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

ALBANY MOLECULAR RESEARCH, INC.,

Plaintiff,

- v -

SANDOZ, INC. and  
DR. REDDY'S LABORATORIES, LTD.,

Defendants.

Civil Action No.

**COMPLAINT**

Plaintiff Albany Molecular Research, Inc. ("AMRI" or "Plaintiff"), by its attorneys, for its Complaint against Defendants Sandoz, Inc. ("Sandoz") and Dr. Reddy's Laboratories, Ltd. ("Reddy") alleges 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 ALLEGRA<sup>®</sup> and ALLEGRA-D<sup>®</sup> drug products for which Sandoz is seeking or has obtained marketing approval from the U.S. Food and Drug Administration ("FDA") and which Sandoz intends to market in the United States immediately upon either FDA approval or expiration of any statutory or regulatory stays.

**The Parties**

2. AMRI is a corporation organized and existing under the laws of Delaware with a principal place of business at 21 Corporate Circle, Albany, New York 12212.

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

4. Upon information and belief, Reddy 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**

5. 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.

6. This Court has personal jurisdiction over Sandoz by virtue of its continuous and systematic contacts with New Jersey, its contacts with New Jersey relating to the subject matter of this action, and its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in New Jersey.

7. This Court has jurisdiction over Reddy by virtue of its presence in New Jersey, and its continuous and systematic contacts with New Jersey relating to the subject matter of this action, and its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in New Jersey.

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

**The Patent**

9. United States Patent No. 7,390,906 (the "'906 patent") duly and legally issued on June 24, 2008 to inventor Thomas E. D'Ambra. A copy is attached as Exhibit A. The '906 patent was initially assigned to AMR Technology, Inc., a subsidiary of AMRI. AMR Technology, Inc. subsequently assigned the '906 patent to AMRI. AMRI is now the owner of the '906 patent.

**Acts Giving Rise to this Action**

10. On information and belief, Sandoz has submitted Abbreviated New Drug Applications ("ANDAs") 76-707 and 77-999, pursuant to Section 505(j)(1) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)(1)), seeking approval to market 30 mg, 60 mg and 180 mg fexofenadine hydrochloride tablets, and 60 mg fexofenadine hydrochloride/120 mg pseudoephedrine hydrochloride tablets (collectively the "ANDA Products").

11. The '906 patent claims, among other things, a process for making fexofenadine hydrochloride using a cyclopropyl ketone intermediate ("CPK intermediate").

12. On information and belief, Reddy is the approved supplier for fexofenadine hydrochloride active pharmaceutical ingredient ("API") to Sandoz for its ANDA Products. The API manufactured by Reddy was made by a process using a CPK intermediate within the scope of claims of the '906 patent.

13. Reddy manufactures the infringing API with knowledge and intent that it will be imported into the United States. On information and belief, Reddy directs and controls such importation.

14. On information and belief, Sandoz intends to engage in commercial manufacture and sale of the ANDA Products, which contain the infringing API, immediately upon receiving FDA approval to do so.

15. On information and belief, Sandoz's commercial manufacture, importation, use or sale of its ANDA Products, which contain the infringing API, will infringe one or more claims of the '906 patent under 35 U.S.C. §271(a) and (g).

16. On information and belief, Sandoz has submitted all information to the FDA necessary to obtain marketing approval for its ANDA Products. On information and belief marketing approval for Sandoz's ANDA Products is imminent, subject only to statutory or regulatory stays. The advanced stage of Sandoz's ANDAs, and its intention to engage in the commercial manufacture, use, offer to sell or sale of its ANDA Products promptly upon receiving FDA approval, create an actual case or controversy with respect to infringement of the '906 patent.

17. Sandoz's infringement has been, and continues to be, willful and deliberate.

18. Plaintiff will be substantially and irreparably damaged and harmed if Sandoz's infringement is not enjoined. Plaintiff does not have an adequate remedy at law.

**WHEREFORE**, Plaintiff respectfully requests the following relief:

(a) A judgment declaring that Defendants' commercial manufacture, importation, use or sale of the infringing API, and Sandoz's commercial manufacture, importation, use or sale of its ANDA Products, infringes the '906 patent;

(b) A judgment permanently enjoining Defendants from making, using, selling, offering to sell, or importing the infringing API or the ANDA Products until after the expiration of the '906 patent;

(c) If Defendants engage in the commercial manufacture, use, offer to sell or sale of the infringing API or Sandoz's ANDA Products prior to the expiration of the '906 patent,

a judgment awarding Plaintiff 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: September 9, 2009

DECOTIIS, FITZPATRICK, COLE &  
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