importation, use or sale of its Fexofenadine/Pseudoephedrine ANDA Tablets, will infringe one or more claims of the '011 and '703 patents under 35 U.S.C. §271(a) and (g).

20. Plaintiffs notified Defendants that their manufacture, importation, use or sale of their fexofenadine products may infringe the '011 and '703 patents. On information and belief, despite this knowledge, Defendants have not altered their conduct to avoid infringement.

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

22. Defendants' infringement has been, and continues to be, willful and deliberate.

23. Plaintiffs will be substantially and irreparably damaged and harmed if Defendants' 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 Defendants' commercial manufacture, importation, use or sale of the fexofenadine hydrochloride drug substance, and Mylan's commercial manufacture, importation, use or sale of its Fexofenadine/Pseudoephedrine ANDA Tablets, will infringe each of the '011 and '703 patents;

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

(c) If Defendants engage in the commercial manufacture, use, offer to sell or sale of the fexofenadine hydrochloride or Mylan's ANDA Tablets 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: April 25, 2006

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