# 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.	<ul> <li>THE BOARD SHOULD ALSO DENY TRIAL ON GROUNDS 1 BECAUSE THEY LACK SUBSTANTIVE MERIT.</li> <li>A. Ground 1 Fails: Argentum has not established a reasonable likelihood that Claims 1 and 25 are anticipated by Segal.</li> </ul>						
		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 <sup>®</sup> Label42					
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4.4					
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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 <sup>®</sup> in the U.S. and Duonase in India demonstrate nonobviousness
7.	Unmet Need: Dymista <sup>®</sup> 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 <sup>®</sup>
CONCLUS	ION

V.

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