UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.	: 8,791,154 B2
APPLICATION NO.	: 13/475607
DATED	: July 29, 2014
INVENTOR(S)	: Daniel A. Gamache et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page:

Item (56), under References Cited, please remove --5,874,414 A 2/1999 Haseloff et al.--.

Signed and Sealed this
Fourteenth Day of October, 2014

Michelle K. Lee

Michelle K. Lee
Deputy Director of the United States Patent and Trademark Office

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Daniel A. Gamache, *et al.*

Serial No: 13/475,607

Group Art Unit: 1629

Confirmation No: 4130

Filed: May 18, 2012

Patent No: 8,791,154 B2

Issue Date: July 29, 2014

Examiner: Tran, My Chau T.

For: HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION

REQUEST FOR CERTIFICATE OF CORRECTION PURSUANT TO 37 C.F.R. § 1.323

COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Patentee respectfully requests that the enclosed Certificate of Correction on Form PTO/SB/44 be issued correcting an error in the above-referenced patent. The exact location where the error occurred in the patent is listed on the enclosed certificate.

The error that appears in this patent is Applicants' error. Payment of the fee due is enclosed herewith. If any fees are inadvertently omitted or if any additional fees are required

or have been overpaid, please appropriately charge or credit those fees to Deposit Account No. 010682 of Alcon Research, Ltd.

Respectfully submitted,

August 13, 2014
Dated

/Scott A. Chapple, 46, 287/
Scott A. Chapple
Reg. No. 46,287

Address for Correspondence:

Scott A. Chapple
IP Legal, Mail Code TB4-8
Alcon Research, Ltd.
6201 South Freeway
Fort Worth, TX 76134-2099
Phone: (817) 551-8793

Attorney Docket: PAT903988-US-NP

PTO/SB/44 (09-07)
Approved for use through 08/31/2013. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 8,791,154 B2

APPLICATION NO.: 13/475,607

ISSUE DATE : July 29, 2014

INVENTOR(S) : Daniel A. Gamache, et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On Page 1, Section (56), under References Cited, please remove --5,874,414 A 2/1999 Haseloff et al.--.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Alcon Research, Ltd.
IP Legal
6201 South Freeway

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	13475607
Filing Date:	18-May-2012
Title of Invention:	HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION
First Named Inventor/Applicant Name:	Daniel A. Gamache
Filer:	Scott Chapple/Candy Sanders
Attorney Docket Number:	PAT903988-US-NP

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Certificate of Correction	1811	1	100	100
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**100**

Electronic Acknowledgement Receipt

EFS ID:	19851582
Application Number:	13475607
International Application Number:	
Confirmation Number:	4130
Title of Invention:	HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION
First Named Inventor/Applicant Name:	Daniel A. Gamache
Customer Number:	26356
Filer:	Scott Chapple/Candy Sanders
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	PAT903988-US-NP
Receipt Date:	13-AUG-2014
Filing Date:	18-MAY-2012
Time Stamp:	11:41:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$100
RAM confirmation Number	7810
Deposit Account	010682
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Certificate of Correction	PAT903988-US-NP_2014-08-13_SUB_Request_for_Certificate_of_Correction__.pdf	82690 2f7ac6500cc9958906ec6ccee06f73b298877fc8	no	2
Warnings:					
Information:					
2	Request for Certificate of Correction	PAT903988-US-NP_2014-08-13_SUB_Form_PTO-SB-44_Certificate_of_Correction_Fillable__.pdf	164668 01a6d8c4bc0d8a267f4a86165e7e5b09e477a6b3	no	2
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30063 fb8a624b30ac1ecbbb5ec7047498360507df89ed	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	277421		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/475,607	07/29/2014	8791154	PAT903988-US-NP	4130

26356 7590 07/09/2014

ALCON
IP LEGAL
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 1 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Daniel A. Gamache, Arlington, TX;
Laman Alani, Fort Worth, TX;
Malay Ghosh, Fort Worth, TX;
Francisco Javier Galán, Barcelona, SPAIN;
Núria Carreras Perdiguer, Barcelona, SPAIN;
Onkar N. Singh, Arlington, TX;

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13475607
Filing Date	2012-05-18
First Named Inventor	Daniel A. Gamache
Art Unit	1629
Examiner Name	Tran, My Chau T.
Attorney Docket Number	PAT903988-US-NP

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
Change(s) applied to document, /N.B.H./ 6/16/2014 /MCT/	1	5874414		1999-02-23	~~Cydex, Inc.~~ Haseloff et al.	
/MCT/	2	6280745	B1	2001-08-28	Flore et al. ~~Alliance Pharmaceutical Corp.~~	
/MCT/	3	6407079	B1	2002-06-18	Muller et al. ~~Janssen Pharmaceutica N.V.~~	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MCT/

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26356 7590 05/08/2014
ALCON
IP LEGAL
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/475,607	05/18/2012	Daniel A. Gamache	PAT903988-US-NP	4130

TITLE OF INVENTION: HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	08/08/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
TRAN, MY CHAU T	1629	514-450000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 Scott A. Chapple
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Alcon Research, Ltd.
(B) RESIDENCE: (CITY and STATE OR COUNTRY): Fort Worth, Texas

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☒ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies .....

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 010682 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
☐ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
☐ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature Scott Chapple Date 13 June 2014
Typed or printed name Scott A. Chapple Registration No. 46,287

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Patent Application Fee Transmittal

Application Number:	13475607
Filing Date:	18-May-2012
Title of Invention:	HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION
First Named Inventor/Applicant Name:	Daniel A. Gamache
Filer:	Scott Chapple/Candy Sanders
Attorney Docket Number:	PAT903988-US-NP

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Publ. Fee- Early, Voluntary, or Normal	1504	1	0	0
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Utility Appl Issue Fee	1501	1	960	960
Publ. Fee- Early, Voluntary, or Normal	1504	1	0	0
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**960**

Electronic Acknowledgement Receipt

EFS ID:	19301240
Application Number:	13475607
International Application Number:	
Confirmation Number:	4130
Title of Invention:	HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION
First Named Inventor/Applicant Name:	Daniel A. Gamache
Customer Number:	26356
Filer:	Scott Chapple/Candy Sanders
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	PAT903988-US-NP
Receipt Date:	13-JUN-2014
Filing Date:	18-MAY-2012
Time Stamp:	15:15:09
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$960
RAM confirmation Number	1672
Deposit Account	010682
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	PAT903988-US-NP_2014-06-13_SUB_Issue_Fee__.pdf	130327 dd7d451005eb36f56dd9d4c6c8d1e825ca898930	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	33615 655b5ae6fafbe2db6cb8c45a3f934ba99c07d24e	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	163942		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/475,607	05/18/2012	Daniel A. Gamache	PAT903988-US-NP	4130

26356 7590 05/23/2014

ALCON
IP LEGAL
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

EXAMINER	
TRAN, MY CHAU T	
ART UNIT	PAPER NUMBER
1629	

NOTIFICATION DATE	DELIVERY MODE
05/23/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent.docketing@alcon.com

Supplemental Notice of Allowability	Application No. 13/475,607	Applicant(s) GAMACHE ET AL.	
	Examiner MY-CHAU T. TRAN	Art Unit 1629	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *05/15/2014*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *9 and 14-39*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20140516* .
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/MY-CHAU T TRAN/
Primary Examiner, Art Unit 1629

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	13/475,607	GAMACHE ET AL.	
	Examiner	Art Unit	
	MY-CHAU T. TRAN	1629	

All participants (applicant, applicant's representative, PTO personnel):

(1) *SCOTT CHAPPLE*. (3)_____.

(2) *MY-CHAU T. TRAN*. (4)_____.

Date of Interview: *15 May 2014*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☒Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *NONE*.

Identification of prior art discussed: *US PATENT 5,874,418 ,*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Mr. Chapple called the examiner on 05/14/2014 and left a message request a phone interview regarding the IDS filed on 02/17/2014. The examiner called Mr. Chapple back on 05/15/2014 and discussed the IDS filed on 02/17/2014, which the examiner have considered and mailed on 05/08/2014. Mr. Chapple informed the examiner that there is a typographical error made in one of the cited US Patents wherein US Patent 5,874,414 should be US Patent 5,874,418. The examiner inform Mr. Chapple that the US Patent 5,874,418 will be considered and cited in the PTO-892, however, if applicant want to remove/delete US Patent 5,874,414, applicant will need to file a Certificate of Correction after issuance of the application .

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/MY-CHAU T TRAN/ Primary Examiner, Art Unit 1629	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Notice of References Cited	Application/Control No. 13/475,607	Applicant(s)/Patent Under Reexamination GAMACHE ET AL.	
	Examiner MY-CHAU T. TRAN	Art Unit 1629	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,874,418	02-1999	Stella et al.	514/58
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

WEST Search History for Application 13475607

Creation Date: 2014051613:43

Interference Searches

Query	DB	Op.	Plur.	Thes.	Date
((olopatadine same ((mass ratio) or dos $ 4 or concentrat $ 3 or ((weight or WT) same (percent or (per cent) or "%")))) and cyclodextrin) and @ pd > 20140501	UPAD	ADJ	YES	ASSIGNEE	05-16-2014
(514/449 | 514/450)![CCLS]	UPAD	ADJ	YES	ASSIGNEE	05-16-2014
olopatadine and ((514/449 | 514/450)![CCLS])	UPAD	ADJ	YES	ASSIGNEE	05-16-2014
(olopatadine same ((mass ratio) or dos $ 4 or concentrat $ 3 or ((weight or WT) same (percent or (per cent) or "%")))) and cyclodextrin	UPAD	ADJ	YES	ASSIGNEE	05-16-2014

Prior Art Searches

Query	DB	Op.	Plur.	Thes.	Date
("20020006443" |"20020150616" |"20030170309" |"20050004074" |"20050191270" |"20050244472" |"20060210645" |"20070020336" |"20080132444" |"20090118262" |"20090232763" |"20090239842" |"20100240625" |"20100249062" |"20100324031" |"3767788" |"3843782" |"3856919" |"3931319" |"3947573" |"4027020" |"4120949" |"4283393" |"4407791" |"4470965" |"4525346" |"4836986" |"4923693" |"5037647" |"5068225" |"5116863" |"5134127" |"5141961" |"5300287" |"5376645" |"5472954" |"5591426" |"5597559" |"5624962" |"5888493" |"6153746" |"6511949" |"6828356" |"7074424" |"7147844" |"7429602" |"7635773").PN.	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
olopatadine and (("20020006443" |"20020150616" |"20030170309" |"20050004074" |"20050191270" |"20050244472" |"20060210645" |"20070020336" |"20080132444" |"20090118262" |"20090232763" |"20090239842" |"20100240625" |"20100249062" |"20100324031" |"3767788" |"3843782" |"3856919" |"3931319" |"3947573" |"4027020" |"4120949" |"4283393" |"4407791" |"4470965" |"4525346" |"4836986" |"4923693"	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014

|"5037647" |"5068225" |"5116863" |"5134127" |"5141961" |"5300287" |"5376645" |"5472954" |"5591426" |"5597559" |"5624962" |"5888493" |"6153746" |"6511949" |"6828356" |"7074424" |"7147844" |"7429602" |"7635773").PN.)					
GAMACHE-DANIEL-A$.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
ALANI-LAMAN$.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
GHOSH-MALAY$.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
GALAN-FRANCISCO-JAVIER$.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
PERDIGUER-NURIA-CARRERAS$.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
SINGH-ONKAR-N$.in.	PGPB,	ADJ	YES	ASSIGNEE	05-16-2014

	USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS				
(GAMACHE-DANIEL-A$.in.) and (ALANI-LAMAN$.in.) and (GHOSH-MALAY$.in.) and (GALAN-FRANCISCO-JAVIER$.in.) and (PERDIGUER-NURIA-CARRERAS$.in.) and (SINGH-ONKAR-N$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
(GAMACHE-DANIEL-A$.in.) and (ALANI-LAMAN$.in.) and (GHOSH-MALAY$.in.) and (GALAN-FRANCISCO-JAVIER$.in.) and (PERDIGUER-NURIA-CARRERAS$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
(GAMACHE-DANIEL-A$.in.) and (ALANI-LAMAN$.in.) and (GHOSH-MALAY$.in.) and (GALAN-FRANCISCO-JAVIER$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
(GAMACHE-DANIEL-A$.in.) and (ALANI-LAMAN$.in.) and (GHOSH-MALAY$.in.) and (GALAN-FRANCISCO-JAVIER$.in.) and (SINGH-ONKAR-N$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
olopatadine.clm. and (GAMACHE-DANIEL-A$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014

olopatadine.clm. and (ALANI-LAMAN$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
olopatadine.clm. and (GHOSH-MALAY$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
olopatadine.clm. and (GALAN-FRANCISCO-JAVIER$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
olopatadine.clm. and (PERDIGUER-NURIA-CARRERAS$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
olopatadine.clm. and (SINGH-ONKAR-N$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
ALCON RESEARCH$.as.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD,	ADJ	YES	ASSIGNEE	05-16-2014

	FPRS				
olopatadine.clm. and (ALCON RESEARCH$.as.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
(ophthalmic (formulation or composition)).clm. and (olopatadine.clm. and GAMACHE-DANIEL-A$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
(ophthalmic (formulation or composition)).clm. and (olopatadine.clm. and SINGH-ONKAR-N$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
(ophthalmic (formulation or composition)).clm. and (olopatadine.clm. and ALCON RESEARCH$.as.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
(514/449 |514/450)![CCLS]	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
olopatadine and ((514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
(ophthalmic (formulation or composition)) and (olopatadine and (514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
cyclodextrin and ((ophthalmic (formulation or composition)) and olopatadine and (514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014

lactam and ((ophthalmic (formulation or composition)) and olopatadine and (514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
polyether and ((ophthalmic (formulation or composition)) and olopatadine and (514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
(polyethylene glycol) and ((ophthalmic (formulation or composition)) and olopatadine and (514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
(ophthalmic (formulation or composition)) and olopatadine	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
cyclodextrin and ((ophthalmic (formulation or composition)) and olopatadine)	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
lactam and ((ophthalmic (formulation or composition)) and olopatadine)	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
lactam and (cyclodextrin and (ophthalmic (formulation or composition)) and olopatadine)	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
(polyethylene glycol) and ((ophthalmic (formulation or composition)) and olopatadine)	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
(polyethylene glycol) and (cyclodextrin and (ophthalmic (formulation or composition)) and olopatadine)	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	05-16-2014
(ophthalmic (formulation or composition)) and olopatadine	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
((ophthalmic (formulation or composition)) and olopatadine) not @AY>2011	PGPB, USPT,	ADJ	YES	ASSIGNEE	05-16-2014

	USOC				
cyclodextrin and ((ophthalmic (formulation or composition)) and olopatadine not @AY>2011)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
lactam and (cyclodextrin and (ophthalmic (formulation or composition)) and olopatadine not @AY>2011)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
(polyethylene glycol) and (cyclodextrin and (ophthalmic (formulation or composition)) and olopatadine not @AY>2011)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
lactam and ((polyethylene glycol) and cyclodextrin and (ophthalmic (formulation or composition)) and olopatadine not @AY>2011)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
(olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and ((ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
(olopatadine same (percent or (per cent) or "%")) and ((ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
cyclodextrin and ((olopatadine same (percent or (per cent) or "%")) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
(polyethylene glycol) and ((olopatadine same (percent or (per cent) or "%")) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
(polyvinylpyrrolidone) and ((polyethylene glycol) and (olopatadine same (percent or (per cent) or "%")) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
("5874414" |"6280745" |"6407079").PN.	USPT	ADJ	YES	ASSIGNEE	05-16-2014
((ophthalmic (formulation or composition)) and olopatadine) and (("5874414" |"6280745" |"6407079").PN.)	USPT	ADJ	YES	ASSIGNEE	05-16-2014
(hydroxypropylmethyl cellulose) and ((ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
(propylene glycol) and ((hydroxypropylmethyl cellulose) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
		ADJ	YES	ASSIGNEE	05-16-2014

mannitol and ((propylene glycol) and (hydroxypropylmethyl cellulose) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC				
(polyethylene glycol) and (mannitol and (propylene glycol) and (hydroxypropylmethyl cellulose) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
(polyvinylpyrrolidone) and ((polyethylene glycol) and mannitol and (propylene glycol) and (hydroxypropylmethyl cellulose) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
cyclodextrin and ((polyvinylpyrrolidone) and (polyethylene glycol) and mannitol and (propylene glycol) and (hydroxypropylmethyl cellulose) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
(olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and (cyclodextrin and (polyvinylpyrrolidone) and (polyethylene glycol) and mannitol and (propylene glycol) and (hydroxypropylmethyl cellulose) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
(olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and cyclodextrin	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
(polyvinylpyrrolidone) and ((olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and cyclodextrin)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
(propylene glycol) and ((polyvinylpyrrolidone) and (olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and cyclodextrin)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
mannitol and ((propylene glycol) and (polyvinylpyrrolidone) and (olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and cyclodextrin)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
(benzalkonium chloride) and (mannitol and (propylene glycol) and (polyvinylpyrrolidone) and (olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and cyclodextrin)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014

(ocular allergy) and ((benzalkonium chloride) and mannitol and (propylene glycol) and (polyvinylpyrrolidone) and (olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and cyclodextrin)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014
("5874414" |"6280745" |"6407079" |"5874418").PN.	USPT	ADJ	YES	ASSIGNEE	05-16-2014
((ophthalmic (formulation or composition)) and olopatadine) and (("5874414" |"6280745" |"6407079" |"5874418").PN.)	USPT	ADJ	YES	ASSIGNEE	05-16-2014
cyclodextrin and (("5874414" |"6280745" |"6407079" |"5874418").PN.)	USPT	ADJ	YES	ASSIGNEE	05-16-2014
(ophthalmic (formulation or composition)) and (cyclodextrin and ("5874414" |"6280745" |"6407079" |"5874418").PN.)	USPT	ADJ	YES	ASSIGNEE	05-16-2014
((ocular allergy) and (benzalkonium chloride) and mannitol and (propylene glycol) and (polyvinylpyrrolidone) and (olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and cyclodextrin) and @pd>20140501	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-16-2014

UNITED STATES PATENT AND TRADEMARK OFFICE

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NOTICE OF ALLOWANCE AND FEE(S) DUE

26356 7590 05/08/2014

ALCON
IP LEGAL
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

EXAMINER
TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
1629	

DATE MAILED: 05/08/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/475,607	05/18/2012	Daniel A. Gamache	PAT903988-US-NP	4130

TITLE OF INVENTION: HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	08/08/2014

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26356 7590 05/08/2014
ALCON
IP LEGAL
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/475,607	05/18/2012	Daniel A. Gamache	PAT903988-US-NP	4130

TITLE OF INVENTION: HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	08/08/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
TRAN, MY CHAU T	1629	514-450000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29
  NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27
  NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status.
  NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/475,607	05/18/2012	Daniel A. Gamache	PAT903988-US-NP	4130

26356 7590 05/08/2014

ALCON
IP LEGAL
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

EXAMINER	
TRAN, MY CHAU T	

ART UNIT	PAPER NUMBER
1629	

DATE MAILED: 05/08/2014

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 13/475,607	Applicant(s) GAMACHE ET AL.	
	Examiner MY-CHAU T. TRAN	Art Unit 1629	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *02/17/2014*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *9 and 14-39*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 12/17/2013 & 2/17/2014
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/MY-CHAU T TRAN/
Primary Examiner, Art Unit 1629

WEST Search History for Application 13475607

Creation Date: 2014050110:56

Interference Searches

Query	DB	Op.	Plur.	Thes.	Date
(514/449 | 514/450)![CCLS]	UPAD	ADJ	YES	ASSIGNEE	05-01-2014
olopatadine and ((514/449 | 514/450)![CCLS])	UPAD	ADJ	YES	ASSIGNEE	05-01-2014
(olopatadine same ((mass ratio) or dos $ 4 or concentrat $ 3 or ((weight or WT) same (percent or (per cent) or "%")))) and cyclodextrin	UPAD	ADJ	YES	ASSIGNEE	05-01-2014

Prior Art Searches

Query	DB	Op.	Plur.	Thes.	Date
("20020006443" |"20020150616" |"20030170309" |"20050004074" |"20050191270" |"20050244472" |"20060210645" |"20070020336" |"20080132444" |"20090118262" |"20090232763" |"20090239842" |"20100240625" |"20100249062" |"20100324031" |"3767788" |"3843782" |"3856919" |"3931319" |"3947573" |"4027020" |"4120949" |"4283393" |"4407791" |"4470965" |"4525346" |"4836986" |"4923693" |"5037647" |"5068225" |"5116863" |"5134127" |"5141961" |"5300287" |"5376645" |"5472954" |"5591426" |"5597559" |"5624962" |"5888493" |"6153746" |"6511949" |"6828356" |"7074424" |"7147844" |"7429602" |"7635773").PN.	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
olopatadine and (("20020006443" |"20020150616" |"20030170309" |"20050004074" |"20050191270" |"20050244472" |"20060210645" |"20070020336" |"20080132444" |"20090118262" |"20090232763" |"20090239842" |"20100240625" |"20100249062" |"20100324031" |"3767788" |"3843782" |"3856919" |"3931319" |"3947573" |"4027020" |"4120949" |"4283393" |"4407791" |"4470965" |"4525346" |"4836986" |"4923693" |"5037647" |"5068225" |"5116863" |"5134127" |"5141961" |"5300287" |"5376645" |"5472954" |"5591426" |"5597559" |"5624962" |"5888493" |"6153746" |"6511949" |"6828356" |"7074424" |"7147844" |"7429602" |"7635773").PN.)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014

GAMACHE-DANIEL-A$.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
ALANI-LAMAN$.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
GHOSH-MALAY$.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
GALAN-FRANCISCO-JAVIER$.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
PERDIGUER-NURIA-CARRERAS$.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
SINGH-ONKAR-N$.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD,	ADJ	YES	ASSIGNEE	04-28-2014

	FPRS				
(GAMACHE-DANIEL-A$.in.) and (ALANI-LAMAN$.in.) and (GHOSH-MALAY$.in.) and (GALAN-FRANCISCO-JAVIER$.in.) and (PERDIGUER-NURIA-CARRERAS$.in.) and (SINGH-ONKAR-N$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
(GAMACHE-DANIEL-A$.in.) and (ALANI-LAMAN$.in.) and (GHOSH-MALAY$.in.) and (GALAN-FRANCISCO-JAVIER$.in.) and (PERDIGUER-NURIA-CARRERAS$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
(GAMACHE-DANIEL-A$.in.) and (ALANI-LAMAN$.in.) and (GHOSH-MALAY$.in.) and (GALAN-FRANCISCO-JAVIER$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
(GAMACHE-DANIEL-A$.in.) and (ALANI-LAMAN$.in.) and (GHOSH-MALAY$.in.) and (GALAN-FRANCISCO-JAVIER$.in.) and (SINGH-ONKAR-N$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
olopatadine.clm. and (GAMACHE-DANIEL-A$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
olopatadine.clm. and (ALANI-LAMAN$.in.)	PGPB, USPT, USOC, EPAB, JPAB,	ADJ	YES	ASSIGNEE	04-28-2014

	DWPI, TDBD, FPRS				
olopatadine.clm. and (GHOSH-MALAY$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
olopatadine.clm. and (GALAN-FRANCISCO-JAVIER$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
olopatadine.clm. and (PERDIGUER-NURIA-CARRERAS$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
olopatadine.clm. and (SINGH-ONKAR-N$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
ALCON RESEARCH$.as.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
olopatadine.clm. and (ALCON RESEARCH$.as.)	PGPB, USPT, USOC,	ADJ	YES	ASSIGNEE	04-28-2014

	EPAB, JPAB, DWPI, TDBD, FPRS				
(ophthalmic (formulation or composition)).clm. and (olopatadine.clm. and GAMACHE-DANIEL-A$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
(ophthalmic (formulation or composition)).clm. and (olopatadine.clm. and SINGH-ONKAR-N$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
(ophthalmic (formulation or composition)).clm. and (olopatadine.clm. and ALCON RESEARCH$.as.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
(514/449 |514/450)![CCLS]	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
olopatadine and ((514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
(ophthalmic (formulation or composition)) and (olopatadine and (514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
cyclodextrin and ((ophthalmic (formulation or composition)) and olopatadine and (514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
lactam and ((ophthalmic (formulation or composition)) and olopatadine and (514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014

polyether and ((ophthalmic (formulation or composition)) and olopatadine and (514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
(polyethylene glycol) and ((ophthalmic (formulation or composition)) and olopatadine and (514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
(ophthalmic (formulation or composition)) and olopatadine	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
cyclodextrin and ((ophthalmic (formulation or composition)) and olopatadine)	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
lactam and ((ophthalmic (formulation or composition)) and olopatadine)	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
lactam and (cyclodextrin and (ophthalmic (formulation or composition)) and olopatadine)	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
(polyethylene glycol) and ((ophthalmic (formulation or composition)) and olopatadine)	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
(polyethylene glycol) and (cyclodextrin and (ophthalmic (formulation or composition)) and olopatadine)	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	04-28-2014
(ophthalmic (formulation or composition)) and olopatadine	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
((ophthalmic (formulation or composition)) and olopatadine) not @AY>2011	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
cyclodextrin and ((ophthalmic (formulation or composition)) and olopatadine not @AY>2011)	PGPB, USPT,	ADJ	YES	ASSIGNEE	04-28-2014

	USOC				
lactam and (cyclodextrin and (ophthalmic (formulation or composition)) and olopatadine not @AY>2011)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
(polyethylene glycol) and (cyclodextrin and (ophthalmic (formulation or composition)) and olopatadine not @AY>2011)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
lactam and ((polyethylene glycol) and cyclodextrin and (ophthalmic (formulation or composition)) and olopatadine not @AY>2011)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
(olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and ((ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
(olopatadine same (percent or (per cent) or "%")) and ((ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
cyclodextrin and ((olopatadine same (percent or (per cent) or "%")) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
(polyethylene glycol) and ((olopatadine same (percent or (per cent) or "%")) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
(polyvinylpyrrolidone) and ((polyethylene glycol) and (olopatadine same (percent or (per cent) or "%")) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
((polyvinylpyrrolidone) and (polyethylene glycol) and (olopatadine same (percent or (per cent) or "%")) and (ophthalmic (formulation or composition)) and olopatadine) and @pd > 20131003	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
("5874414" |"6280745" |"6407079").PN.	USPT	ADJ	YES	ASSIGNEE	04-28-2014
((ophthalmic (formulation or composition)) and olopatadine) and (("5874414" |"6280745" |"6407079").PN.)	USPT	ADJ	YES	ASSIGNEE	04-28-2014
(hydroxypropylmethyl cellulose) and ((ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
(propylene glycol) and ((hydroxypropylmethyl cellulose) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014

mannitol and ((propylene glycol) and (hydroxypropylmethyl cellulose) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
(polyethylene glycol) and (mannitol and (propylene glycol) and (hydroxypropylmethyl cellulose) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
(polyvinylpyrrolidone) and ((polyethylene glycol) and mannitol and (propylene glycol) and (hydroxypropylmethyl cellulose) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
cyclodextrin and ((polyvinylpyrrolidone) and (polyethylene glycol) and mannitol and (propylene glycol) and (hydroxypropylmethyl cellulose) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
(olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and (cyclodextrin and (polyvinylpyrrolidone) and (polyethylene glycol) and mannitol and (propylene glycol) and (hydroxypropylmethyl cellulose) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
(olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and cyclodextrin	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
(polyvinylpyrrolidone) and ((olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and cyclodextrin)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
(propylene glycol) and ((polyvinylpyrrolidone) and (olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and cyclodextrin)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
mannitol and ((propylene glycol) and (polyvinylpyrrolidone) and (olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and cyclodextrin)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014
(benzalkonium chloride) and (mannitol and (propylene glycol) and (polyvinylpyrrolidone) and (olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and cyclodextrin)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	04-28-2014

(ocular allergy) and ((benzalkonium chloride) and mannitol and (propylene glycol) and (polyvinylpyrrolidone) and (olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and cyclodextrin)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	05-01-2014

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13475607
Filing Date	2012-05-18
First Named Inventor	Daniel A. Gamache
Art Unit	1629
Examiner Name	My Chau T Tran
Attorney Docket Number	PAT903988-US-NP

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MCT/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13475607
	Filing Date	2012-05-18
	First Named Inventor	Daniel A. Gamache
	Art Unit	1629
	Examiner Name	My Chau T Tran
	Attorney Docket Number	PAT903988-US-NP

/MCT/	1	International Preliminary Report on Patentability for corresponding PCT/US2012/038663 with mailing date November 28, 2013	☐

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EXAMINER SIGNATURE

Examiner Signature	/My-Chau Tran/	Date Considered	04/28/2014

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13475607	GAMACHE ET AL.
	Examiner	**Art Unit**
	MY-CHAU T TRAN	1629

CPC								
Symbol							**Type**	**Version**
A61K		47	/	48969			I	2013-01-01
C08B		37	/	0015			I	2013-01-01
C08L		5	/	16			I	2013-01-01
A61K		31	/	335			F	2013-01-01
A61K		47	/	32			A	2013-01-01
A61K		9	/	08			I	2013-01-01
A61K		9	/	0048			I	2013-01-01
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CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
			/					
			/					

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 27	
/MY-CHAU T TRAN/ Primary Examiner.Art Unit 1629 (Primary Examiner)	05/01/2014 (Date)	O.G. Print Claim(s) 9	O.G. Print Figure NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13475607	GAMACHE ET AL.
	Examiner	**Art Unit**
	MY-CHAU T TRAN	1629

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
514	450	A	6	1	K	31 / 335 (2006.01.01)						
CROSS REFERENCE(S)												
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)											
514	449											

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 27	
/MY-CHAU T TRAN/ Primary Examiner.Art Unit 1629 (Primary Examiner)	05/01/2014 (Date)	O.G. Print Claim(s) 9	O.G. Print Figure NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13475607	GAMACHE ET AL.
	Examiner	**Art Unit**
	MY-CHAU T TRAN	1629

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1	5	17	21	33										
	2	6	18	22	34										
	3	7	19	23	35										
	4	8	20	24	36										
	5	9	21	25	37										
	6	10	22	26	38										
	7	11	23	27	39										
	8	12	24												
1	9	13	25												
	10	14	26												
	11	15	27												
	12	16	28												
	13	17	29												
2	14	18	30												
3	15	19	31												
4	16	20	32												

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 27	
/MY-CHAU T TRAN/ Primary Examiner.Art Unit 1629 (Primary Examiner)	05/01/2014 (Date)	O.G. Print Claim(s) 9	O.G. Print Figure NONE

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13475607	GAMACHE ET AL.
	Examiner	Art Unit
	MY-CHAU T TRAN	1629

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	03/28/2013	10/01/2013	05/01/2014						
	1	÷	✓	-						
	2	÷	✓	-						
	3	÷	✓	-						
	4	÷	✓	-						
	5	÷	✓	-						
	6	÷	✓	-						
	7	÷	✓	-						
	8	÷	✓	-						
1	9	÷	✓	=						
	10	÷	✓	-						
	11	÷	N	-						
	12	÷	N	-						
	13	÷	✓	-						
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3	15	÷	✓	=						
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18	30			=						
19	31			=						
20	32			=						
21	33			=						
22	34			=						
23	35			=						
24	36			=						

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
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	Examiner	Art Unit
	MY-CHAU T TRAN	1629

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	03/28/2013	10/01/2013	05/01/2014						
25	37			=						
26	38			=						
27	39			=						

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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First Named Inventor	Daniel A. Gamache
Art Unit	1629
Examiner Name	Tran, My Chau T.
Attorney Docket Number	PAT903988-US-NP

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
/MCT/	1	5874414		1999-02-23	Cydex, Inc.	
/MCT/	2	6280745	B1	2001-08-28	Alliance Pharmaceutical Corp.	
/MCT/	3	6407079	B1	2002-06-18	Janssen Pharmaceutica N.V.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13475607
	Filing Date	2012-05-18
	First Named Inventor	Daniel A. Gamache
	Art Unit	1629
	Examiner Name	Tran, My Chau T.
	Attorney Docket Number	PAT903988-US-NP

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

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EXAMINER SIGNATURE

Examiner Signature	/My-Chau Tran/	Date Considered	04/28/2014

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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www.uspto.gov

BIB DATA SHEET

CONFIRMATION NO. 4130

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
13/475,607	05/18/2012	514	1629	PAT903988-US-NP

APPLICANTS

INVENTORS

Daniel A. Gamache, Arlington, TX;
Laman Alani, Fort Worth, TX;
Malay Ghosh, Fort Worth, TX;
Francisco Javier Galán, Barcelona, SPAIN;
Núria Carreras Perdiguer, Barcelona, SPAIN;
Onkar N. Singh, Arlington, TX;

**** CONTINUING DATA ***************************

This appln claims benefit of 61/487,789 05/19/2011
and claims benefit of 61/548,957 10/19/2011

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

06/01/2012

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /MY-CHAU T TRAN/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		TX	5	25	4

ADDRESS

ALCON
IP LEGAL
6201 SOUTH FREEWAY
FORT WORTH, TX 76134
UNITED STATES

TITLE

HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION

FILING FEE RECEIVED		
3390	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

BIB (Rev. 05/07).

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13475607	GAMACHE ET AL.
	Examiner	Art Unit
	MY-CHAU T TRAN	1629

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
514	449, 450	10/02/2013	MCT
UPDATED	UPDATED - see printout	04/28/2014	MCT

SEARCH NOTES		
Search Notes	Date	Examiner
PALM Inventors; WEST - see printout; STN - see printout; SciFinder - see printout	10/01/2013	MCT
Reviewed for ODP the following Patent(s) and/or Application(s): 13/183,194	10/01/2013	MCT
UPDATED - see printout	04/28/2014	MCT

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
514	449, 450; see printout	05/01/2014	MCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	Gamache, Daniel et al.
Serial No.	:	13/475,607
Filed	:	May 18, 2013
Confirmation No.	:	4130
Examiner	:	Tran, My Chau T
Group Art Unit	:	1629
For	:	High Concentration Olopatadine Ophthalmic Composition

AMENDMENT AND RESPONSE

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madam:

This paper is submitted in response to the Office Action dated October 17, 2013, for which the three-month date for response is January 17, 2013.

A request for a one-month extension of time to respond is included herewith along with the required fee. This one-month extension will bring the due date to February 17, 2013. If any request or fee is deficient or absent, consider this paragraph such a request and authorization to deduct said fees from Alcon Research, Ltd., Deposit Account No. **010682**.

Allowance of the application is respectfully requested.

Amendments to the Claims are reflected in the listing of claims that begins on page 2 of this paper.

Remarks begin on page 7 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

Claims 1-8 (cancelled)

Claim 9 (currently amended): An aqueous ophthalmic solution ~~composition~~ for treatment of ocular allergic conjunctivitis, the solution ~~composition~~ comprising:

at least 0.67 w/v % olopatadine dissolved in the solution;

PEG having a molecular weight of 300 to 500;

polyvinylpyrrolidone; ~~and~~

hydroxypropyl-γ-cyclodextrin;

benzalkonium chloride; and

water. ~~cyclodextrin derivative selected from β-cyclodextrin derivative, γ-cyclodextrin or both.~~

Claims 10-13 (cancelled)

Claim 14 (currently amended): A solution ~~composition~~ as in claim 9 further comprising borate.

Claim 15 (currently amended): A solution ~~composition~~ as in claim 14 further comprising a polyol ~~polyol~~.

Claim 16 (currently amended): An aqueous ophthalmic solution ~~composition~~ for treatment of ocular allergic conjunctivitis, the solution ~~composition~~ comprising:

at least 0.67 w/v % but no greater than 1.0 w/v% olopatadine dissolved in the solution;

2.0 w/v % to 6.0 w/v% PEG having a molecular weight of 300 to 500 ~~wherein the concentration of the PEG in solution is from about 2.0 w/v % to about 6.0 w/v%~~;

~~a lactam polymer wherein the lactam polymer is polyvinylpyrrolidone and the concentration of the polyvinylpyrrolidone in solution is from about~~ 2.0 w/v % to ~~about~~ 6.0 w/v% polyvinylpyrrolidone; ~~and~~

at leat 0.5 w/v% but no greater than 2.0 w/v% cyclodextrin ~~a β-cyclodextrin derivative or a γ-cyclodextrin~~ derivative selected from the group consisting of SAE-β-cyclodextrin, HP-γ-cyclodextrin, HP-β-cyclodextrin and combinations thereof, ~~and HP β-cyclodextrin wherein the concentration of the cyclodextrin β-cyclodextrin derivative or the γ-cyclodextrin derivative is at least 0.5 w/v% but no greater than 2.0 w/v%~~; and

water.

Claim 17 (currently amended): A solution ~~composition~~ as in claim ~~claims~~ 16 further comprising borate at a concentration of at least ~~about~~ 0.18 w/v % but less than ~~about~~ 0.5 w/v%.

Claim 18 (currently amended): A solution ~~composition~~ as in claim 17 further comprising a polyol ~~polyol~~.

Claim 19 (currently amended): A solution ~~composition~~ as in claim 18 wherein the polyol is propylene glycol ~~include polyethylene glycol~~ at a concentration of at least 0.4 w/v% but no greater than 2.2 w/v%.

Claim 20 (currently amended): An aqueous ophthalmic solution ~~composition~~ for treatment of ocular allergic conjunctivitis, the solution ~~composition~~ comprising:

at least 0.67 w/v % but no greater than 1.0 w/v% olopatadine dissolved in the solution;

2.0 w/v % to 6.0 w/v% PEG having a molecular weight of 300 to 500 ~~wherein the concentration of the PEG in solution is from about 2.0 w/v % to about 6.0 w/v%~~;

~~a lactam polymer wherein the lactam polymer is polyvinylpyrrolidone and the concentration of the polyvinylpyrrolidone in solution is from about~~ 2.0 w/v % to ~~about~~ 6.0 w/v% polyvinylpyrrolidone; ~~and~~

at least 0.5 w/v% but no greater than 2.0 w/v% hydroxypropyl-γ-cyclodextrin ~~in the composition at a concentration of at least 0.5 w/v% but no greater than 2.0 w/v%~~; and

water.

Claim 21 (currently amended): A solution ~~composition~~ as in claim ~~claims~~ 20 further comprising borate at a concentration of at least ~~about~~ 0.18 w/v % but less than ~~about~~ 0.5 w/v%.

Claim 22 (currently amended): A solution ~~composition~~ as in claim 21 further comprising a polyol ~~polyol~~.

Claim 23 (currently amended) A solution ~~composition~~ as in claim 22 wherein the polyol is propylene glycol ~~include polyethylene glycol~~ at a concentration of at least 0.4 w/v% but no greater than 2.2 w/v%.

Claim 24 (currently amended): A method of treating at least one ocular allergy symptom ~~symptoms~~ in humans, the method comprising:

topically applying to an eye of a human an amount of the solution ~~composition~~ of ~~claim 20~~ claim 16 sufficient to treat the at least one ocular allergy symptom ~~to an eye of a human~~.

Claim 25 (currently amended): A method as in claim 24 wherein the step of topically applying the solution ~~composition~~ includes dispensing at least one drop of the solution to the eye ~~an eyedrop from an eyedropper~~.

Claim 26 (new): A method as in claim 25 wherein the at least one ocular allergy symptom includes ocular itching.

Claim 27 (new): A solution as in claim 9 further comprising hydroxypropylmethyl cellulose.

Claim 28 (new): A solution as in claim 16 further comprising at least 0.15 w/v% but no greater than 1.0 w/v% hydroxypropylmethyl cellulose.

Claim 29 (new): A solution as in claim 20 further comprising at least 0.15 w/v% but no greater than 1.0 w/v% hydroxypropylmethyl cellulose.

Claim 30 (new): A solution as in claim 15 wherein the polyol is mannitol.

Claim 31 (new): A solution as in claim 18 wherein the polyol is mannitol solution at a concentration that is at least 0.05 w/v% but no greater than 0.5 w/v%.

Claim 32 (new): A solution as in claim 22 wherein the polyol is mannitol at a concentration that is at least 0.05 w/v% but no greater than 0.5 w/v%.

Claim 33 (new): An aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising:

at least 0.67 w/v % but no greater than 1.0 w/v% olopatadine dissolved in the solution;

2.0 w/v % to 6.0 w/v% PEG having a molecular weight of 300 to 500;

2.0 w/v % to 6.0 w/v% polyvinylpyrrolidone;

at least 0.5 w/v% but no greater than 2.0 w/v% hydroxypropyl-γ-cyclodextrin;

greater than 0.003 w/v% but less than 0.03 w/v% benzalkonium chloride; and

water;

wherein the pH of the solution is 6.0 to 7.8 and the osmolality of the solution is 200 to 400mOsm/kg.

Claim 34 (new): A solution as in claim 33 further comprising at least 0.15 w/v% but no greater than 1.0 w/v% hydroxypropylmethyl cellulose

Claim 35 (new): A solution as in claim 34 wherein:

i) the concentration of PEG is at least 3.0 w/v% but no greater than 5.0 w/v%;

ii) the concentration of polyvinylpyrrolidone is at least 3.0 w/v% but no greater than 5.0 w/v%; and

iii) the concentration of hydroxypropyl methylcellulose is at least 0.3 w/v% but no greater than 0.5 w/v%.

Claim 36 (new): A solution as in claim 35 further comprising:

at least 0.18 w/v% but less than 0.4 w/v% boric acid; and

at least 0.05 w/v% but no greater than 0.5 w/v% mannitol.

Claim 37 (new): A method of treating ocular allergy symptoms in humans, the method comprising:

topically applying to an eye of a human an amount of the solution of claim 35 sufficient to treat ocular allergy symptoms.

Claim 38 (new): A method as in claim 37 wherein the step of topically applying the solution includes dispensing at least one drop of the solution to the eye.

Claim 39 (new): A method as in claim 38 wherein the ocular allergy symptoms include ocular itching.

REMARKS

The Office Action of October 17, 2013 rejected claims 1-10, 14, 15, 18 and 19, objected to claim 13, but indicated that claim as being allowable if rewritten in independent format. The Office Action also allowed claims 16-17 and 20-25. Applicants thank Examiner Tran for the indication of allowed and allowable subject matter. By this Amendment, Applicants have amended the claims to leave only allowed and allowable subject matter pending. Specifically, Applicants have cancelled claims 1-8 and 10-13, have amended claims 9, 16, 19, 20, 21 and 23 and added new claims 26-30. Applicants respectfully request that the claims of the present application be formally allowed.

I. Election/Restriction Requirement

The Office Action deemed the Election Requirement issued for the present application to be proper and withdrew claims 11 and 12 based upon that Requirement. Without acquiescing in the Requirement, Applicants have canceled claims 11 and 12.

II. Claim Rejections under 35 USC 112

The Office Action rejected claims 18 and 19 suggesting that those claims do not further limit the claim upon which they depend. In particular, the Office Action suggests that PEG is a polyol and that the recitation of the inclusion of a polyol in the composition in claims 18 and 19 is not further limiting. Applicants believe this rejection was made because claim 19 inadvertently recited polyethylene glycol (PEG) as a polyol. However, because of the definition of polyol in the specification of the present application, it is clear that PEG would not be considered a polyol for purposes of the present application. Specifically, the specification, at page 11, lines 21-24, reads:

> As used herein, the term 'polyol' includes any compound having at least one hydroxyl group on each of two adjacent carbon atoms that are not in trans configuration relative to each other.

PEG does not fall into this definition. Further, claim 19 has been amended to recite the polyol as propylene glycol. Propylene glycol does fall within the definition of polyol in the present

application. As such, Applicants respectfully request that the rejection of claims 18 and 19 be withdrawn.

In the event that Examiner Tran still believes that the term "polyol" raises an issue with respect to the claims, Applicants respectfully request that Examiner Tran phone the undersigned so that such issue can be expeditiously resolved.

III. Claim Rejections under 35 USC 102/103

The Office Action rejected claims 1-10, 14, and 15 under 35 USC 102 or 35 USC 103 as being anticipated by or obvious and unpatentable over one or both of the following references: US Patent Application Publication 2011/0082145; U.S. Patent Application Publication 2004/0198828. However, the Office Action only objected to claim 13, but indicated the claim allowable if rewritten in independent format. Further, the Office Action allowed claims 16-17 and 20-25. Without acquiescing in the rejection of claims 1-10, 14 and 15 Applicants have amended the claims to leave only allowed or allowable subject matter still pending. Specifically, Applicants have canceled claim 1-8, have rewritten independent claim 9 to include the subject matter of claim 13 such that claim 9 and its dependents are allowable and have left the allowed claims pending. Applicants have also amended the claims to be in a more desired format. In the event that Examiner Tran believes that any of the claim amendments raises an issue with respect to the allowability of the claims, Applicants respectfully request that Examiner Tran phone the undersigned so that such issue can be expeditiously resolved.

I. New Claims

Applicants have added new claims 26-38. These claims are drawn to preferred embodiments of the present application. These claims are narrower in scope than the currently allowed and allowable claims. As such, Applicants respectfully request that these new claims be entered and allowed. In the event that Examiner Tran believes that any of the new claims raise an issue with respect the allowability of the present application, Applicants respectfully request that Examiner Tran phone the undersigned so that such issue can be expeditiously resolved.

In view of the above, Applicants respectfully request formal allowance of the present application.

CONCLUSION:

Applicants respectfully request allowance of the claims of the present application. Should the Examiner have any questions regarding this Amendment, please feel free to contact the undersigned attorney at the phone number listed below.

Respectfully submitted,

ALCON RESEARCH, LTD.

February 17, 2014
Date

/Scott A. Chapple, Reg. 46,287/
Scott A. Chapple
Reg. No. 46,287

Address for Correspondence:
Alcon Research, Ltd.
Scott A. Chapple, IP Legal
6201 S. Freeway, Mail Code TB4-8
Fort Worth, TX 76134-2099
Phone: 817-551-8793

Attorney Docket: PAT903988-US-NP

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13475607
Filing Date	2012-05-18
First Named Inventor	Daniel A. Gamache
Art Unit	1629
Examiner Name	Tran, My Chau T.
Attorney Docket Number	PAT903988-US-NP

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5874414		1999-02-23	Cydex, Inc.	
	2	6280745	B1	2001-08-28	Alliance Pharmaceutical Corp.	
	3	6407079	B1	2002-06-18	Janssen Pharmaceutica N.V.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13475607
	Filing Date	2012-05-18
	First Named Inventor	Daniel A. Gamache
	Art Unit	1629
	Examiner Name	Tran, My Chau T.
	Attorney Docket Number	PAT903988-US-NP

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13475607
	Filing Date	2012-05-18
	First Named Inventor	Daniel A. Gamache
	Art Unit	1629
	Examiner Name	Tran, My Chau T.
	Attorney Docket Number	PAT903988-US-NP

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott A. Chapple, 46,287/	Date (YYYY-MM-DD)	2014-02-17
Name/Print	Scott A. Chapple	Registration Number	46,287

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	13475607
Filing Date:	18-May-2012
Title of Invention:	HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION
First Named Inventor/Applicant Name:	Daniel A. Gamache
Filer:	Scott Chapple/Barbara McKenzie
Attorney Docket Number:	PAT903988-US-NP

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Claims in Excess of 20	1202	13	80	1040
Independent claims in excess of 3	1201	1	420	420
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Extension - 1 month with $0 paid	1251	1	200	200
Miscellaneous:				
			Total in USD ($)	**1660**

Electronic Acknowledgement Receipt

EFS ID:	18218732
Application Number:	13475607
International Application Number:	
Confirmation Number:	4130
Title of Invention:	HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION
First Named Inventor/Applicant Name:	Daniel A. Gamache
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	PAT903988-US-NP
Receipt Date:	17-FEB-2014
Filing Date:	18-MAY-2012
Time Stamp:	16:07:15
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1660
RAM confirmation Number	10223
Deposit Account	010682
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees) Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees) Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		PAT903988-US-NP_2014-02-17_RESP.pdf	121551 aa238d79ab55ee9617aea038f208dcd053ba2d26	yes	10

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Claims	2	6
Applicant Arguments/Remarks Made in an Amendment	7	10

Warnings:

Information:

2	Information Disclosure Statement (IDS) Form (SB08)	PAT903988-US-NP_2014-02-17_IDS_fillable.pdf	612225 805dc976f333db145c95686594decaee82a6b0d7	no	4

Warnings:

Information:

3	Fee Worksheet (SB06)	fee-info.pdf	33874 d22c43c7f04e55996bbb32668f2a0df853b542d2	no	2

Warnings:

Information:

Total Files Size (in bytes):	767650

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Electronic Patent Application Fee Transmittal

Application Number:	13475607
Filing Date:	18-May-2012
Title of Invention:	HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION
First Named Inventor/Applicant Name:	Daniel A. Gamache
Filer:	Scott Chapple/Barbara McKenzie
Attorney Docket Number:	PAT903988-US-NP

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	18218799
Application Number:	13475607
International Application Number:	
Confirmation Number:	4130
Title of Invention:	HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION
First Named Inventor/Applicant Name:	Daniel A. Gamache
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	PAT903988-US-NP
Receipt Date:	17-FEB-2014
Filing Date:	18-MAY-2012
Time Stamp:	16:13:53
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	10275
Deposit Account	010682
Authorized User	

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Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Fee Worksheet (SB06)	fee-info.pdf	30596 99cd88e0e6071b4fde3de8d97a5db913db1246f1	no	2

Warnings:

Information:

Total Files Size (in bytes):	30596

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New Applications Under 35 U.S.C. 111
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National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/475,607	Filing Date 05/18/2012	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	02/17/2014	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 27	Minus	** 25	= 2	X $80 =	160
	Independent (37 CFR 1.16(h))	* 4	Minus	***4	= 0	X $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	160

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/DEBORAH POLLARD/

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13475607
Filing Date	2012-05-18
First Named Inventor	Daniel A. Gamache
Art Unit	1629
Examiner Name	My Chau T Tran
Attorney Docket Number	PAT903988-US-NP

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13475607
	Filing Date	2012-05-18
	First Named Inventor	Daniel A. Gamache
	Art Unit	1629
	Examiner Name	My Chau T Tran
	Attorney Docket Number	PAT903988-US-NP

	1	International Preliminary Report on Patentability for corresponding PCT/US2012/038663 with mailing date November 28, 2013	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13475607
	Filing Date	2012-05-18
	First Named Inventor	Daniel A. Gamache
	Art Unit	1629
	Examiner Name	My Chau T Tran
	Attorney Docket Number	PAT903988-US-NP

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Scott A. Chapple, 46,287/	Date (YYYY-MM-DD)	2013-12-16
Name/Print	Scott A. Chapple	Registration Number	46,287

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PATENT COOPERATION TREATY

ADVANCE E-MAIL

PCT

NOTIFICATION CONCERNING TRANSMITTAL OF COPY OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (CHAPTER I OF THE PATENT COOPERATION TREATY)
(PCT Rule 44bis.1(c))

From the INTERNATIONAL BUREAU

To:

SCOTT A. CHAPPLE
Alcon Research, Ltd.
IP Legal, Mail Code TB4-8
6201 South Freeway
Fort Worth, Texas 76134-2099
ETATS-UNIS D'AMERIQUE

Date of mailing *(day/month/year)* 28 November 2013 (28.11.2013)	
Applicant's or agent's file reference 3988-WO-F	**IMPORTANT NOTICE**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2012/038663	18 May 2012 (18.05.2012)	19 May 2011 (19.05.2011)

Applicant
ALCON RESEARCH, LTD. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. +41 22 338 82 70

Authorized officer
Simin Baharlou

e-mail: pt09.pct@wipo.int

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 3988-WO-F	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2012/038663	International filing date *(day/month/year)* 18 May 2012 (18.05.2012)	Priority date *(day/month/year)* 19 May 2011 (19.05.2011)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ALCON RESEARCH, LTD.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☒	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 19 November 2013 (19.11.2013)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Simin Baharlou e-mail: pt09.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2012/038663	18.05.2012	19.05.2011

International Patent Classification (IPC) or both national classification and IPC
INV. A61K31/335 A61K9/00 A61P27/14

Applicant
ALCON RESEARCH, LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465	see form PCT/ISA/210	Economou, Dimitrios Telephone No. +49 89 2399-0

Form PCT/ISA/237 (Cover Sheet) (July 2009)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	4-23
	No:	Claims	1-3, 24, 25
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-25
Industrial applicability (IA)	Yes:	Claims	1-25
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1). Claims 24-25 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) / 67.1(iv) PCT.

The patentability can be dependent upon the formulation of the claims. The EPO, for example, does not recognise as patentable claims to the use of a compound in medical treatment, but may allow claims to a product, in particular substances or compositions for use in a first or further medical treatment.

2). Reference is made to the following documents:

Reference is made to the following documents:

D1=WO 2009/003199

D2=WO 96/39147

D3=WO 01/54687

D4=WO 2008/015695

All of the documents **D1**-**D3** disclose compositions comprising at least 0.7% olopatadin for the treatment of allergic eye diseases. Hence the subject-matter of claims 1-2 and 24-25 is not novel

D1 discloses compositions comprising at least 0.7% olopatadin for the treatment of allergic eye diseases (see example 20). Example 20 discloses also the composition in the presence of SBE-gamma-CD. Hence the subject-matter of claim 3 is also not novel.

The closest prior art is **D1** which discloses high concentrations of olopatadine in aqueous solution suitable for ophthalmic administration (see example 20). Said document refers also to the additional compounds which appear to routineously used in the technical field (e.g PVP, PEG, boric acid, polyols, HPMC, preservatives; see the passages mentioned in the ISR).

Additionally, from **D4** the use of PEG, HPMC, PVP, BAK for solubilization of olopatadine have been mentioned in examples A-M in which however, the highest amount of olopatadine has reached 0.665 % but with an insufficient physical stability. Compositions comprising 0.527 % olopatadine are mentioned in example 1 which comprise HP-beta-cyclodextrin, HPMC and benzalkonium chloride. Hence, as it appears from **D1** or **D4**, cyclodextrins, PVP, HPMC, PEG are obvious i the technical field and therefore the subject-matter of the present application does not appear to involve an inventive step.

Re Item VII

Certain defects in the international application

As it appears from the description tailoring of the compositions of the present application appears to be a challenge for the person skilled in the art. The compositions must be stable, must comprise olopatadine in high concentrations (at least 0.67 %), thus exhibiting consistent efficacy against late phase symptoms of allergic conjunctivitis and must have sufficient antimicrobial activity to provide desired levels of preservation efficacy.

As it is evident from **table B** cyclodextrin can significantly enhance the solubility of olopatadine in in aqueous solutions. However, must be present in a concentration of at least 1.5 % since amounts of 1 % HP-beta-cyclodextrin do not solubilize at least 0.67 % of olopatadine. From **table C** however, can be seen that 1.5% HP-beta-cyclodextrin significantly inhibits the ability of a preservative to provide desired preservation to an aqueous solution. From **table E** it is evident that formulations having high concentrations of olopatadine show desirable preservation by combining PVP with a relatively low amount of HP-beta-cyclodextrin by using BAK and boric acid as preservatives. **Tables F** and **G** show that formulations comprising SBE-beta-CD do not provide desired levels of preservation.

The only compositions which appear to possess the above mentioned properties are probably the compositions mentioned on **table J** of the description. These compositions comprise however, specific components, in particular amounts. Claims which are roughly similar to the compositions of table J are claims 20-23. For the invention as defined in any of the other claims the description does not comprise at least a way of how the skilled person would carry out the invention, since it appears the desired ef-

fects cannot be achieved without undue burden. Hence, the present application does not fulfil the requirements of art. 5 PCT as regards subject-matter as defined in claims 1-19 and 24-25.

Re Item VIII

Certain observations on the international application

It is clear from the description from page 3, line 19 to page 4, line 2 that the following features are essential to the definition of the invention:

-a cyclodextrin

-a lactam polymer

-a polyether

-a pH of 5.5 to 8

-an osmolality of 200 to 450 (units mentioned on page 14, lines 16-20)

-a preservative and a borate and/or polyol.

Since independent claims 1, 9,16 and 20 do not contain this feature it does not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

Electronic Acknowledgement Receipt

EFS ID:	17679057
Application Number:	13475607
International Application Number:	
Confirmation Number:	4130
Title of Invention:	HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION
First Named Inventor/Applicant Name:	Daniel A. Gamache
Customer Number:	26356
Filer:	Scott Chapple/Candy Sanders
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3988 US
Receipt Date:	17-DEC-2013
Filing Date:	18-MAY-2012
Time Stamp:	11:37:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	PAT903988-US-NP_2013-12-17_IDS_fillable__.pdf	612158 2aa7fda1f965fa2060ab481fcfcb2d34b76efc79	no	4

Warnings:	
Information:	

A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

2	Other Reference-Patent/App/Search documents	PAT903988_REF_PCT-US2012-038663_IPRP___.pdf	283145 77754228e4dd35e5aa36d74d7e166fa4d56dd167	no	8

Warnings:

Information:

Total Files Size (in bytes):	895303

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/475,607	05/18/2012	Daniel A. Gamache	3988 US	4130

26356 7590 10/17/2013

ALCON
IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

EXAMINER	
TRAN, MY CHAU T	

ART UNIT	PAPER NUMBER
1629	

NOTIFICATION DATE	DELIVERY MODE
10/17/2013	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent.docketing@alcon.com

Office Action Summary	Application No. 13/475,607	Applicant(s) GAMACHE ET AL.	
	Examiner MY-CHAU T. TRAN	Art Unit 1629	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/15/2013*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-25* is/are pending in the application.

5a) Of the above claim(s) *11 and 12* is/are withdrawn from consideration.

6)☒ Claim(s) *16,17 and 20-25* is/are allowed.

7)☒ Claim(s) *1-10,14,15,18 and 19* is/are rejected.

8)☒ Claim(s) *13* is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *05/18/2012* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some * c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Application and Claims Status

1. The present application is being examined under the pre-AIA first to invent provisions.

2. Applicant's amendment and response filed 05/15/2013 are acknowledged and entered.

3. Claims 1-25 were pending. No claims were amended, added, and/or cancelled.

Therefore, claims 1-25 are currently pending.

Election/Restrictions

4. Applicant's election with traverse of the species of ophthalmic composition in the reply filed on 05/15/2013 is acknowledged. Applicants election is as follows: "*Applicants elect, with traverse, the composition described in the table below:*

Ingredients	w/v%
Olopatadine (Olopatadine HCl)	0.7
Polyether (PEG)	4.0
Lactam Polymer (PVP)	4.0
Viscosity Agent (HEC)	0.1 (if used w/ HPMC or other viscosity agent) 0.3 (if used w/o HPMC or other viscosity agent)
Viscosity Agent (HPMC)	0.15 (if used w/ HEC or other viscosity agent) 0.35 (if used w/o HEC or other viscosity agent)
Chelating agent (Disodium EDTA)	0.005
Borate (Boric Acid)	0.3

cyclodextrin derivative	1.5
Polyol (Mannitol)	0.3
Polyol (Propylene Glycol)	1.0
Tonicity Agent (Sodium Chloride)	0.35
Preservative (BAK)	0.01
pH adjusting agents (NaOH or HCl)	sufficient to achieve pH = 7.0
purified water	Q.S. 100

,,

The traversal is on the ground that "*Election/Restriction Requirements are to be based upon the claims of an application and should indicate where different species are within the claims. The Election Requirement for the present application has failed to do that*", in which applicant specifically cites MPEP § 803 and 806.01. This is not found persuasive because 1) as clearly stated in the previous Office Action, this is a species election regarding the various claimed species of ophthalmic composition wherein each claimed ophthalmic composition have distinct formulation. See especially instant claims 1, 9, 16, and 20. Each distinct formulation has different concentration of active agent and/or different type of excipients, diluents, vehicles, and/or carriers that result in distinct claimed ophthalmic composition. Moreover, applicants have not provided any evidence and/or clearly state on record that each of the claimed ophthalmic composition does not have distinct formulation. 2) The MPEP citations provided by applicant does not specifically relates to the species election that is require by the previous Office Action. Applicants should read MPEP § 806.04(b), 806.04(e), 806.04(f), and 806.04(h) that are specifically related to the species election requirement. Thus, the instant application meets the species election requirement.

The requirement is still deemed proper and is therefore made FINAL.

5. Claims 11 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to ***nonelected species***, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 05/15/2013. Accordingly, claims 1-10 and 13-25 are under consideration in this Office Action.

Priority

6. This instant application claims benefits to two provisional application, which are 61/487,789 filed 05/19/2011 and 61/548,957 filed 10/19/2011, under 35 U.S.C. 119(e).

Claim Rejections - 35 USC § 112

7. The following is a quotation of 35 U.S.C. 112(d):

> (d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), fourth paragraph:

> Subject to the [fifth paragraph of 35 U.S.C. 112 (pre-AIA)], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

8. Claims 18 and 19 are rejected under 35 U.S.C. 112(d) or pre-AIA 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends. Here, instant claim 18 recites the limitation of "*further comprising polyol*". Instant claim 19 recites the limitation of "*wherein the polyol include polyethylene glycol at a concentration of at least 0.4 w/v% but no greater than 2.2 w/v%*". Instant claim 16 for which

claims 18 and 19 depend recites the limitation of "*PEG having a molecular weight of 300 to 500 wherein the concentration of the PEG in solution is from about 2.0 w/v % to about 6.0 w/v%*". The acronym of PEG is defined in the instant specification as polyethylene glycol (see pg. 2, lines 26-27). Consequently, claims 18 and 19 do not further limit the subject matter of instant claim 16. Applicant may cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 2, and 4-8 are rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by Schneider et al. (US Patent Application Publication 2011/0082145 A1; *Filing Date 10/01/2010*).

For ***claims 1, 2, and 4-8***, Schneider et al. disclose formulations of olopatadine and their use for treating and/or preventing allergic or inflammatory disorders of the eye, ear, skin, and nose (see e.g. Abstract; sections: [0002], [0009], and [0018]). In one embodiment, the pharmaceutical aqueous solution composition is an ophthalmic formulation to be administered to the eye of a patient for the treatment of ocular disorder that includes allergic and/or inflammatory

conditions of the eye (refers to instant claimed limitation of ophthalmic composition and eyedropper) (see e.g. sections: [0018] and [0048]-[0050]). The solution composition comprises olopatadine and ophthalmologically acceptable preservatives, surfactants, viscosity enhancers, penetration enhancers, buffers, tonicity agents, and water to form an aqueous, sterile ophthalmic solution, suspension, or emulsion (refers to instant claimed limitation of olopatadine and water) (see e.g. sections: [0040]-[0041], [0044]-[0045], [0048]-[0049], and [0051]-[0053]). The concentration of olopatadine is at least 0.05 % w/v, i.e. the concentration lower limit is 0.05 % w/v without any upper limit (refers to instant claimed limitation of at least 0.67 w/v % olopatadine and instant claim 2) (see e.g. section [0045]). The type of lubricants and/or viscosity agents include polyethylene glycols (PEGs) and polyvinylpyrrolidones (PVPs) (refers to instant claims 4-7) (see e.g. section [0052]). The solution composition comprises an osmolality of about 150-450 mOsm and a pH of about 3.0 to about 8.5 (refers to instant claim 8) (see e.g. sections: [0053]-[0054]).

Therefore, the solution composition of Schneider et al. does anticipate the instant claimed invention.

Claim Rejections - 35 USC § 103

11. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-8 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Schneider et al. (US Patent Application Publication 2011/0082145 A1; *Filing Date 10/01/2010*) and Abelson et al. (US Patent Application Publication 2004/0198828 A1).

For ***claims 1, 2, and 4-8***, Schneider et al. disclose formulations of olopatadine and their use for treating and/or preventing allergic or inflammatory disorders of the eye, ear, skin, and nose (see e.g. Abstract; sections: [0002], [0009], and [0018]). In one embodiment, the pharmaceutical aqueous solution composition is an ophthalmic formulation to be administered to the eye of a patient for the treatment of ocular disorder that includes allergic and/or inflammatory conditions of the eye (refers to instant claimed limitation of ophthalmic composition and eyedropper) (see e.g. sections: [0018] and [0048]-[0050]). The solution composition comprises olopatadine and ophthalmologically acceptable preservatives, surfactants, viscosity enhancers, penetration enhancers, buffers, tonicity agents, and water to form an aqueous, sterile ophthalmic solution, suspension, or emulsion (refers to instant claimed limitation of olopatadine and water) (see e.g. sections: [0040]-[0041], [0044]-[0045], [0048]-[0049], and [0051]-[0053]). The concentration of olopatadine is at least 0.05 % w/v, i.e. the concentration lower limit is 0.05 % w/v without any upper limit (refers to instant claimed limitation of at least 0.67 w/v % olopatadine and instant claim 2) (see e.g. section [0045]). The type of lubricants and/or viscosity agents include polyethylene glycols (PEGs) and polyvinylpyrrolidones (PVPs) (refers to instant claims 4-7) (see e.g. section [0052]). The solution composition comprises an osmolality of about 150-450 mOsm and a pH of about 3.0 to about 8.5 (refers to instant claim 8) (see e.g. sections: [0053]-[0054]).

The teachings of Schneider et al. differ from the presently claimed invention as follows:

For ***claim 3***, Schneider et al. fail to disclose a solubilizer such as cyclodextrins and its derivatives.

However, Abelson et al. teach the limitations that are deficient in Schneider et al. as follows:

For ***claim 3***, Abelson et al. disclose pharmaceutical compositions for the treatment of ocular allergies (see e.g. Abstract; sections: [0004], [0006], and [0019]). The pharmaceutical compositions comprises long-acting anti-histamine agent such as olopatadine and a variety of carriers such as water and polyvinylpyrrolidone (see e.g. sections: [0022] and [0035]). The pharmaceutical compositions for ocular administration include other type of ingredients that meet the prerequisites for ocular tolerability such as tonicity enhancers, preservatives, solubilizers, non-toxic excipients, demulcents, sequestering agents and pH adjusting agents (see e.g. sections: [0037]-[0047]). The type of solubilizers includes a cyclodextrin such as alpha-, beta- or gamma-cyclodextrin, e.g. alkylated, hydroxyalkylated, carboxyalkylated or alkyloxycarbonylalkylated derivatives, or mono- or diglycosyl-alpha-, beta or gamma-cyclodextrin, mono- or dimaltosyl-alpha-, beta or gamma-cyclodextrin or panosyl-cyclodextrin (see e.g. section [0042]).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a solubilizer such as cyclodextrins and its derivatives as taught by Abelson et al. in the composition of Schneider et al. One of ordinary skill in the art would have been motivated to disclose a solubilizer such as cyclodextrins and its derivatives in the composition of Schneider et al. for the advantage of providing a solution form of the active ingredient in order to provide better penetration to a target site of action and better dosage consistency (Abelson: section [0042]; Schneider: section [0007]). Additionally, both Schneider

et al. and Abelson et al. disclose that the pharmaceutical composition is an ophthalmic formulation to be administered to the eye of a patient for the treatment of ocular allergies (Schneider: section [0048]; Abelson: section [0037]). Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Schneider et al. and Abelson et al. because it is art recognize that it is more desirable for the active ingredients of a pharmaceutical composition to be in a solution form (Schneider: section [0007]).

Therefore, the combine teachings of Schneider et al. and Abelson et al. do render the invention of the instant claims *prima facie* obvious.

13. Claims 9, 10, 14, and 15 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Schneider et al. (US Patent Application Publication 2011/0082145 A1; *Filing Date 10/01/2010*) and Abelson et al. (US Patent Application Publication 2004/0198828 A1).

For ***claims 9, 10, 14 and 15***, Schneider et al. disclose formulations of olopatadine and their use for treating and/or preventing allergic or inflammatory disorders of the eye, ear, skin, and nose (see e.g. Abstract; sections: [0002], [0009], and [0018]). In one embodiment, the pharmaceutical aqueous solution composition is an ophthalmic formulation to be administered to the eye of a patient for the treatment of ocular disorder that includes allergic and/or inflammatory conditions of the eye (refers to instant claimed limitation of ophthalmic composition and eyedropper) (see e.g. sections: [0018] and [0048]-[0050]). The solution composition comprises olopatadine and ophthalmologically acceptable preservatives, surfactants, viscosity enhancers, penetration enhancers, buffers, tonicity agents, and water to form an aqueous, sterile ophthalmic solution, suspension, or emulsion (refers to instant claimed limitation of olopatadine dissolved in

solution) (see e.g. sections: [0040]-[0041], [0044]-[0045], [0048]-[0049], and [0051]-[0053]). The concentration of olopatadine is at least 0.05 % w/v, i.e. the concentration lower limit is 0.05 % w/v without any upper limit (refers to instant claimed limitation of at least 0.67 w/v % olopatadine) (see e.g. section [0045]). The type of lubricants and/or viscosity agents include polyethylene glycols (PEGs) and polyvinylpyrrolidones (PVPs) (refers to instant claimed limitation of PEG and polyvinylpyrrolidone) (see e.g. section [0052]). The type of preservative includes benzalkonium chloride (refers to instant claim 10) (see e.g. sections: [0051]-[0052). The type of buffering agents includes borates (refers to instant claim 14), and the type of tonicity-adjusting agents includes mannitol (refers to instant claim 15) (see e.g. section [0052]). The solution composition comprises an osmolality of about 150-450 mOsm and a pH of about 3.0 to about 8.5 (see e.g. sections: [0053]-[0054]).

The teachings of Schneider et al. differ from the presently claimed invention as follows:

For ***claim 9***, Schneider et al. fail to disclose (a) a solubilizer such as cyclodextrins and its derivatives; and (b) the type of PEG having a molecular weight of 300 to 500.

However, Abelson et al. teach the limitations that are deficient in Schneider et al. as follows:

For ***claim 9***, Abelson et al. disclose pharmaceutical compositions for the treatment of ocular allergies (see e.g. Abstract; sections: [0004], [0006], and [0019]). The pharmaceutical compositions comprises long-acting anti-histamine agent such as olopatadine and a variety of carriers such as water and polyvinylpyrrolidone (see e.g. sections: [0022] and [0035]). The pharmaceutical compositions for ocular administration include other type of ingredients that meet the prerequisites for ocular tolerability such as tonicity enhancers, preservatives, solubilizers, non-toxic excipients, demulcents, sequestering agents and pH adjusting agents (see

e.g. sections: [0037]-[0047]). The type of solubilizers includes a cyclodextrin such as alpha-, beta- or gamma-cyclodextrin, e.g. alkylated, hydroxyalkylated, carboxyalkylated or alkyloxycarbonylalkylated derivatives, or mono- or diglycosyl-alpha-, beta or gamma-cyclodextrin, mono- or dimaltosyl-alpha-, beta or gamma-cyclodextrin or panosyl-cyclodextrin (see e.g. section [0042]). The type of buffers includes borate (see e.g. section [0038]). The type of tonicity enhancers includes mannitol (see e.g. section [0039]). The type of preservative includes benzalkonium chloride (see e.g. section [0039]). The type of non-toxic excipients includes polyethylene glycols that are designated 200, 300, 400, and 600 (see e.g. section [0044]).

(a) It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a solubilizer such as cyclodextrins and its derivatives as taught by Abelson et al. in the composition of Schneider et al. One of ordinary skill in the art would have been motivated to disclose a solubilizer such as cyclodextrins and its derivatives in the composition of Schneider et al. for the advantage of providing a solution form of the active ingredient in order to provide better penetration to a target site of action and better dosage consistency (Abelson: section [0042]; Schneider: section [0007]). Additionally, both Schneider et al. and Abelson et al. disclose that the pharmaceutical composition is an ophthalmic formulation to be administered to the eye of a patient for the treatment of ocular allergies (Schneider: section [0048]; Abelson: section [0037]). Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Schneider et al. and Abelson et al. because it is art recognize that it is more desirable for the active ingredients of a pharmaceutical composition to be in a solution form (Schneider: section [0007]).

(b) It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose the type of PEG having a molecular weight of 300 to 500 in the composition of Schneider et al. One of ordinary skill in the art would have been motivated to disclose the type of PEG having a molecular weight of 300 to 500 in the composition of Schneider et al. since the type of non-toxic excipients would be a choice of experimental design and is considered within the purview of the cited prior art. Moreover, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Schneider et al. and Abelson et al. because the pharmaceutical composition of both Schneider et al. and Abelson et al. include pharmaceutical carriers that is specific for an ophthalmic formulation (Schneider: section [0048]; Abelson: section [0037]).

Therefore, the combine teachings of Schneider et al. and Abelson et al. do render the invention of the instant claims *prima facie* obvious.

Allowable Subject Matter

14. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. Claims 16-17 and 20-25 are allowable.

16. The following is a statement of reasons for the indication of allowable subject matter:

A. The instant claims 16-17 are allowable for the reason that the cited prior arts do not teach or fairly suggest the presently claimed composition comprising '*at least 0.67 w/v % but no greater than 1.0 w/v% olopatadine dissolved in solution; PEG having a molecular weight of 300 to 500 wherein the concentration of the PEG in solution is from about 2.0 w/v % to about 6.0 w/v%; a lactam polymer wherein the lactam polymer is polyvinylpyrrolidone and the concentration of the polyvinylpyrrolidone in solution is from about 2.0 w/v % to about 6.0 w/v%; and the concentration of the β-cyclodextrin derivative or the y-cyclodextrin derivative is at least 0.5 w/v% but no greater than 2.0 w/v%*'.

B. The instant claims 20-25 are allowable for the reason that the cited prior arts do not teach or fairly suggest the presently claimed composition and method of using the claimed composition wherein the claimed composition comprises '*at least 0.67 w/v % but no greater than 1.0 w/v% olopatadine dissolved in solution; PEG having a molecular weight of 300 to 500 wherein the concentration of the PEG in solution is from about 2.0 w/v % to about 6.0 w/v%; a lactam polymer wherein the lactam polymer is polyvinylpyrrolidone and the concentration of the polyvinylpyrrolidone in solution is from about 2.0 w/v % to about 6.0 w/v%; and hydroxypropyl-y-cyclodextrin in the composition at a concentration of at least 0.5 w/v% but no greater than 2.0 w/v%*'.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T. TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Monday - Friday: 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey S. Lundgren can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MY-CHAU T. TRAN/
Primary Examiner, Art Unit 1629

October 8, 2013

Notice of References Cited	Application/Control No. 13/475,607	Applicant(s)/Patent Under Reexamination GAMACHE ET AL.	
	Examiner MY-CHAU T. TRAN	Art Unit 1629	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,641,805	06-1997	Hayakawa et al.	514/450
*	B	US-6,995,186 B2	02-2006	Castillo et al.	514/450
*	C	US-2004/0198828 A1	10-2004	Abelson et al.	514/571
*	D	US-2011/0082145 A1	04-2011	Schneider et al.	514/235.2
*	E	US-2012/0015953 A1	01-2012	Beauregard et al.	514/250
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

WEST Search History for Application 13475607

Creation Date: 2013100613:37

Prior Art Searches

Query	DB	Op.	Plur.	Thes.	Date
("20020006443" |"20020150616" |"20030170309" |"20050004074" |"20050191270" |"20050244472" |"20060210645" |"20070020336" |"20080132444" |"20090118262" |"20090232763" |"20090239842" |"20100240625" |"20100249062" |"20100324031" |"3767788" |"3843782" |"3856919" |"3931319" |"3947573" |"4027020" |"4120949" |"4283393" |"4407791" |"4470965" |"4525346" |"4836986" |"4923693" |"5037647" |"5068225" |"5116863" |"5134127" |"5141961" |"5300287" |"5376645" |"5472954" |"5591426" |"5597559" |"5624962" |"5888493" |"6153746" |"6511949" |"6828356" |"7074424" |"7147844" |"7429602" |"7635773").PN.	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-02-2013
olopatadine and (("20020006443" |"20020150616" |"20030170309" |"20050004074" |"20050191270" |"20050244472" |"20060210645" |"20070020336" |"20080132444" |"20090118262" |"20090232763" |"20090239842" |"20100240625" |"20100249062" |"20100324031" |"3767788" |"3843782" |"3856919" |"3931319" |"3947573" |"4027020" |"4120949" |"4283393" |"4407791" |"4470965" |"4525346" |"4836986" |"4923693" |"5037647" |"5068225" |"5116863" |"5134127" |"5141961" |"5300287" |"5376645" |"5472954" |"5591426" |"5597559" |"5624962" |"5888493" |"6153746" |"6511949" |"6828356" |"7074424" |"7147844" |"7429602" |"7635773").PN.)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-02-2013
GAMACHE-DANIEL-A$.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
ALANI-LAMAN$.in.	PGPB, USPT, USOC,	ADJ	YES	ASSIGNEE	10-02-2013

	EPAB, JPAB, DWPI, TDBD, FPRS				
GHOSH-MALAY$.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
GALAN-FRANCISCO-JAVIER$.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
PERDIGUER-NURIA-CARRERAS$.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
SINGH-ONKAR-N$.in.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
(GAMACHE-DANIEL-A$.in.) and (ALANI-LAMAN$.in.) and (GHOSH-MALAY$.in.) and (GALAN-FRANCISCO-JAVIER$.in.) and (PERDIGUER-NURIA-CARRERAS$.in.) and (SINGH-ONKAR-N$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
(GAMACHE-DANIEL-A$.in.) and	PGPB,	ADJ	YES	ASSIGNEE	10-02-2013

(ALANI-LAMAN$.in.) and (GHOSH-MALAY$.in.) and (GALAN-FRANCISCO-JAVIER$.in.) and (PERDIGUER-NURIA-CARRERAS$.in.)	USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS				
(GAMACHE-DANIEL-A$.in.) and (ALANI-LAMAN$.in.) and (GHOSH-MALAY$.in.) and (GALAN-FRANCISCO-JAVIER$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
(GAMACHE-DANIEL-A$.in.) and (ALANI-LAMAN$.in.) and (GHOSH-MALAY$.in.) and (GALAN-FRANCISCO-JAVIER$.in.) and (SINGH-ONKAR-N$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
olopatadine.clm. and (GAMACHE-DANIEL-A$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
olopatadine.clm. and (ALANI-LAMAN$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
olopatadine.clm. and (GHOSH-MALAY$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013

olopatadine.clm. and (GALAN-FRANCISCO-JAVIER$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
olopatadine.clm. and (PERDIGUER-NURIA-CARRERAS$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
olopatadine.clm. and (SINGH-ONKAR-N$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
ALCON RESEARCH$.as.	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
olopatadine.clm. and (ALCON RESEARCH$.as.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
(ophthalmic (formulation or composition)).clm. and (olopatadine.clm. and GAMACHE-DANIEL-A$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD,	ADJ	YES	ASSIGNEE	10-02-2013

	FPRS				
(ophthalmic (formulation or composition)).clm. and (olopatadine.clm. and SINGH-ONKAR-N$.in.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
(ophthalmic (formulation or composition)).clm. and (olopatadine.clm. and ALCON RESEARCH$.as.)	PGPB, USPT, USOC, EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
(514/449 |514/450)![CCLS]	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-02-2013
olopatadine and ((514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-02-2013
(ophthalmic (formulation or composition)) and (olopatadine and (514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-02-2013
cyclodextrin and ((ophthalmic (formulation or composition)) and olopatadine and (514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-02-2013
lactam and ((ophthalmic (formulation or composition)) and olopatadine and (514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-02-2013
polyether and ((ophthalmic (formulation or composition)) and olopatadine and (514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-02-2013
(polyethylene glycol) and ((ophthalmic (formulation or composition)) and olopatadine and (514/449 |514/450)![CCLS])	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-02-2013
(ophthalmic (formulation or composition)) and olopatadine	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013

cyclodextrin and ((ophthalmic (formulation or composition)) and olopatadine)	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
lactam and ((ophthalmic (formulation or composition)) and olopatadine)	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
lactam and (cyclodextrin and (ophthalmic (formulation or composition)) and olopatadine)	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
(polyethylene glycol) and ((ophthalmic (formulation or composition)) and olopatadine)	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
(polyethylene glycol) and (cyclodextrin and (ophthalmic (formulation or composition)) and olopatadine)	EPAB, JPAB, DWPI, TDBD, FPRS	ADJ	YES	ASSIGNEE	10-02-2013
(ophthalmic (formulation or composition)) and olopatadine	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-02-2013
((ophthalmic (formulation or composition)) and olopatadine) not @AY>2011	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-02-2013
cyclodextrin and ((ophthalmic (formulation or composition)) and olopatadine not @AY>2011)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-02-2013
lactam and (cyclodextrin and (ophthalmic (formulation or composition)) and olopatadine not @AY>2011)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-02-2013
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lactam and ((polyethylene glycol) and cyclodextrin and (ophthalmic (formulation or composition)) and olopatadine not @AY>2011)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-02-2013

(olopatadine same ((mass ratio) or dos$4 or concentrat$3 or ((weight or WT) same (percent or (per cent) or "%")))) and ((ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-03-2013
(olopatadine same (percent or (per cent) or "%")) and ((ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-03-2013
cyclodextrin and ((olopatadine same (percent or (per cent) or "%")) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-03-2013
(polyethylene glycol) and ((olopatadine same (percent or (per cent) or "%")) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-03-2013
(polyvinylpyrrolidone) and ((polyethylene glycol) and (olopatadine same (percent or (per cent) or "%")) and (ophthalmic (formulation or composition)) and olopatadine)	PGPB, USPT, USOC	ADJ	YES	ASSIGNEE	10-03-2013

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STN Express Query Summary
ALL L# QUERIES AND ANSWER SETS ARE DELETED AT LOGOFF
LOGOFF? (Y)/N/HOLD:y

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L2             1 SEA FILE=CAPLUS SPE=ON  ABB=ON  PLU=ON  US2012-475607/AP
L3             1 DUP REMOVE L1 L2 (1 DUPLICATE REMOVED)
D IBIB ABS HITSTR

FILE 'REGISTRY' ENTERED AT 20:56:54 ON 01 OCT 2013

FILE 'CAPLUS' ENTERED AT 20:57:03 ON 01 OCT 2013
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FILE 'REGISTRY' ENTERED AT 20:57:08 ON 01 OCT 2013
L5             6 SEA FILE=REGISTRY SPE=ON  ABB=ON  PLU=ON  L4
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DISPLAY SET NOTICE

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L6               STR 140462-76-6
L7           120 SEA FILE=REGISTRY FAM FUL L6
DISPLAY SET NOTICE

FILE 'REGISTRY' ENTERED AT 20:58:52 ON 01 OCT 2013
L8               STR 113806-05-6
L9           120 SEA FILE=REGISTRY FAM FUL L8
E OLOPATADINE/CN
L10            1 SEA FILE=REGISTRY SPE=ON  ABB=ON  PLU=ON  OLOPATADINE/CN
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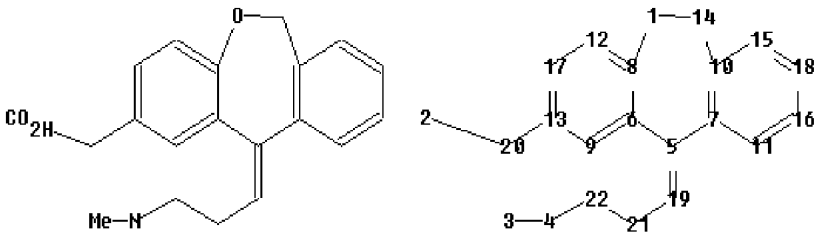
D L10

L11 1 SEA FILE=REGISTRY SPE=ON ABB=ON PLU=ON OLOPATADINE/CN

D

L12 STRUCTURE UPLOADED

STRUCTURE: C:\Users\mtran7\Documents\STN Express 8.4\Queries\Olopatadine.str



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2 3 4 19 20 21 22
ring nodes :
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ring bonds :
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13-17 15-18 16-18
exact/norm bonds :
1-8 1-14 4-22 5-6 5-7 10-14
exact bonds :
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normalized bonds :
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Match level :
1:Atom 2:CLASS 3:CLASS 4:CLASS 5:Atom 6:Atom 7:Atom 8:Atom 9:Atom 10:Atom
11:Atom 12:Atom 13:Atom 14:Atom 15:Atom 16:Atom 17:Atom 18:Atom 19:CLASS
20:CLASS 21:CLASS 22:CLASS

D

L13 140 SEA FILE=REGISTRY SSS FUL L12

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OCT 2013

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L*** DEL 136 S L14 AND L15 AND L16 AND L17 AND L18

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L22 104 SEA FILE=MFE SPE=ON ABB=ON PLU=ON OLOPATADINE AND L21

L23 1 SEA FILE=MFE SPE=ON ABB=ON PLU=ON (POLYETHER OR (POLYETHYLEN E GLYCOL) OR PEG) AND L22

D IBIB ABS HITSTR L23

L24 0 SEA FILE=MFE SPE=ON ABB=ON PLU=ON (OPHTHALMIC COMPOSITION) AND L22

L25 28 SEA FILE=MFE SPE=ON ABB=ON PLU=ON (OPHTHALMIC) AND L22

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L*** DEL 215 S L14 AND L15 AND L16 AND L17 AND L18

L*** DEL 136 S L14 AND L15 AND L16 AND L17 AND L18

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L27 37 SEA FILE=MFE SPE=ON ABB=ON PLU=ON (POLYETHER OR (POLYETHYLEN E GLYCOL) OR PEG) AND L26

L28 20 SEA FILE=MFE SPE=ON ABB=ON PLU=ON (OPHTHALMIC) AND L27

D IBIB ABS HITSTR L28 1-20

E GAMACHE DANIEL/AU

L29 223 SEA FILE=MFE SPE=ON ABB=ON PLU=ON ("GAMACHE DANIEL"/AU OR "GAMACHE DANIEL A"/AU OR "GAMACHE DANIEL A DR"/AU OR "GAMACHE DANIEL ANDRE"/AU)

E ALANI LAMAN/AU

L30 65 SEA FILE=MFE SPE=ON ABB=ON PLU=ON ("ALANI LAMAN"/AU OR "ALANI LAMAN A"/AU OR "ALANI LAMAN L"/AU OR "ALANI LAMAN LYNN"/AU)

E GHOSH MALAY/AU

L31 194 SEA FILE=MFE SPE=ON ABB=ON PLU=ON ("GHOSH MALAY"/AU OR "GHOSH MALAY K"/AU OR "GHOSH MALAY KUMAR"/AU)

E GALAN FRANCISCO/AU

L32 42 SEA FILE=MFE SPE=ON ABB=ON PLU=ON ("GALAN FRANCISCO"/AU OR "GALAN FRANCISCO JAVIER"/AU OR "GALAN FRANCISCO M"/AU)

E PERDIGUER NURIA/AU

L33 5 SEA FILE=MFE SPE=ON ABB=ON PLU=ON ("PERDIGUER NURIA"/AU OR "PERDIGUER NURIA CARRERAS"/AU)

E SINGH ONKAR/AU

L34 481 SEA FILE=MFE SPE=ON ABB=ON PLU=ON "SINGH ONKAR"/AU OR ("SINGH ONKAR N"/AU OR "SINGH ONKAR NATH"/AU)

L35 2 SEA FILE=MFE SPE=ON ABB=ON PLU=ON L29 AND L30 AND L31 AND L32 AND L33 AND L34

D IBIB ABS HITSTR L35 1-2

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L37 1786 SEA FILE=MFE SPE=ON ABB=ON PLU=ON L7

L38 1786 SEA FILE=MFE SPE=ON ABB=ON PLU=ON L9

L39 1508 SEA FILE=MFE SPE=ON ABB=ON PLU=ON L11

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L45 37 DUP REMOVE L44 (0 DUPLICATES REMOVED)

L46 20 SEA FILE=MFE SPE=ON ABB=ON PLU=ON (OPHTHALMIC) AND L44

D IBIB ABS IND L46 1-20

Session Began October 01, 2013 at 11:48 PM

Task Began October 01, 2013 11:48 PM

Explore substances by ID: olopatadine (ID 1)

Answer Type: *Substances*
Result Count: *1*

Retrieve reference information in 1 substance (ID 2)

From ID: 1
Answer Type: *References*
Result Count: *505*

Refine by research topic (ID 3)

Research Topic: ophthalmic
From ID: 2
Answer Type: *References*
Result Count: *184*

Refine by research topic (ID 4)

Research Topic: PEG
From ID: 3
Answer Type: *References*
Result Count: *19*

Full text accessed for solutions from PCT Int. Appl. Pages: 29pp. 2008

Detailed display

From ID: 4
Type: Self-preserved aqueous pharmaceutical compositions comprising borate/polyol and zinc system

Detailed display

From ID: 4
Type: Medicament comprising an active substance combination for the treatment of allergy symptoms

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13475607	GAMACHE ET AL.
	Examiner	Art Unit
	MY-CHAU T TRAN	1629

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
514	449, 450	10/02/2013	MCT

SEARCH NOTES		
Search Notes	Date	Examiner
PALM Inventors; WEST - see printout; STN - see printout; SciFinder - see printout	10/01/2013	MCT
Reviewed for ODP the following Patent(s) and/or Application(s): 13/183,194	10/01/2013	MCT

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13475607	GAMACHE ET AL.
	Examiner	Art Unit
	MY-CHAU T TRAN	1629

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	03/28/2013	10/01/2013							
	1	÷	✓							
	2	÷	✓							
	3	÷	✓							
	4	÷	✓							
	5	÷	✓							
	6	÷	✓							
	7	÷	✓							
	8	÷	✓							
	9	÷	✓							
	10	÷	✓							
	11	÷	N							
	12	÷	N							
	13	÷	✓							
	14	÷	✓							
	15	÷	✓							
	16	÷	=							
	17	÷	=							
	18	÷	=							
	19	÷	=							
	20	÷	=							
	21	÷	=							
	22	÷	=							
	23	÷	=							
	24	÷	=							
	25	÷	=							

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	Gamache, Daniel A. et al.
Serial No.	:	13/475,607
Filed	:	May 18, 2012
Confirmation No.	:	4130
Examiner	:	Tran, My Chau T.
Group Art Unit	:	1629
For	:	High Concentration Olopatadine Ophthalmic Composition

RESPONSE TO ELECTION/RESTRICTION REQUIREMENT DATED APRIL 18, 2013

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This paper is submitted in response to the Election/Restriction Requirement dated April 18, 2013 for which the one-month date for response is May 18, 2013.

Applicant believes that no extension of time is required for this response. However, should such request or fee be deficient or absent, consider this paragraph such a request and authorization to deduct said fees from Alcon Research, Ltd. Deposit Account No. **010682**.

REMARKS

A. Status of the Claims

This application was originally filed with claims 1-25. A listing of the claims is provided below.

B. Election Requirement under 35 U.S.C. §121 and/or 372

An Election Requirement was issued under 35 U.S.C. §121 and/or §372. The Election Requirement provides no guidance as to which claims contain species from which Applicants are required to elect. Applicants suggest that such an Election Requirement is improper as is further discussed below. The Election Requirement does suggest that applicants need to elect a single composition for prosecution on the merits and needs to identify ingredients and concentrations of those ingredients within the composition. In an attempt to comply with this Election Requirement, Applicants elect, with traverse, the composition described in the table below:

Ingredients	w/v%
Olopatadine (Olopatadine HCl)	0.7
Polyether (PEG)	4.0
Lactam Polymer (PVP)	4.0
Viscosity Agent (HEC)	0.1 (if used w/ HPMC or other viscosity agent) 0.3 (if used w/o HPMC or other viscosity agent)
Viscosity Agent (HPMC)	0.15 (if used w/ HEC or other viscosity agent) 0.35 (if used w/o HEC or other viscosity agent)
Chelating agent (Disodium EDTA)	0.005
Borate (Boric Acid)	0.3

cyclodextrin derivative	1.5
Polyol (Mannitol)	0.3
Polyol (Propylene Glycol)	1.0
Tonicity Agent (Sodium Chloride)	0.35
Preservative (BAK)	0.01
pH adjusting agents (NaOH or HCl)	sufficient to achieve pH = 7.0
purified water	Q.S. 100

All of claims 1-25 read on the elected species

C. Traverse

As suggested, the Election Requirement provides no guidance as to which claims contain species from which Applicants are required to elect. An indication of which claims include which species is required for issuance of an election restriction requirement. Section 803 of the MPEP reads as follows:

> There are two criteria for a proper requirement for restriction between patentably distinct inventions:
>
> - (A) The inventions must be independent... or distinct as claimed; and
> - (B) There * > would < be a serious burden on the examiner if restriction is > not < required. (emphasis added)

Further, section 806.01 of the MPEP reads as follows:

> In passing upon questions of double patenting and restriction, it is the claimed subject matter that is considered and such claimed subject matter must be compared in order to determine the question of distinctness or independence. (emphasis added)

Further yet, 37 C.F.R. 1.146 reads:

> In the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable... (emphasis added)

These sections of the MPEP make clear that Election/Restriction Requirements are to be based upon the claims of an application and should indicate where different species are within the claims. The Election Requirement for the present application has failed to do that. As such, Applicants request that the requirement be withdrawn.

In an effort to expedite prosecution, Applicants have provided an election of a reasonably specific composition within this Response. While Applicants have made a good faith effort to comply with the request of the Election Requirement, Applicants make no acquiescence in the Election/Restriction requirement and specifically maintain the right to amend claims as necessary or desired during further prosecution of the present application.

Applicants believe the claims of the present application are in condition for allowance and request that allowance of the claim be considered. The Examiner is invited to contact the undersigned attorney at 817-615-5288 with any questions, comments or suggestions relating to the instant application.

Respectfully submitted,

ALCON RESEARCH, LTD.

May 15, 2013
Date

By: _____
Scott A. Chapple
Registration No. 46,287

Address for Correspondence:
Scott A. Chapple, IP Legal
Alcon Research, Ltd.
6201 South Freeway, Mail Code TB4-8
Fort Worth, Texas 76134-2099
Phone: 817-615-5288
Atty Docket No.: 3988 US

What Is Claimed Is:

Claim 1 (original): An ophthalmic composition for treatment of ocular allergic conjunctivitis, the composition comprising:

at least 0.67 w/v % olopatadine; and

water.

Claim 2 (original): A composition as in claim 1 wherein the concentration of olopatadine is at least 0.7 w/v% and is dissolved in solution.

Claim 3 (original): A composition as in claim 1 further comprising a γ-cyclodextrin derivative, a β-cyclodextrin derivative or both to aid in the solubility of the olopatadine.

Claim 4 (original): A composition as in claim 1 further comprising a lactam polymer to aid in the solubility of the olopatadine.

Claim 5 (original): A composition as in claim 4 wherein the lactam polymer is polyvinylpyrrolidone.

Claim 6 (original): A composition as in claims 1 further comprising a polyether.

Claim 7 (original): A composition as in claim 6 wherein the polyether is polyethylene glycol.

Claim 8 (original): A composition as in claim 1 wherein the composition is disposed in an eyedropper, has a pH of 5.5 to 8.0 and an osmolality of 200 to 450.

Claim 9 (original): An ophthalmic composition for treatment of ocular allergic conjunctivitis, the composition comprising:

at least 0.67 w/v % olopatadine dissolved in solution;

PEG having a molecular weight of 300 to 500;

polyvinylpyrrolidone; and

cyclodextrin derivative selected from β-cyclodextrin derivative, γ-cyclodextrin or both.

Claim 10 (original): A composition as in claim 9 further comprising a preservative selected from a polymeric quaternary ammonium compound and benzalkonium chloride.

Claim 11 (original): A composition as in claim 10 wherein the cyclodextrin derivative is hydroxypropyl- β-cyclodextrin or sulfoalkyl ether β-cyclodextrin.

Claim 12 (original): A composition as in claim 11 wherein the β-cyclodextrin derivative is hydroxypropyl- β-cyclodextrin when the preservative is the benzalkonium chloride and the β-cyclodextrin derivative is sulfoalkyl ether β-cyclodextrin when the preservative is the polymeric quaternary ammonium compound.

Claim 13 (original): A composition as in claim 10 wherein the preservative is benzalkonium chloride and the cyclodextrin derivative is hydroxypropyl-γ-cyclodextrin.

Claim 14 (original): A composition as in claim 9 further comprising borate.

Claim 15 (original): A composition as in claim 14 further comprising polyol.

Claim 16 (original): An ophthalmic composition for treatment of ocular allergic conjunctivitis, the composition comprising:

at least 0.67 w/v % but no greater than 1.0 w/v% olopatadine dissolved in solution;

PEG having a molecular weight of 300 to 500 wherein the concentration of the PEG in solution is from about 2.0 w/v % to about 6.0 w/v%;

a lactam polymer wherein the lactam polymer is polyvinylpyrrolidone and the concentration of the polyvinylpyrrolidone in solution is from about 2.0 w/v % to about 6.0 w/v%; and

a β-cyclodextrin derivative or a γ-cyclodextrin derivative selected from SAE-β-cyclodextrin, HP-γ-cyclodextrin and HP-β-cyclodextrin wherein the

concentration of the β-cyclodextrin derivative or the γ-cyclodextrin derivative is at least 0.5 w/v% but no greater than 2.0 w/v%.

Claim 17 (original): A composition as in claims 16 further comprising borate at a concentration of at least about 0.18 w/v % but less than about 0.5 w/v%.

Claim 18 (original): A composition as in claim 17 further comprising polyol.

Claim 19 (original): A composition as in claim 18 wherein the polyol include polyethylene glycol at a concentration of at least 0.4 w/v% but no greater than 2.2 w/v%.

Claim 20 (original): An ophthalmic composition for treatment of ocular allergic conjunctivitis, the composition comprising:

at least 0.67 w/v % but no greater than 1.0 w/v% olopatadine dissolved in solution;

PEG having a molecular weight of 300 to 500 wherein the concentration of the PEG in solution is from about 2.0 w/v % to about 6.0 w/v%;

a lactam polymer wherein the lactam polymer is polyvinylpyrrolidone and the concentration of the polyvinylpyrrolidone in solution is from about 2.0 w/v % to about 6.0 w/v%; and

hydroxypropyl-γ-cyclodextrin in the composition at a concentration of at least 0.5 w/v% but no greater than 2.0 w/v%.

Claim 21 (original): A composition as in claims 20 further comprising borate at a concentration of at least about 0.18 w/v % but less than about 0.5 w/v%.

Claim 22 (original): A composition as in claim 21 further comprising polyol.

Claim 23 (original): A composition as in claim 22 wherein the polyol include polyethylene glycol at a concentration of at least 0.4 w/v% but no greater than 2.2 w/v%.

Claim 24 (original): A method of treating ocular allergy symptoms, the method comprising:

topically applying the composition of claim 20 to an eye of a human.

Claim 25 (original): A method as in claim 24 wherein the step of topically applying the composition includes dispensing an eyedrop from an eyedropper.

Electronic Acknowledgement Receipt

EFS ID:	15781172
Application Number:	13475607
International Application Number:	
Confirmation Number:	4130
Title of Invention:	HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION
First Named Inventor/Applicant Name:	Daniel A. Gamache
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3988 US
Receipt Date:	15-MAY-2013
Filing Date:	18-MAY-2012
Time Stamp:	12:13:12
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		PAT903988-US-NP_2013-05-15_RESP.pdf	321445 8cd8be30b3304a3b91b08d914b25514796 3e2fcc	yes	9

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response to Election / Restriction Filed	1	5
	Claims	6	9
Warnings:			
Information:			
	Total Files Size (in bytes):	321445	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/475,607	Filing Date 05/18/2012	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	05/15/2013	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 25	Minus	** 25	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 4	Minus	***4	= 0	X $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	0

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/RUTH LLOYD/

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/475,607	05/18/2012	Daniel A. Gamache	3988 US	4130

26356 7590 04/18/2013

ALCON
IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

EXAMINER	
TRAN, MY CHAU T	

ART UNIT	PAPER NUMBER
1629	

NOTIFICATION DATE	DELIVERY MODE
04/18/2013	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent.docketing@alcon.com

Office Action Summary	Application No. 13/475,607	Applicant(s) GAMACHE ET AL.	
	Examiner MY-CHAU T. TRAN	Art Unit 1629	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2012*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-25* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☐ Claim(s) _____ is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some * c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Interim copies:

a)☐ All b)☐ Some c)☐ None of the: Interim copies of the priority documents have been received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Application and Claims Status

1. Claims 1-25 are currently pending and are under consideration in this Office Action.

Election/Restrictions

2. This application contains claims directed to the following patentably distinct species of the claimed invention.

(A) *A single specific ophthalmic composition* - Applicants are required to elect a single ophthalmic composition to be examined in their claimed invention to the treatment of a condition associated with an ocular allergic conjunctivitis. Applicants should identify the active agent(s) and the excipient(s)/diluent(s)/vehicle(s)/carrier(s) by ***name and amount*** for the elected single ophthalmic composition. For example, the ophthalmic composition includes the chemical compounds claimed in instant claims 1-23, or the chemical compounds disclosed in the instant specification on the following pages 5-14.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Each of the species identified above is directed to patently distinct species, wherein each of the species is materially and/or functionally different for the others. Further, it is a significant burden to examine more than a single species of each of the species categories as set forth above because the art is divergent and not necessarily coextensive. Art related to a given species that is

materially and/or functionally different from the others would not necessarily disclose or make obvious each of the species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. See MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Because the above restriction/election requirement is complex, a telephone call to Applicant to request an oral election was not made. See MPEP § 812.01.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (e.g., if the amendment is not supported *in ipsis verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T. TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Monday - Friday: 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey S. Lundgren can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MY-CHAU T. TRAN/
Primary Examiner, Art Unit 1629

April 15, 2013

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13475607	GAMACHE ET AL.
	Examiner	Art Unit
	MY-CHAU T TRAN	1629

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	03/28/2013								
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PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	13475607
Filing Date	2012-05-18
First Named Inventor	Daniel A. Gamache
Art Unit	1629
Examiner Name	
Attorney Docket Number	3988 US

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
/MCT/	1	3767788		1973-10-23	Rankin	
	2	3843782		1974-10-22	Krezanoski et al.	
	3	3856919		1974-12-24	Rankin	
	4	3931319		1976-01-06	Green et al.	
	5	3947573		1976-03-30	Rankin	
	6	4027020		1977-05-31	Green et al.	
	7	4120949		1978-10-17	Bapatla et al.	
/MCT/	8	4283393		1981-08-11	Field et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MCT/

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	Attorney Docket Number	3988 US

/MCT/	9	4407791		1983-10-04	Stark	
	10	4470965		1984-09-11	Wolf et al.	
	11	4525346		1985-06-25	Stark	
	12	4836986		1989-06-06	Ogunbiyi et al.	
	13	4923693		1990-05-08	Michalos	
	14	5037647		1991-08-06	Chowhan et al.	
	15	5068225		1991-11-26	Pennell et al.	
	16	5116863		1992-05-26	Oshima et al.	
	17	5134127		1992-07-28	Stella et al.	
	18	5141961		1992-08-25	Coapman	
/MCT/	19	5300287		1994-04-05	Park	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MCT/

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/MCT/	20	5376645		1994-12-27	Stella et al.	
	21	5472954		1995-12-05	Loftsson	
	22	5591426		1997-01-07	Dabrowski et al.	
	23	5597559		1997-01-28	Olejnik et al.	
	24	5624962		1997-04-29	Takeuchi et al.	
	25	5888493		1999-03-30	Sawaya	
	26	6153746		2000-11-28	Shah et al.	
	27	6511949		2003-01-28	Nitta et al.	
	28	6828356		2004-12-07	Su et al.	
	29	7074424		2006-07-11	Avila et al.	
/MCT/	30	7147844		2006-12-12	Hamano et al.	

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	Attorney Docket Number	3988 US

/MCT/	31	7429602		2008-09-30	Trach et al.	
/MCT/	32	7635773		2009-12-22	Antle	

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
/MCT/	1	20020006443		2002-01-17	Curatolo et al.	
	2	20020150616		2002-10-17	Vandecruys	
	3	20030170309		2003-09-11	Babcock et al.	
	4	20050004074		2005-01-06	Lyons et al.	
	5	20050191270		2005-09-01	Gruening et al.	
	6	20050244472		2005-11-03	Hughes et al.	
/MCT/	7	20060210645		2006-09-21	Du Mee et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MCT/

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/MCT/	8	20070020336		2007-01-25	Loftsson et al.	
	9	20080132444		2008-06-05	Li et al.	
	10	20090118262		2009-05-07	Rohrs et al.	
	11	20090232763		2009-09-17	Kabra et al.	
	12	20090239842		2009-09-24	Trach et al.	
	13	20100240625		2010-09-23	Abelson et al.	
	14	20100249062		2010-09-30	Matsumura et al.	
/MCT/	15	20100324031		2010-12-23	Kabra	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
/MCT/	1	0862414	EP		2001-12-05	Novartis AG		☐

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	Art Unit	1629
	Examiner Name	
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/MCT/	2	0998304	EP		2003-08-20	Janssen Pharmaceutica N.V.		☐
/MCT/	3	2169508	GB		1986-07-16	Smith and Nephew Associated Companies plc		☐
/MCT/	4	2001-158750	JP		2001-06-12	Lion Corp.		☒
/MCT/	5	88/08709	WO		1988-11-17	MDR Group, Inc.		☐
/MCT/	6	90/04971	WO		1990-05-17	M.D.R. Group, Inc.		☐
/MCT/	7	91/09523	WO		1991-07-11	Allergan Inc.		☐
/MCT/	8	96/39147	WO		1996-12-12	Alcon Laboratories, Inc.		☐
/MCT/	9	01/54687	WO		2001-08-02	Alcon Universal Ltd.		☐
/MCT/	10	2003/013481	WO		2003-02-20	Khamar et al.		☐
/MCT/	11	2006/011044	WO		2006-02-02	Pfizer Products Inc.		☐
/MCT/	12	2008/015695	WO		2008-02-07	Sun Pharmaceutical Ind. Ltd.		☐

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/MCT/	13	2009/003199	WO		2008-12-31	Cydex Pharmaceuticals, Inc.		☐
/MCT/	14	2010/107689	WO		2010-09-23	Aciex Therapeutics, Inc.		☐
/MCT/	15	2 391 076	CA		2001-05-25	Boehringer Ingelheim International GmbH		☐
/MCT/	16	1 004 309	EP		2000-05-31	Senju Pharmaceutical Co., Ltd.		☐
/MCT/	17	1 231 920	EP		2007-02-07	Boehringer Ingelheim International GmbH		☐
/MCT/	18	1 994 931	EP		2008-11-26	Meiji Seika Kaisha Ltd.		☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
/MCT/	1	CHIGBU, "The management of allergic eye disease in primary eye care", Contact Lens & Anterior Eye, 32, pgs 260-272, 2009	☐
/MCT/	2	CHIGBU, "The pathophysiology of ocular allergy: A review", Contact Lens & Anterior Eye, 32, pgs. 3-15, 2009	☐
/MCT/	3	CIPRANDI et al., "Cetirizine reduces inflammatory cell recruitment and ICAM-1 (or CD54) expression on conjunctival epithelium in both early- and late-phase reactions after allergen-specific challenge", J Allergy Clin Immunol, vol. 95, no. 2, pgs 612-621, Feb. 1995	☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MCT/

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/MCT/	4	DU BUSKE, "Clinical comparison of histamine H1-receptor antagonist drugs", J Allergy Clin Immunol, vol. 98, no. 6, part 3, pgs. S307-S318, Dec. 1996	☐
/MCT/	5	FUKUDA et al., "Critical role of IgE-dependent mast cell activiation in a murine model of allergic conjunctivitis", J Allergy Clin Immunol, vol. 124, no. 4, 827-833.e2, Oct. 2009	☐
/MCT/	6	International Search Report for corresponding PCT/US2012/038663 with mailing date July 25, 2012	☐
/MCT/	7	International Written Opinion for corresponding PCT/US2012/038663 with mailing date July 25, 2012	☐
/MCT/	8	IZUSHI et al., "The role of histamine H1 receptors in late-phase reaction of allergic conjunctivitis", European Journal of Pharmacology, 440:79-82, 2002	☐
/MCT/	9	LEONARDI and ABELSON, "Double-Masked, Randomized, Placebo-Controlled Clinical Study of the Mast Cell-Stabilizing Effects of Treatment with Olopatadine in the Conjunctival Allergen Challenge Model in Humans", Clinical Therapeutics, vol. 25, no. 10, pgs. 2539-2552, 2003	☐
/MCT/	10	OZAKI et al., "Mast-cell activation augments the late phase reaction in experimental immune-mediated blepharoconjunctivitis", Graefe's Arch Clin Exp Ophthalmol, 241:394-402, 2003	☐
/MCT/	11	UETA et al., letter to editor, "Development of eosinophilic conjunctival inflammation at late-phase reaction in mst cell-deficient mice", J Allergy Clin Immunol, pgs 476-478, Aug. 2007	☐
/MCT/	12	VOGELSON et al., "Preclinical and Clinical Antiallergic Effect of Olopatadine 0.2% Solution 24 Hours after Topical Ocular Administration", Allergy and Asthma Proc., Vol. 25, No. 1, pgs 69-75, Jan-Feb 2004	☐
/MCT/	13	YANNI et al., "The In Vitro and In Vivo Ocular Pharmacology of Olopatadine (AL-4943A), an Effective Anti-Allegic/ Antihistaminic Agent", Journal of Ocular Pharmacology and Therapeutics, Vol. 12, No. 4, 1996	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

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	Attorney Docket Number	3988 US

EXAMINER SIGNATURE			
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/475,607	05/18/2012	Daniel A. Gamache	3988 US

CONFIRMATION NO. 4130

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Title:HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION

Publication No.US-2012-0295967-A1
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	13475607
Filing Date	2012-05-18
First Named Inventor	Daniel A. Gamache
Art Unit	1629
Examiner Name	
Attorney Docket Number	3988 US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3767788		1973-10-23	Rankin	
	2	3843782		1974-10-22	Krezanoski et al.	
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	11	2006/011044	WO		2006-02-02	Pfizer Products Inc.		☐
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	13	2009/003199	WO		2008-12-31	Cydex Pharmaceuticals, Inc.		☐
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	3	CIPRANDI et al., "Cetirizine reduces inflammatory cell recruitment and ICAM-1 (or CD54) expression on conjunctival epithelium in both early- and late-phase reactions after allergen-specific challenge", J Allergy Clin Immunol, vol. 95, no. 2, pgs 612-621, Feb. 1995	☐

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	Art Unit	1629
	Examiner Name	
	Attorney Docket Number	3988 US

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Name/Print	Scott A. Chapple	Registration Number	46,287

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Application Number:	13475607
International Application Number:	
Confirmation Number:	4130
Title of Invention:	HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION
First Named Inventor/Applicant Name:	Daniel A. Gamache
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
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Attorney Docket Number:	3988 US
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Warnings:					
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29	Non Patent Literature	Ozaki_2003_GACEO_394-402.pdf	898816 8fe6f149f7c469d08b64ef014fd711711aea3ce0	no	10
Warnings:					
Information:					
30	Non Patent Literature	Ueta_LettertoEditor_2007_JACI_476-478.pdf	332944 4512981bc86b31d395384a4e9953e7831e696310	no	4
Warnings:					
Information:					
31	Non Patent Literature	Vogelson_2004_AAP_69-75.pdf	635120 082c55b4296484105b458e0acc4b0d76fcc7be4e	no	7
Warnings:					
Information:					
32	Non Patent Literature	Yanni_1996_JOPT.pdf	663910 f88dce36098510add5a1011a4f561d99eb563408	no	12
Warnings:					
Information:					
			Total Files Size (in bytes):	33172496	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/475,607	05/18/2012	1629	1930	3988 US	25	4

CONFIRMATION NO. 4130

UPDATED FILING RECEIPT

26356
ALCON
IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

OC000000055125577

Date Mailed: 07/05/2012

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Daniel A. Gamache, Arlington, TX;
Laman Alani, Fort Worth, TX;
Malay Ghosh, Fort Worth, TX;
Francisco Javier Galán, Barcelona, SPAIN;
Núria Carreras Perdiguer, Barcelona, SPAIN;
Onkar N. Singh, Arlington, TX;

Power of Attorney: The patent practitioners associated with Customer Number 26356

Domestic Priority data as claimed by applicant

This appln claims benefit of 61/487,789 05/19/2011
and claims benefit of 61/548,957 10/19/2011

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.)

If Required, Foreign Filing License Granted: 06/01/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/475,607**

Projected Publication Date: 11/22/2012

Non-Publication Request: No

Early Publication Request: No

Title

HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION

Preliminary Class

514

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as

set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 13/475,607

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	380
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	620
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	250
TOTAL CLAIMS (37 CFR 1.16(i))	25 minus 20 =	* 5			OR	x 60 =	300
INDEPENDENT CLAIMS (37 CFR 1.16(h))	4 minus 3 =	* 1				x 250 =	250
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1800

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)	OR	RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Daniel A. Gamache et al.

U.S. Serial No.: 13/475,607

Confirmation No.: 4130

Filed: May 18, 2012

Examiner:

Group Art Unit: 11629

CERTIFICATE OF FILING VIA EFS-WEB

I hereby certify that this correspondence is being submitted to the Mail Stop Missing Parts; Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450 via EFS-Web on this date:

26 June 2012.

By: /Barbara McKenzie/
Barbara McKenzie

For: HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION

RESPONSE TO NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

Mail Stop Missing Parts
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This paper is submitted in response to the Notice To File Missing Parts of Nonprovisional Application – Filing Date Granted mailed June 4, 2012. Applicants submit herewith a fully executed Declaration And Power Of Attorney. Applicants respectfully submit that no additional parts are required to be filed in the above-referenced application, and, therefore, the application should be processed accordingly.

The Commissioner is hereby authorized to charge payment of the following fee and any additional fees which may be required associated with this communication to **Deposit Account No. 010682** of Alcon Research, Ltd.

1. The fee amount of $130.00 for late submission of an executed Oath or Declaration under 37 CFR 1.16(f).

Respectfully submitted,

Alcon Research, Ltd.

June 26, 2012

Scott A. Chapple
Reg. No. 46,287

Address for Correspondence:
Alcon Research, Ltd.
Scott A. Chapple, IP Legal
6201 S. Freeway, TB4-8
Fort Worth, TX 76134-2099
Phone: 817-615-5288

Attorney Docket: 3988 US

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, we hereby declare that:

Our residence, post office address and citizenship are as stated below next to our names.

We believe we are the original, first and joint inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled:

HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION

described and claimed herewith and further identified as Attorney Docket No. 3988 US the specification of which (check one)

(X) is attached hereto.

( ) was filed by an authorized person on my behalf on _____, as Application Serial No. _____ and was amended on _____ (if applicable)

We hereby state that we have reviewed and understand the contents of the above-identified specification, including the claims as amended by any amendment referred to above.

We acknowledge the duty to disclose information which is known to me to be material to patentability as defined in Section 1.56.

We hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT international application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s):			**Priority Claimed**	
Application Number	**Country**	**Filed (Month/Day/Year)**	**Yes**	**No**

We hereby claim the benefit under 35 USC §119(e) of any United States provisional application(s) listed below.

Prior Provisional Application(s):		Priority Claimed	
Application Number	Filed (Month/Day/Year)	Yes	No
61/487,789	05/19/2011	X	
61/548,957	10/19/2011	X	

We hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s), or Section 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of Title 35, United States Code, Section 112. We acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

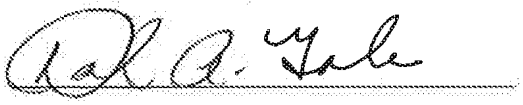
Prior U.S. Application(s):		Status: Patent, Pending, Abandoned
Application Number	Filed (Month/Day/Year)	

We hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

We hereby appoint those patent practitioners associated with Customer No. **26356** as my attorneys, with full power of substitution and revocation, to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith.

Full name of Inventor: Daniel A. Gamache

Address: 5610 Hunterwood Lane
Arlington, Texas 76017

Inventor's Signature: 

Date: 6-20-2012

Citizenship: United States of America

Full name of Inventor: Laman Alani

Address: 6809 Shadow Creek Court
Fort Worth, Texas 76132

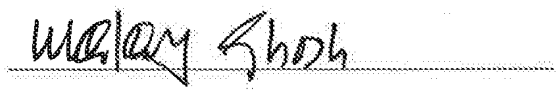
Inventor's Signature: 

Date: 6/19/2012

Citizenship: United States of America

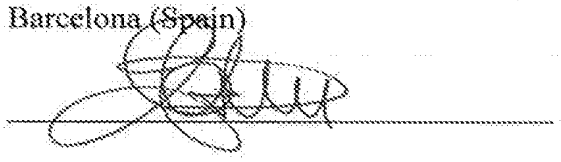
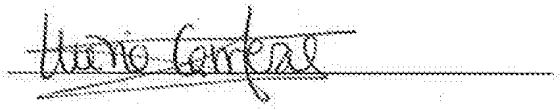
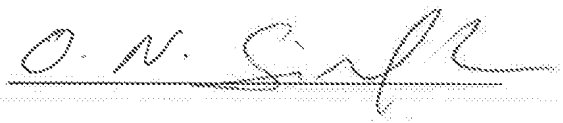
Full name of Inventor: Malay Ghosh

Address: 4221 Kirkland Court
Fort Worth, Texas 76109

Inventor's Signature: 

Date: 6/19/2012

Citizenship: United States of America

Full name of Inventor:	Francisco Javier Galán
Address:	c/ Dels Pins, 19 08329 Teià Barcelona (Spain)
Inventor's Signature:	
Date:	22 MAY 2012
Citizenship:	Spain
Full name of Inventor:	Núria Carreras Perdiguer
Address:	Ametller, 9 08140 Calades de Montbui Barcelona (Spain)
Inventor's Signature:	
Date:	11.MAY 12
Citizenship:	Spain
Full name of Inventor:	Onkar N. Singh
Address:	5606 Rachel Court Arlington, Texas 76017
Inventor's Signature:	
Date:	06-04-2012
Citizenship:	United States of America

Address for Correspondence:
Alcon Research, Ltd.
Scott A. Chapple, IP Legal
6201 South Freeway, TB4-8
Fort Worth, Texas 76134
Phone: 817-615-5288
Docket No.: 3988 US

Customer No.: 26356

Electronic Patent Application Fee Transmittal

Application Number:	13475607
Filing Date:	18-May-2012
Title of Invention:	HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION
First Named Inventor/Applicant Name:	Daniel A. Gamache
Filer:	Scott Chapple/Barbara McKenzie
Attorney Docket Number:	3988 US

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Late filing fee for oath or declaration	1051	1	130	130
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**130**

Electronic Acknowledgement Receipt

EFS ID:	13106589
Application Number:	13475607
International Application Number:	
Confirmation Number:	4130
Title of Invention:	HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION
First Named Inventor/Applicant Name:	Daniel A. Gamache
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3988 US
Receipt Date:	26-JUN-2012
Filing Date:	18-MAY-2012
Time Stamp:	14:11:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$130
RAM confirmation Number	384
Deposit Account	010682
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant Response to Pre-Exam Formalities Notice	3988_US_MissingPartsResponse_062612.pdf	67454 bccb6ee4fef3e3127d88a0d3b77e84c119a39e8a	no	2
Warnings:					
Information:					
2	Oath or Declaration filed	3988_US_Decl-POA_signed.pdf	299206 79b623effb9a5451439410d96b2c5b944d167291	no	6
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30372 551f9acef6a7aec0abc1858c953e24d9e68cfd92	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	397032		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

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National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 13/475,607

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	380
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	620
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	250
TOTAL CLAIMS (37 CFR 1.16(i))	25 minus 20 =	* 5			OR	x 60 =	300
INDEPENDENT CLAIMS (37 CFR 1.16(h))	4 minus 3 =	* 1				x 250 =	250
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1800

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/475,607	05/18/2012	1629	1800	3988 US	25	4

CONFIRMATION NO. 4130

26356
ALCON
IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

FILING RECEIPT

OC000000054601503

Date Mailed: 06/04/2012

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Applicant(s)

Daniel A. Gamache, Arlington, TX;
Laman Alani, Fort Worth, TX;
Malay Ghosh, Fort Worth, TX;
Francisco Javier Galán, Barcelona, SPAIN;
Núria Carreras Perdiguer, Barcelona, SPAIN;
Onkar N. Singh, Arlington, TX;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This appln claims benefit of 61/487,789 05/19/2011
and claims benefit of 61/548,957 10/19/2011

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The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/475,607**

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

Title

HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION

Preliminary Class

514

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/475,607	05/18/2012	Daniel A. Gamache	3988 US

CONFIRMATION NO. 4130

26356
ALCON
IP LEGAL, TB4-8
6201 SOUTH FREEWAY
FORT WORTH, TX 76134

FORMALITIES LETTER

Date Mailed: 06/04/2012

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

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Electronic Acknowledgement Receipt

EFS ID:	12817309
Application Number:	13475607
International Application Number:	
Confirmation Number:	4130
Title of Invention:	HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION
First Named Inventor/Applicant Name:	Daniel A. Gamache
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
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HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION

Cross-Reference to Related Application

The present application claims priority based on U.S. Provisional Patent Application Serial No. 61/487,789 filed May 19, 2011 and U.S. Provisional Patent Application Serial No. 61/548,957 filed October 19, 2011.

Technical Field of the Invention

The present invention relates to an ophthalmic composition containing a relatively high concentration of olopatadine. More particularly, the present invention relates to an ophthalmic aqueous solution containing a relatively high concentration of solubilized olopatadine wherein the solution is capable of providing enhanced relief from symptoms of ocular allergic disorders (e.g., conjunctivitis) in the early phase, the late phase or preferably both phases.

Background of the Invention

Individuals suffering from allergic conjunctivitis experience symptoms such as ocular irritation, itchiness, redness and the like. It has been found that these symptoms are significantly reduced using topical ophthalmic solutions containing olopatadine. Such solutions are sold under the tradenames PATANOL® and PATADAY®, which are both commercially available from Alcon Laboratories, Inc., Fort Worth, TX.

These marketed solutions were generally believed to be the most efficacious products known for addressing symptoms of allergic conjunctivitis. Surprisingly, and as discussed further below, it has been discovered that relatively high concentration solutions of olopatadine provide significantly improved reduction of late phase ocular allergic conjunctivitis symptoms in addition to relief from early phase symptoms. Even more surprising, it has been discovered that such high concentrations of olopatadine also provide significantly improved reduction of redness in the early phase. Further, it has been discovered that enhanced relief from these early and late phase symptoms can be achieved through once a day

dosing of relatively high concentration olopatadine solution as opposed to greater dosing frequencies.

The discovery of improved reduction of early and late phase symptoms is quite significant and desirable for individuals suffering from allergic conjunctivitis. Generally, these discoveries can provide patients greater relief from itching and provide better aesthetic appearance to the eye. Further, avoiding more frequent dosing is more convenient for patients and helps assure better compliance. Further yet, improved early prevention and/or reduction of redness is particularly desirable since patients generally have a desire to keep as much redness out of their eyes as possible.

The discovery that relatively high concentration solutions of olopatadine can relieve late phase ocular allergic conjunctivitis symptoms provides hope to sufferers of ocular allergic conjunctivitis that a single dose of olopatadine per day could provide a substantial degree of full day relief from their symptoms. However, the development of a multi-dose ophthalmic solution that includes high concentrations of olopatadine necessary to achieve desired levels of efficacy is extremely difficult and complex.

Solubilizing high concentrations of olopatadine in a stable manner has proven difficult by itself. Olopatadine, by itself, is only soluble in water (pH about 7.0) at room temperature up to a concentration of about 0.18 w/v%. However, it is desirable to achieve solubilization of much higher concentrations of olopatadine in an effort to treat late phase allergic conjunctivitis.

Solubilizing such higher concentrations of olopatadine has proven difficult. As one example, excipients such as polyethylene glycol (PEG) 400 and polyvinylpyrrolidone (PVP), when used at reasonably desirable concentrations, have proven incapable, alone or in combination, of solubizing sufficient concentrations of olopatadine in compositions having approximately neutral pH. Thus, innovation is required to solubilize a sufficient concentration of olopatadine.

In the process of such innovation, is has been discovered that higher molecular weight PEGs such as PEG 6000 can significantly enhance solubility of olopatadine. However, such PEGs cause risk of discomfort when administered to humans. It has also been discovered that cyclodextrins, such as hydroxypropyl-γ-

cyclodextrin, hydroxypropyl-β-cyclodextrin and sulfoalkyl ether-β-cyclodextrin, have the ability to solubilize significantly higher concentrations of olopatadine. However, use of undesirably high concentrations of cyclodextrins has been found to reduce olopatadine efficacy and/or preservation efficacy of solutions. As such, still further innovation was needed to create a desirable olopatadine formulation that not only solubilized sufficient amounts of olopatadine, but also allowed the formulation to achieve other desirable pharmaceutical characteristics.

Thus, the present invention is directed at an ophthalmic composition that can provide high concentrations of olopatadine topically to the eye. Further, the present invention is directed to such a composition wherein the olopatadine is solubilized in solution in a stable manner, the composition exhibits consistent efficacy against late phase symptoms of allergic conjunctivitis, the composition exhibits sufficient antimicrobial activity to provide desired levels of preservation efficacy or any combination thereof.

Summary of the Invention

The present invention is directed to an ophthalmic composition for treatment of allergic conjunctivitis. The composition will include a relatively high concentration of olopatadine, preferably at least 0.67 w/v % olopatadine, preferably dissolved in solution. The composition will typically include a cyclodextrin, and more particularly, a γ-cyclodextrin derivative and/or a β-cyclodextrin derivative to aid in solubilizing the olopatadine. The cyclodextrin derivative is preferably hydroxypropyl-γ-cyclodextrin (HP-γ-CD), hydroxypropyl- β-cyclodextrin (HP- β-CD), sulfoalkyl ether β-cyclodextrin (SAE- β-CD)(e.g., sulfobutyl ether β-cyclodextrin (SBE-β-CD)), or a combination thereof. The composition will typically include a lactam polymer (e.g., polyvinylpyrrolidone (PVP)) to aid in the solubilization of the olopatadine. The composition will also typically include a polyether (e.g., polyethylene glycol (PEG)) for enhancing solubility and/or aiding in achieving the desired tonicity. It is generally desirable for the composition to be disposed in an eyedropper, have a pH of 5.5 to 8.0, to have an osmolality of 200 to 450, to have a viscosity of 10 to 200 cps or any combination thereof. The composition will also typically include a preservative to allow the composition to achieve United States and/or European Pharmacopeia preservation standards. Preferred preservatives include a polymeric quaternary ammonium compound, such

as polyquaternium-1, and benzalkonium chloride. The composition also typically includes borate and/or polyol to aid in achieving desired preservation.

The present invention also contemplates a method of treating ocular allergy symptoms. The method will include topically applying a composition having a defined combination of the characteristics described above to an eye of a human. This step of topically applying the composition preferably includes dispensing an eyedrop from an eyedropper.

Brief Description of the Drawings

FIG. 1 is a graph of mean conjunctival redness determined by a conjunctival allergen challenge (CAC) at 27 minutes.

FIG. 2 is a graph of mean conjunctival redness determined by a conjunctival allergen challenge (CAC) at16 hours.

FIG. 3 is a graph of mean total redness determined by a conjunctival allergen challenge (CAC) at 24 hours.

FIG. 4 is a graph of mean ocular itching determined by a conjunctival allergen challenge (CAC) at 24 hours.

FIG. 5 is a graph of mean conjunctival redness determine by a conjunctival allergen challenge (CAC) at 24 hours.

Detailed Description of the Invention

The present invention is predicated upon the provision of an ophthalmic composition for treatment of allergic conjunctivitis. The ophthalmic composition is preferably an aqueous solution. The ophthalmic composition includes a relatively high concentration of olopatadine solubilized in aqueous solution. The ophthalmic composition also includes a unique set of excipients for solubilizing the olopatadine while maintaining comfort of the composition and/or efficacy of the composition in treating symptoms associate with allergic conjunctivitis, particularly symptoms associated with late phase allergic conjunctivitis. Preferably, the composition

exhibits improved late phase efficacy in reducing ocular itching, ocular redness or both. The composition also preferably exhibits improved early phase efficacy in reducing ocular redness relative to vehicle and/or relative to lower concentrations of olopatadine. In a preferred embodiment, the ophthalmic composition is a multi-dose ophthalmic composition that also exhibits a required degree of preservation efficacy.

Unless indicated otherwise, all component amounts (i.e., concentrations) are presented on a weight volume percent (w/v%) basis and all references to concentrations of olopatadine are to olopatadine free base.

Olopatadine is a known compound that can be obtained by the methods disclosed in U.S. Pat. No. 5,116,863, the entire contents of which are hereby incorporated by reference in the present specification for all purposes. The formulation of the present invention contains at least 0.50%, more typically at least 0.55%, more typically at least 0.6% or 0.65%, even more typically at least 0.67% or 0.68%, still more typically at least 0.7%, possibly at least 0.75% and even possibly at least 0.85% but typically no greater than 1.5% more typically no greater than 1.0%, still more typically no greater than 0.8%, possibly no greater than 0.75% and even possibly no greater than 0.72% of olopatadine where concentrations of olopatadine typically represent concentrations of olopatadine in free base form if the olopatadine is added to the composition as a salt. These lower limits of concentrations of olopatadine are particularly important since it has been found that efficacy of olopatadine in aqueous ophthalmic solutions in reducing late phase allergy symptoms and enhanced reduction of early phase redness begins to show improvement at concentrations greater than 0.5 w/v% of olopatadine and begins to show statistically significant improvements in reducing late phase allergy symptoms at concentrations of about 0.7 w/v% olopatadine and above (e.g., at least 0.65 w/v%, at least 0.67 w/v% or at least 0.68 w/v%). Most preferably, the concentration of the olopatadine in the composition is 0.7 w/v%.

Generally, olopatadine will be added in the form of a pharmaceutically acceptable salt. Examples of the pharmaceutically acceptable salts of olopatadine include inorganic acid salts such as hydrochloride, hydrobromide, sulfate and phosphate; organic acid salts such as acetate, maleate, fumarate, tartrate and citrate; alkali metal salts such as sodium salt and potassium salt; alkaline earth metal salts such as magnesium salt and calcium salt; metal salts such as aluminum salt and

zinc salt; and organic amine addition salts such as triethylamine addition salt (also known as tromethamine), morpholine addition salt and piperidine addition salt. The most preferred form of olopatadine for use in the solution compositions of the present invention is the hydrochloride salt of (Z)-11-(3-dimethylaminopropylidene)-6,11-dihydro-dibenz-[b,e]oxepin-2-acetic acid. When olopatadine is added to the compositions of the present invention in this salt form, 0.77% olopatadine hydrochloride is equivalent to 0.7% olopatadine free base, 0.88% olopatadine hydrochloride is equivalent to 0.8% olopatadine free base, and 0.99% olopatadine hydrochloride is equivalent to 0.9% olopatadine free base.

Generally, it is preferred that the entire concentration of olopatadine is dissolved in the composition as a water based or aqueous solution. However, it is contemplated that olopatadine could be only partially dissolved. For example, a portion of the olopatadine could be in solution with the remainder being in suspension.

The composition of the present invention also preferably includes cyclodextrin derivative and more preferably β-cyclodextrin derivative, γ-cyclodextrin derivative or both to aid in solubilizing the olopatadine (i.e., as a solubilizer). The β-cyclodextrin derivative, γ-cyclodextrin derivative or combination thereof is typically present in the composition at a concentration that is at least 0.5% w/v, more typically at least 1.0% w/v and even possibly at least 1.3% w/v, but is typically no greater than 4.0% w/v, typically no greater than 3.2% w/v and even possibly no greater than 2.8% w/v. Preferably, the total concentration of cyclodextrin is from 0.9 w/v% to 3.2 w/v%.

The specific amount of β-cyclodextrin derivative, γ-cyclodextrin derivative or combination thereof in a particular composition will typically depend upon the type or combination of types of derivatives used. One particularly desirable β-cyclodextrin derivative is a hydroxy alkyl-β-cyclodextrin such as hydroxypropyl-β-cyclodextrin (HP-β-CD). One particularly desirable γ-cyclodextrin derivative is a hydroxy alkyl-γ-cyclodextrin such as hydroxypropyl-γ-cyclodextrin (HP-γ-CD). Another particularly desirable β-cyclodextrin derivative is sulfoalkyl ether-β-cyclodextrin (SAE-β-CD), particularly sulfobutyl ether-β-cyclodextrin (SBE-β-CD). It is contemplated that a combination of hydroxypropyl-β-cyclodextrin, hydroxypropyl- γ -cyclodextrin and/or sulfoalkyl ether-β-cyclodextrin derivative may be employed in a single composition, but it is typically desirable to use only

one of the three as the sole or substantially the sole (i.e., at least 90% by weight of the cyclodextrin component) cyclodextrin derivative.

When HP-β-CD is employed as the sole or substantially sole β-cyclodextrin derivative, it is typically present in the composition at a concentration that is at least 0.5% w/v, more typically at least 1.0% w/v and even more typically at least 1.3% w/v, but is typically no greater than 3.0% w/v, typically no greater than 2.2% w/v and is typically no greater than 1.7% w/v. When HP-γ-CD is employed as the sole or substantially sole γ-cyclodextrin derivative, it is typically present in the composition at a concentration that is at least 0.5% w/v, more typically at least 1.0% w/v and even more typically at least 1.3% w/v, but is typically no greater than 3.0% w/v, typically no greater than 2.2% w/v and is typically no greater than 1.7% w/v. When SAE-β-CD is employed as the sole or substantially sole β-cyclodextrin derivative, it is typically present in the composition at a concentration that is at least 0.3% w/v, more typically at least 0.7% w/v and even more typically at least 0.9% w/v, but is typically no greater than 2.4% w/v, typically no greater than 1.5% w/v and is typically no greater than 1.1% w/v.

HP-β-CD is a commodity product and pharmaceutical grades of HP-β-CD can be purchased from a variety of sources, for example, from SIGMA ALDRICH, which has its corporate headquarters in St. Louis, Missouri or ASHLAND SPECIALTY INGREDIENTS, headquartered in Wayne, New Jersey. HP-γ-CD is a commodity product and pharmaceutical grades of HP-γ-CD can be purchased from a variety of sources, for example, from SIGMA ALDRICH, which has its corporate headquarters in St. Louis, Missouri or ASHLAND SPECIALTY INGREDIENTS, headquartered in Wayne, New Jersey. SAE-β-CD can be formed based upon the teachings of U.S. Patent Nos. 5,134,127 and 5,376,645, which are incorporated herein by reference for all purposes. It is generally preferred, however, to use purified SAE-β-CD. Purified SAE-β-CD is preferably formed in accordance with the teachings of U.S. Patent Nos. 6,153,746 and 7,635,773. Purified SAE-β-CD is commercially available under the tradename CAPTISOL® from CyDex Pharmaceuticals, Inc., Lenexa, KS.

With regard to γ-cyclodextrin derivative and β-cyclodextrin derivative in the composition of the present invention, it has been found that undesirably high concentrations of γ-cyclodextrin derivative and/or β-cyclodextrin derivative can significantly interfere with preservation efficacy of the compositions, particularly

when benzalkonium chloride and/or polymeric quaternary ammonium compound are employed as preservation agents. Thus, lower concentrations of γ-cyclodextrin derivative and/or β-cyclodextrin derivative are typically preferred. Advantageously, it has also been found, however, that the ability of the γ-cyclodextrin derivative and β-cyclodextrin derivatives in solubilizing olopatadine is very strong and relatively low concentrations of γ-cyclodextrin derivative and/or β-cyclodextrin derivative can solubilize significant concentrations of olopatadine in aqueous solution. As such, more desirable and reasonable concentrations of additional solubilizing agent can be used to aid in solubilizing the desired amounts of olopatadine.

Further, it has been found that a composition formed using a combination of solubilizing agents such as polyvinylpyrrolidone, tyloxapol, polyethylene glycol and others to solubilize relatively high concentrations of olopatadine in the absence of γ-cyclodextrin derivative and/or β-cyclodextrin derivative will typically lack long term stability or shelf life. It has been found that such a composition will typically begin to precipitate after undesirably short periods of time. Thus, it is important to employ the γ-cyclodextrin derivative and/or β-cyclodextrin derivative in combination with one or more additional solubilizers.

As such, the ophthalmic composition of the present invention includes at least one solubilizing agent (i.e., solubilizer), but possibly two or more solubilizing agents, in addition to cyclodextrin. The additional solubilizing agents can include surfactants such as castor oil, polysorbate or others. Preferably, the additional solubilizing agent[s] includes one or more polymers. One preferred polymer for aiding in solubilizing the olopatadine is lactam polymer. Another preferred polymer for aiding in solubilizing the olopatadine is polyether.

As used herein, the phrase "lactam polymer" refers to any polymer formed from more than one lactam monomer. The lactam polymer is typically present in the composition at a concentration that is at least 1.0% w/v, more typically at least 3.0% w/v and even more typically at least 3.7 % w/v, but is typically no greater than 8.0% w/v, typically no greater than 5.0% w/v and is typically no greater than 4.3% w/v. Polyvinylpyrrolidone (PVP) is the most preferred lactam polymer and can be the only or substantially the only lactam polymer. Thus, in a preferred embodiment, the lactam polymer consists or consists essentially of only PVP. The average molecular weight of the lactam polymer, particularly when it is PVP, is at

least 20,000, more typically at least 46,000 and even more typically at least 54,000 but is typically no greater than 90,000, more typically no greater than 70,000 and still more typically no greater than 62,000. One preferred PVP is sold under the tradenames PLASDONE® K29/32 or K30, which have an average molecular weight of approximately 50,000 and are commercially available from ASHLAND SPECIALTY INGREDIENTS, headquartered in Wayne, NJ, USA.

The polyether can aid in the solubility of olopatadine in the composition and/or can provide tonicity to the composition (i.e., act as a tonicity agent). The polyether is typically present in the composition at a concentration that is at least 1.0% w/v, more typically at least 3.0% w/v and even more typically at least 3.7 % w/v, but is typically no greater than 8.0% w/v, typically no greater than 5.0% w/v and is typically no greater than 4.3% w/v. Polyethylene glycol (PEG) is the most preferred polyether and can be the only or substantially the only polyether polymer. Thus in a preferred embodiment, the polyether consists or consist essentially of only PEG. The average molecular weight of the PEG will typically depend upon the particular solubility and particular tonicity desired for the composition. In a preferred embodiment, the average molecular weight of the polyether, particularly when it is PEG, is at least 200, more typically at least 320 and even more typically at least 380 but is typically no greater than 800, more typically no greater than 580 and still more typically no greater than 420. One preferred PEG is PEG400.

It may also be desirable for the ophthalmic composition of the present invention to include a viscosity enhancing agent in order to enhance residence time of the composition upon the cornea when the composition is topically administered. Examples of potentially suitable viscosity enhancing agent include, without limitation, carboxyvinyl polymer, galactomannan, hyaluronic acid, cellulosic polymer, any combination thereof or the like. In a preferred embodiment, the ophthalmic composition includes hydroxyethyl cellulose (HEC), hydroxylpropylmethyl cellulose (HPMC) or both. One preferred HEC is sold under the tradename NASTROSOL® 250HX, which is commercially available from Hercules Incorporated, Aqualon Division, Argyle, TX. One preferred HPMC is sold under the tradename E4M 2910 and is commercially available from Dow Chemical, Midland, MI.

The amounts and molecular weights of HPMC and/or HEC used in the composition will depend upon the viscosity, osmolality and other attributes to be

achieved for the composition. As used herein, viscosity is measured by a Brookfield viscometer (LVDVI+, CP-42, 12 RPM and a temperature of 25 °C). In a preferred embodiment, the viscosity of the composition is at least 2.0 centipoise (cps), more typically at least 15 cps, even more typically at least 21 cps and even possibly at least 27 cps, but is typically no greater than 65 cps, typically no greater than 40 cps, more typically nor greater than 33 cps and even possibly no greater than 30 cps. Advantageously, and as further discussed below, viscosity within these ranges has been discovered to be more desirable for producing desired droplet sizes when the composition of the present invention is topically delivered from an eye dropper.

The preferred average molecular weight of HEC, when used, is typically in the range of 90,000 to 1,300,000 (e.g., approximately 1,000,000). The preferred average molecular weight of HPMC is typically in the range of 10,000 to 1,500,000 and more typically in the range of 189,000 to 688,000).

When HPMC is used alone, it is typically present in composition at a concentration that is at least 0.15% w/v, more typically at least 0.3% w/v and even more typically at least 0.5% w/v, but is typically no greater than 1.5% w/v, typically no greater than 1.0% w/v and is typically no greater than 0.7% w/v. When HEC is used alone, it is typically present in the composition at a concentration that is at least 0.1% w/v, more typically at least 0.25% w/v and even more typically at least 0.45% w/v, but is typically no greater than 1.4% w/v, typically no greater than 0.9% w/v and is typically no greater than 0.65% w/v. Advantageously, when HPMC and HEC are used to together, they may produce a synergistic viscosity effect which allows the use of low concentrations of these excipients to produce the desired viscosity of the compositions. When HPMC and HEC are used in combination, HPMC is typically present in composition at a concentration that is at least 0.05% w/v, more typically at least 0.1% w/v and even more typically at least 0.2% w/v, but is typically no greater than 1.0% w/v, typically no greater than 0.55% w/v and is typically no greater than 0.4% w/v. When HPMC and HEC are used in combination, HEC is typically present in composition at a concentration that is at least 0.02% w/v, more typically at least 0.06% w/v and even more typically at least 0.09% w/v, but is typically no greater than 0.6% w/v, typically no greater than 0.3% w/v and is typically no greater than 0.17% w/v. Notably, in at least some embodiments of the present invention,

HPMC is a preferred viscosity enhancing agent since, as the data present below shows, it can also aid in solubilizing the olopatadine.

The composition can also include buffering agents and/or tonicity agents. Suitable tonicity-adjusting agents and/or buffering agents include, but are not limited to, mannitol, sodium chloride, glycerin, sorbitol, phosphates, borates, acetates and the like.

Borate is a highly preferred buffering agent and will typically be included in the composition of the present invention. As used herein, the term "borate" shall refer to boric acid, salts of boric acid, borate derivatives and other pharmaceutically acceptable borates, or combinations thereof. Most suitable are: boric acid, sodium borate, potassium borate, calcium borate, magnesium borate, manganese borate, and other such borate salts. Typically, when used, the borate is at least about 0.05 w/v %, more typically at least about 0.18 w/v % and even possibly at least about 0.27 w/v % of the ophthalmic composition and is typically less than about 1.0 w/v %, more typically less than about 0.75 w/v % and still more typically less than about 0.4 w/v %, and even possibly less than about 0.35 w/v % of the ophthalmic composition.

The composition of the present invention can also include polyol. As used herein, the term "polyol" includes any compound having at least one hydroxyl group on each of two adjacent carbon atoms that are not in *trans* configuration relative to each other. The polyol can be linear or cyclic, substituted or unsubstituted, or mixtures thereof, so long as the resultant complex is water soluble and pharmaceutically acceptable. Examples of such compounds include: sugars, sugar alcohols, sugar acids and uronic acids. Preferred polyols are sugars, sugar alcohols and sugar acids, including, but not limited to: mannitol, glycerin, xylitol, sorbitol and propylene glycol. It is contemplated that the polyol may be comprised of two or more different polyols.

When both borate and polyol are present in the composition, borate typically interacts with polyol, such as glycerol, propylene glycol, sorbitol and mannitol, or any combination thereof to form borate polyol complexes. The type and ratio of such complexes depends on the number of OH groups of a polyol on adjacent carbon atoms that are not in trans configuration relative to each other. It shall be understood that weight/volume percentages of the ingredients polyol and borate

include those amounts whether as part of a complex or not. Advantageously, the borate and polyol can act as buffers and/or tonicity agents and can also aid in enhancing preservation efficacy of the composition.

In a preferred embodiment of the invention, the composition includes propylene glycol, glycerine or both. It has been found that γ-cyclodextrin derivatives and/or β-cyclodextrin derivatives tend to inhibit preservation efficacy within the formulations of the present invention, however, propylene glycol in the presence of borate appears to significantly limit this inhibition. Moreover, it has been found that glycerine often acts in a manner very similar to propylene glycol when used for aiding preservation. When used, propylene glycol, glycerine or a combination thereof is typically present in the composition at a concentration that is at least 0.4 w/v%, more typically at least 0.65 w/v% and even possibly at least 0.85 w/v% but is typically no greater than 5.0 w/v%, more typically no greater than 2.2 w/v% and even more typically no greater than 1.7 w/v%.

In a same or alternative preferred embodiment of the invention, the composition includes mannitol, sorbitol or both. Mannitol may also aid preservation of the composition of the present invention when used in the presence of borate. Moreover, it has been found that sorbitol often acts in a manner very similar to mannitol when used for aiding preservation. When used, mannitol, sorbitol or a combination thereof is typically present in the composition at a concentration that is at least 0.05 w/v%, more typically at least 0.2 w/v% and even possibly at least 0.4 w/v% but is typically no greater than 3.0w/v%, more typically no greater than 1.0 w/v% and even more typically no greater than 0.5 w/v%.

The composition of the present invention typically includes a preservative. Potential preservatives include, without limitation, hydrogen peroxide, benzalkonium chloride (BAK), polymeric quaternary ammonium compound (PQAM), biquanides, sorbic acid, chlorohexidine or others. Of these, benzalkonium chloride and polymeric quaternary ammonium compound such as polyquaternium-1 have proven quite desirable.

The polymeric quaternary ammonium compounds useful in the compositions of the present invention are those which have an antimicrobial effect and which are ophthalmically acceptable. Preferred compounds of this type are described in U.S. Pat. Nos. 3,931,319; 4,027,020; 4,407,791; 4,525,346; 4,836,986; 5,037,647 and

5,300,287; and PCT application WO 91/09523 (Dziabo et al.). The most preferred polymeric ammonium compound is polyquaternium-1, otherwise known as POLYQUAD® with a number average molecular weight between 2,000 to 30,000. Preferably, the number average molecular weight is between 3,000 to 14,000.

When used, the polymeric quaternary ammonium compound is generally used in the composition of the present invention in an amount that is greater than about 0.00001 w/v %, more typically greater than about 0.0003 w/v % and even more typically greater than about 0.0007 w/v % of the ophthalmic composition. Moreover, the polymeric quaternary ammonium compound is generally used in the composition of the present invention in an amount that is less than about 0.01 w/v %, more typically less than about 0.007 w/v %, even more typically less than 0.003 w/v%, still more typically less than 0.0022 w/v% and even possibly less than about 0.0015 w/v % of the ophthalmic composition.

BAK is generally used in the composition of the present invention in an amount that is greater than about 0.001 w/v %, more typically greater than about 0.003 w/v % and even more typically greater than about 0.007 w/v % of the ophthalmic composition. Moreover, BAK is generally used in the composition of the present invention in an amount that is less than about 0.1 w/v %, more typically less than about 0.03 w/v % and even more typically less than about0.020 or 0.015 w/v % of the ophthalmic composition.

It is also contemplated that the composition of the present invention may benefit from the use of two different polyols, borate and a preservative (e.g., BAK or polymeric quaternary ammonium compound) to provide enhanced preservations efficacy. Examples of such systems are disclosed in U.S. Patent Publication Nos. 2009/0232763 and 2010/0324031, which are expressly incorporated herein in their entirety for all purposes.

Notably, it has been found that polymeric ammonium compound is particularly desirable for preserving compositions containing SAE-β-CD while BAK is particularly desirable for preserving compositions containing hydroxypropyl beta or gamma cyclodextrin derivatives. It has also been found that filtration (e.g., micron filtration) of the preservative followed by aseptic addition of the preservative to the sterile composition can aid preservation efficacy.

It is contemplated that the composition of the present invention can include a variety of additional ingredients. Such ingredients include, without limitation, additional therapeutic agents, additional or alternative antimicrobial agents, suspension agents, surfactants, additional or alternative tonicity agents, additional or alternative buffering agents, anti-oxidants, additional or alternative viscosity-modifying agents, chelating agents any combinations thereof or the like.

The compositions of the present invention will generally be formulated as sterile aqueous solutions. The compositions of the present invention are also formulated so as to be compatible with the eye and/or other tissues to be treated with the compositions. The ophthalmic compositions intended for direct application to the eye will be formulated so as to have a pH and tonicity that are compatible with the eye. It is also contemplated that the compositions can be suspensions or other types of solutions.

The composition of the present invention will typically have a pH in the range of 4 to 9, preferably 5.5 to 8.5, and most preferably 5.5 to 8.0. Particularly desired pH ranges are 6.0 to 7.8 and more specifically 6.4 to 7.2. The compositions will have an osmolality of 200 to 400 or 450 milliosmoles per kilogram (mOsm/kg), more preferably 240 to 360 mOsm/kg.

It is generally preferred that the composition of the present invention be provided in an eye dropper that is configured to dispense the composition as eyedrops topically to the cornea of the eye. However, desired size of a single eyedrop (i.e., droplet size) for the ophthalmic composition can be difficult to accomplish. It has been discovered that the cyclodextrin in the composition imparts a relatively high surface energy to the composition. In turn, droplet size tends to be relatively high. It has been discovered, however, that by dispensing droplets through a relatively small orifice and/or by maintaining the viscosity of the composition within the ranges discussed above, desired droplet size can be achieved. Desired droplet size is typically at least 10 µl, more typically at least 18 µl and even more typically at least 23 µl, but is typically no greater than 60 µl, typically no greater than 45 µl and is typically no greater than 33 µl. Advantageously, this droplet size for the composition with the concentrations of olopatadine specified herein allows an individual to dispense one droplet per eye once a day and receive relief from symptoms of ocular allergic conjunctivitis

generally, but particularly receive relief from late phase symptoms ocular allergic conjunctivitis.

In a preferred embodiment, the composition of the present invention is a multi-dose ophthalmic compositions that have sufficient antimicrobial activity to allow the compositions to satisfy the USP preservative efficacy requirements, as well as other preservative efficacy standards for aqueous pharmaceutical compositions.

The preservative efficacy standards for multi-dose ophthalmic solutions in the U.S. and other countries/regions are set forth in the following table:

Preservative Efficacy Test ("PET") Criteria
(Log Order Reduction of Microbial Inoculum Over Time

	Bacteria	Fungi
USP 27	A reduction of 1 log (90%), by day 7; 3 logs (99.9%) by day 14; and no increase after day 14	The compositions must demonstrate over the entire test period, which means no increases of 0.5 logs or greater, relative to the initial inoculum
Japan	3 logs by 14 days; and no increase from day 14 through day 28	No increase from initial count at 14 and 28 days
Ph. Eur. A[1]	A reduction of 2 logs (99%) by 6 hours; 3 logs by 24 hours; and no recovery after 28 days	A reduction of 2 logs (99%) by 7 days, and no increase thereafter
Ph. Eur. B	A reduction of 1 log at 24 hours; 3 logs by day 7; and no increase thereafter	A reduction of 1 log (90%) by day 14, and no increase thereafter
FDA/ISO 14730	A reduction of 3 logs from initial challenge at day 14; and a reduction of 3 logs from rechallenge	No increase higher than the initial value at day 14, and no increase higher than the day 14 rechallenge count through day 28

[1]There are two preservative efficacy standards in the European Pharmacopoeia ' "A" and "B".

The standards identified above for the USP 27 are substantially identical to the requirements set forth in prior editions of the USP, particularly USP 24, USP 25 and USP 26.

Advantages and Problems Overcome

The olopatadine ophthalmic composition of the present invention can provide multiple advantages over the olopatadine compositions that came before it. The composition disclosed herein provides an aqueous ophthalmic composition having a relatively high concentration of olopatadine that provides enhanced relief from late phase allergic conjunctivitis and early phase allergic conjuctivitis. Surprisingly and advantageously, preferred compositions of the present invention, as shown in FIGs. 1 through 5 and tables K through O, showed improved reduction in early phase redness, in late phase redness and in late phase itching. It is surprising that the enhanced concentration of olopatadine showed such significant reduction in late phase symptoms. It is even more surprising that the enhanced concentration of olopatadine showed enhanced reduction of early phase redness since it was generally believed that itching and redness would show similar responses to different concentrations of olopatadine.

Further, the composition can solubilize the relatively high concentration of olopatadine in solution form suitable as an eyedrop where other formulations have failed. Further yet, the composition can solubilize the higher concentrations of olopatadine while maintaining efficacy in treatment of the symptoms of allergic conjunctivitis where other efforts to develop such a solution have failed. Still further, the compositions can, when in multi-dose form, pass preservation efficacy standards where other compositions have failed.

As an additional advantage, it has been discovered that, for the particular composition of the present invention, composition containing HP-γ-CD have unexpectedly been found to be more susceptible to preservation. It has also unexpectedly been found to have solubility characteristics similar to the other beta cyclodextrin derivative discussed herein. This discovery has been particularly advantageous in providing a composition that is capable of solubilizing relatively high concentrations of olopatadine, capable of being stable for extended time periods and capable of robust preservation relative to both European and United States preservation efficacy standards.

It is still further advantageous that the cyclodextrin does not appear to interfere with the efficacy of the olopatadine. In particular, cyclodextrins have been found to entrap other drugs in a manner that does not allow those drugs to later release and show efficacy. However, this was not the case for olopatadine and was particularly not the case for HP-γ-CD.

Applicants specifically incorporate the entire contents of all cited references in this disclosure. Further, when an amount, concentration, or other value or parameter is given as either a range, preferred range, or a list of upper preferable values and lower preferable values, this is to be understood as specifically disclosing all ranges formed from any pair of any upper range limit or preferred value and any lower range limit or preferred value, regardless of whether ranges are separately disclosed. Where a range of numerical values is recited herein, unless otherwise stated, the range is intended to include the endpoints thereof, and all integers and fractions within the range. It is not intended that the scope of the invention be limited to the specific values recited when defining a range.

Other embodiments of the present invention will be apparent to those skilled in the art from consideration of the present specification and practice of the present invention disclosed herein. It is intended that the present specification and examples be considered as exemplary only with a true scope and spirit of the invention being indicated by the following claims and equivalents thereof.

Table A below provides a listing of exemplary ingredients suitable for an exemplary preferred formulation of the ophthalmic composition of the present invention and a desired weight/volume percentage for those ingredients. It shall be understood that the following Table A is exemplary and that certain ingredients may be added or removed from the Table and concentrations of certain ingredients may be changed while the formulation can remain within the scope of the present invention, unless otherwise specifically stated.

TABLE A

Ingredient	w/v percent
Olopatadine (Olopatadine HCl)	0.7
Polyether (PEG)	4.0
Lactam Polymer (PVP)	4.0
Viscosity Agent (HEC)	0.1 (if used w/ HPMC or other viscosity agent) 0.3 (if used w/o HPMC or other viscosity agent)
Viscosity Agent (HPMC)	0.15 (if used w/ HEC or other viscosity agent) 0.35 (if used w/o HEC or other viscosity agent)
Chelating agent (Disodium EDTA)	0.005
Borate (Boric Acid)	0.3
γ-cyclodextrin derivative and or β-cyclodextrin derivative	1.0 for SAE-β-CD or 1.5 HP-β-CD or 1.5 HP-γ-CD
Polyol (Mannitol)	0.3
Polyol (Propylene Glycol)	1.0
Tonicity Agent (Sodium Chloride)	0.35
Preservative	0.01 for BAK or 0.0015 PQAM
pH adjusting agents (NaOH or HCl)	sufficient to achieve pH = 7.0
purified water	Q.S. 100

The following examples are presented to further illustrate selected embodiments of the present invention. The formulations shown in the examples were prepared using procedures that are well-known to persons of ordinary skill in the field of ophthalmic pharmaceutical compositions.

EXAMPLES

Preparatory Example 1

Ingredients	Composition (w/w)
Olopatadine hydrochloride	0.77 g
Hydroxypropyl-β-Cyclodextrin(HP-β-CD)	1.5 g
PEG400(Polyethylene glycol 400)	4.0 g
PVP(Polyvinylpyrrolidone K30)	4.0 g
HPMC (Methocel E4m Premium)	0.6 g
HEC(Natrosol 250HX)	0.3 g
Disodium EDTA	0.01 g
Mannitol	0.6 g
Boric Acid	0.3 g
Benzalkonium Chloride	0.01 g
HCl / NaOH	q.s. to pH 7.0
Purified water	q.s. to 100 g

In a clean suitable and tared glass bottle, add and dissolve HPMC with an amount of purified water at 90-95°C equivalent to about 15% of the required batch size. Mix by stirring until homogenization. Bring to the 35% of the final weight with purified water and mix by stirring with propeller until complete dispersion. Add HEC and mix by stirring until homogenization. Steam sterilize the solution (122°C/20 min) and cool afterwards (Part A).In a separate vessel with a stir bar, add an amount of purified water equivalent to about 40% of the required batch size. Add and dissolve batch quantities of weighed PEG400, PVP, HP-β-CD, Olopatadine HCl, Boric Acid, Mannitol, EDTA and BAC, allowing each component to dissolve before adding the next component. Check the pH and adjust to 7.0 ± 0.1 with the required amount of NaOH 2N (Part B). In a laminar flow hood (sterile conditions), filter the solution Part B into the glass bottle containing the autoclaved fraction (Part A), using GV PVDF membrane, 0.22 μm filter unit and stir until homogenization. Mix by stirring with propeller for 15 min. Check

the pH and adjust to 7.0 ± 0.1 with the required amount of NaOH 1N/HCl 1N, if necessary. Bring to final weight with sterile purified water and stir until homogenization.

Preparatory Example 2

Ingredients	Composition (w/w)
Olopatadine hydrochloride	0.77 g
Hydroxypropyl-β-Cyclodextrin (HP-β-CD)	1.5 g
PVP(Polyvinylpyrrolidone K30)	4.0 g
PEG400(Polyethylene glycol 400)	4.0 g
HPMC (Methocel E4m Premium)	0.2 g
HEC(Natrosol 250HX)	0.125 g
Disodium EDTA	0.01 g
Boric Acid	0.3 g
Benzalkonium Chloride	0.01 or 0.015 g
NaOH 1N	0.83 ml
HCl 1N	0.58 ml
HCl / NaOH	q.s. to pH 7.0
Purified water	q.s. to 100 g

In a clean suitable and tared glass bottle, add and dissolve HPMC with an amount of purified water at 90-95°C equivalent to about 15% of the required batch size. Mix by stirring until homogenization. Bring to the 30% of the final weight with purified water and mix by stirring with propeller until complete dispersion. Add HEC and mix by stirring until homogenization (Part A). In a clean beaker with stir bar, weigh an amount of purified water equivalent to about 40% of the required batch size. Heat and maintain this water around 70-75°C. Add NaOH 1N and mix by moderate stirring. Add PVP and dissolve under agitation during 20 minutes. Add HCl 1N, mix and quickly cool down to 30-40°C. Add and dissolve batch quantities of PEG400, HP-β-CD, Olopatadine HCl, Boric Acid, EDTA and BAC, allowing each component to dissolve before adding the next component. Check the pH of the solution and adjust to 6.8 ± 0.1 with the required amount of

NaOH 2N (Part B). Transfer Part B to Part A and stir the batch until it is homogenous. Bring to the 85% of the final weight with purified water and stir until homogenization. Steam sterilize the solution (122°C/20 min) and cool afterwards. In a laminar flow hood (sterile conditions), check the pH and adjust to 7.0 ± 0.1 with the required amount of NaOH 1N/HCl 1N, if necessary. Bring to final weight with sterile purified water and stir until homogenization.

Formulary Examples A through I in Table B below

Formulary Examples A through I show the solubility of olopatadine in different formulations.

Ingredients	A	B	C	D	E
PEG 400	4	4	4	4	3.8
Dibasic Sodium Phosphate, anhydrous	0.15	-	-	-	0.5
Hydroxypropyl-β-Cyclodextrin	-	1.5	1.5	1.5	1
Sulfobutyl ether β Cyclodextrin	2	-	-	-	-
PVP K29/32	5	5	3	4	1.5
Polysorbate 80	0.1	-	-	-	-
Tyloxapol	-	-	-	-	-
Natrosol 250HX	0.3	0.3	0.3	0.3	-
HPMC 2910	0.6	0.6	0.6	0.6	-
Boric Acid	-	0.3	0.3	0.3	-
Sodium Chloride	0.15	-	-	-	-
Mannitol	-	0.6	0.6	0.6	-
Benzalkonium Chloride	0.01	0.01	0.01	0.01	0.01
Disodium EDTA	0.01	0.01	0.01	0.01	0.01
Sodium Hydroxide/ Hydrochloric Acid quantity sufficient to achieve pH of 7.4					
Purified water quantity sufficient to 100%					
Olopatadine Solubility (%)	1.064	0.901	0.725	0.811	0.461

Ingredients	F	G	H	I
PEG 400	6	6	6	6
Dibasic Sodium Phosphate, anhydrous	0.5	0.5	0.5	0.5
Hydroxypropyl-β-Cyclodextrin	-	1	1	1
Sulfobutyl ether β Cyclodextrin	-	-	-	-
PVP K29/32	1.5	-	1.5	1.5
Polysorbate 80	-	-	-	-
Tyloxapol	-	-	-	0.05
Natrosol 250HX	-	-	-	-
HPMC 2910	-	-	-	-
Boric Acid	-	-	-	-
Sodium Chloride	-	-	-	-
Mannitol	-	-	-	-
Benzalkonium Chloride	0.01	0.01	0.01	0.01
Disodium EDTA	0.01	0.01	0.01	0.01
Sodium Hydroxide/ Hydrochloric Acid quantity sufficient to achieve pH of 7.4				
Purified water quantity sufficient to 100%				
Olopatadine Solubility (%)	0.352	0.450	0.513	0.494

As can be seen, cyclodextrin can significantly enhance the solubility of olopatadine in aqueous solution. Moreover, it will be understood that the formulations of lower solubility, particularly those without cyclodextrin, will also typically exhibit worse solubility characteristics over time and tend to form precipitates.

Formulary Example J through M in Table C below

Formulary Examples J through M show the preservation efficacy of olopatadine containing formulations both with and without β-cyclodextrin.

Ingredients	J	K	L	M
Olopatadine HCL	0.77	0.77	0.77	0.77
PEG 400	-	4	-	-
Sodium Pyruvate	-		-	-
Dibasic Sodium Phosphate, anhydrous	0.15	0.15	0.15	0.1
Purified Guar	-	-	-	0.17
Hydroxypropyl-β-Cyclodextrin	1.5	-	-	5
PVP K30	2	3	3	-
Tyloxapol	-	-	0.2	-
Polysorbate 80	-	0.1	-	-
Natrosol 250HX		0.3	0.3	-
HPMC 2910	-	0.6	0.6	-
Boric Acid	-	-	-	0.17
Sodium Borate, decahydrate	-	-	-	0.5
Propylene Glycol	-	-	-	-
Sodium Chloride	-	0.15	0.55	0.1
Mannitol	2.5	-	-	-
Sorbitol	-	-	-	1
Sodium Citrate, dihydrate	-	-	-	0.35
Benzalkonium Chloride	0.01	0.01	0.01	0.01
Polyquaternium-1	-	-	-	-
Disodium EDTA	0.01	0.01	0.01	-
Sodium Hydroxide/ Hydrochloric Acid	q.s. to pH 7.0	q.s. to pH 7.0	q.s. to pH 7.0	q.s. to pH 7.0
Purified water	q.s. to 100%	q.s. to 100%	q.s. to 100%	q.s. to 100%
PET	Log_{10} Unit Reduction			
S. aureus 6 h/24h/7 d/14d/28d	0.1/1.9 /5.0/5. 0/5.0	5.0/5.0/ 5.0/5.0/ 5.0	1.5/5.0/ 5.0/5.0/ 5.0	0.0/0.0/ 0.9/3.3/ 5.0
P. aerugin 6 h/24h/7 d/14d/28d	4.9/4.9 /4.9/4. 9/4.9	4.9/4.9/ 4.9/4.9/ 4.9	4.9/4.9/ 4.9/4.9/ 4.9	0.3/0.5/ 0.0/0.0/ 0.5
E. coli 6 h/24h/7 d/14d/28d	2.8/4.9 /4.9/4. 9/4.9	4.9/4.9/ 4.9/4.9/ 4.9	4.9/4.9/ 4.9/4.9/ 4.9	0.1/0.2/ 1.4/3.3/ 5.0

C. albican 7 d/14d/28d	4.3/5.1 /5.1/4. 1/4.1	5.1/5.1/ 5.1/5.1/ 5.1	2.5/5.1/ 5.1	0.7/2.7/ 3.2
A. niger 7 d/14d/28d	0.8/0.9 /1.3	2.1/4.2/ 4.9	0.7/1.7/ 2.3	1.2/1.1/ 1.5

As can be seen, cyclodextrin derivatives can significantly inhibit the ability of a preservative to provide desired preservation to an aqueous formulation.

As an added advantage, it has also been discovered that HPMC can aid in solubilizing olopatadine. This effect is shown in Table D below.

TABLE D

% PVP K29/32	% SBE-CD	% PEG 400	% HPMC	Concentration (mg/mL)	Final pH
4	1.5	4	-	6.13	6.97
4	2.0	4	-	6.74	6.97
4	2.2	4	-	6.97	7.01
4	2.3	4	-	7.16	7.02
4	2.5	4	-	7.34	6.98
4	1.5	4	0.6	7.46	6.96
4	2.0	4	0.6	8.11	7.06
4	2.2	4	0.6	8.62	7.02
4	2.3	4	0.6	8.66	7.01
4	2.5	4	0.6	9.04	7.04

Table E below presents several formulations (N through Q) that can solubilize a high concentration of olopatadine using PVP in combination with a relatively low amount of HP-β-CD and that show desirable preservation using a combination of BAK and Boric Acid. Notably, PEG and HPMC are also believed to be aiding in the solubility of olopatadine.

TABLE E

Ingredients	N	O	P	Q
Olopatadine HCL	0.77	0.77	0.77	0.77
PEG 400	4	4	4	4
Hydroxypropyl-β-Cyclodextrin	1.5	1.5	1.5	1.5
PVP K29/32	4	4	4	4
Natrosol 250HX	0.3	0.3	0.3	0.125
HPMC 2910	0.6	0.6	0.6	0.2
Boric Acid	0.3	0.3	0.3	0.3
Disodium EDTA	0.01	0.01	0.01	0.01
Benzalkonium Chloride	0.01	0.01	0.01	0.01
Polyquaternium-1	-	-	-	-
Sodium Hydroxide/ Hydrochloric Acid	q.s. to pH 7	q.s. to pH 7	q.s. to pH 7	q.s. to pH 7
Purified water	q.s. to 100%	q.s. to 100%	q.s. to 100%	q.s. to 100%
PET Result	Log $_{10}$ Unit Reduction			
S. aureus 6 h/24h/7 d/14d/28d	0.4/3.6/4.9/4.9/4.9	0.2/1.4/5.0/5.0/5.0	0.3/2.9/4.9/4.9/4.9	0.4/3.2/5.0/5.0/5.0
P. aerugin 6 h/24h/7 d/14d/28d	5.0/5.0/5.0/5.0/5.0	5.1/5.1/5.1/5.1/5.1	5.0/5.0/5.0/5.0/5.0	5.2/5.2/5.2/5.2/5.2
E. coli 6 h/24h/7 d/14d/28d	4.9/4.9/4.9/4.9/4.9	2.7/5.1/5.1/5.1/5.1	2.1/5.1/5.1/5.1/5.1	2.3/5.1/5.1/5.1/5.1
C. albican 7 d/14d/28d	4.9/4.9/4.9	2.5/4.8/4.8	1.6/4.1/5.0	2.4/4.6/4.6
A. niger 7 d/14d/28d	3.8/5.2/5.2	3.6/5.1/5.1	4.3/5.2/5.2	3.9/4.7/5.2

Tables F and G below show the difficulty associated with preservation of formulations (R through X) containing SBE-β-CD.

TABLE F

Ingredient	R	S	T	U
Olopatadine HCl	0.77	0.77	0.77	0.77
Sulfobutylether-β-Cyclodextrin	0.75	0.75	0.75	0.75
PVP K29/32	4	4	4	4
PEG 400	2	2	2	2
Natrosol 250HX	-	-	-	-
HPMC 2910	0.6	0.6	0.6	0.6
Boric Acid	0.6	0.3	0.3	0.3
Mannitol	-	-	**0.2**	-
Disodium EDTA	-	0.01	0.01	0.01
Polyquaternium-1	**0.001**	-	-	-
BAC	-	**0.02**	**0.02**	-
Benzododecinium Bromide	-	-	-	-
Sorbic Acid	-	-	-	**0.2**
Thimerosal	-	-	-	-
Chlorhexidine Digluconate	-	-	-	-
NaOH/HCl	q.s. to pH 7.0	q.s. to pH 7.0	q.s. to pH 7.0	q.s. to pH 6.0
Purified water	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100
PET RESULTS				
S. aureus 6 h/24h/7 d/14d/28d	1.8/2.8/5.0/5.4/	0.0/0.5/4.7/	0.0/0.4/4.7/	0.1/0.1/4.7/
P. aerugin 6 h/24h/7 d/14d/28d	0.6/0.8/5.4/5.4/	5.0/5.0/5.0/	5.0/5.0/5.0/	5.0/5.0/5.0/
E. coli 6 h/24h/7 d/14d/28d	1.2/3.2/5.4/5.4/	1.4/3.1/5.1/	1.7/3.2/5.1/	0.2/0.3/5.1/
C. albicans 7 d/14d/28d	0.3/1.5/	0.7/	0.6	0.1/
A. Niger 7 d/14d/28d	0.7/0.7/	2.1/	1.2	1.1/

5

TABLE G

Ingredients	V	W	X
Olopatadine HCl	0.77	0.77	0.77
Sulfobutylether-β-Cyclodextrin	0.75	0.75	0.75
PVP K29/32	4	4	4
PEG 400	2	2	2
Natrosol 250HX	-	-	-
HPMC 2910	0.6	0.6	0.6
Boric Acid	0.3	0.3	0.3
Mannitol	-	-	-
Disodium EDTA	0.01	0.01	0.01
Polyquaternium-1	-	-	-
BAC	-	-	-
Benzododecinium Bromide	**0.02**	-	-
Sorbic Acid	-	-	-
Thimerosal	-	**0.01**	-
Chlorhexidine Digluconate	-	-	**0.01**
NaOH/HCl	q.s. to pH 7.0	q.s. to pH 7.0	q.s. to pH 7.0
Purified water	q.s. to 100	q.s. to 100	q.s. to 100
	PET RESULTS		
S. aureus 6 h/24h/7 d/14d/28d	0.0/0.1/4.7/	0.0/0.0/4.7/	0.0/0.4/4.7/
P. aerugin 6 h/24h/7 d/14d/28d	5.0/5.0/5.0/	5.0/5.0/5.0/	5.0/5.0/5.0/
E. coli 6 h/24h/7 d/14d/28d	0.6/1.3/5.1/	1.1/5.0/5.0/	1.0/3.9/5.0/
C. albicans 7 d/14d/28d	0.5/	5.8/	3.9/
A. Niger 7 d/14d/28d	1.2/	5.0/	1.4

Tables H and I show the achievement of significantly improved preservation of formulations (Y through II), which also contain SBE-β-CD.

TABLE H

Ingredients	Y	Z	AA	BB	CC	DD
			+ + +	+ + -	+-+	-+-
Olopatadine HCl	0.77	0.77	0.77	0.77	0.77	0.77
Sulfobutylether-β-Cyclodextrin	1.5	1.5	1	1	1	0.75
PVP K29/32	4	4	4	4	4	4
PEG 400	4	4	2	2	2	2
Natrosol 250HX	0.3	0.3	-	-	-	-
HPMC 2910	0.6	0.6	0.6	0.6	0.6	0.6
Boric Acid	0.3	0.3	0.3	0.3	0.3	0.3
Mannitol	0.6	-	-	-	-	-
Propylene glycol	-	1	1	0.5	1	0.5
Polyquaternium-1	0.001	0.001	0.002	0.002	0.001	0.002
Sodium Hydroxide and/or Hydrochloric acid Qs to pH 7.2						
Purified Water Qs to 100						
PET DATA						
S. aureus 6 h/24h/7 d/14d/28d	0.9/1.7/4.9/ 4.9/4.9	1.2/1.6/4.9/ 4.9/4.9	1.6/2.2/4.7/ 4.7/4.7	1.6/2.4/4.7/ 4.7/4.7	1.8/2.0/4.7/ 4.7/4.7	2.1/2.9/5.05 .0/
P. aerugin 6 h/24h/7 d/14d/28d	3.4/4.9/4.9/ 4.9/4.9	0.3/1.4/5.2/ 5.2/5.2	0.0/1.0/4.6/ 5.1/5.1	0.2/1.2/5.1/ 5.1/5.1	0.1/1.0/5.1/ 5.1/5.1	0.6/1.5/5.45 .4/
E. coli 6 h/24h/7 d/14d/28d	1.9/4.2/4.9/ 4.9/4.9	1.0/2.7/5.2/ 5.2/5.2	0.3/1.6/4.8/ 4.8/4.8	1.7/4.8/4.8/ 4.8/4.8	0.3/1.2/4.8/ 4.8/4.8	2.2/4.9/5.45 .4/
C. albican 7 d/14d/28d	0.1/0.4/0.4	0.9/1.1/2.1	1.2/2.5/	1.0/2.2/	0.8/2.3/	0.9/2.7/
A. niger 7 d/14d/28d	3.6/3.6/3.1	1.0/1.0/1.0	0.6/0.7/	0.2/0.8/	0.2/0.8/	0.6/0.8/

TABLE I

FID	EE	FF	GG	HH	II
	-++	---	+--	--+	NA
Olopatadine HCl	0.77	0.77	0.77	0.77	0.77
Sulfobutylether-β-Cyclodextrin	0.75	0.75	1	0.75	0.75
PVP K29/32	4	4	4	4	4
PEG 400	2	2	2	2	2
Natrosol 250HX	-	-	-	-	-
HPMC 2910	0.6	0.6	0.6	0.6	0.6
Boric Acid	0.3	0.3	0.3	0.3	0.6
Mannitol	-	-	-	-	-
Propylene glycol	1	0.5	0.5	1	-
Polyquaternium-1	0.002	0.001	0.001	0.001	0.001
Sodium Hydroxide and/or Hydrochloric acid Qs to pH 7.2					
Purified Water Qs to 100					
PET DATA					
S. aureus 6 h/24h/7 d/14d/28d	2.0/3.1/4.7/ 4.7/4.7	0.7/1.2/4.7/ 4.7/4.7	1.5/1.8/4.7/ 4.7/4.7	2.0/2.9/5.05 .0/	1.8/2.8/5.05 .4/
P. aerugin 6 h/24h/7 d/14d/28d	0.5/1.4/5.1/ 5.1/5.1	0.0/0.4/2.0/ 1.2/0.2	0.4/1.1/5.1/ 5.1/5.1	0.6/6.3/5.45 .4/	0.6/0.8/5.45 .4/
E. coli 6 h/24h/7 d/14d/28d	1.6/4.6/4.8/ 4.8/4.8	0.0/0.0/0.00 .0/2.6	0.2/0.8/4.8/ 4.8/4.8	2.4/5.2/5.45 .4/	1.2/3.2/5.45 .4/
C. albican 7 d/14d/28d	1.1/2.7/	0.6/1.9/	0.7/1.9/	0.3/2.4/	0.3/1.5/
A. niger 7 d/14d/28d	0.7/0.8/	0.7/0.9/	0.7/0.8/	0.7/0.8/	0.7/0.7/

Table J illustrates that formula preservation can best be achieved using HP-γ-CD. In particular, formulas JJ through TT in Table J exhibit robust preservation

relative to both European and United States preservation standards. This is particularly surprising when the data in Table J is compared with the data in Tables A, B and E since there is no readily identifiable reason that the formulations containing HP-γ-CD should exhibit greater preservation efficacy relative to the formulations containing HP-β-CD.

TABLE J

Formula	**JJ**	**KK**	**LL**	**MM**	**NN**	**OO**
Batch #	11-63920	11-63921	11-63900	11-63901	11-63902	11-63922
Component						
Olopatadine Hydrochloride	0.77	0.77	0.77	0.77	0.77	0.77
HP-γ-CD	1.5	1.5	1.5	1.5	1.5	1.5
Povidone K29/32	4	4	4	4	4	4
PEG 400	4	4	4	4	4	4
HPMC 2910 E4M	0.4	0.4	0.4	0.4	0.4	0.4
Boric acid	0.3	0.3	0.3	0.3	0.3	0.3
Mannitol	0.2	0.2	0.2	0.2	0.2	0.2
Disodium EDTA	-	-	-	-	-	0.005
Benzalkonium Chloride	0.015	0.0125	0.01	0.0075	0.005	0.015
Sodium Hydroxide and/or Hydrochloric acid Qs to pH 7.2						
Purified Water Qs to 100						
PET DATA						
S.aureus 6h/24h/7d/14d/28d	4.9/4.9/4.9/4.9/4.9	4.9/4.9/4.9/4.9/4.9	4.8/4.8/4.8/4.8/4.8	4.8/4.8/4.8/ 4.8/4.8	4.8/4.8/4.8/ 4.8/4.8	4.9/4.9/4.9/ 4.9/4.9
P.aeruginosa 6h/24h/7d/14d/28d	4.9/4.9/4.9/4.9/4.9	4.9/4.9/4.9/4.9/4.9	4.9/4.8/4.9/4.9/4.9	4.9/4.9/4.9/ 4.9/4.9	4.9/4.9/4.9/ 4.9/4.9	4.9/4.9/4.9/ 4.9/4.9
E.coli 6h/24h/7d/14d/28d	5.0/5.0/5.0/5.0/5.0	2.6/5.0/5.0/5.0/5.0	1.1/3.0/4.9/4.9/4.9	0.9/1.8/4.9/ 4.9/4.9	0.4/1.2/4.9/ 4.9/4.9	5.0/5.0/5.0/ 5.0/5.0
C.albican 6h/24h/7d/14d/28d	4.8/4.8/4.8	4.8/4.8/4.8	4.9/4.9/4.9	4.9/4.9/4.9	4.9/4.9/4.9	4.8/4.8/4.8
A.niger 6h/24h/7d/14d/28d	5.1/5.1/5.1	5.1/5.1/5.1	5.1/5.1/5.1	5.1/5.1/5.1	5.1/5.1/5.1	5.1/5.1/5.1
Test Results						
pH Initial	**7.31**	**7.25**	**7.25**	**7.20**	**7.29**	**7.25**

TABLE J CONTINUED

FID	PP	QQ	RR	SS	TT
Batch #	11-63923	11-63899	11-63905	11-63908	11-64011
Component					
Olopatadine Hydrochloride	0.77	0.77	0.77	0.77	0.77
HP-γ-CD	1.5	1.5	1.5	1.5	1.5
Povidone K29/32	4	4	4	4	4
PEG 400	4	4	4	4	4
HPMC 2910 E4M	0.4	0.4	0.4	0.4	0.4
Boric acid	0.3	0.3	0.3	0.3	0.3
Mannitol	0.2	0.2	0.2	0.2	0.2
Disodium EDTA	0.005	0.005	0.005	0.005	0.005
Benzalkonium Chloride	0.0125	0.01	0.0075	0.005	0.01
Sodium Hydroxide and/or Hydrochloric acid Qs to pH 7.2					
Purified Water Qs to 100					
PET DATA					
S.aureus 6h/24h/7d/14d/28d	4.9/4.9/4.9/ 4.9/4.9	4.8/4.8/4.8/ 4.8/4.8	4.8/4.8/4.8/ 4.8/4.8	4.9/4.9/4.9/ 4.9/4.9	5.0/5.0/5.0/5 .0/5.0
P.aeruginosa 6h/24h/7d/14d/28d	4.9/4.9/4.9/ 4.9/4.9	4.9/4.9/4.9/4 .9/4.9	4.9/4.9/4.9/ 4.9/4.9	4.9/4.9/4.9/ 4.9/4.9	5.0/5.0/5.0/5 .0/5.0
E.coli 6h/24h/7d/14d/28d	5.0/5.0/5.0/5 .0/5.0	4.9/4.9/4.9/ 4.9/4.9	4.9/4.9/4.9/ 4.9/4.9	5.0/5.0/5.0/ 5.0/5.0	5.1/5.1/5.1/5 .1/5.1
C.albican 6h/24h/7d/14d/28d	4.8/4.8/4.8	4.9/4.9/4.9	4.9/4.9/4.9	4.8/4.8/4.8	4.9/4.9/4.9
A.niger 6h/24h/7d/14d/28d	4.4/5.1/5.1	5.1/5.1/4.9	5.1/5.1/5.1	4.4/5.1/5.1	5.3/5.3/5.3
Test Results					
pH Initial	**7.24**	**7.24**	**7.23**	**7.28**	**7.29**

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Tables K through O below corresponding to graphs in FIGS. 1 through 5, provide results from a conjunctival allergen challenge (CAC) study of a high concentration olopatadine composition as compared to a marketed lower concentration olopatadine composition (marketed as PATADAY® by Alcon Laboratories, Inc., a Novartis Company). The CAC study was performed according to a standard CAC model that instills allergen in the eye (the challenge) and then makes determinations of ocular redness and ocular itching at time points (determination times) after the challenge. The CAC study was performed by ORA, Inc., Andover, Massachusetts, United States, 01810, which uses a model accepted by the food and drug administration (FDA). It is noted that in tables K through O and FIGs. 1 through 5, the references to 0.77% olopatadine are references to olopatadine HCL and actually represent 0.7% olopatadine as base and the references to 0.2% olopatadine are references to 0.22% olopatadine HCL and 0.2% olopatadine as base.

In the CAC model, each patient is dosed with drug or vehicle and exposed to allergen at specific challenge times. The challenge times for the study were 27 minutes, 16 hours and 24 hours after dosing. Thereafter, itching is determined at determination times of 3, 5 and 7 minutes after challenge times and redness is determined at determination times of 7, 15 and 20 minutes after the challenge times. Therefore, patients received three doses of drug or vehicle and each dose was followed by an allergen challenge and then the itching and redness determination are made as discussed. Results from the determination times are provided in Tables K through O and the graphs of FIGS. 1 through 5.

Redness scores are determined on a scale of 0 to 4 by visual observation and the patient is asked to rate their ocular itching on a scale of 0 to 4 to attain itching scores and in each score 0 is the least and 4 is greatest. The results of those determinations at those time points are provided in Tables K through O and the graphs of FIGS. 1 through 5. Each of Tables K through O provide a mean score (Mean), a standard deviation (Std) to that score, a number (N) of patients, a minimum (Min) score determined for any of the patients, a maximum (Max) score determined for any of the patients and p-values for indications of statistical significance with a p-value of less than 0.05 indicating statistical significance.

Table K below provides data relative to mean conjunctival redness as determined by the conjunctival allergen challenge (CAC) study 27 minutes after challenge and that data is provided as a graph in FIG 1.

TABLE K

Conjunctival Redness (Onset-of-Action CAC)

		Mean	Std	N	Min	Max	By Time p-value	Overall p-value
7min	**Olopatadine 0.77%**	0.8	0.7	63	0	3		
	Olopatadine 0.2%	1.3	0.8	63	0	3	<.0001	<.0001
	Vehicle	2.1	0.7	60	0	3	<.0001	<.0001
15min	**Olopatadine 0.77%**	1.1	0.9	63	0	3		
	Olopatadine 0.2%	1.9	0.8	63	0	3	<.0001	
	Vehicle	2.3	0.6	60	1	4	<.0001	
20min	**Olopatadine 0.77%**	1.1	0.8	63	0	3		
	Olopatadine 0.2%	1.9	0.8	63	0	3	<.0001	
	Vehicle	2.3	0.7	60	0	4	<.0001	

Main Effect of Treatment p-value=<.0001
Treatment by Time Interaction p-value=0.0036

As can be seen in Table K and FIG. 1, olopatadine at a concentration of 0.7% (note that the 0.77% above is for olopatadine HCl and represents 0.7% olopatadine) provides statistically significant (i.e., $p < 0.05$) relief of redness at onset-of-action relative to both vehicle and olopatadine 0.2%. Further, olopatadine at a concentration of 0.7% provides more that a 1.0 unit difference relative to vehicle in relief of redness. Olopatadine at this concentration is believed to be the first antihistamine/mast cell stabilizer to provide such a difference. This data is particularly surprising since, prior to this CAC study, there was no indication that a high concentrations olopatadine composition would provide any additional reduction in redness at onset-of-action.

Olopatadine's IC_{50} value or half maximal inhibitory concentration (IC_{50}) for inhibition of human conjunctival mast cell degranulation is in the 500 to 600 μM range. Olopatadine's binding affinity (Ki) value for histamine binding to the H1 receptor is in the 30 to 50 nM range. The molar concentration of olopatadine in a 0.1% solution of olopatadine is approximately 2.5 mM. These values suggest that a

0.1% solution of olopatadine should have more than a sufficient quantity of olopatadine to provide maximal inhibition of human conjunctival mast cell degranulation and maximal fully histamine binding.

In particular, for inhibition of mast cell degranulation, these values indicate that when a 0.1% solution of olopatadine is dosed onto the eye, there is exposure to 5 times the IC_{50} value for mast cell degranulation (500 μM vs 2.5 mM). When a 0.2% olopatadine solution is dosed to the eye, the exposure increases from approximately 2.5 mM (for a 0.1% solution) to 5 mM or about 10 times excess drug for inhibition of mast cell degranulation. Because olopatadine does not have any vasoconstrictive effect, which would typically reduce redness, this inhibition of redness is believed to result from inhibition of the release of the mast cell mediators brought about by the mast cell degranulation. As such, a 0.1% or 0.2% solution of olopatadine should provide full inhibition of redness at onset of action since both of these solutions provide excess olopatadine for inhibiting mast cell degranulation.

Surprisingly, however, the data in Table K and FIG. 1 show that a 0.7% solution of olopatadine prevents redness even better than a 0.2% solution of olopatadine at onset of action. Even more surprising, it provides a statistically significant difference in redness inhibition relative the 0.2% solution at onset of action.

In contrast to this surprising discovery relative to redness, a similar finding was not made for itching (see Table KK below), which is believed to be avoided through histamine binding.

TABLE KK

Ocular Itching
(Onset-of-Action CAC)

		Mean	Std	N	Min	Max	By Time p-value	Overall p-value
3min	**Olopatadine 0.77%**	0.4	0.7	63	0	3		
	Olopatadine 0.2%	0.4	0.6	63	0	3	0.8434	
	Vehicle	1.9	1.1	60	0	4	<.0001	
5min	**Olopatadine 0.77%**	0.6	0.8	63	0	3		
	Olopatadine 0.2%	0.7	0.7	63	0	3	0.5341	
	Vehicle	2.1	1.1	60	0	4	<.0001	
7min	**Olopatadine 0.77%**	0.5	0.7	63	0	3		
	Olopatadine 0.2%	0.7	0.8	63	0	4	0.3667	0.5441
	Vehicle	2.0	1.1	60	0	4	<.0001	<.0001

Main Effect of Treatment p-value=<.0001
Treatment by Time Interaction p-value=0.4025

The similarity in itching values for olopatadine 0.7% and olopatadine 0.2% for itching at onset of action are to be expected since 0.2% olopatadine and 0.7% olopatadine both provide enough olopatadine to provide maximal inhibition of itching at onset of action. Thus, the above discussed finding relative to redness at onset of action is quite unique.

Table L below provides data relative to mean conjunctival redness determined by the CAC study 16 hours after challenge and that data is provided as a graph in FIG 2.

TABLE L

Conjunctival Redness
(16hrs Duration CAC)

		Mean	Std	N	Min	Max	By Time p-value	Overall p-value
7min	**Olopatadine 0.77%**	1.3	0.8	65	0	3		
	Olopatadine 0.2%	1.6	0.7	65	1	3	0.0123	0.0056
	Vehicle	1.8	0.8	65	1	3	<.0001	0.0001
15min	**Olopatadine 0.77%**	1.5	0.8	65	0	4		
	Olopatadine 0.2%	1.9	0.7	65	1	4	0.0061	
	Vehicle	1.9	0.8	65	1	4	0.0013	
20min	**Olopatadine 0.77%**	1.5	0.8	65	0	4		
	Olopatadine 0.2%	1.9	0.7	65	1	4	0.0061	
	Vehicle	1.9	0.9	65	1	4	0.0015	

Main Effect of Treatment p-value=0.0004
Treatment by Time Interaction p-value=0.0077

As can be seen in Table L and FIG. 2, olopatadine at a concentration of 0.7% provides statistically significant relief of redness at 16 hours relative to both vehicle and olopatadine 2%.

Table M below provides data relative to mean total redness determined by the CAC study 24 hours after challenge and that data is provided as a graph in FIG 3. Mean total redness is a summation three redness determinations: i) conjunctival; ii) episcleral; and iii) ciliary, each taken on a scale of 1 through 4.

TABLE M

Total Redness
(24hrs Duration CAC)

		Mean	Std	N	Min	Max	By Time p-value	Overall p-value
7min	**Olopatadine 0.77%**	4.1	2.6	66	0	10		
	Olopatadine 0.2%	5.4	2.4	66	1	11	0.0022	0.0073
	Vehicle	6.1	2.3	68	1	10	<.0001	<.0001
15min	**Olopatadine 0.77%**	5.0	2.9	66	0	10		
	Olopatadine 0.2%	6.2	2.3	66	1	11	0.0086	
	Vehicle	6.7	2.3	68	1	11	<.0001	
20min	**Olopatadine 0.77%**	5.4	2.9	66	1	11		
	Olopatadine 0.2%	6.3	2.3	66	2	11	0.0383	
	Vehicle	6.6	2.6	68	1	11	0.0040	

Main Effect of Treatment p-value=0.0003
Treatment by Time Interaction p-value=0.0136

As can be seen in Table M and FIG. 3, olopatadine at a concentration of 0.7% provides statistically significant relief of total redness at 24 hours relative to both vehicle and olopatadine 2%.

Table N below provides data relative to ocular itching determined by the CAC study 24 hours after challenge and that data is provided as a graph in FIG 4.

TABLE N

Ocular Itching
(24hrs Duration CAC)

		Mean	Std	N	Min	Max	By Time p-value	Overall p-value
3min	**Olopatadine 0.77%**	0.9	0.8	66	0	3		
	Olopatadine 0.2%	1.4	0.8	66	0	3	0.0010	
	Vehicle	2.5	0.8	68	1	4	<.0001	
5min	**Olopatadine 0.77%**	1.1	0.9	66	0	3		
	Olopatadine 0.2%	1.5	0.9	66	0	4	0.0107	
	Vehicle	2.6	0.8	68	0	4	<.0001	
7min	**Olopatadine 0.77%**	1.1	0.9	66	0	3		
	Olopatadine 0.2%	1.5	1.0	66	0	4	0.0149	0.0034
	Vehicle	2.5	0.9	68	0	4	<.0001	<.0001

Main Effect of Treatment p-value=<.0001
Treatment by Time Interaction p-value=0.3221

As can be seen in Table N and FIG. 4, olopatadine at a concentration of 0.7% provides statistically significant relief of ocular itching at 24 hours relative to both vehicle and olopatadine 2%.

Table O below provides data relative to ocular itching determined by the CAC study 24 hours after challenge and that data is provided as a graph in FIG 5.

TABLE O

Conjunctival Redness
(24hrs Duration CAC)

		Mean	Std	N	Min	Max	By Time p-value	Overall p-value
7min	**Olopatadine 0.77%**	1.5	0.8	66	0	3		
	Olopatadine 0.2%	1.9	0.8	66	0	4	0.0016	0.0075
	Vehicle	2.1	0.8	68	1	4	<.0001	<.0001
15min	**Olopatadine 0.77%**	1.8	0.9	66	0	4		
	Olopatadine 0.2%	2.1	0.7	66	0	4	0.0131	
	Vehicle	2.3	0.7	68	1	4	<.0001	
20min	**Olopatadine 0.77%**	1.8	0.9	66	0	4		
	Olopatadine 0.2%	2.1	0.7	66	1	4	0.0402	
	Vehicle	2.3	0.9	68	1	4	0.0024	

Main Effect of Treatment p-value=0.0002
Treatment by Time Interaction p-value=0.1540

As can be seen in Table O and FIG. %, olopatadine at a concentration of 0.7% provides statistically significant relief of conjunctival redness at 24 hours relative to both vehicle and olopatadine 2%.

We Claim:

1. An ophthalmic composition for treatment of ocular allergic conjunctivitis, the composition comprising:
at least 0.67 w/v % olopatadine; and
water.

2. A composition as in claim 1 wherein the concentration of olopatadine is at least 0.7 w/v% and is dissolved in solution.

3. A composition as in claim 1 further comprising a γ-cyclodextrin derivative, a β-cyclodextrin derivative or both to aid in the solubility of the olopatadine.

4. A composition as in claim 1 further comprising a lactam polymer to aid in the solubility of the olopatadine.

5. A composition as in claim 4 wherein the lactam polymer is polyvinylpyrrolidone.

6. A composition as in claims 1 further comprising a polyether.

7. A composition as in claim 6 wherein the polyether is polyethylene glycol.

8. A composition as in claim 1 wherein the composition is disposed in an eyedropper, has a pH of 5.5 to 8.0 and an osmolality of 200 to 450.

9. An ophthalmic composition for treatment of ocular allergic conjunctivitis, the composition comprising:
at least 0.67 w/v % olopatadine dissolved in solution;
PEG having a molecular weight of 300 to 500;
polyvinylpyrrolidone; and
cyclodextrin derivative selected from β-cyclodextrin derivative, γ-cyclodextrin or both.

10. A composition as in claim 9 further comprising a preservative selected from a polymeric quaternary ammonium compound and benzalkonium chloride.

11. A composition as in claim 10 wherein the cyclodextrin derivative is hydroxypropyl- β-cyclodextrin or sulfoalkyl ether β-cyclodextrin.

12. A composition as in claim 11 wherein the β-cyclodextrin derivative is hydroxypropyl- β-cyclodextrin when the preservative is the benzalkonium chloride and the β-cyclodextrin derivative is sulfoalkyl ether β-cyclodextrin when the preservative is the polymeric quaternary ammonium compound.

13. A composition as in claim 10 wherein the preservative is benzalkonium chloride and the cyclodextrin derivative is hydroxypropyl-γ-cyclodextrin.

14. A composition as in claim 9 further comprising borate.

15. A composition as in claim 14 further comprising polyol.

16. An ophthalmic composition for treatment of ocular allergic conjunctivitis, the composition comprising:

at least 0.67 w/v % but no greater than 1.0 w/v% olopatadine dissolved in solution;

PEG having a molecular weight of 300 to 500 wherein the concentration of the PEG in solution is from about 2.0 w/v % to about 6.0 w/v%;

a lactam polymer wherein the lactam polymer is polyvinylpyrrolidone and the concentration of the polyvinylpyrrolidone in solution is from about 2.0 w/v % to about 6.0 w/v%; and

a β-cyclodextrin derivative or a γ-cyclodextrin derivative selected from SAE-β-cyclodextrin, HP-γ-cyclodextrin and HP-β-cyclodextrin wherein the concentration of the β-cyclodextrin derivative or the γ-cyclodextrin derivative is at least 0.5 w/v% but no greater than 2.0 w/v%.

17. A composition as in claims 16 further comprising borate at a concentration of at least about 0.18 w/v % but less than about 0.5 w/v%.

18. A composition as in claim 17 further comprising polyol.

19. A composition as in claim 18 wherein the polyol include polyethylene glycol at a concentration of at least 0.4 w/v% but no greater than 2.2 w/v%.

20. An ophthalmic composition for treatment of ocular allergic conjunctivitis, the composition comprising:

at least 0.67 w/v % but no greater than 1.0 w/v% olopatadine dissolved in solution;

PEG having a molecular weight of 300 to 500 wherein the concentration of the PEG in solution is from about 2.0 w/v % to about 6.0 w/v%;

a lactam polymer wherein the lactam polymer is polyvinylpyrrolidone and the concentration of the polyvinylpyrrolidone in solution is from about 2.0 w/v % to about 6.0 w/v%; and

hydroxypropyl-γ-cyclodextrin in the composition at a concentration of at least 0.5 w/v% but no greater than 2.0 w/v%.

21. A composition as in claims 20 further comprising borate at a concentration of at least about 0.18 w/v % but less than about 0.5 w/v%.

22. A composition as in claim 21 further comprising polyol.

23. A composition as in claim 22 wherein the polyol include polyethylene glycol at a concentration of at least 0.4 w/v% but no greater than 2.2 w/v%.

24. A method of treating ocular allergy symptoms, the method comprising:

topically applying the composition of claim 20 to an eye of a human.

25 A method as in claim 24 wherein the step of topically applying the composition includes dispensing an eyedrop from an eyedropper.

Abstract

The present invention is an ophthalmic composition containing a relatively high concentration of olopatadine. The composition is typically an ophthalmic aqueous solution containing relatively high concentrations of olopatadine solubilized within the solution. The composition is preferably capable of providing enhanced relief from symptoms of ocular allergic conjunctivitis, particularly late phase symptoms of ocular allergic conjunctivitis.

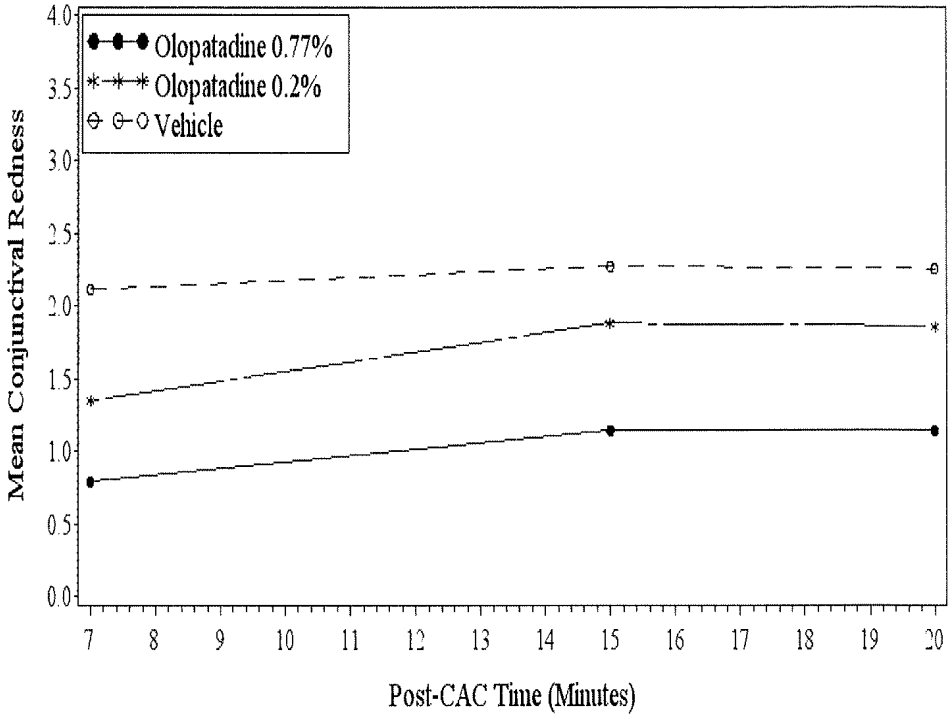

Olopatadine 0.77%
Olopatadine 0.2%
Vehicle
Mean Conjunctival Redness
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
7
8
9
10
11
12
13
14
15
16
17
18
19
20
Post-CAC Time (Minutes)

FIG. 1

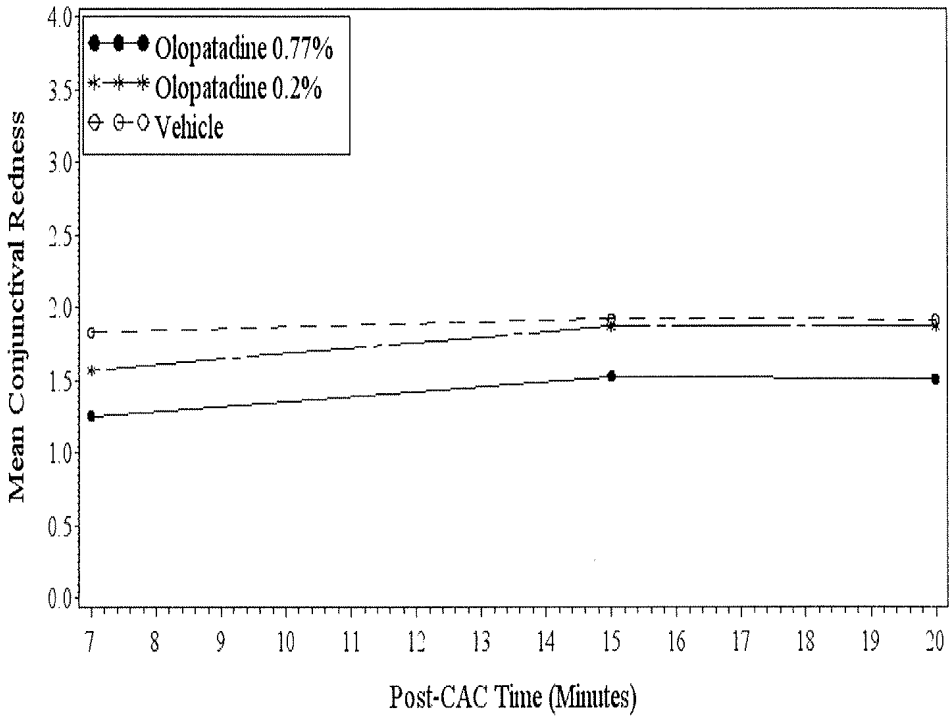

Olopatadine 0.77%
Olopatadine 0.2%
Vehicle
Mean Conjunctival Redness
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
7
8
9
10
11
12
13
14
15
16
17
18
19
20
Post-CAC Time (Minutes)

FIG. 2

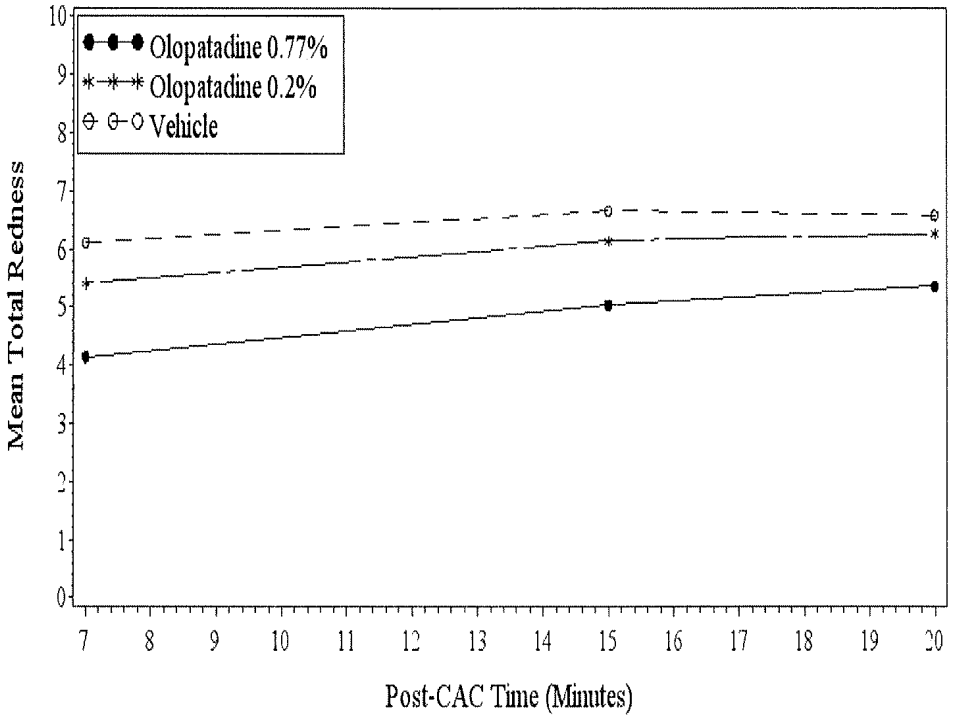

Olopatadine 0.77%
Olopatadine 0.2%
Vehicle
Mean Total Redness
0
1
2
3
4
5
6
7
8
9
10
7
8
9
10
11
12
13
14
15
16
17
18
19
20
Post-CAC Time (Minutes)

FIG. 3

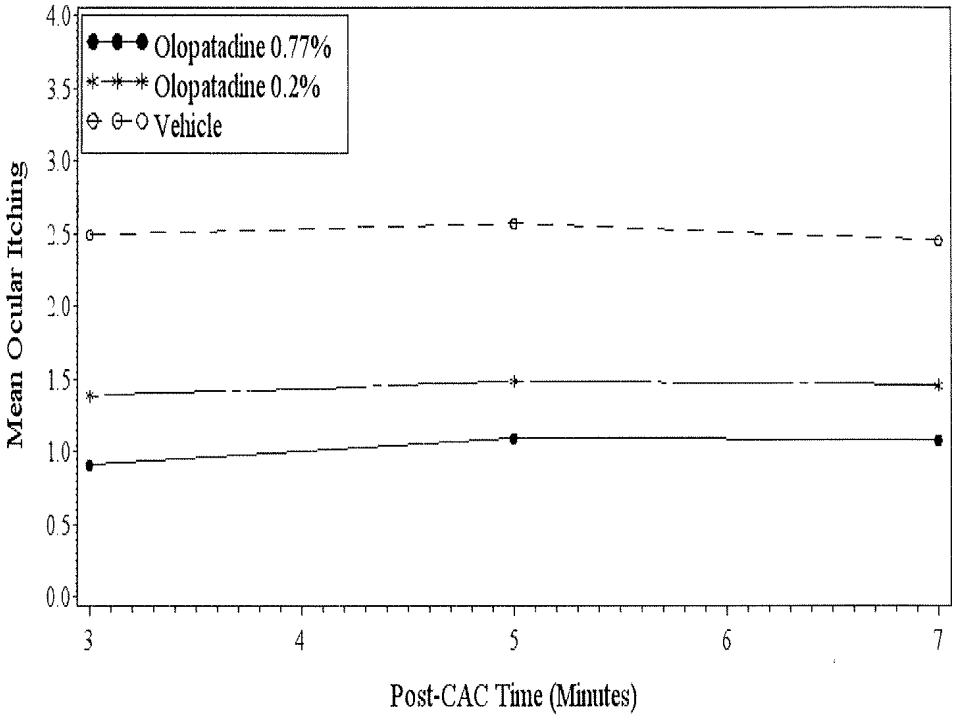
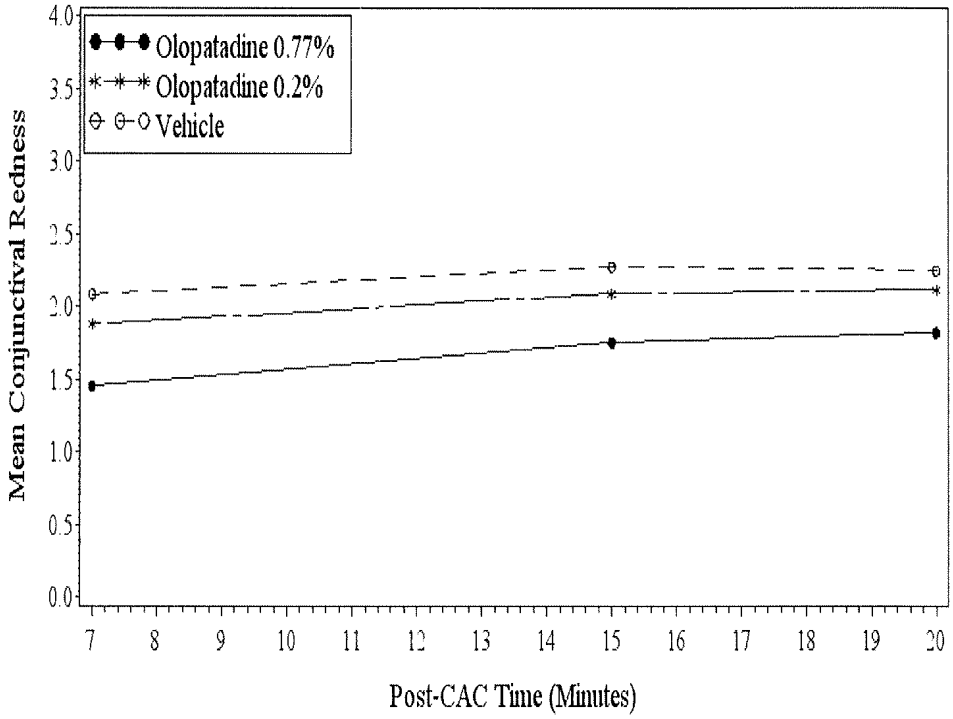

Olopatadine 0.77%
Olopatadine 0.2%
Vehicle
Mean Ocular Itching
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
3
4
5
6
7
Post-CAC Time (Minutes)

FIG. 4


Olopatadine 0.77%
Olopatadine 0.2%
Vehicle
Mean Conjunctival Redness
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
7
8
9
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19
20
Post-CAC Time (Minutes)

FIG. 5

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, we hereby declare that:

Our residence, post office address and citizenship are as stated below next to our names.

We believe we are the original, first and joint inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled:

HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION

described and claimed herewith and further identified as Attorney Docket No. 3988 US the specification of which (check one)

(X) is attached hereto.

( ) was filed by an authorized person on my behalf on _____, as Application Serial No. _____ and was amended on _____ (if applicable)

We hereby state that we have reviewed and understand the contents of the above-identified specification, including the claims as amended by any amendment referred to above.

We acknowledge the duty to disclose information which is known to me to be material to patentability as defined in Section 1.56.

We hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT international application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s):			Priority Claimed	
Application Number	**Country**	**Filed (Month/Day/Year)**	**Yes**	**No**

We hereby claim the benefit under 35 USC §119(e) of any United States provisional application(s) listed below.

Prior Provisional Application(s):		Priority Claimed	
Application Number	Filed (Month/Day/Year)	Yes	No
61/487,789	05/19/2011	X	
61/548,957	10/19/2011	X	

We hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s), or Section 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of Title 35, United States Code, Section 112. We acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Prior U.S. Application(s):		Status: Patent, Pending, Abandoned
Application Number	Filed (Month/Day/Year)	

We hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

We hereby appoint those patent practitioners associated with Customer No. 26356 as my attorneys, with full power of substitution and revocation, to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith.

Full name of Inventor:	Daniel A. Gamache
Address:	5610 Hunterwood Lane Arlington, Texas 76017
Inventor's Signature:	_____
Date:	_____
Citizenship:	United States of America

Full name of Inventor:	Laman Alani
Address:	6809 Shadow Creek Court Fort Worth, Texas 76132
Inventor's Signature:	_____
Date:	_____
Citizenship:	United States of America

Full name of Inventor:	Malay Ghosh
Address:	4221 Kirkland Court Fort Worth, Texas 76109
Inventor's Signature:	_____
Date:	_____
Citizenship:	United States of America

Full name of Inventor:	Francisco Javier Galán
Address:	c/ Dels Pins, 19 08329 Teià Barcelona (Spain)
Inventor's Signature:	_____
Date:	_____
Citizenship:	Spain
Full name of Inventor:	Núria Carreras Perdiguer
Address:	Ametller, 9 08140 Calades de Montbui Barcelona (Spain)
Inventor's Signature:	_____
Date:	_____
Citizenship:	Spain
Full name of Inventor:	Onkar N. Singh
Address:	5606 Rachel Court Arlington, Texas 76017
Inventor's Signature:	_____
Date:	_____
Citizenship:	United States of America

Address for Correspondence:
Alcon Research, Ltd.
Scott A. Chapple, IP Legal
6201 South Freeway, TB4-8
Fort Worth, Texas 76134
Phone: 817-615-5288
Docket No.: 3988 US

Customer No.: 26356

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION
First Named Inventor/Applicant Name:	Daniel A. Gamache
Filer:	Scott Chapple/Barbara McKenzie
Attorney Docket Number:	3988 US

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility application filing	1011	1	380	380
Utility Search Fee	1111	1	620	620
Utility Examination Fee	1311	1	250	250
Pages:				
Claims:				
Claims in excess of 20	1202	5	60	300
Independent claims in excess of 3	1201	2	250	500
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**2050**

Electronic Acknowledgement Receipt

EFS ID:	12817309
Application Number:	13475607
International Application Number:	
Confirmation Number:	4130
Title of Invention:	HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION
First Named Inventor/Applicant Name:	Daniel A. Gamache
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3988 US
Receipt Date:	18-MAY-2012
Filing Date:	
Time Stamp:	17:22:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$2050
RAM confirmation Number	4272
Deposit Account	010682
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		3988_US_Appln-final_051812.pdf	2386476 6302957ccd2bc296e3b1cd51b6842ee8900c1240	yes	48

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	39
Claims	40	42
Abstract	43	43
Drawings-only black and white line drawings	44	48

Warnings:

Information:

2	Oath or Declaration filed	3988_US_Decl-POA_unsigned.pdf	170512 e6e84d8fa5bba27214192e17f4e8bdc8c23a1fe8	no	5

Warnings:

Information:

3	Fee Worksheet (SB06)	fee-info.pdf	37950 42cd26414a4f264df67a668515899b39e626387f	no	2

Warnings:

Information:

Total Files Size (in bytes):	2594938

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Electronic Acknowledgement Receipt

EFS ID:	12817309
Application Number:	13475607
International Application Number:	
Confirmation Number:	4130
Title of Invention:	HIGH CONCENTRATION OLOPATADINE OPHTHALMIC COMPOSITION
First Named Inventor/Applicant Name:	Daniel A. Gamache
Customer Number:	26356
Filer:	Scott Chapple/Barbara McKenzie
Filer Authorized By:	Scott Chapple
Attorney Docket Number:	3988 US
Receipt Date:	18-MAY-2012
Filing Date:	
Time Stamp:	17:22:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
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Payment was successfully received in RAM	$2050
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Deposit Account	010682
Authorized User	

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Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)	
Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)	
Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		3988_US_Appln-final_051812.pdf	2386476 6302957ccd2bc296e3b1cd51b6842ee8900c1240	yes	48

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	39
Claims	40	42
Abstract	43	43
Drawings-only black and white line drawings	44	48

Warnings:					
Information:					
2	Oath or Declaration filed	3988_US_Decl-POA_unsigned.pdf	170512 e6e84d8fa5bba27214192e17f4e8bdc8c23a1fe8	no	5
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	37950 42cd26414a4f264df67a668515899b39e626387f	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2594938		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

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National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.