

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC
Petitioner

v.

CIPLA LTD.
Patent Owner

Patent No. 8,168,620
Issue Date: May 1, 2012
Title: COMBINATION OF AZELASTINE AND STEROIDS

Inter Partes Review No.: IPR2017-00807

DECLARATION OF ROBERT P. SCHLEIMER, Ph.D.

Exhibit 1002

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 E. Claim Limitation 25.1: “A nasal spray formulation comprising” 14

 F. Claim Limitation 25.2: “(i) azelastine, or a pharmaceutically acceptable salt thereof,” 15

 G. Claim Limitation 25.3: “(iii) a pharmaceutically acceptable ester of fluticasone,” 15

 H. Claim Limitation 25.4: “and (iii) a pharmaceutically acceptable carrier or excipient therefor.” 15

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 A. The cited references disclose all of the claim elements 18

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I, Robert Schleimer, do declare as follows:

I. Introduction

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.

2. I have been retained as an expert witness on behalf of Argentum Pharmaceuticals LLC for a *inter partes* review of U.S. Patent No. 8,168,620 (Ex. 1001). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$400 per hour for any consulting and \$600 per hour for any deposition appearances. I understand that my declaration accompanies a petition for *inter partes* review involving the above-mentioned U.S. Patent.

II. My Background And Qualifications

3. My area of expertise is in the field of allergy and immunology. At Northwestern University's Feinberg School of Medicine, I am presently the Chief of the Division of Allergy-Immunology in the Department of Medicine, the Roy and Elaine Patterson Professor of Medicine, and a Professor of Medicine in the Division of Allergy-Immunology. I am also a Professor in the Departments of Microbiology-Immunology and Otolaryngology - Head and Neck Surgery. My research areas include the mechanisms of pathogenesis and treatment of a variety

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of allergic and inflammatory diseases associated with allergy, including chronic rhinosinusitis, asthma, hay fever, rhinitis, food allergy and others. I also study the mechanisms of action of anti-inflammatory glucocorticoids, with a focus on the molecular and cellular mechanisms underlying disease and steroid action as well as developing strategies for new treatments.

4. I obtained a Bachelor of Arts in Biology from the University of California, San Diego in 1974 and a Ph.D. from the University of California, Davis in Pharmacology, Toxicology, and Immunology in 1979.

5. Additionally, I have been a named author on over 300 scientific papers, served as an editor or on the editorial board of ten different journals, and I have trained a large number of graduate and undergraduate students as well as postdoctoral fellows. I am currently on the Editorial Boards of the American Journal of Respiratory Cell and Molecular Biology, the Journal of Allergy, and Allergology International.

6. My *curriculum vitae* is attached as Ex. 1051 to this document.

7. In view of my experiences and expertise outlined above and provided in my *curriculum vitae*, I am an expert in the field of allergy and immunology.

III. List Of Documents Considered In Formulating My Opinion

8. In formulating my opinion, I considered the following documents:

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