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 WARNER CARR, M.D.

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VII.	Claim Construction						
VIII.	State of the Art						
	A.	Many of the treatment options available in 2002 had overlapping effects in treating AR.	.14				
	В.	A POSA would have known that co-administration of antihistamines and steroids provided no meaningful benefit as compared to steroids alone.	.18				
	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.	.28				
IX.	The art did not motivate a POSA to combine azelastine and fluticasone into a fixed-dose combination as recited in claims 1, 4-6, 24-26, 29, and 42-44.						
	A.	The art as a whole did not motivate a POSA to develop an inflexible fixed-dose combination	.41				
	B.	The art as a whole did not motivate a POSA to develop a fixed-dose combination that would be expected to yield no clinical benefit but exhibit increased side effects.	.41				



	C.	for us	art as a whole did not motivate a POSA to select azelastine se in a fixed-dose combination with a steroid in order to ove compliance.	42		
	D.	A POSA would not have been motivated to select azelastine based on any anti-inflammatory activity4				
	E.	A POSA would not have been motivated to pursue a fixed-dose combination of an antihistamine and a steroid				
X.	Objective indicia of non-obviousness suggests that the challenged claims are not obvious.					
	A.	Dr. Schleimer was present at the trial in district court				
	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.	48		
		2.	Dymista [®] shows an unexpected improvement in efficacy when compared to the closest prior art.	50		
		3.	Dymista® exhibits an unexpectedly fast onset of action compared to the closest prior art.	53		
		4.	Dymista® has unexpectedly reduced side effects as compared to either azelastine or fluticasone monotherapies.	56		
	C.		sta [®] satisfies a long-felt but unmet need in the treatment	59		
		1.	Dymista® satisfies the long-felt need for more effective AR treatment.	60		
		2.	Dymista® satisfies the long-felt need for an AR treatment with a faster onset	60		



Inter Partes Review of U.S. Patent No. 8,168,620 Declaration of Dr. Warner Carr (Exhibit 2147)

	3. Dymista [®] satisfies the long-felt need for an AR treatment with fewer side effects.	62
D.	FDA was skeptical of Dymista [®]	64
E.	Dymista [®] has been widely praised in the industry as the new gold standard for the treatment of AR	66
F.	Dymista [®] , Duonase, and several Indian copycat products are covered by the challenged claims.	67



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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