

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

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

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U.S. Patent and Trademark Office
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Alexandria, VA 22313-1450

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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 Pharmaceuticals¹ 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:

¹In 2007, Meda acquired MedPointe Pharmaceuticals. I will refer to both companies as “Meda.”

*Inter Partes Review of U.S. Patent No. 8,168,620
Second Declaration of Alexander Dominic D’Addio, Ph.D.(Exhibit 2148)*

<i>Cipla’s Exhibit #²</i>	<i>Description</i>
2004	Alexander Dominic D’Addio, Ph.D. <i>Curriculum Vitae</i>
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, <i>et al.</i> U.S. Patent No. 8,071,073 (Filed November 22, 2005; Issued December 6, 2011)
2060	Dang, Phuong Grace, <i>et al.</i> 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)

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

2122	2003.11.11 Email and attachment from Mary Lehr to Gul Balwani (PTX0255)
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Exhibit CIP2061 is a laboratory notebook that contains the observations of the laboratory technicians as they conducted their testing and experimentation. As the Vice President of Product and Process Development, I was ultimately responsible for ensuring Meda had policies and procedures in place with respect to recording information in our laboratory notebooks, and that our policies and procedures were complied with. It was our policy for the technicians to record information, data, or observations at or as near as possible to the time an event occurred. Also, it was the regular practice of Meda to record information, data, or observations relating to Meda's research and development work in laboratory notebooks. Laboratory notebooks like CIP2061 were kept in the ordinary course of Meda's regularly conducted research and development activities of drug products.

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

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