UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AGILA SPECIALTIES INC. and MYLAN LABORATORIES LIMITED, *Petitioners*,

V.

CEPHALON, INC. *Patent Owner*.

Case IPR2016-00026 Patent No. 8,791,270 B2

CEPHALON, INC.'S PRELIMINARY PATENT OWNER RESPONSE PURSUANT TO 37 C.F.R. § 42.107



TABLE OF CONTENTS

I.	INT	RODUCTION	1	
II.	BACKGROUND			
	A.	The Inventors Identified a Problem Not Recognized in the Art	3	
	B.	The Inventions of the '270 Patent	6	
	C.	FDA Approval and Market Response	7	
	D.	Petitioners' ANDA Filing	8	
III.	PETITIONERS FAILED TO IDENTIFY ALL OF THE REAL			
	PAI	RTIES-IN-INTEREST		
	A.	The Legal Standard	9	
	B.	Petitioners Should Have Identified Mylan Inc. and Mylan Pharmaceuticals Inc. as Real Parties-in-Interest	10	
IV.		FINITIONERS' PROPOSED CLAIM CONSTRUCTIONS AND FINITION OF AN ORDINARY ARTISAN	16	
V.		E PETITION FAILS TO MAKE THE SHOWING	10	
	RE	QUIRED UNDER 35 U.S.C. § 314(a)	17	
	A.	Ground 1 : Petitioners Have Not Demonstrated a Reasonable Likelihood that They Will Prove that Claims 1, 2, 7-10, 13-16,		
		19, and 20 Are Anticipated by Maas	17	
		1. Claims 1, 2, 10, 13 and 16		
		2. Claims 2, 10, 13 and 16	22	
		3. Claims 7-10, 13-15, 19 and 20	23	
	В.	Ground 2 : Petitioners Have Not Demonstrated a Reasonable Likelihood that They Will Prove that Claims 1-20 Are Obvious		
		over Maas and Teagarden	2.5	



Patent Owner's Preliminary Response

VII.	CON	NCLUSION	44	
VI.	PETITIONERS' GROUNDS ARE REDUNDANT AND VIOLATE THE BOARD'S RULES			
	D.	Ground 4 : Petitioners Have Not Demonstrated a Reasonable Likelihood that They Will Prove that Claims 20-23 Are Obvious over Maas, Teagarden and The Rote List.	41	
	C.	Ground 3 : Petitioners Have Not Demonstrated a Reasonable Likelihood that They Will Prove that Claims 13 and 19 Are Obvious over Maas, Teagarden and Gust.	39	
		Teagarden	29 35	
		 Petitioners Fail to Establish Why an Ordinary Artisan Would Have Targeted the Claimed Degradant Profiles with a Reasonable Likelihood of Success	26	
		1. Petitioners Fail to Establish Why an Ordinary Artisan		



TABLE OF AUTHORITIES

	Page(s)
Cases	
Agila Specialties Inc. v. Cephalon, Inc., IPR2015-00503, Paper 4 (PTAB Dec. 24, 2014)	11
Agila Specialties Inc. v. Cephalon, Inc., IPR2015-00503, Paper 10 (PTAB July 20, 2015)	29, 36
Agila Specialties Inc. v. Cephalon, Inc., IPR2015-00503, Paper 16 (PTAB Oct. 7, 2015)	11
Agila Specialties Inc. v. Cubist Pharm., Inc., IPR2015-00131, Paper 4, IPR2015-00132, Paper 4, IPR2015- 00141, Paper 1, IPR2015-00142, Paper 1, IPR2015-00143, IPR2015-00144, Paper 1 (PTAB Oct. 23, 2014)	11, 12
Allergan, Inc. v. Apotex Inc., 754 F.3d 952 (Fed. Cir. 2014)	21
Aruze Gaming Macau, Ltd. v. MGT Gaming, Inc., IPR2014-01288, Paper 13 (PTAB Feb. 20, 2015)	10
Atlanta Gas Light Co. v. Bennett Regulator Guards, Inc., IPR2013-00453, Paper 88 (PTAB Jan. 6, 2015)	9, 15
Cadence Pharm. Inc. v. Exela PharmSci Inc., 780 F.3d 1364 (Fed. Cir. 2015)	32
Fresenius Kabi USA, LLC v. Cephalon, Inc., IPR2016-00098, Paper 2 (PTAB Oct. 28, 2015)	
Galderma S.A. v. Allergan Industrie, SAS, IPR2014-01422, Paper 14 (PTAB Mar. 5, 2015)	9, 10, 14
Gonzalez v. Banco Cent. Corp., 27 F 3d 751 (1st Cir. 1994)	14



Illumina, Inc. v. Tr. of Columbia Univ., IPR2012-0006, Paper 43 (PTAB May 10, 2013)	43
Liberty Mutual Ins. Co. v. Progressive Casualty Ins. Co., CBM2012-0003 Paper 7 (PTAB Oct. 25, 2012)	43
Mylan Pharm. Inc. v. Baxter Int'l Inc., IPR2016-00217, Paper 3 and IPR2016-00218, Paper 3 (PTAB Nov. 19, 2015)	11
Mylan Pharm. Inc. v. Nissan Chem. Indus. Ltd., IPR2015-01069, Paper 12 (PTAB Aug. 28, 2015)	14, 16
Oracle Corp. v. Clouding IP, LLC, IPR2013-00075, Paper 15 (PTAB June 13, 2013)	43
Reflectix, Inc. v. Promethean Insulation Tech. LLC, IPR2015-00044, Paper 18 (PTAB Jan. 20, 2015)	15
Scaltech Inc. v. Retec/Tetra, LLC, 178 F.3d 1378 (Fed. Cir. 2014)	21
Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991)	18
TRW Auto. US L.L.C. v. Magna Elecs. Inc., IPR2014-00257, Paper 16 (PTAB Apr. 8, 2013)	35
Zerto, Inc. v. EMC Corp., IPR2014-01254, Paper 32 (PTAB Feb. 12, 2015)	9, 10
Zoll Lifecor Corp. v. Philips Elecs. N. Am. Corp., IPR2013-00609, Paper 15 (PTAB Mar. 20, 2014)	9, 15
Statutes	
35 U.S.C. § 312(a)	9, 15
35 U.S.C. § 315(b)	15
25 H C C & 225(d)	11



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.

