



Kancheepuram District, Tamil Nadu, India. Upon information and belief, defendant is registered to do business in New Jersey and has appointed Corporation Services Company of West Trenton, New Jersey as its registered agent in New Jersey for the receipt of service of process.

**JURISDICTION AND VENUE**

3. This action arises under the Patent Laws of the United States, Title 35, United States Code and the Food and Drug Laws of the United States, Title 21, United States Code. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

4. Venue is proper in this judicial district under 28 U.S.C. § 1391(c).

**CLAIM FOR PATENT INFRINGEMENT**

5. On March 4, 1997, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 5,607,697 entitled, "Taste Masking Particles For Oral Dosage Forms" ("the '697 Patent").

6. CIMA is the owner of the entire right, title, and interest in and to the '697 Patent.

7. Pursuant to an exclusive license granted by CIMA, Schering Corporation ("Schering") markets a drug product including the active ingredient desloratadine covered by the '697 Patent.

8. Schering has approval from the United States Food and Drug Administration ("FDA") to market desloratadine orally disintegrating tablets in 2.5 mg and 5 mg dosages under the brand name CLARINEX® RediTabs®.

9. CLARINEX® RediTabs® is indicated in the FDA's list of "Approved Drug Products With Therapeutic Equivalents Evaluations," also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's Abbreviated New Drug

Application ("ANDA") to obtain approval of the ANDA applicant's drug product from the provisions of 21 U.S.C. § 355(j).

10. The FDA's "Orange Book" also lists patents associated with approved drugs. The '697 Patent is one of the patents listed in the "Orange Book" in association with CLARINEX® RediTabs® (desloratadine orally disintegrating tablets).

11. Upon information and belief, Orchid submitted ANDA No. 78-356 to the FDA, under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), in order to obtain approval to engage in the commercial manufacture, use, or sale of desloratadine orally disintegrating tablets, 2.5 mg and 5 mg, a generic version of CLARINEX® RediTabs®, before the expiration date of the '697 Patent.

12. On or about August 25, 2006, Orchid sent a notice of certification to CIMA and Schering pursuant to 21 U.S.C. § 355(j)(2)(B), for the purpose of meeting requirements allowing it to file an ANDA as prescribed by that statute, stating that Orchid had filed an ANDA designated as 78-356, requesting FDA approval to market a generic version of CLARINEX® RediTabs® desloratadine orally disintegrating tablets in 2.5 mg and 5 mg dosages before the expiration of the '697 Patent.

13. Orchid alleged in the Notice of Certification that the claims of the '697 Patent are not valid and/or not infringed by its proposed desloratadine products.

14. The submission of an application under 21 U.S.C. § 355(j) for a drug claimed in a patent or for the drug use claimed in a patent is an act of infringement pursuant to 35 U.S.C. § 271(e)(2) if the applicant seeks FDA marketing approval effective prior to the expiration of the patent. Orchid's submission of an ANDA for approval to sell desloratadine orally disintegrating

tablets in 2.5 mg and 5 mg dosages prior to the expiration of the '697 Patent constitutes an act of infringement.

15. Upon information and belief, after a reasonable opportunity for further investigation or discovery, the evidence will likely show that the proposed desloratadine products offered by Orchid will, if approved and marketed, infringe the '697 Patent.

16. Upon information and belief, Orchid is aware that the proposed desloratadine products, if approved, will be made, used, and/or sold in contravention of CIMA's rights in and to the '697 Patent, thus rendering this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, CIMA prays for the following relief:

A. A judgment that the '697 Patent remains valid and enforceable, and is infringed under 35 U.S.C. § 271(e)(2) by Orchid's filing of its ANDA No. 78-356;

B. An Order that the effective date of the approval of ANDA No. 78-356 be subsequent to the latest expiration date of the '697 Patent;

C. An injunction prohibiting defendant from commercially manufacturing, selling, using, or importing desloratadine orally disintegrating tablets in 2.5 mg and 5 mg dosages, or otherwise infringing one or more claims of the '697 Patent;

D. Damages and/or other monetary relief, pursuant to 35 U.S.C. § 284, for any commercial manufacture, use, or sale of desloratadine orally disintegrating tablets falling within the scope of one or more claims of the '697 Patent by defendant prior to the expiration of the '697 Patent;

E. An award of CIMA's interests, costs, and reasonable attorney fees incurred in prosecuting this action; and

F. Such other and further relief as this Court may deem just and proper.

LERNER, DAVID, LITTENBERG,  
KRUMHOLZ & MENTLIK, LLP  
*Attorneys for Plaintiff CIMA LABS INC.*

Dated: October 18, 2006

By: s/ Paul H. Kochanski  
Paul H. Kochanski