UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC

Petitioner

v.

CIPLA LIMITED

Patent Owner

Case No. IPR2017-00807

U.S. Patent No. 8,168,620

PATENT OWNER RESPONSE

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U.S. Patent and Trademark Office
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I. INTRODUCTION

The challenged claims cover a combination nasal spray formulation with two active ingredients: azelastine hydrochloride ("azelastine") and fluticasone propionate ("fluticasone"). Cipla's successful combination formulation of these two ingredients was a breakthrough: the world's first combination of an intranasal antihistamine (azelastine) with an intranasal corticosteroid (fluticasone). Indeed, Cipla's invention was the first time ***any*** of the myriad available allergic rhinitis ("AR") treatments were ever combined into a nasal spray formulation, by ***anyone***, ***anywhere***. As a result, Dymista®, the U.S. commercial embodiment of Cipla's invention remains, more than fifteen years later, the only fixed-dose nasal spray combination approved by the Food and Drug Administration ("FDA") for the treatment of AR. Faced with the groundbreaking nature of Cipla's invention, Petitioner resorts to hindsight, relying either on art that was already considered—and overcome—during prosecution to build its case, or art that contradicts Petitioner's obviousness theories.

Petitioner has failed to prove that Hettche, Phillipps, and Segal render claims 1, 4-6, 24-26, and 29 obviousness. First, Petitioner's evidence falls far short of demonstrating that a person of ordinary skill in the art ("POSA") would have been motivated by the prior art to select azelastine, or to combine azelastine and fluticasone into a combination formulation. Instead, Petitioner and its clinical

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