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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. TEVA PHARMACEUTICALS USA INC. and AMINO CHEMICALS LTD., DIPHARMA S.P.A., and DIPHARMA FRANCIS, Sr.l., Defendants.	Civil Action No. 04-1078 (JAG) **SECOND AMENDED AND SUPPLEMENTAL COMPLAINT**

Plaintiffs Aventis Pharmaceuticals Inc. ("Aventis") and AMR Technology, Inc. ("AMR"), by their attorneys, for their Second Amended and Supplemental Complaint against Teva Pharmaceuticals USA Inc. ("Teva"), 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 a generic version of Aventis's ALLEGRA® drug product for which Teva has obtained marketing approval

from the U.S. Food and Drug Administration ("FDA") and which Teva is marketing in the United States. This action also relates to generic versions of Aventis' ALLEGRA® drug product for which Barr Laboratories, Inc. ("Barr") has obtained approval from the FDA and which Barr has marketed in the United States after being induced to engage in such marketing by Teva. Aventis and AMR assert that Defendants' conduct constitutes infringement and induced infringement under 35 U.S.C. § 271 of one or more of the claims in patents assigned to AMR and licensed to Aventis.

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, Teva is a corporation organized and existing under the laws of Delaware, has its principal place of business at 650 Cathill Road, Sellersville, Pennsylvania, and has regular and established places of business at 92 Route 46 East, Elmwood Park, New Jersey 07407 and at 8-10 Gloria Lane, Fairfield, New Jersey 07004, and is registered to do business in New Jersey.

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 Teva by virtue of, *inter alia*, Teva'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, its regular and established places of business at 92 Route 46 East, Elmwood Park, New Jersey and at 8-10 Gloria Lane, Fairfield, 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. Teva submitted Abbreviated New Drug Application ("ANDA") 76-447 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 30 mg, 60 mg and 180 mg fexofenadine hydrochloride tablets ("Teva's Fexofenadine Products"). Teva has received approval from the FDA to market Teva's Fexofenadine Products and Teva intends to and has sold certain of Teva's Fexofenadine Products in the United States.

17. On information and belief, the fexofenadine hydrochloride drug substance contained in Teva's Fexofenadine Products has been manufactured by Amino and DiPharma with knowledge and intent that it will be imported into the United States.

18. Barr submitted ANDAs 76-169, 76-191 and 76-236 to the FDA under Section 505(j)(1) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)(l)), seeking approval to engage in the commercial manufacture, use and sale of 60 mg fexofenadine hydrochloride capsules, 30 mg, 60 mg and 180 mg fexofenadine hydrochloride tablets, and 60 mg fexofenadine hydrochloride/120 mg pseudoephedrine hydrochloride tablets (collectively, "Barr's Fexofenadine Products"). Barr has received approval from the FDA to market certain of Barr's Fexofenadine Products.

19. On information and belief, the fexofenadine hydrochloride drug substance contained in Barr's Fexofenadine Products has been manufactured by Ranbaxy Laboratories Ltd. and Ranbaxy Pharmaceuticals Inc. (collectively "Ranbaxy"). Ranbaxy manufactured the products with knowledge and intent that they would be imported into the United States. On information and belief, Ranbaxy directed and controlled such importation.

20. On or about September 6, 2005, Barr and Teva entered into an agreement whereby Barr transferred its 180-day exclusivity period under 21 U.S.C. § 355 to Teva after Barr

triggered that exclusivity period through a commercial sale or sales of certain of Barr's Fexofenadine Products.

21. After Barr's transfer of the 180-day exclusivity period to Teva, Teva has engaged in the use or sale of certain of Teva's Fexofenadine Products in the United States.

22. The '011 and '703 patents claim fexofenadine intermediates and processes for making fexofenadine. Defendants' conduct has infringed those patents.

23. Defendants had notice of the '011 Patent and the '703 Patent at the time of their infringement.

24. Plaintiffs notified Defendants that their manufacture, importation, use or sale of the fexofenadine hydrochloride drug substance and Teva's 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.

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

26. Plaintiffs have been substantially and irreparably damaged and harmed by Defendants' infringement. Plaintiffs do not have an adequate remedy at law.

27. Plaintiffs have also suffered damages from Defendants' infringement.

Count I
Declaratory Judgment of Patent Infringement

28. Plaintiffs repeat and reallege the facts of paragraphs 1-27 above.

29. Defendants' sale of the fexofenadine hydrochloride drug substance, Teva's sale of Teva's Fexofenadine Products and Defendants' continuing intention to engage in commercial manufacture, use, sale or offers to sell of the fexofenadine hydrochloride drug substance and Teva's Fexofenadine Product create an actual case or controversy with respect to the

infringement of the '011 and '703 patents.

Count II
Patent Infringement

30. Plaintiffs repeat and reallege the facts of paragraphs 1-27 above.

31. Defendants' commercial manufacture, importation, use or sale of the fexofenadine hydrochloride drug substance, and Teva's use or sale of Teva's Fexofenadine Products has infringed one or more claims of the '011 and '703 patents under 35 U.S.C. §271(a) and (g).

Count III
Inducement of Patent Infringement

32. Plaintiffs repeat and reallege the facts of paragraphs 1-27 above.

33. Teva actively, knowingly and intentionally induced Barr's infringement by inducing Barr to engage in the commercial manufacture, importation, use or sale of certain of Barr's Fexofenadine Products that infringed one or more claims of the '011 and '703 patents, under 35 U.S.C. §271(a), (b) and (g).

34. On information and belief, Barr would not have made commercial sale or sales of certain of Barr's Fexofenadine Products so as to trigger its 180-day exclusivity period but for the agreement with Teva to transfer the exclusivity to Teva.

35. Teva's inducement of Barr to sell infringing products is infringement under 35 U.S.C. §271(b)

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment that Defendants' commercial manufacture, importation, use or sale of the fexofenadine hydrochloride drug substance, and Teva's commercial manufacture,

importation, use or sale of Teva's Fexofenadine Products has infringed and 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 drug substance or Teva's Fexofenadine Products until after expiration of each of the '011 and '703 patents;

(c) A judgment that Teva induced Barr to engage in the commercial manufacture, importation, use, or sale of Barr's Fexofenadine Products resulting in infringement of each of the '011 and '703 patents.

(d) A judgment awarding Plaintiffs damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

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

(f) Costs and expenses in this action; and

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

Dated: April 25, 2006

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