

# EXHIBIT 7

DT05 Rec'd PCT/PTO 14 DEC 2004

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application

Amar LULLA et al.

Serial No.: To be assigned (National Stage of PCT/GB03/02557 filed June 13, 2003)

Filed: December 14, 2004

For: COMBINATION OF AZELASTINE AND STEROIDS

**PRELIMINARY AMENDMENT**

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Prior to the calculation of the filing fee, please amend the above-identified application as

follows:

IN THE SPECIFICATION

Please add the following paragraph on a new line after the title:

This application is a §371 National Stage Application of International Application No. PCT/GB03/02557, filed on 13 June 2003, claiming the priority of Great Britain Patent Application No. 0213739.6 filed on 14 June 2002, the entire disclosures of which are herein incorporated by reference in their entirety.

IN THE ABSTRACT

After the last page of claims, insert on a new page the Abstract shown on the attached sheet (ATTACHMENT I).

IN THE CLAIMS

Please cancel claim 43.

1. (Currently Amended) A pharmaceutical formulation which comprises azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and a steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, ~~preferably the formulation being in a form suitable for nasal or ocular administration.~~

2. (Original) A pharmaceutical formulation according to claim 1, wherein said azelastine is present as azelastine hydrochloride.

3. (Currently Amended) A formulation according to claim 1 ~~or 2~~, wherein the steroid is beclomethasone or a pharmaceutically acceptable ester thereof, mometasone or a pharmaceutically acceptable ester thereof, fluticasone or a pharmaceutically acceptable ester thereof, budesonide or cyclofenide, in any chiral form or mixture.

4. (Original) A formulation according to claim 3, wherein the steroid is beclomethasone propionate, mometasone furoate, mometasone furoate monohydrate, fluticasone propionate or fluticasone valerate.

5. (Currently Amended) A formulation according to claim 1 ~~any of claims 1 to 4~~, which contains the steroid in an amount from about 50 micrograms/ml to about 5 mg/ml of the formulation.

6. (Currently Amended) A formulation according to claim 1 ~~any of claims 1 to 5~~, wherein the formulation has a particle size of less than about 10  $\mu\text{m}$ , ~~preferably less than 5  $\mu\text{m}$ .~~

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