UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES INC.,

Petitioner

v.

POZEN INC. and HORIZON PHARMA USA, INC.,

Patent Owners

U.S. Patent No. 9,220,698 to Ault et al.

Inter Partes Review No. Unassigned

DECLARATION OF MEYER N. SOLNY, M.D.



TABLE OF CONTENTS

				Page				
I.	QUALIFICATIONS AND BACKGROUND							
	A.	Education and Experience						
	B.	Mate	erials Considered	3				
	C.	Scop	oe of Work	4				
II.	SUM	1MAR	MARY OF OPINIONS4					
III.	LEG	LEGAL STANDARDS5						
IV.	PER	ERSON OF ORDINARY SKILL IN THE ART7						
V.	BAC	BACKGROUND ON NSAID-RELATED GASTRIC INJURY7						
VI.	U.S.	S. PATENT NO. 9,220,698 (Ex. 1001)8						
VII.	SCOPE AND CONTENT OF THE PRIOR ART REFERENCES							
	A.	U.S.	Patent No. 6,926,907 (Ex. 1004)	13				
	B.	U.S.	Patent No. 8,557,285 (Ex. 1005)	17				
	C.	Howden 2005 (Ex. 1006)19						
	D.	EC-Naprosyn Prescribing Information (Ex. 1009)20						
	E. Other Art that Informs Person of Ordinary Skill's Knowledge							
		1.	Zegerid (omeprazole) Powder for Oral Suspension Prescribing Information (2004) (Ex. 1010)					
		2.	Goldstein (Ex. 1011)	21				
		3.	Hochberg (Ex. 1012)	22				
VIII.	UNPATENTABILITY OF THE '698 PATENT23							
	A.	A. Claims 1-7 of the '698 Patent Are Anticipated or Obvious over the '285 Patent						



		1.	'285 patent	.23	
		2.	Claim 2 is anticipated by or obvious over the '285 patent	.26	
		3.	Claims 3 and 4 are anticipated or obvious over the '285 patent	.27	
		4.	Claims 5 and 6 are anticipated or obvious over the '285 patent	.28	
		5.	Claim 7 is anticipated or obvious over the '285 patent	.28	
	В.	All Claims of the '698 Patent Are Obvious Over the '285 patent in View of Howden 2005 and EC-Naprosyn			
		1.	The method of claim 1 is obvious over the '285 patent in view of Howden 2005 and EC-Naprosyn		
		2.	Claim 2 is obvious over the '285 patent in view of Howden and EC-Naprosyn	.30	
		3.	Claims 3 and 4 are obvious over the '285 patent in view of Howden 2005 and EC-Naprosyn	.31	
		4.	Claims 5 and 6 are obvious over the '285 patent in view		
			of Howden 2005 and EC-Naprosyn	.31	
		5.	Claim 7 is obvious over the '285 patent in view of Howden 2005 and EC-Naprosyn	.31	
IX.	NO SUPPOSED SECONDARY CONSIDERATIONS OVERCOME THE OBVIOUSNESS ANALYSIS				
	A.	The	698 Patent Does Not Demonstrate Any Unexpected Result	.32	
	B.	Ther	e Is No Evidence of Industry Skepticism of the '698 Patent	.34	
	C.	The	698 Patent Has Not Met Any Long-Felt, but Unmet Need	.34	
X.	CON	CLUS	SION	.35	



X.

I, Meyer N. Solny, M.D., have been retained by counsel for Petitioner 1. Dr. Reddy's Laboratories Inc. ("DRL"). I understand that DRL is petitioning for inter partes review ("IPR") of U.S. Patent No. 9,220,698 to Ault et al. ("the '698 patent") (Ex. 1001), which is assigned to Pozen Inc. and Horizon Pharma USA, Inc. ("Patent Owners"), to request that the United States Patent and Trademark Office cancel certain claims of the '698 patent as unpatentable. I submit this expert declaration in support of DRL's IPR petition for the '698 patent. I have been informed by counsel that DRL's inter parte petition will be accompanied by a timely motion for joinder under 37 C.F.R. §42.122(b) to the previously filed IPR2017-01995 by Mylan Pharmaceuticals Inc. I have been further informed that on March 08, 2018 the Board instituted trial on Mylan's IPR. Paper 18 in IPR2017-01995. I have been also informed that Mylan's IPR was supported by the expert declarations of Drs. Michael Mayersohn, Ph.D. and David C. Metz, M.D. I have been further informed by counsel that in order to facilitate resolution of substantially similar inter parte petitions concerning the same patent claims and stating the same or substantially similar grounds for invalidity, the Board accepts the use of the language from the prior expert declarations, provided that the petitioner's expert supports the opinions stated in such prior declarations. Like Dr. Metz, I am a gastroenterologist. I have reviewed the materials cited in this declaration, which are also the materials cited in Dr. Metz' declaration. In view of the above, I agree and adopt the opinions



stated in Dr. Metz' declaration, which are reiterated below.

I. QUALIFICATIONS AND BACKGROUND

A. Education and Experience

- 2. I am a Board Certified Gastroenterologist and Gastrointestinal Endoscopist. I have been practicing medicine in the field of gastroenterology for over 38 years with a special emphasis on upper gastrointestinal (GI) tract disease states.
- 3. I am board certified in gastroenterology and in internal medicine, and listed as Top Doctor 2013-2017 (Castle Conolly).
- 4. I received a Bachelor of Arts from the Yeshiva University, New York, New York, in 1970. In 1974, I received a Medical Doctor (M.D.) degree from Columbia University, College of Physicians & Surgeons and Masters of Business Administration (MBA) from Columbia Business School in 2000.
- 5. From 1974 to 1975, I interned in medicine at the New York Hospital Cornell Medical Center. From 1975 to 1977, I was a Junior and then Senior Assistant Resident in Medicine at the New York Hospital Cornell Medical Center.
- 6. From 1977 to 1979, I was a Fellow at the Division of Gastroenterology in the same center.
- 7. For over 38 years, I have maintained an active and ongoing solo private practice in internal medicine and gastroenterology, while practicing as an Assistant



DOCKET

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.

