

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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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

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*Inter Partes* Review No. IPR2017-00807

**PETITIONER REPLY TO PATENT OWNER RESPONSE**

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## I. INTRODUCTION

The prior art teachings in this case are remarkably clear. The two drugs required by the claims, azelastine and fluticasone, were already commercialized nasal sprays as of the filing date, with doctors regularly prescribing the two together to treat severe AR. The Segal reference provides clear motivational teachings for combining these two drugs into a single spray—which would have satisfied even the more rigid TSM test pre-*KSR*. Nor does the '620 Patent describe any critical formulation requirements, using only well-known excipients in standard concentrations to arrive at the claimed formulation, thus disproving any litigation-inspired allegations regarding reasonable expectation of success.

Hemmed in by these indisputable prior art teachings, Cipla offers selective-but-misleading excerpts from the record to create an impression of uncertainty in the art, and a superficial appearance of secondary considerations. None of Cipla's arguments withstand scrutiny, nor do they overcome the overwhelming obviousness of the challenged claims. *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1484 (Fed. Cir. 1997) (finding “combination” drug obvious over secondary considerations).

## II. CLAIM CONSTRUCTION

Cipla advances a claim construction of “pharmaceutical formulations that are tolerable to patients, that are homogeneous, and that be suitably deposited onto

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