### UNITED STATES PATENT AND TRADEMARK OFFICE

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## BEFORE THE PATENT TRIAL AND APPEAL BOARD

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### ARGENTUM PHARMACEUTICALS LLC

Petitioner

v.

### CIPLA LIMITED

Patent Owner

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Case No. IPR2017-00807

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

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# DECLARATION OF WARNER CARR, M.D.

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	A.	Many of the treatment options available in 2002 had overlapping effects in treating AR.	14			
	B.	A POSA would have known that co-administration of antihistamines and steroids provided no meaningful benefit as compared to steroids alone.	17			
	C.	The treatment recommendations and general practices prior to the date of invention were consistent with the co-administration studies' findings, and would not have encouraged a POSA to pursue a fixed-dose combination	26			
IX.	A POSA would not have been able to envision a combination of azelastine and fluticasone from among the more than 800 million combinations disclosed in Segal					
X.	The art taught away from claims 1, 4-6, 24-26, 29, and 42-44					
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	B.	The art as a whole taught away from fixed-dose combinations that yielded no clinical benefit but exhibited increased side effects.	39			



	C.	in a f	art as a whole taught away from selecting azelastine for use ixed-dose combination with a steroid in order to improve bliance	39		
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XI.	•		ndicia of non-obviousness suggest that the challenged not obvious.	41		
	A.	Dr. S	chleimer was present at the trial in district court	41		
	B.	The patents-in-suit exhibit several significant, unexpected clinical results.				
		1.	From a clinical perspective, the closest prior art comprises the studies and review articles finding no additional benefit from adding an antihistamine to a steroid.	43		
		2.	Dymista® shows an unexpected improvement in efficacy when compared to the closest prior art	45		
		3.	Dymista® exhibits an unexpectedly fast onset of action compared to the closest prior art.	48		
		4.	Dymista <sup>®</sup> has unexpectedly reduced side effects as compared to either azelastine or fluticasone monotherapies.	51		
	C.	Dymista® satisfies a long-felt but unmet need in the treatment of AR.				
		1.	Dymista <sup>®</sup> satisfies the long-felt need for more effective AR treatment.	55		
		2.	Dymista® satisfies the long-felt need for an AR treatment with a faster onset.	55		
		3.	Dymista® satisfies the long-felt need for an AR treatment	57		



Inter Partes Review of U.S. Patent No. 8,168,620 Declaration of Dr. Warner Carr (Exhibit 2001)

D.	Dymista® has been widely praised in the industry as the new gold standard for the treatment of AR	59
E.	Dymista <sup>®</sup> , Duonase, and several Indian copycat products are covered by the challenged claims.	60



I, Warner Carr, do declare as follows:

### I. Introduction

- 1. I am over the age of eighteen (18) and otherwise competent to make this declaration.
- 2. Patent Owner Cipla Ltd. ("Cipla") has retained me as an expert witness in the *inter partes* review matter referenced above concerning U.S. Patent No. 8,168,620 ("the '620 patent") (EX1001). I understand that this petition for *inter partes* review was filed by Argentum Pharmaceuticals LLC ("Argentum").
- 3. I am being compensated for my time in connection with this matter at my customary rate of \$800 per hour, and my compensation does not depend upon the ultimate outcome of this case. I will also be compensated for any reasonable expenses that arise in connection with this matter, including travel costs incurred while conducting activities associated with this *inter partes* review.
- 4. I have been asked by Cipla to review and respond to Argentum's petition and the supporting declaration submitted by Dr. Robert Schleimer.

# II. Professional and Educational Background

5. I am currently a Partner and Vice-President of Allergy and Asthma Associates of Southern California and I am the Co-Medical Director of Southern California Research. I have served in both positions since 2009 after joining the practice in 2007.



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