UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CIPLA LIMITED, Petitioner

V .

ALCON RESEARCH, LTD., Patent Owner.

U.S. Patent No. 8,791,154 to Gamache *et al*.
Issue Date: July 29, 2014
Title: High Concentration Olopatadine Ophthalmic Composition

Inter Partes Review No.: IPR2018-01020

inter raries Review No., IF R2016-01020

Corrected Petition for *Inter Partes* Review of U.S. Patent No. 8,791,154 Under 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-.80, 42.100-.123

Mail Stop "PATENT BOARD"

Patent Trial and Appeal Board U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450



TABLE OF CONTENTS

		<u>Pag</u>	<u> </u>			
I.	INTRODUCTION1					
II.	OVERVIEW1					
III.	STANDING (37 C.F.R. § 42.104(a); PROCEDURAL STATEMENTS)					
IV.	MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1))2					
	A. Each Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))					
	B.	Notice of Related Matters (37 C.F.R. § 42.8(b)(2))	2			
		1. Judicial Matters	2			
		2. Administrative Matters	3			
	C.	Designation of Lead and Back-Up Counsel and Service (37 C.F.R. §§ 42.8(b)(3), 42.8(b)(4), 42.10(a), and 42.10(b))	.3			
V.	STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR (37 C.F.R. § 42.22(a))					
VI.	THE	'154 PATENT	4			
	A.	Claim Construction	4			
VII.		E OF THE CLAIMS ARE ENTITLED TO THE PRIORITY E OF PROVISIONAL APPLICATION 61/487,789	.7			
VIII.	A PE	RSON OF ORDINARY SKILL IN THE ART	8			
IX.	IDENTIFICATION OF CHALLENGE (37 C.F.R. § 42.104(b))					
X.	INVA	ALIDITY ANALYSIS1	0			
	A.	Ground 1: Claims 1-27 Are Rendered Obvious by Bhowmick in View of Yanni, and Castillo	0			
		1. The Level of Ordinary Skill in the Pertinent Art and the Scope and Content of the Prior Art	1			



		(i) Yanni	13
		(iii) Castillo	14
2.	Diffe	erences between the Claims and the Prior Art	14
	a.	Claim 1	14
		(i) "An aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising"	
		(ii) "at least 0.67 w/v % olopatadine dissolved	
		in the solution"	
		(iii) "PEG having a molecular weight of 300 to	
		500"	
		(iv) "polyvinylpyrrolidone"	
		(v) "hydroxypropyl-γ-cyclodextrin"	
		(vi) "benzalkonium chloride"	
		(vii) "Water"	
		(viii) The Fact That Yanni May Teach	
		Suspensions In Certain Instances Should Not Dissuade the Board from Instituting IPR	
		(ix) The Skilled Artisan Would Not Be	
		Dissuaded from Using Multiple Solubilizing	
		Agents	
		(x) Reasonable Expectation of Success	
	b.	Claims 4 and 8	
	c.	Claim 21	
	d.	Claims 2, 5, and 9	33
	e.	Claims 3, 6, 10 and 18	34
	f.	Claims 7 and 11	
	g.	Claims 19 and 20	
	h.	Claim 24	
	i.	Claims 12–14 and 25–27	
	j.	Claims 15–17 and 22	
	k.	Claim 23	38
		Claims 1–27 Are Rendered Obvious by Schneider in ayakawa, Bhowmick, and Castillo	
1.		Level of Ordinary Skill in the Pertinent Art and the pe and Content of the Prior Art	42
	-	_	



B.

	2.	Differences between the Claims and the Prior Art			
		a.	The P	Prior Art	42
			(i)	Schneider	42
			(ii)	Hayakawa	
		b.	` /	ı 1	
			(i)	"An aqueous ophthalmic solution for	
			()	treatment of ocular allergic conjunctivitis,	
				the solution comprising"	44
			(ii)	"at least 0.67 w/v % olopatadine dissolved	
			\	in the solution"	44
			(iii)	"PEG having a molecular weight of 300 to	
			` /	500"	45
			(iv)	"polyvinylpyrrolidone"	
			(v)	"hydroxypropyl-γ-cyclodextrin"	
			(vi)	"benzalkonium chloride"	
			(vii)	"Water"	48
			(viii)	Reasonable Expectation of Success	48
		c.		4 and 8	
		d.	Claim	21	53
		e.	Claim	s 2, 5, and 9	56
		f.	Claim	s 3, 6, 10 and 18	56
		g.	Claim	s 7 and 11	57
		h.	Claim	s 19 and 20	58
		i.	Claim	24	59
		j.	Claim	s 12–14 and 25–27	59
		k.	Claim	s 15–17 and 22	60
		1.	Claim	23	61
	and i	D			
C.				's Decision Not to Invalidate the '154 Patent	<i>(</i> 2
	Snou	na Not	Dissua	de the PTAB from Instituting Review	62
	1.	The	Challen	ge before the Board Is Not the Same	
	1.			hat Was before the District Court	62
		Cilai	iciige i	na was ocioic the District Court	02
	2.	The l	District	Court Focused Too Heavily on Preferred	
		Emb	odimen	ts	63
	2				
	3.			Court Focused Too Heavily on the	
		Com	mercial	Formulations	64



	D.	Obje	Objective Indicia of Non-Obviousness			
		1.	No Unexpected Results	65		
		2.	No Commercial Success	66		
		3.	No Failure of Others	67		
ΧI	CONCLUSION					



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.

