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

SECOND DECLARATION OF ROBERT P. SCHLEIMER, Ph.D.

Exhibit 1144

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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. Background and Qualifications

3. My background and qualifications remain essentially unchanged from my first declaration, EX1003. My most recent *curriculum vitae* is concurrently submitted with this document as EX1163.

III. Basis for My Opinions

4. In formulating my opinion, I reviewed Dr. Carr's Second Declaration (CIP2147), his deposition transcript (EX1142), and relied on the documents cited herein.

IV. Summary of My Opinions

5. It remains my opinion that claims 1, 5-6, 24-26 and 29[1] would have been obvious to a person of ordinary skill in the art (POSA) in view of the combined teachings of Segal, Hettche and Phillipps for the reasons I gave in my first declaration (EX1003) and the additional reasons I give herein. Segal, as well as Cramer expressly suggested a single nasal spray containing the active ingredients of Dymista®, azelastine hydrochloride ("azelastine") and fluticasone propionate ("fluticasone"). The clinical art also establishes the use of these drugs together for the treatment of allergic rhinitis. However, it did not mandate the inflexible approach of only treatment by the individual monotherapies. The complementarity of antihistamine/steroid pairing and particularly of azelastine/fluticasone, the anti-inflammatory properties of azelastine when topically applied, and the expected convenience and compliance would also have prompted a POSA to develop a single nasal spray containing these ingredients.

[1] Dr. Carr's contention that I agree with him that claims 4 and 42-44 are non-obvious because I did not discuss their obviousness is presumptuous. Counsel did not ask me to consider these claims because it asked a formulation expert to weigh in on them. To be clear, I consider the combination of azelastine and fluticasone in a formulation suitable for nasal administration to be obvious for claims 4 and 42-44 for the same reasons as all the claims discussed herein.

V. Person of Ordinary Skill in the Art and Obviousness

6. I stand by my previous testimony regarding the POSA described in my first Declaration. EX1003 ¶¶11-12. Dr. Carr suggests that "knowledge of and experience in treatment is more relevant in the context of the '620 patent than laboratory experiments." CIP2147 ¶19. I agree that clinical knowledge is relevant to a POSA in the present context. I disagree to the extent he suggests that knowledge of the cellular basis of allergic rhinitis (AR) is somehow less relevant to the development and use of pharmaceuticals to treat this condition.

VI. The early and late phase reactions of AR were well known and clinically relevant prior to June 14, 2002

7. Dr. Carr's assertion that "several laboratory concepts" upon which I rely "were tested in vivo and were found not to affect patients" (*Id.* ¶19) is wrong and a mischaracterization of the state of the art prior to June 14, 2002. The early phase reaction (EPR) and late phase reaction (LPR) are not merely laboratory concepts as Dr. Carr would have it, but are established phases of AR (AR) that can in fact be clinically distinguished. EX1041, 455; EX1035, 341; EX1003 ¶¶27-28. For example, if a person with seasonal allergies to ragweed steps outdoors in the morning on the first day of ragweed season, that person can experience immediate sneezing and runny nose (the EPR), while later that evening can experience complete nasal blockage and inability to sleep due to her symptoms (LPR).

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