UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
HOPEWELL PHARMA VENTURES, INC., Petitioner,
V.
MERCK SERONO SA, Patent Owner.
Case IPR2023-00481 Patent 8,377,903

### PATENT OWNER'S PRELIMINARY RESPONSE



## **TABLE OF CONTENTS**

I.	Introduction1					
II.	Background					
III.	Person Of Ordinary Skill In The Art					
IV.	Clair	n Con	struction	6		
V.	Petitioner Is Not Reasonably Likely To Prevail On Ground I10					
	A.	Petit	ioner Fails To Establish That Bodor And Stelmasiak			
		Disc	lose Or Suggest All Claim Limitations	17		
		1.	Neither Bodor Nor Stelmasiak Discloses Or Suggests			
			The Claimed Weight-Based Oral, Induction Or			
			Maintenance Dosing	17		
		2.	Neither Bodor Nor Stelmasiak Discloses Or Suggests A			
			Maintenance Period As Claimed	21		
	В.	Petit	ioner Has Not Established Any Motivation To Combine			
		Bodo	or With Stelmasiak To Arrive At The Challenged Claims	29		
		1.	A POSA Would Not Have Been Motivated To Adopt			
			Weight-Based Dosing	29		
		2.	A POSA Would Not Have Been Motivated To Combine			
			Bodor With Stelmasiak To Arrive At The Claimed			
			Induction Doses	30		



	3.	A POSA Would Not Have Been Motivated To			
		Re-Treat Patients After Bodor's 10-Month			
		Cladribine-Free Period37			
	4.	A POSA Would Not Have Been Motivated To Combine			
		Bodor With Stelmasiak To Arrive At The Claimed 1.7			
		Mg/Kg Maintenance Dose			
	5.	Petitioner's Routine Optimization Arguments Fail To			
		Explain How A POSA Would Have Been Motivated To			
		Arrive At Claimed Dosing Methods40			
C.	Petit	Petitioner Has Not Established Any Reasonable Expectation			
	Of S	uccess In Combining Bodor's Method With Stelmasiak			
	Arrive At The Challenged Claims45				
	1.	A POSA Would Not Have Reasonably Expected To			
		Arrive At The Claimed Weight-Based Dosing46			
	2.	A POSA Would Not Have Reasonably Expected To			
		Arrive At The Claimed 1.7-3.5 Mg/Kg Total Induction			
		Dose By Modifying Bodor's Method In View Of			
		Stelmasiak46			
	3.	A POSA Would Not Have Reasonably Expected To			
		Treat RRMS Or Early SPMS Using The Claimed About			



			8-10- Or 10-Month Cladribine-Free Period By	
			Modifying Bodor's Method In View Of Stelmasiak	47
		4.	A POSA Would Not Have Reasonably Expected To	
			Arrive At The Claimed About 1.7 Mg/Kg Maintenance	
			Dose By Modifying Bodor's Method In View Of	
			Stelmasiak	49
		5.	A POSA Would Not Have Reasonably Expected To	
			Arrive At A Safe And Effective Method Of Treating	
			RRMS Or Early SPMS As Claimed By Modifying	
			Bodor's Method In View Of Stelmasiak	50
VI.	Obje	ctive I	ndicia Support Non-Obviousness	52
VII.	The Petition Should Be Denied Under 35 U.S.C. § 325(d)5			53
	A.	The	Office Already Considered Petitioner's Alleged Prior	
		Art A	And Arguments	53
		1.	Becton Dickinson Factors (a) And (b): Asserted Art	
			Was Considered During Examination	54
		2.	Becton Dickinson Factor (d): Petitioner's And The	
			Examiner's Arguments Are Not Materially Different	55
	B.	Petiti	ioner Has Not Identified A Material Error By The	
		Exan	niner	58



	1.	Becton Dickinson Factor (c): Asserted Art Was	
		Evaluated During Examination	59
	2.	Becton Dickinson Factor (e): Petitioner Has Not	
		Identified Material Examiner Error	60
	3.	Becton Dickinson Factor (f): Additional Evidence	
		Does Not Warrant Reconsideration	63
<b>3</b> / <b>1   1</b>	C 1:		<i>C</i> 1



# DOCKET A L A R M

# Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

# **Real-Time Litigation Alerts**



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## **Advanced Docket Research**



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

# **Analytics At Your Fingertips**



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

#### API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

#### **LAW FIRMS**

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

#### **FINANCIAL INSTITUTIONS**

Litigation and bankruptcy checks for companies and debtors.

### **E-DISCOVERY AND LEGAL VENDORS**

Sync your system to PACER to automate legal marketing.

