## 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 HUGH DAVID CHARLES SMYTH, PH.D.

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VIII.	Segal does not enable the azelastine/fluticasone combination formulations of claims 1 and 25			
IX.	azelas	June 2002, a POSA would have been led away from combining stine and fluticasone into a fixed-dose combination formulation, and a A would not have had a reasonable expectation of success		
	A.	A POSA would not have been motivated to combine azelastine and fluticasone into a fixed-dose combination because of the difficulties in doing so and the lack of guidance in the prior art		
	В.	The prior art taught that fluticasone would aggregate when co- formulated with another active ingredient, which would have led a POSA away from combining azelastine and fluticasone into a fixed- dose combination formulation and would have undercut any reasonable expectation of success		
	C.	Cramer's Example III would have been led away from combining azelastine and fluticasone into a fixed-dose combination, and would have undercut any reasonable expectation of success		
i.		Dr. Govindarajan's and Dr. Herpin's testing confirms Ms. Malhotra's		
fi	ndings			
ii. E		Routine experimentation would not remedy the shortcomings of e III		
Х.	As of June 2002, a POSA would have been led away from using the excipients recited in claims 42-44 in an azelastine/fluticasone combination formulation, and would not have had a reasonable expectation of success31			
	А.	The prior art would have led a POSA away from using the thickening agents "microcrystalline cellulose and sodium carboxymethyl cellulose" as recited in claims 42-44		

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### Inter Partes Review of U.S. Patent No. 8,168,620 Declaration of Hugh David Charles Smyth, Ph.D.(Exhibit 2007)

	B.	The prior art would have led a POSA away from employing a three preservative combination of "edetate disodium" / "benzalkonium chloride" / "phenyl ethyl alcohol" as recited in claims 42-44	
	C.	The prior art would not have led a POSA to use "glycerin" as the isotonicity agent as recited in claims 42-44.	36
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I, Hugh Charles David Smyth, do declare as follows:

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

## I. Introduction

2. I have been retained as an expert witness by Cipla Ltd. ("Cipla") in the above *inter partes* review matter concerning U.S. Patent No. 8,168,620 ("the '620 patent") (EX1001) that was filed by Petitioner Argentum Pharmaceuticals LLC ("Argentum"). Counsel has informed me that Argentum has challenged the patentability of claims 1, 4-6, 24-26, 29, and 42-44 (collectively "the challenged claims").

3. I have been asked by Cipla to review Argentum's Petition and the declaration submitted on behalf of Argentum by Dr. Maureen Donovan, and to respond to those documents to the extent that their contents fall within my expertise.

4. I am being compensated for my time in connection with this *inter partes* review matter at a rate of \$600 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 incurred in conducting activities at counsel's request.

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## II. Professional and educational background

5. I am presently an Associate Professor with Tenure (Hamm Endowed Faculty Fellow) in the College of Pharmacy at the University of Texas, Austin. I have held this position since 2011. I am also an Adjunct Associate Scientist at the Lovelace Respiratory Research Institute in Albuquerque, New Mexico, a position I have held since 2009. From 2009 to 2011, I served as an Assistant Professor in the College of Pharmacy at the University of Texas, Austin. From 2005 to 2009, I was an Assistant Professor in the College of Pharmacy at the University of New Mexico. And from 2004 to 2005, I was a Research Assistant Professor in the College of Pharmacy at the University of North Carolina, Chapel Hill.

6. I received a Bachelor of Pharmacy in 1995 from the University of Otago, in Dunedin, New Zealand. In 1997, I earned a Post Graduate Diploma in Pharmacy, with Distinction, from the University of Otago. In 2000, I received my Ph.D. in Pharmaceutical Sciences from the University of Otago. My thesis topic was the "Investigation of Electrically Assisted Drug Delivery in the Percutaneous Delivery of Peptides." From 2001 to 2003, I was a Post-Doctoral Fellow at the School of Pharmacy at the University of North Carolina, Chapel Hill.

7. My current research focuses on the development of novel methods for drug delivery including nasal, inhalation, transdermal, ophthalmic, and oral delivery systems for a variety of diseases.

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