

EXHIBIT A

Asserted Patents Directed to Pharmaceutical Formulations Useful to Prevent or Minimize



(12) **United States Patent**
Lulla et al.

(10) **Patent No.:** US 8,163,723 B2
(45) **Date of Patent:** Apr. 24, 2012

(54) **COMBINATION OF AZELASTINE AND STEROIDS**

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(73) **Assignee:**CIPLA Limited, Mumbai (IN)

(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 77 days.

(21) **App. No.:** 12/879,515

(22) **Filed:** Sep. 18, 2010

(65) **Prior Publication Data**
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Related U.S. Application Data
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(30) **Foreign Application Priority Data**
Jun. 14, 2002 (IN) 0211739.6

(51) **Int. Cl.**
A61K 31/55 (2006.01)

(52) **U.S. Cl.** B14971

(58) **Field of Classification Search** *None*
See application file for complete search history.

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The present invention relates to and formulations. More particularly, but not exclusively, the present invention relates to pharmaceutical products and formulations for preventing or minimizing allergic reactions. In particular, but not exclusively, the present invention relates to pharmaceutical products and formulations for preventing or minimizing allergic reactions. In particular, but not exclusively, the present invention relates to pharmaceutical products and formulations for preventing or minimizing allergic reactions. In particular, but not exclusively, the present invention relates to pharmaceutical products and formulations for preventing or minimizing allergic reactions.

Such allergic reactions commonly occur in response to allergen-related and vasomotor-related symptoms. Such allergic reactions commonly occur in response to allergen-related and vasomotor-related symptoms.

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Office Action
(2/19/00, 8/1/00)
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(57)
A pharmaceutical product or formulation, which comprises azelastine or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and a steroid or physiologically functional derivative thereof, and a steroid or physiologically functional derivative thereof, and a steroid or physiologically functional derivative thereof, preferably the product or formulation being in a form suitable for nasal or ocular administration.
28 Claims, No Drawings

EXHIBIT B

Allergic Rhinitis Impacts Patients



Prevalence of AR

16.9 million adults diagnosed with AR in 2011

- Affects 2 of every 10 adults
- Affects 4 of every 10 children

Impact on quality of life

AR results in an estimated 3.8 million missed days of school

- Causes significant sleep impairment, associated with psychiatric issues
- In children: Symptoms of AR impair cognitive processing and ability to concentrate in school
- In adults: Symptoms decrease workplace productivity, increase absenteeism, reduction in productivity and increased healthcare costs

References:

- American College of Asthma, Allergy and Immunology.
- Bloom B et al. Vital Health

EXHIBIT C

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