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

DECLARATION OF ALEXANDER DOMINIC D'ADDIO, Ph.D.

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I, Alexander Dominic D'Addio, declare that:

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

I. Introduction

2. In connection with this *inter partes* review proceeding, I have been asked by Cipla Ltd. ("Cipla") to explain the pharmaceutical development of Dymista®, Meda Pharmaceutical Inc.'s ("Meda") azelastine-fluticasone combination nasal spray. During the course of Dymista®'s development, Meda and its predecessor MedPointe Pharmaceuticals[1] failed to formulate and develop a nasal spray containing a single formulation of azelastine and fluticasone, and subsequently licensed the application that became U.S. Patent No. 8,168,620 ("the '620 patent") from Cipla Ltd.

3. I am being compensated for my time in connection with this *inter partes* review matter at a rate of $400 per hour, and my compensation does not depend upon the ultimate outcome of this case. I will also be compensated for any reasonable expenses, including travel costs.

4. This declaration is based on my own personal knowledge of Meda's research and development of the allergy treatment Dymista®.

5. For this declaration, I rely on the following documents:

Cipla's Exhibit #[2]	***Description***
2004	Alexander Dominic D'Addio, Ph.D. *Curriculum Vitae*

[1]In 2007, Meda acquired MedPointe Pharmaceuticals. I will refer to both companies as "Meda."

[2] Throughout this declaration, I will refer to these exhibits as "[Exhibit Number], [paragraph/page number(s)]."

2049	2006 Cipla-Meda License Agreement with Quality Agreement (PTX1016)
2054	MedPointe Making Medicine Better: Astelin® Day Life CyclePlan, November 1, 2002 (PTX1005)
2055	MedPointe Product & Process Development Program Priorities and Issues - September 9, 2002 (PTX0143)
2056	Astelin Nasal Spray Life Cycle Management Projects (Preliminary Plan) (PTX1006)
2057	2006.02.06 Email from Paul Edick to Dennis Fuge re: Pfeiffer Bi Dose Nasal Spray System (PTX0149)
2058	2006.03.21 Email and attachment from Kalidas Kale to Alex D'Addio re: Astelin – Flonase Combination Product Feasibility Assessment Plan (PTX0151)
2059	Dang, Phuong Grace, *et al.* U.S. Patent No. 8,071,073 (Filed November 22, 2005; Issued December 6, 2011)
2060	Dang, Phuong Grace, *et al.* U.S. Patent No. 8,518,919 (Filed November 10, 2011; Issued August 27, 2013)
2061	MedPointe Laboratory Notebook No. 1044 - Excerpts (PTX0142)
2120	MedPointe Product & Process Development, Program Priorities and Issues - November 18, 2002, "Commercial Product Technical Support" (PTX0144)
2121	2006.02.06 Email from Richard Spivey to Alex D'Addio re: Pfeiffer Bi Dose Nasal Spray System (PTX0150)
2122	2003.11.11 Email and attachment from Mary Lehr to Gul Balwani (PTX0255)

II. Background – Education, Expertise and Responsibility

6. I obtained my bachelor's degree in chemistry from Kean University in 1975. In 1983, I received my Ph.D. in analytical chemistry from Seton Hall University.

7. For 26 years, I was involved in the research and development of allergy-related products for Meda and its predecessors, MedPointe Pharmaceuticals and Carter-Wallace. Until February 2017, I was the Vice President of Scientific Affairs and Medical Communications at

Meda. I first joined Carter-Wallace as a laboratory supervisor in 1990. At Carter-Wallace, I was promoted to department head in 1993 and eventually became a director in 1997. After MedPointe Pharmaceuticals acquired the Wallace Laboratories division of Carter-Wallace in 2001, I was appointed Vice President of Product and Process Development, a position that I held until 2010. In that position, I supervised the research and development of new drug products for MedPointe and for Meda after its 2007 acquisition of MedPointe.

8. I was involved in the research and development of Meda's azelastine hydrochloride nasal sprays, Astelin® and Astepro®. In October 2002, Meda began to investigate an azelastine and steroid nasal spray combination project under my direction. I was involved in all aspects of research, clinical development, Food and Drug Administration ("FDA") approval, launch, and post-approval support of the product that eventually became Dymista®. My duties included overseeing the scientific effort to determine the feasibility of developing a combination nasal spray.

9. As Vice President of Product and Process Development, I oversaw Meda's Product & Process Development (PPD) group. From within the PPD group, the Formulation Development (FD) group was responsible for the research and development of potential new drugs, as well as the support of current drug products in Meda's portfolio. The FD group included Dr. Kalidas Kale, Mr. Gul Balwani, and Mr. John D'Aconti, among others. In 2002, Mr. Gul Balwani was appointed lead formulator of the group. My CV appears at CIP2004.

III. Product Journey

10. Throughout the 1990s, Meda was working to develop an azelastine hydrochloride ("azelastine") nasal spray formulation for the treatment of symptoms of allergic rhinitis. During that time, Meda had significant experience with formulating azelastine. In fact, by 2002 Meda

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