

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.*  
Case No.: IPR2018-01020

U.S. Patent No. 9,533,053 to Gamache *et al.*  
Case No.: IPR2018-01021

---

**DECLARATION OF DR. PAUL A. LASKAR PH.D.**

**Table of Contents**

I.	INTRODUCTION .....	1
II.	MY EXPERIENCE AND QUALIFICATIONS .....	2
III.	LIST OF MATERIALS CONSIDERED .....	6
IV.	LEGAL STANDARD .....	7
A.	Obviousness.....	7
V.	NONE OF THE CLAIMS ARE ENTITLED TO THE PRIORITY DATE OF PROVISIONAL APPLICATION 61/487,789 .....	10
VI.	PERSON OF ORDINARY SKILL IN THE ART (“POSA”).....	12
VII.	THE GAMACHE PATENTS.....	14
VIII.	CLAIM CONSTRUCTION .....	16
IX.	SCOPE AND CONTENT OF THE PRIOR ART.....	18
A.	Olopatadine .....	19
B.	Cyclodextrins.....	21
C.	Ophthalmic Formulations of Olopatadine For Treatment of Allergic Conjunctivitis .....	25
1.	Bhowmick .....	25
2.	Yanni .....	26
3.	Castillo .....	27
4.	Schneider.....	27
5.	Hayakawa.....	28
6.	Abelson .....	29
X.	INVALIDITY OF THE ’154 PATENT .....	30
A.	Claims 1-27 of the ’154 Patent are Rendered Obvious by Bhowmick in View of Yanni and Castillo .....	30
1.	Claim 1 .....	31

*Declaration of Paul A. Laskar, Ph.D.*

a)	“An aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising”.....	31
b)	“at least 0.67 w/v % olopatadine dissolved in the solution”.....	32
c)	“PEG having a molecular weight of 300 to 500” .....	34
d)	“polyvinylpyrrolidone”.....	36
e)	“hydroxypropyl- $\gamma$ -cyclodextrin” .....	38
f)	“benzalkonium chloride”.....	39
g)	“Water” .....	39
h)	Even if Yanni May Teach Suspensions in Certain Instances that Would Not Render the Gamache Patents any Less Obvious .....	40
i)	The Skilled Artisan Would Not Be Dissuaded From Using Multiple Solubilizing Agents .....	44
j)	Reasonable Expectation of Success.....	47
2.	Claims 4 and 8.....	48
3.	Claim 21 .....	54
4.	Claims 2, 5, and 9.....	56
5.	Claims 3, 6, 10, and 18 .....	57
6.	Claims 7 and 11.....	58
7.	Claims 19 and 20.....	58
8.	Claim 24.....	59
9.	Claims 12-14 and 25-27.....	60
10.	Claims 15-17 and 22 .....	61
11.	Claim 23 .....	62
B.	Ground 2: Claims 1-27 are Rendered Obvious by Schneider in view of Hayakawa, Bhowmick, and Castillo .....	63
1.	Claim 1 .....	63
a)	“An aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising”.....	63
b)	“at least 0.67 w/v % olopatadine dissolved in the solution”.....	64
c)	“PEG having a molecular weight of 300 to 500” .....	65
d)	“polyvinylpyrrolidone”.....	66
e)	“hydroxypropyl- $\gamma$ -cyclodextrin” .....	67

*Declaration of Paul A. Laskar, Ph.D.*

f)	“benzalkonium chloride” .....	68
g)	“Water” .....	68
h)	Reasonable Expectation of Success.....	68
2.	Claim 4 and 8 .....	69
3.	Claim 21 .....	73
4.	Claims 2, 5, and 9.....	76
5.	Claims 3, 6, 10, and 18 .....	77
6.	Claims 7 and 11.....	77
7.	Claims 19 and 20.....	78
8.	Claim 24.....	79
9.	Claims 12-14 and 25-27.....	80
10.	Claims 15-17 and 22 .....	80
11.	Claim 23 .....	81
XI.	INVALIDITY OF THE '053 PATENT .....	83
A.	Ground 1: Claims 1-13 are Rendered Obvious by Bhowmick in view of Yanni, Castillo, and Abelson .....	83
1.	The Level of Ordinary Skill in the Pertinent Art and the Scope and Content of the Prior Art.....	83
2.	Differences Between the Claims and the Prior Art .....	83
a)	Claim 1.....	83
(1)	“An aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising” .....	83
(2)	“at least 0.67 w/v % olopatadine dissolved in the solution” .....	84
(3)	“PEG having a molecular weight of 200 to 800” .....	86
(4)	“polyvinylpyrrolidone” .....	88
(5)	“a cyclodextrin selected from the group consisting of SAE-β-cyclodextrin, hydroxypropyl-β-cyclodextrin and hydroxypropyl-γ-cyclodextrin; and” .....	90
(6)	“Water”.....	90
(7)	Reasonable Expectation of Success .....	91
b)	Claim 8.....	91

*Declaration of Paul A. Laskar, Ph.D.*

c)	Claim 2.....	92
d)	Claims 3 and 9 .....	93
e)	Claims 4 and 10 .....	93
f)	Claims 5 and 11 .....	94
g)	Claims 6 and 12 .....	94
h)	Claims 7 and 13 .....	95
B.	Ground 2: Claims 1-13 are Rendered Obvious by Schneider in view of Hayakawa, Bhowmick, Castillo, and Abelson.....	97
1.	The Level of Ordinary Skill in the Pertinent Art and the Scope and Content of the Prior Art.....	97
2.	Differences Between the Claims and the Prior Art .....	98
a)	The Prior Art.....	98
b)	Claim 1.....	98
(1)	“An aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising” .....	98
(2)	“at least 0.67 w/v % olopatadine dissolved in the solution” .....	98
(3)	“PEG having a molecular weight of 200 to 800” .....	99
(4)	“polyvinylpyrrolidone” .....	101
(5)	“a cyclodextrin selected from the group consisting of SAE-β-cyclodextrin, hydroxypropyl-β-cyclodextrin and hydroxypropyl-γ-cyclodextrin; and” .....	102
(6)	“Water”.....	102
(7)	Reasonable Expectation of Success .....	103
c)	Claim 8.....	103
d)	Claim 2.....	104
e)	Claims 3 and 9 .....	105
f)	Claims 4 and 10 .....	105
g)	Claims 5 and 11 .....	106
h)	Claims 6 and 12 .....	106
i)	Claims 7 and 13 .....	107

# 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.