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

PATENT OWNER PRELIMINARY RESPONSE UNDER 37 C.F.R. § 42.107(a)

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Patent Owner's Preliminary Response IPR2017-00807

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II.	CLA	AIM CONSTRUCTION					
III.	THE BOARD SHOULD DENY TRIAL ON GROUNDS 1, 2, AND 3 BECAUSE EACH HAS A THRESHOLD FAILURE						
	A.	argu	cipation Ground 1 presents the same anticipation ment using substantially the same art as was overcome ng prosecution				
	В.	Obviousness Grounds 2 and 3 are fatally deficient as a matter of law because Argentum failed to address various evidence of objective indicia of which it had knowledge					
		1.	Argentum knew of Cipla's well-developed objective indicia evidence because it observed, and its experts testified about, the same evidence in the <i>Apotex</i> trial				
		2.	Cipla will be severely prejudiced if trial is instituted despite Argentum's failure to address Cipla's objective indicia evidence in its Petition				
IV.	 THE BOARD SHOULD ALSO DENY TRIAL ON GROUNDS 1 BECAUSE THEY LACK SUBSTANTIVE MERIT. A. Ground 1 Fails: Argentum has not established a reasonable likelihood that Claims 1 and 25 are anticipated by Segal. 						
		1.	Segal does not describe azelastine and fluticasone in single formulation				

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	2.	form	l does not enable the "nasal spray" / "dosage suitable for nasal administration" of claims 1 25		
В.	Ground 2 fails: Argentum has failed to establish a reasonable likelihood that Claims 1, 4-6, 24-26, and 29 are obvious over Segal, Hettche, and Phillipps				
	1.		clinical art taught away from the co- inistration of an antihistamine and a steroid		
		(a)	The art established that antihistamines and steroids had redundant mechanisms of action <i>in</i>		
		(b)	<i>vivo</i>		
		(c)	therapy		
	2.	The art as a whole taught away from a fixed-dose combination of an antihistamine and a steroid			
	3.	POS azela	ew of the anticipated formulation difficulties, a A would not have been motivated to formulate astine and fluticasone into a nasal spray with a bonable expectation of success		
		(a)	Argentum fails to establish that co-formulating azelastine and fluticasone into a combination formulation was known in 2002		
		(b)	No reasonable expectation of success exists because a POSA knew that combining fluticasone with another active ingredient in a		
		(c)	suspension formulation led to aggregation		

Ground 3 Fails: Argentum has failed to establish a reasonable likelihood that claims 42-44 would have been obvious over Segal, Hettche, Phillipps, and Flonase [®] Label42					
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. 40					
Grounds 2 and 3 Fail: Compelling objective indicia of non- obviousness support the validity of the challenged claims					
Cipla's objective indicia evidence has a nexus to the challenged claims					
Unexpected results: The claimed formulation exhibits unexpected formulation and clinical results					
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	(b) The claimed formulations are unexpectedly suitable for nasal administration in light of the prior art
3.	Failure of Others: sophisticated pharmaceutical companies failed to develop a combined formulation
4.	Acquiescence: Meda's decision to take a royalty- bearing license to Cipla's patents supports nonobviousness
5.	Skepticism: Both Meda and FDA were skeptical of the feasibility and desirability of a fixed-dose azelastine/fluticasone formulation
6.	Commercial Success: Sales of Dymista [®] in the U.S. and Duonase in India demonstrate nonobviousness
7.	Unmet Need: Dymista [®] satisfied a long-felt but unmet need for better AR treatment
8.	No alleged "blocking patents" undercut Cipla's commercial success and long-felt need evidence
9.	Copying: Duonase was subjected to widespread copying in India
10.	Praise: Industry leaders praised Dymista [®]
CONCLUS	ION

V.

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