

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

AYLA PHARMA LLC,  
Petitioner

v.

ALCON RESEARCH, LLC,  
Patent Owner.

U.S. Patent No. 9,533,053 to Gamache et al.

Issue Date: January 3, 2017

Title: High Concentration Olopatadine Ophthalmic Composition

---

*Inter Partes* Review No.: IPR2020-00295

---

**Petition for *Inter Partes* Review of U.S. Patent No. 9,533,053 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>Page</u>
I. INTRODUCTION .....	1
II. OVERVIEW .....	1
III. STANDING (37 C.F.R. § 42.104(a); PROCEDURAL STATEMENTS).....	3
IV. MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1)).....	3
A. Each Real Party in Interest (37 C.F.R. § 42.8(b)(1)) .....	3
B. Notice of Related Matters (37 C.F.R. § 42.8(b)(2)).....	4
1. Judicial Matters.....	4
2. Administrative Matters .....	4
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)).....	5
V. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR (37 C.F.R. § 42.22(a)) .....	5
VI. THE '053 PATENT .....	5
A. Claim Construction .....	6
VII. NONE OF THE CLAIMS ARE ENTITLED TO THE PRIORITY DATE OF PROVISIONAL APPLICATION 61/487,789 .....	8
VIII. A PERSON OF ORDINARY SKILL IN THE ART .....	10
IX. IDENTIFICATION OF CHALLENGE (37 C.F.R. § 42.104(b)) .....	11
X. INVALIDITY ANALYSIS.....	12
A. Ground 1: Claims 1-13 are Rendered Obvious by Bhowmick in View of Yanni and Castillo .....	13
1. The Level of Ordinary Skill in the Pertinent Art and the Scope and Content of the Prior Art .....	14

2.	Differences between the Claims and the Prior Art.....	17
a.	Claim 1 .....	17
b.	Claim 8 .....	31
c.	Claim 2 .....	32
d.	Claims 3 and 9 .....	32
e.	Claims 4 and 10 .....	33
f.	Claims 5 and 11 .....	33
g.	Claims 6 and 12 .....	34
h.	Claims 7 and 13 .....	35
B.	Ground 2: Claims 1-13 Are Rendered Obvious by Schneider in View of Hayakawa, Bhowmick and Castillo.....	38
1.	The Level of Ordinary Skill in the Pertinent Art and the Scope and Content of the Prior Art .....	39
2.	Differences between the Claims and the Prior Art.....	39
a.	The Prior Art.....	39
b.	Claim 1 .....	42
c.	Claim 8 .....	49
d.	Claim 2 .....	50
e.	Claims 3 and 9 .....	50
f.	Claims 4 and 10 .....	51
g.	Claims 5 and 11 .....	51
h.	Claims 6 and 12 .....	52
i.	Claims 7 and 13 .....	53
C.	Ground 3: Claims 1-13 Are Rendered Obvious by Bhowmick, Schneider and Castillo .....	54
1.	The Level of Ordinary Skill in the Pertinent Art and the Scope and Content of the Prior Art .....	54
2.	Differences Between the Claims and the Prior Art.....	54
a.	Claim 1 .....	54
b.	Claim 8 .....	58
c.	Claim 2 .....	59
d.	Claims 3 and 9 .....	59
e.	Claims 4 and 10 .....	60

f.	Claims 5 and 11 .....	60
g.	Claims 6 and 12 .....	61
h.	Claims 7 and 13 .....	61
D.	The District Court’s Decision Not to Invalidate the ’154 Patent Should Not Dissuade the PTAB from Instituting Review .....	62
1.	The District Court Did Not Rule on the Validity of the ’053 Patent.....	62
2.	The Board Instituted Review of the Claims of the ’154 Patent.....	62
3.	The District Court Focused Too Heavily on Preferred Embodiments.....	63
4.	The District Court Focused Too Heavily on the Commercial Formulations.....	63
E.	Objective Indicia of Non-Obviousness.....	64
1.	No Unexpected Results.....	65
2.	No Commercial Success .....	65
3.	No Failure of Others .....	66
XI.	CONCLUSION .....	67

## TABLE OF AUTHORITIES

	<b>Page(s)</b>
<b>Cases</b>	
<i>Alcon Research, Ltd. v. Apotex Inc.</i> , 687 F.3d 1362 (Fed. Cir. 2012).....	20
<i>Alcon Research, Ltd. v. Cipla Limited</i> , 1-17-cv-01244 (D. Del.).....	4
<i>Alcon Research, Ltd. v. Lupin Limited</i> , 1-17-cv-00321 (D. Del.).....	4
<i>Alcon Research, Ltd. v. Watson Labs. Inc.</i> , 1-17-cv-00252 (D. Del.).....	4
<i>Amgen Inc. v. Alexion Pharmaceuticals Inc.</i> , IPR2019-00740 (P.T.A.B. Aug. 20, 2019).....	12
<i>Amneal Pharms. LLC v. Hospira, Inc.</i> , IPR2016-01577 (P.T.A.B. Feb. 9, 2017).....	66
<i>Amneal Pharms. LLC v. Purdue Pharma L.P.</i> , IPR2016-01412 (P.T.A.B. Feb. 14, 2017).....	39, 65
<i>Amneal Pharms. LLC v. Purdue Pharma L.P.</i> , IPR2016-01413 (P.T.A.B. Jan. 18, 2017).....	39
<i>Amneal Pharms. LLC v. Supernus Pharms., Inc.</i> , IPR2013-00368 (P.T.A.B. Dec. 17, 2013).....	65
<i>Apotex, Inc. v. Alcon Research Ltd.</i> , IPR2016-01640 (P.T.A.B. Aug. 18, 2016).....	1
<i>Argentum Pharm. LLC v. Alcon Research, Ltd.</i> , IPR2016-00544 (P.T.A.B. Feb. 2, 2016).....	1, 6
<i>Ariad Pharms., Inc. v. Eli Lilly &amp; Co.</i> , 598 F.3d 1336 (Fed. Cir. 2010) (en banc) .....	9
<i>Bayer Pharma AG v. Watson Laboratories, Inc.</i> , 874 F.3d 1316 (Fed. Cir. 2017).....	65

# 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.