Filed: October 7, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
MYLAN PHARMACEUTICALS INC., SAWAI USA, INC., AND SAWAI PHARMACEUTICAL CO., LTD.,
Petitioner,
v.
BIOGEN MA INC.,
Patent Owner.
Case No. IPR2018-0143 ¹ U.S. Patent No. 8,399,514

PETITIONER'S REPLY TO BIOGEN'S PATENT OWNER RESPONSE

¹ Case IPR2019-00789 has been joined with this proceeding.



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I.	The	Claim	s of the '514 Patent Were Obvious		
	A.		SAs Were Motivated to Optimize the DMF Daily e		
	B.		SAs Would Have Reasonably Expected 480 mg/day e Efficacious		
		1.	Schimrigk Demonstrated 360 mg/day and 720 mg/day Were Efficacious		
		2.	The January 2006 Press Release Confirmed Successful RRMS Treatment with DMF Monotherapy		
		3.	DMF's Use to Treat Psoriasis Supports Obviousness		
		4.	Kappos 2006 Abstract Confirmed that 360 mg/day and 720 mg/day Were Efficacious		
		5.	The Kappos Presentation Provided More Confirmation That 360 mg/day Was Efficacious		
		6.	Petitioner Has Not Relied on Fox/Gold or the EMA to support its Prima Facie Case		
		7.	POSAs Would Not Have Looked to Doses Higher Than 720 mg/day		
		8.	WO '342 Provides Additional Confirmatory Evidence of a Reasonable Expectation of Success		
		9.	The Ground 4 References Likewise Provide a Reasonable Expectation of Success		
	C.	All Dependent Claims Are Obvious			
	D.	•	gen's Secondary Considerations Fail to Overcome the na Facie Case		
		1.	Biogen Has Not Established Unexpected Results		
		2.	Biogen Has Not Established Commercial Success		



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