UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.	: 11,311,482 B2
APPLICATION NO.	: 16/179561
DATED	: April 26, 2022
INVENTOR(S)	: Arturo Angel and Radhakrishnan Pillai

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

In the Claims

Column 15, Claim 9, Line 13: Delete "carbomer polymer type B" and insert in its place --carbomer copolymer type B--.

Column 16, Claim 10, Line 3: Delete "0.3-0.5 weight % carbomer polymer type B" and insert in its place --0.3-0.5 weight % carbomer copolymer type B--.

Column 16, Claim 11, Line 19: Delete "0.4 weight % carbomer polymer type B" and insert in its place --0.4 weight % carbomer copolymer type B--.

Signed and Sealed this
Fourteenth Day of March, 2023

Katherine Kelly Vidal

Katherine Kelly Vidal
Director of the United States Patent and Trademark Office

Padagis Ex. 1002
IPR Petition - USP 11,311,482

I hereby certify that this correspondence is being filed with the United States Patent and Trademark Office via the Office electronic filing system on February 15, 2023.

KILPATRICK TOWNSEND & STOCKTON LLP

By: /Sharleen Lane/
Sharleen Lane

PATENT
Attorney Docket No.: 095920-004130US-1241000
Client Ref. No.: DOW-P05877-2-C2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Arturo Angel *et al.*

Application No.: 16/179,561

Patent No.: 11,311,482

Issued: April 26, 2022

For: TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

Customer No.: 112120

Confirmation No.: 1370

Examiner: Kathrien Ann Hartsfield

Art Unit: 1627

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

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

Commissioner:

Pursuant to 37 C.F.R. § 1.323, Applicant submits this Request for Certificate of Correction to correct typographical errors in claims 9, 10, and 11. The desired corrections are set forth on the attached form PTO/SB/44.

The errors sought to be corrected are errors of a typographical nature made in good faith by the Applicant and are mistakes of minor character. Specifically, Applicant seeks to correct the term "carbomer polymer type B" in claims 9, 10, and 11 and to recite in its place "carbomer copolymer type B." Support for this correction is found, for example, in Table 2 of the specification as filed, at page 13, paragraph [0044].

It is believed that the proposed corrections do not involve changes which would constitute new matter or require reexamination.

77048942V.1

Padagis Ex. 1002
IPR Petition - USP 11,311,482

The Commissioner is hereby authorized to charge the fee set forth in 37 C.F.R. §1.20(a) of $160 for issuing a Certificate of Correction. The Commissioner is also authorized to charge any additional fees due or credit any overpayment in connection with this paper to Deposit Account No. 20-1430.

Respectfully submitted,

/Eugenia Garrett-Wackowski/

Eugenia Garrett-Wackowski
Reg. No. 37,330

KILPATRICK TOWNSEND & STOCKTON LLP

Attachment

PTO/SB/44 (09-07)
Approved for use through 03/31/2023. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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.
(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 11,311,482

APPLICATION NO.: 16/179,561

ISSUE DATE : April 26, 2022

INVENTOR(S) : Arturo Angel; Radhakrishnan Pillai

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:

In the Claims

Column 15, claim 9, line 13: Delete "carbomer polymer type B" and insert in its place --carbomer copolymer type B--.

Column 16, claim 10, line 3: Delete "0.3-0.5 weight % carbomer polymer type B" and insert in its place --0.3-0.5 weight % carbomer copolymer type B--.

Column 16, claim 11, line 19: Delete "0.4 weight % carbomer polymer type B" and insert in its place --0.4 weight % carbomer copolymer type B--.

MAILING ADDRESS OF SENDER (Please do not use Customer Number below):
Kilpatrick Townsend & Stockton LLP
Mailstop: IP Docketing - 22, 1100 Peachtree Street, Suite 2800
Atlanta GA 30309

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. 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 1.0 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: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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.

Padagis Ex. 1002
IPR Petition - USP 11,311,482

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
16/179,561	02/15/2023 07:37:49 PM ET	095920-004130US-1241000

Title of Invention

TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	11311482
CONFIRMATION #	1370	FILED BY	Sharleen Lane
PATENT CENTER #	61603653	AUTHORIZED BY	Eugenia Garrett-Wackowski
CUSTOMER #	112120	FILING DATE	11/02/2018
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Arturo Angel

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 8444	E20232EJ38427707	Sharleen Lane

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1811	CERTIFICATE OF CORRECTION	160.00	1	160.00
			TOTAL AMOUNT:	$160.00

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 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.

Padagis Ex. 1002
IPR Petition - USP 11,311,482

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
16/179,561	**02/15/2023 07:37:49 PM ET**	**095920-004130US-1241000**

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TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

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CUSTOMER #	112120	FIRST NAMED INVENTOR	Arturo Angel
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Eugenia Garrett-Wackowski

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
095920-004130US_COC_PTOSB44.pdf	2	Request for Certificate of Correction	760 KB
095920-004130US_REQ.pdf	2	Request for Certificate of Correction	135 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
095920-	82C3BEF53F7A5B4CB9C2792FD4F8F1BEE51F7200D67E189CE

004130US_COC_PTOSB44.pdf	A33416E46A44AA03C04075F5F9A2D3F34BEA5BC1D4940A5C4BAA0CAA47D848C9FE414F772742F6D
095920-004130US_REQ.pdf	32A8FB76C36A58817630EF16CA3331A863BFCA07640747B8170B795DB216E937E5369D60F63A8EE3C34DBED932AB234814F6D1E7447B59D69AFA010C224C948

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.

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New International Application Filed with the USPTO as a Receiving Office

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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.
16/179,561	04/26/2022	11311482	095920-004130US-1241000	1370

112120 7590 04/06/2022

Bausch Health / Kilpatrick Townsend & Stockton LLP
Mailstop: IP Docketing - 22
1100 Peachtree Street
Suite 2800
Atlanta, GA 30309

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 0 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 Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

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

Arturo Angel, Santa Rosa, CA;
Radhakrishnan Pillai, Santa Rosa, CA;

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

BAUSCH HEALTH US, LLC, Bridgewater, NJ;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

IR103 (Rev. 10/09)

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (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)

112120 7590 03/11/2022

Bausch Health / Kilpatrick Townsend & Stockton LLP
Mailstop: IP Docketing - 22
1100 Peachtree Street
Suite 2800
Atlanta, GA 30309

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 transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

Sharleen Lane	(Typed or printed name)
/Sharleen Lane/	(Signature)
March 16, 2022	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/179,561	11/02/2018	Arturo Angel	095920-004130US-1241000	1370

TITLE OF INVENTION: TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	06/13/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
CRUZ, KATHRIEN ANN	1627	514-337000

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/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or 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 Kilpatrick Townsend & Stockton LLP
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 must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: BAUSCH HEALTH US, LLC

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Bridgewater, NJ

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

4a. Fees submitted: ☒ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

☒ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 20-1430

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

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.
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.
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 /Andrew Presley/ Date March 16, 2022

Typed or printed name Andrew Presley Registration No. 69,844

PTOL-85 Part B (08-18) Approved for use through 01/31/2020 OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Padagis Ex. 1002
IPR Petition - USP 11,311,482

Electronic Patent Application Fee Transmittal	
Application Number:	16179561
Filing Date:	02-Nov-2018
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Arturo Angel
Filer:	Andrew David Presley/Sharleen Lane
Attorney Docket Number:	095920-004130US-1241000

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

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:				
UTILITY APPL ISSUE FEE	1501	1	1200	1200

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1200**

Electronic Acknowledgement Receipt	
EFS ID:	45247385
Application Number:	16179561
International Application Number:	
Confirmation Number:	1370
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Arturo Angel
Customer Number:	112120
Filer:	Andrew David Presley/Sharleen Lane
Filer Authorized By:	Andrew David Presley
Attorney Docket Number:	095920-004130US-1241000
Receipt Date:	16-MAR-2022
Filing Date:	02-NOV-2018
Time Stamp:	20:40:26
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$1200
RAM confirmation Number	E20223FK41003423
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

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)	095920-004130US_ISSUEFEE.PDF	161411 7ead2922b4f6258a1fd404c773c43c9f25086448	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	37886 56988e6c7c01647a13412776111bbf31c143ed53	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	199297		

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
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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

NOTICE OF ALLOWANCE AND FEE(S) DUE

112120 7590 03/11/2022

Bausch Health / Kilpatrick Townsend & Stockton LLP
Mailstop: IP Docketing - 22
1100 Peachtree Street
Suite 2800
Atlanta, GA 30309

EXAMINER	
CRUZ, KATHRIEN ANN	
ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 03/11/2022

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/179,561	11/02/2018	Arturo Angel	095920-004130US-1241000	1370

TITLE OF INVENTION: TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	06/13/2022

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. 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: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (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)

112120 7590 03/11/2022

Bausch Health / Kilpatrick Townsend & Stockton LLP
Mailstop: IP Docketing - 22
1100 Peachtree Street
Suite 2800
Atlanta, GA 30309

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 transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/179,561	11/02/2018	Arturo Angel	095920-004130US-1241000	1370

TITLE OF INVENTION: TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	06/13/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
CRUZ, KATHRIEN ANN	1627	514-337000

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/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or 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 must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). 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. Fees submitted: ❑Issue Fee ❑Publication Fee (if required) ❑Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

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.
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.
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. _____

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.
16/179,561	11/02/2018	Arturo Angel	095920-004130US-1241000	1370

112120 7590 03/11/2022

Bausch Health / Kilpatrick Townsend & Stockton LLP
Mailstop: IP Docketing - 22
1100 Peachtree Street
Suite 2800
Atlanta, GA 30309

EXAMINER	
CRUZ, KATHRIEN ANN	
ART UNIT	**PAPER NUMBER**
1627	

DATE MAILED: 03/11/2022

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 30 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.

Padagis Ex. 1002
IPR Petition - USP 11,311,482

Notice of Allowability	Application No. 16/179,561	Applicant(s) Angel et al.	
	Examiner KATHRIEN A CRUZ	Art Unit 1627	AIA (FITF) Status Yes

-- 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 1/12/2022.
   ☐ 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 See Continuation Sheet . 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 1/12/2022 and 2/16/2022.
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 _____.

/KATHRIEN A CRUZ/
Primary Examiner, Art Unit 1627

Continuation of 3. The allowed claim(s) is/are: 13,17-18,20-22,31,35-36 and 39-40

Padagis Ex. 1002
IPR Petition - USP 11,311,482

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: The reasons for allowance as previously stated in the Notice of Allowance dated 1/12/2022 is maintained. Additionally, the Information Disclosure Statements dated 1/12/2022 and 2/16/2022 has been considered.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN A. CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached Monday - Thursday 8-6pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

Padagis Ex. 1002
IPR Petition - USP 11,311,482

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kortney L. Klinkel can be reached on (571) 270-5239. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KATHRIEN A CRUZ/
Primary Examiner, Art Unit 1627

Padagis Ex. 1002
IPR Petition - USP 11,311,482

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/179,561	Angel et al.
	Examiner	**Art Unit**
	KATHRIEN A CRUZ	1627

CPC						
Symbol					**Type**	**Version**
A61K	/	9	/	107	F	2013-01-01
A61K	/	9	/	0014	I	2013-01-01
A61P	/	17	/	00	I	2018-01-01
A61K	/	31	/	4436	I	2013-01-01
A61K	/	47	/	34	I	2013-01-01
A61K	/	47	/	14	I	2013-01-01
A61K	/	47	/	44	I	2013-01-01
A61P	/	17	/	10	I	2018-01-01
A61K	/	9	/	06	I	2013-01-01
A61K	/	47	/	06	I	2013-01-01
A61K	/	47	/	32	I	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	11	
/KATHRIEN A CRUZ/ Primary Examiner, Art Unit 1627	25 February 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	ONE	NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20220225

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/179,561	Angel et al.
	Examiner	**Art Unit**
	KATHRIEN A CRUZ	1627

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61K9/107	/	9	/	107
A61K9/00	/	9	/	00
A61P17/00	/	17	/	00
A61K31/4436	/	31	/	4436
A61K47/34	/	47	/	34
A61K47/14	/	47	/	14
A61K47/44	/	47	/	44
A61P17/10	/	17	/	10
A61K9/06	/	9	/	06
A61K47/06	/	47	/	06
A61K47/32	/	47	/	32

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
514	337

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner) (Date)		**Total Claims Allowed:** 11	
/KATHRIEN A CRUZ/ Primary Examiner, Art Unit 1627 (Primary Examiner)	25 February 2022 (Date)	O.G. Print Claim(s) ONE	O.G. Print Figure NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20220225

Padagis Ex. 1002
IPR Petition - USP 11,311,482

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/179,561	Angel et al.
	Examiner	**Art Unit**
	KATHRIEN A CRUZ	1627

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

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 11	
/KATHRIEN A CRUZ/ Primary Examiner, Art Unit 1627 (Primary Examiner)	25 February 2022 (Date)	O.G. Print Claim(s) ONE	O.G. Print Figure NONE

U.S. Patent and Trademark Office Part of Paper No.: 20220225

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/179,561	Angel et al.
	Examiner	Art Unit
	KATHRIEN A CRUZ	1627

CPC - Searched*		
Symbol	Date	Examiner

CPC Combination Sets - Searched*		
Symbol	Date	Examiner
A61K31/4436 OR A61K47/06 OR A61K47/14 OR A61K47/32 OR A61K47/34 OR A61K47/44 OR A61K9/0014 OR A61K9/06 OR A61K9/107 OR A61P17/00 OR A61P17/10	08/05/2020	kc
A61K31/4436 OR A61K47/06 OR A61K47/14 OR A61K47/32 OR A61K47/34 OR A61K47/44 OR A61K9/0014 OR A61K9/06 OR A61K9/107 OR A61P17/00 OR A61P17/10	12/16/2021	kc
A61K31/4436 OR A61K47/06 OR A61K47/14 OR A61K47/32 OR A61K47/34 OR A61K47/44 OR A61K9/0014 OR A61K9/06 OR A61K9/107 OR A61P17/00 OR A61P17/10	02/25/2022	kc

US Classification - Searched*			
Class	Subclass	Date	Examiner
514	337	12/16/2021	kc

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

/KATHRIEN A CRUZ/ Primary Examiner, Art Unit 1627	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/179,561	Angel et al.
	Examiner	Art Unit
	KATHRIEN A CRUZ	1627

Search Notes		
Search Notes	**Date**	**Examiner**
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	03/15/2019	kc
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	10/23/2019	kc
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	02/24/2020	kc
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	08/05/2020	kc
INVENTOR	08/05/2020	kc
PE2E (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT , IBM_TDB)	12/16/2021	kc
INVENTOR	12/16/2021	kc
CONSULTED SPE KLINKEL	12/16/2021	kc
PE2E (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT , IBM_TDB)	02/25/2022	kc
INVENTOR	02/25/2022	kc

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
514	337	12/16/2021	kc
514	337	02/25/2022	kc

/KATHRIEN A CRUZ/ Primary Examiner, Art Unit 1627	

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	3	"20190133942".pn.	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/16 04:47 PM
L2	245	(("ANGEL A".ine. OR "ARTURO A".ine. OR "ARTURO; ANGEL".ine. OR "LEE TAEK KWON".ine. OR "PILLAI R".ine. OR "PILLAI; RADHAKRISHNAN".ine. OR "RADHAKRISHNAN P".ine.))	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/16 04:48 PM
L3	28	L2 AND tazarotene	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/16 04:49 PM
L4	627026	((A61K31/4436 OR A61K47/06 OR A61K47/14 OR A61K47/32 OR A61K47/34 OR A61K47/44 OR A61K9/0014 OR A61K9/06 OR A61K9/107 OR A61P17/00 OR A61P17/10).cpc.)	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/16 05:04 PM
L5	6350	L4 AND tazarotene	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/16 05:04 PM
L6	4	L5 AND "oil in water"	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/16 05:05 PM
L7	3414	514/337	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/16 05:05 PM
L8	88	L7 AND tazarotene	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT;	OR	ON	ON	2021/12/16 05:06 PM

			IBM_TDB)				
L9	0	L8 AND "oil in water"	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/16 05:07 PM
L10	2	"20190231797"	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/25 01:02 PM
L11	2	"20210145847"	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/25 01:06 PM
L12	2	"20210330681"	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/25 01:07 PM
L13	4	L6	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/25 01:10 PM
L14	0	L9	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/25 01:11 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N1	2252	514/337	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/16 05:07 PM
N2	63	N1 AND tazarotene	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/16 05:07 PM
N3	0	N2 AND "oil in water"	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/16 05:08 PM
N4	63	N2	(US-PGPUB; USPAT)	OR	ON	ON	2022/02/25 01:11 PM
N5	0	N3	(US-PGPUB; USPAT)	OR	ON	ON	2022/02/25 01:11 PM

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/179,561
	Filing Date	November 2, 2018
	First Named Inventor	Arturo Angel
	Art Unit	1627
	Examiner Name	Kathrien Ann Cruz
	Attorney Docket Number	095920-004130US-1241000

U.S. PATENTS						
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

U.S. PATENT APPLICATION PUBLICATIONS						
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

FOREIGN PATENT DOCUMENTS								
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]

NON-PATENT LITERATURE DOCUMENTS			
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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
/K.A.C/	1.	Allergan. "Drug Approval Package", Medical Review(s) on Tazorac™ cream, part 1, Sept 25, 2000, 32 pages.	
/K.A.C/	2.	Medical Review, Part 2. Drug Approval Package for Tazorac (tazarotene cream). Application No.: 021184. Approval Date: 9/29/2000. accessdata.fda.gov/drugsatfda_docs/nda/2000/21-184_Tazorac.cfm	

EXAMINER SIGNATURE			
Examiner Signature	/KATHRIEN A CRUZ/	Date Considered	02/25/2022

*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	16/179,561
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	First Named Inventor	Arturo Angel
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	Attorney Docket Number	095920-004130US-1241000

U.S. PATENTS						
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.	10,426,787	B2	2019-10-01	Dow et al.	

U.S. PATENT APPLICATION PUBLICATIONS						
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
	2.	2019/0231797	A1	2019-08-01	Dow et al.	
	3.	2021/0145847	A1	2021-05-20	Dow et al.	
	4.	2021/0330681	A1	2021-10-28	Dow et al.	

FOREIGN PATENT DOCUMENTS								
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]

NON-PATENT LITERATURE DOCUMENTS			
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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	5.	Tazorac (Highlights of Prescribing Information, LABEL (fda.gov), 12/2013), 14 pages.	

EXAMINER SIGNATURE			
Examiner Signature	/KATHRIEN A CRUZ/	Date Considered	02/25/2022

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[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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /K.A.C/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/179,561
	Filing Date	November 2, 2018
	First Named Inventor	Arturo Angel
	Art Unit	1627
	Examiner Name	Kathrien Ann Cruz
	Attorney Docket Number	095920-004130US-1241000

U.S. PATENTS						
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

U.S. PATENT APPLICATION PUBLICATIONS						
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

FOREIGN PATENT DOCUMENTS								
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]

NON-PATENT LITERATURE DOCUMENTS			
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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1.	Allergan. "Drug Approval Package", Medical Review(s) on Tazorac™ cream, part 1, Sept 25, 2000, 32 pages.	
	2.	Medical Review, Part 2. Drug Approval Package for Tazorac (tazarotene cream). Application No.: 021184. Approval Date: 9/29/2000. accessdata.fda.gov/drugsatfda_docs/nda/2000/21-184_Tazorac.cfm	

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

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[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.

Electronic Acknowledgement Receipt	
EFS ID:	45017740
Application Number:	16179561
International Application Number:	
Confirmation Number:	1370
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Arturo Angel
Customer Number:	112120
Filer:	Andrew David Presley/Sharleen Lane
Filer Authorized By:	Andrew David Presley
Attorney Docket Number:	095920-004130US-1241000
Receipt Date:	16-FEB-2022
Filing Date:	02-NOV-2018
Time Stamp:	21:11:15
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		095920-004130US_IDS.pdf	227743 694eabad8f8413235d8964ba5ecfeacd30eb4bb1	yes	3

	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Transmittal Letter		1	2	
	Information Disclosure Statement (IDS) Form (SB08)		3	3	
Warnings:					
Information:					
2	Non Patent Literature	Allergan_DrugApprovalPackage_Tazorac_MedicalReview_Part1_09-25-2000_32pages.pdf	1492707 caa7d0e8d16777ac6057e0e9c49ff96931734e7d	no	32
Warnings:					
Information:					
3	Non Patent Literature	Medical_Review_Part2_Tazorac_21-184.PDF	2202700 9911ed286aaf9832d5a13b645f8122c126b80424	no	32
Warnings:					
Information:					
		Total Files Size (in bytes):	3923150		

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.

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on February 16, 2022.

KILPATRICK TOWNSEND & STOCKTON LLP

By: /Sharleen Lane/
Sharleen Lane

PATENT
Attorney Docket No.: 095920-004130US-1241000
Client Ref. No.: DOW-P05877-2-C2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Arturo Angel

Application No.: 16/179,561

Filed: November 2, 2018

For: TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

Customer No.: 112120

Confirmation No.: 1370

Examiner: Kathrien Ann Cruz

Art Unit: 1627

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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

Commissioner:

The references cited on attached form PTO/SB/08A are being called to the attention of the Examiner. In accordance with the provisions of 37 CFR §1.98(a)(2), copies of any cited U.S. Patents and U.S. Patent Application Publications are not provided. Copies of the remaining cited references are provided.

It is respectfully requested that the cited references be expressly considered during the prosecution of this application and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

This Information Disclosure Statement is being filed before the mailing of a first Office Action after the filing of a Request for Continued Examination under 37 CFR §1.114. Therefore, under 37 CFR §1.97(b)(4), Applicant believes that no fee is required for submission of this statement. However, if any fees are due for the submission of this Information Disclosure Statement, please deduct those fees from Deposit Account No. 20-1430.

Respectfully submitted,

Andrew D. Presley
Registration No. 69,844

KILPATRICK TOWNSEND & STOCKTON LLP

Attachment

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/179,561
	Filing Date	November 2, 2018
	First Named Inventor	Arturo Angel
	Art Unit	1627
	Examiner Name	Kathrien Ann Cruz
	Attorney Docket Number	095920-004130US-1241000

U.S. PATENTS						
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.	10,426,787	B2	2019-10-01	Dow et al.	

U.S. PATENT APPLICATION PUBLICATIONS						
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
	2.	2019/0231797	A1	2019-08-01	Dow et al.	
	3.	2021/0145847	A1	2021-05-20	Dow et al.	
	4.	2021/0330681	A1	2021-10-28	Dow et al.	

FOREIGN PATENT DOCUMENTS								
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]

NON-PATENT LITERATURE DOCUMENTS			
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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	5.	Tazorac (Highlights of Prescribing Information, LABEL (fda.gov), 12/2013), 14 pages.	

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

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[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.

Electronic Patent Application Fee Transmittal	
Application Number:	16179561
Filing Date:	02-Nov-2018
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Arturo Angel
Filer:	Andrew David Presley/Sharleen Lane
Attorney Docket Number:	095920-004130US-1241000

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

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($)
Miscellaneous:				
RCE- 2ND AND SUBSEQUENT REQUEST	1820	1	2000	2000
		Total in USD ($)		**2000**

Electronic Acknowledgement Receipt	
EFS ID:	44732973
Application Number:	16179561
International Application Number:	
Confirmation Number:	1370
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Arturo Angel
Customer Number:	112120
Filer:	Andrew David Presley/Sharleen Lane
Filer Authorized By:	Andrew David Presley
Attorney Docket Number:	095920-004130US-1241000
Receipt Date:	12-JAN-2022
Filing Date:	02-NOV-2018
Time Stamp:	20:31:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$2000
RAM confirmation Number	E20221BK32194799
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Continued Examination (RCE)	095920-004130US_RCE.PDF	1351846 0f765267d4196b56b0dd02c8842a7a6d4a8df6b8	no	3
Warnings:					
Information:					
2		095920-004130US_IDS.pdf	230561 f61435af6d5c328b25e4435512e6730ca9360822	yes	3

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	2
	Information Disclosure Statement (IDS) Form (SB08)	3	3

Warnings:					
Information:					
3	Non Patent Literature	Tazorac_LABEL_2013.pdf	6223017 e32c87b6ad12cd86978a672a8f167b765206b98a	no	14
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	38029 defe607220acc53643645 1660801dfb18e77002b	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	7843453		

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

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New International Application Filed with the USPTO as a Receiving Office

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Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	16/179,561	Filing Date	2018-11-02	Docket Number (if applicable)	095920-004130US-1241000	Art Unit	1627
First Named Inventor	Arturo Angel			Examiner Name	Kathrien Ann Cruz		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☑ Enclosed

- ☐ Amendment/Reply
- ☑ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☑ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 201430

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

✓ Patent Practitioner Signature

Applicant Signature

EFS - Web 2.1.16

Padagis Ex. 1002
IPR Petition - USP 11,311,482

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	/Andrew Presley/	Date (YYYY-MM-DD)	2022-01-11
Name	Andrew D. Presley	Registration Number	69844

This collection of information is required by 37 CFR 1.114. 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 1.11 and 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, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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 records.

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.

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on January 12, 2022.

KILPATRICK TOWNSEND & STOCKTON LLP

By: /Sharleen Lane/
Sharleen Lane

PATENT
Attorney Docket No.: 095920-004130US-1241000
Client Ref. No.: DOW-P05877-2-C2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Arturo Angel Application No.: 16/179,561 Filed: November 2, 2018 For: TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES Customer No.: 112120	Confirmation No.: 1370 Examiner: Kathrien Ann Cruz Technology Center/Art Unit: 1627 **SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

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

Commissioner:

The references cited on attached form PTO/SB/08A are being called to the attention of the Examiner. In accordance with the provisions of 37 CFR §1.98(a)(2), copies of any cited U.S. Patents and U.S. Patent Application Publications are not provided. Copies of the remaining cited references are provided.

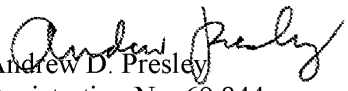
It is respectfully requested that the cited references be expressly considered during the prosecution of this application and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

This Information Disclosure Statement is being filed concurrently with the filing of a Request for Continued Examination under 37 CFR §1.114. Therefore, under 37 CFR §1.97(b)(4), Applicant believes that no fee is required for submission of this statement. However, if any fees are due for the submission of this Information Disclosure Statement, please deduct those fees from Deposit Account No. 20-1430.

Respectfully submitted,



Andrew D. Presley
Registration No. 69,844

KILPATRICK TOWNSEND & STOCKTON LLP

Attachment

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

112120 7590 01/04/2022

Bausch Health / Kilpatrick Townsend & Stockton LLP
Mailstop: IP Docketing - 22
1100 Peachtree Street
Suite 2800
Atlanta, GA 30309

EXAMINER	
CRUZ, KATHRIEN ANN	
ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 01/04/2022

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/179,561	11/02/2018	Arturo Angel	095920-004130US-1241000	1370

TITLE OF INVENTION: TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	04/04/2022

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. 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: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (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)

112120 7590 01/04/2022

Bausch Health / Kilpatrick Townsend & Stockton LLP
Mailstop: IP Docketing - 22
1100 Peachtree Street
Suite 2800
Atlanta, GA 30309

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 transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/179,561	11/02/2018	Arturo Angel	095920-004130US-1241000	1370

TITLE OF INVENTION: TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	04/04/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
CRUZ, KATHRIEN ANN	1627	514-337000

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/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or 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 must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). 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. Fees submitted: ❑Issue Fee ❑Publication Fee (if required) ❑Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

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.
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.
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. _____

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.
16/179,561	11/02/2018	Arturo Angel	095920-004130US-1241000	1370

112120 7590 01/04/2022

Bausch Health / Kilpatrick Townsend & Stockton LLP
Mailstop: IP Docketing - 22
1100 Peachtree Street
Suite 2800
Atlanta, GA 30309

EXAMINER	
CRUZ, KATHRIEN ANN	
ART UNIT	**PAPER NUMBER**
1627	

DATE MAILED: 01/04/2022

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 30 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.

Padagis Ex. 1002
IPR Petition - USP 11,311,482

Notice of Allowability	**Application No.** 16/179,561	**Applicant(s)** Angel et al.	
	Examiner KATHRIEN A CRUZ	**Art Unit** 1627	**AIA (FITF) Status** Yes

-- 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 7/15/2021.
   ☐ 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 See Continuation Sheet . 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. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/KATHRIEN A CRUZ/
Primary Examiner, Art Unit 1627

Continuation of 3. The allowed claim(s) is/are: 13,17-18,20-22,31,35-36 and 39-40

Padagis Ex. 1002
IPR Petition - USP 11,311,482

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: Applicants amendment of claims to recite tazarotene as a sole active agent renders the obviousness rejection moot. Because Dow teaches that tazarotene and halobetasol is synergistically and there is no motivation to administer tazarotene alone in view of Dow. Thus, the instant claims are free of art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN A. CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached Monday - Thursday 8-6pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

Padagis Ex. 1002
IPR Petition - USP 11,311,482

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Korney L. Klinkel can be reached on (571) 270-5239. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KATHRIEN A CRUZ/
Primary Examiner, Art Unit 1627

Padagis Ex. 1002
IPR Petition - USP 11,311,482

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/179,561	Angel et al.
	Examiner	Art Unit
	KATHRIEN A CRUZ	1627

CPC - Searched*		
Symbol	Date	Examiner

CPC Combination Sets - Searched*		
Symbol	Date	Examiner
A61K31/4436 OR A61K47/06 OR A61K47/14 OR A61K47/32 OR A61K47/34 OR A61K47/44 OR A61K9/0014 OR A61K9/06 OR A61K9/107 OR A61P17/00 OR A61P17/10	08/05/2020	kc
A61K31/4436 OR A61K47/06 OR A61K47/14 OR A61K47/32 OR A61K47/34 OR A61K47/44 OR A61K9/0014 OR A61K9/06 OR A61K9/107 OR A61P17/00 OR A61P17/10	12/16/2021	kc

US Classification - Searched*			
Class	Subclass	Date	Examiner
514	337	12/16/2021	kc

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

/KATHRIEN A CRUZ/ Primary Examiner, Art Unit 1627	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/179,561	Angel et al.
	Examiner	Art Unit
	KATHRIEN A CRUZ	1627

Search Notes		
Search Notes	**Date**	**Examiner**
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	03/15/2019	kc
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	10/23/2019	kc
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	02/24/2020	kc
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	08/05/2020	kc
INVENTOR	08/05/2020	kc
PE2E (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT , IBM_TDB)	12/16/2021	kc
INVENTOR	12/16/2021	kc
CONSULTED SPE KLINKEL	12/16/2021	kc

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
514	337	12/16/2021	kc

/KATHRIEN A CRUZ/ Primary Examiner, Art Unit 1627	

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/179,561	Angel et al.
	Examiner	**Art Unit**
	KATHRIEN A CRUZ	1627

CPC							
Symbol						**Type**	**Version**
A61K	/	9	/	107		F	2013-01-01
A61K	/	9	/	0014		I	2013-01-01
A61P	/	17	/	00		I	2018-01-01
A61K	/	31	/	4436		I	2013-01-01
A61K	/	47	/	34		I	2013-01-01
A61K	/	47	/	14		I	2013-01-01
A61K	/	47	/	44		I	2013-01-01
A61P	/	17	/	10		I	2018-01-01
A61K	/	9	/	06		I	2013-01-01
A61K	/	47	/	06		I	2013-01-01
A61K	/	47	/	32		I	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	11	
/KATHRIEN A CRUZ/ Primary Examiner, Art Unit 1627	16 December 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	ONE	NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20211216

Padagis Ex. 1002
IPR Petition - USP 11,311,482

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/179,561	Angel et al.
	Examiner	**Art Unit**
	KATHRIEN A CRUZ	1627

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61K9/107	/	9	/	107
A61K9/00	/	9	/	00
A61P17/00	/	17	/	00
A61K31/4436	/	31	/	4436
A61K47/34	/	47	/	34
A61K47/14	/	47	/	14
A61K47/44	/	47	/	44
A61P17/10	/	17	/	10
A61K9/06	/	9	/	06
A61K47/06	/	47	/	06
A61K47/32	/	47	/	32

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
514	337

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner) (Date)		**Total Claims Allowed:** 11	
/KATHRIEN A CRUZ/ Primary Examiner, Art Unit 1627 (Primary Examiner)	16 December 2021 (Date)	O.G. Print Claim(s) ONE	O.G. Print Figure NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20211216

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/179,561	Angel et al.
	Examiner	**Art Unit**
	KATHRIEN A CRUZ	1627

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

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 11	
/KATHRIEN A CRUZ/ Primary Examiner, Art Unit 1627 (Primary Examiner)	16 December 2021 (Date)	O.G. Print Claim(s) ONE	O.G. Print Figure NONE

U.S. Patent and Trademark Office — Part of Paper No.: 20211216

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	3	"20190133942".pn.	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/16 04:47 PM
L2	245	(("ANGEL A".ine. OR "ARTURO A".ine. OR "ARTURO; ANGEL".ine. OR "LEE TAEK KWON".ine. OR "PILLAI R".ine. OR "PILLAI; RADHAKRISHNAN".ine. OR "RADHAKRISHNAN P".ine.))	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/16 04:48 PM
L3	28	L2 AND tazarotene	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/16 04:49 PM
L4	627026	((A61K31/4436 OR A61K47/06 OR A61K47/14 OR A61K47/32 OR A61K47/34 OR A61K47/44 OR A61K9/0014 OR A61K9/06 OR A61K9/107 OR A61P17/00 OR A61P17/10).cpc.)	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/16 05:04 PM
L5	6350	L4 AND tazarotene	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/16 05:04 PM
L6	4	L5 AND "oil in water"	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/16 05:05 PM
L7	3414	514/337	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/16 05:05 PM
L8	88	L7 AND tazarotene	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT;	OR	ON	ON	2021/12/16 05:06 PM

			IBM_TDB)				
L9	0	L8 AND "oil in water"	(US-PGPUB; USPAT; USOCR; FIT (CN, FR, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/16 05:07 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N1	2252	514/337	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/16 05:07 PM
N2	63	N1 AND tazarotene	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/16 05:07 PM
N3	0	N2 AND "oil in water"	(US-PGPUB; USPAT)	OR	ON	ON	2021/12/16 05:08 PM

Bibliographic Data

Application No: 16/179,561

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /KATHRIEN A CRUZ/ Examiner's Signature | Initials

Title: TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/02/2018	514	1627	095920-004130US-1241000
RULE			

APPLICANTS

BAUSCH HEALTH US, LLC, Bridgewater, NJ,

INVENTORS

Arturo Angel, Santa Rosa, CA, UNITED STATES

Radhakrishnan Pillai, Santa Rosa, CA, UNITED STATES

CONTINUING DATA

This application is a CIP of 15977088 05/11/2018ABN

15977088 has PRO of 62505421 05/12/2017

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

STATE OR COUNTRY

UNITED STATES

ADDRESS

Bausch Health / Kilpatrick Townsend & Stockton LLP
Mailstop: IP Docketing - 22
1100 Peachtree Street
Suite 2800
Atlanta, GA 30309
UNITED STATES

FILING FEE RECEIVED

$1,720

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	16/179,561	Filing Date	2018-11-02	Docket Number (if applicable)	095920-004130US-1241000	Art Unit	1627
First Named Inventor	Arturo Angel			Examiner Name	Cruz, Kathrien Ann		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☑ Enclosed

- ☑ Amendment/Reply
- ☐ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☑ Other Petition for 5-mo Extension of Time

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☑ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 201430

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

✓ Patent Practitioner Signature

Applicant Signature

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Signature of Registered U.S. Patent Practitioner			
Signature	/Andrew Presley/	Date (YYYY-MM-DD)	2021-07-15
Name	Andrew D. Presley	Registration Number	69844

This collection of information is required by 37 CFR 1.114. 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 1.11 and 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, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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 records.

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:	16179561
Filing Date:	02-Nov-2018
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Arturo Angel
Filer:	Andrew David Presley/Sharleen Lane
Attorney Docket Number:	095920-00413US-1241000

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

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($)
Extension - 5 months with $0 paid	1255	1	3160	3160
Miscellaneous:				
RCE- 1ST REQUEST	1801	1	1360	1360
		Total in USD ($)		**4520**

Electronic Acknowledgement Receipt	
EFS ID:	43262709
Application Number:	16179561
International Application Number:	
Confirmation Number:	1370
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Arturo Angel
Customer Number:	112120
Filer:	Andrew David Presley/Sharleen Lane
Filer Authorized By:	Andrew David Presley
Attorney Docket Number:	095920-00413US-1241000
Receipt Date:	15-JUL-2021
Filing Date:	02-NOV-2018
Time Stamp:	16:14:27
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$4520
RAM confirmation Number	E20217EG14550342
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Extension of Time	095920-004130US_EOT.pdf	164003 e81421a7443a9bf2c98ed0185beebc635aa90937	no	1
Warnings:					
Information:					
2		095920-004130US_AMDAF.pdf	313818 11bfcff93d274f8f7ff7dd5ab0f38cdb9894f7c5	yes	12

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment Submitted/Entered with Filing of CPA/RCE	1	1
	Claims	2	5
	Applicant Arguments/Remarks Made in an Amendment	6	12

Warnings:					
Information:					
3	Request for Continued Examination (RCE)	095920-004130US_RCE.pdf	1351881 85a15ece93b46ee2f95242c8f1292f3bc4cfa2c3	no	3
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	32462 daf269820172f90ebd66fbad6f7b07e32ed08565	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1862164		

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/AIA/22 (10-20)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)	Docket Number (Optional) 095920-004130US-1241000
Application Number 16/179,561	Filed November 2, 2018
For TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES	
Art Unit 1627	Examiner Cruz, Kathrien Ann

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	Micro Entity Fee	
☐ One month (37 CFR 1.17(a)(1))	$220	$110	$55	$_____
☐ Two months (37 CFR 1.17(a)(2))	$640	$320	$160	$_____
☐ Three months (37 CFR 1.17(a)(3))	$1,480	$740	$370	$_____
☐ Four months (37 CFR 1.17(a)(4))	$2,320	$1,160	$580	$_____
☒ Five months (37 CFR 1.17(a)(5))	$3,160	$1,580	$790	$3,160

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 20-1430.

☒ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71 Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

☒ attorney or agent of record. Registration Number 69,844

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____

/Andrew Presley/	2021-07-15
Signature	Date
Andrew D. Presley	(415) 273-4310
Typed or printed name	Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☐ Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.136(a). 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 1.11 and 1.14. This collection is estimated to take 6 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, 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Padagis Ex. 1002
IPR Petition - USP 11,311,482

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on July 15, 2021.

KILPATRICK TOWNSEND & STOCKTON LLP

By: /Sharleen Lane/
Sharleen Lane

PATENT
Attorney Docket No.: 095920-004130US-1241000
Client Ref. No.: DOW-P05877-2-C2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Arturo Angel et al.

Application No.: 16/179,561

Filed: November 2, 2018

For: TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

Customer No.: 112120

Confirmation No.: 1370

Examiner: Cruz, Kathrien Ann

Technology Center/Art Unit: 1627

AMENDMENT / RESPONSE TO OFFICE ACTION

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

Commissioner:

In response to the Final Office Action mailed August 10, 2020, and further to the Notice of Panel Decision from Pre-Appeal Brief Review mailed January 15, 2021, please enter the following amendments and consider the following remarks:

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

Remarks begin on page 6 of this paper.

Padagis Ex. 1002
IPR Petition - USP 11,311,482

AMENDMENTS TO THE CLAIMS

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

Listing of Claims:

1-12. (Canceled)

13. (Currently amended) A method of treating acne vulgaris, the method comprising topically applying a pharmaceutical composition once per day to an affected area of a body of a subject suffering from acne vulgaris[[;]], wherein ~~the composition comprises~~:

~~tazarotene or a pharmaceutically acceptable tazarotenic acid salt present in the composition at a positive concentration from about 0.01 to 0.049 percent by weight of the composition; and~~

the composition comprises tazarotene at a concentration of about 0.045 percent by weight of the composition as a sole active pharmaceutical ingredient;

~~a dermatologically acceptable oil-in-water emulsion vehicle; wherein said~~ the composition is an oil-in-water emulsion lotion comprising an oil phase and an aqueous phase;

the oil phase comprises a dicarboxylic acid ester and a mineral oil at a total concentration of 10-12 percent by weight of the composition;

the aqueous phase comprises water and a carbomer homopolymer, wherein the concentration of the carbomer homopolymer is 0.5-0.7 percent by weight of the composition; and

the composition further comprises a polymeric emulsifier at a concentration of 0.3-0.5 percent by weight of the composition.

14-16. (Canceled)

17. (Currently amended) The method of claim[[16]] 13, wherein the dicarboxylic acid ester in the oil phase ~~of the emulsion comprises~~ is diethyl sebacate.

Padagis Ex. 1002
IPR Petition - USP 11,311,482

18. (Currently amended) The method of claim 13, wherein the oil phase ~~of the emulsion~~ comprises diethyl sebacate and light mineral oil.

19. (Canceled)

20. (Currently amended) The method of claim 13, wherein said applying is carried out ~~once per day~~ for at least eight weeks.

21. (Currently amended) The method of claim 13, wherein said applying is carried out ~~once per day~~ for at least twelve weeks.

22. (Currently amended) The method of claim 13, wherein said applying is carried out ~~once per day~~ for twelve weeks.

23-30. (Canceled)

31. (Currently amended) The method of claim 13, wherein the tazarotene ~~or tazarotenic acid salt is dissolved in a liquid oil component of the emulsion~~ is in solution in the oil phase of the oil-in-water emulsion lotion.

32-34. (Canceled)

35. (Previously presented) The method of claim 13, wherein the composition has a pH of about 4 to about 6.

36. (Currently amended) The method of claim 13, wherein the composition consists essentially of:

~~0.01-0.049~~0.045 weight % tazarotene;
diethyl sebacate;
light mineral oil;
sorbitan monooleate;
sorbitol solution, 70%;
methylparaben;
propylparaben;
edetate disodium dihydrate;

carbomer polymer type B;

carbomer homopolymer type A;

sodium hydroxide;

purified water.

37-38. (Canceled)

39. (Currently amended) The method of claim 13, wherein the composition consists essentially of:

~~0.04-0.049~~ 0.045 weight % tazarotene;

2.5-3.5 weight % diethyl sebacate;

7.5-8.5 weight % light mineral oil;

0.05-0.2 weight % sorbitan monooleate;

10-11 weight % sorbitol solution, 70%;

0.1-0.2 weight % methylparaben;

0.02-0.04 weight % propylparaben;

0.03-0.06 weight % edetate disodium dihydrate;

0.3-[[0.05]]0.5 weight % carbomer polymer type B;

0.5-0.7 weight % carbomer homopolymer type A;

sodium hydroxide, q.s. to pH 5.5 ±0.5; and

purified water, q.s. to 100 weight %.

40. (Previously presented) A method of treating acne vulgaris, the method comprising topically applying a pharmaceutical composition to an affected area of a body of a subject suffering from acne vulgaris; wherein the composition consists essentially of:

0.045 weight % tazarotene;

2.97 weight % diethyl sebacate;

8.03 weight % light mineral oil;

0.1 weight % sorbitan monooleate;

10.7 weight % sorbitol solution, 70%;

0.17 weight % methylparaben;

0.03 weight % propylparaben;

0.05 weight % edetate disodium dihydrate;

0.4 weight % carbomer polymer type B;

0.6 weight % carbomer homopolymer type A;

sodium hydroxide, q.s. to pH 5.5 ±0.5; and

purified water, q.s. to 100 weight %.

REMARKS

Upon entry of the present amendment, claims 13, 17-18, 20-22, 31, 35-36, and 39-40 will be pending in this application. Claims 13, 17-18, 20-22, 31, 36, and 39 are amended, and claims 14-16, 19, 23-30, 32-34, and 37-38 are canceled without disclaimer or prejudice to future prosecution. No new matter is added. Based on the following remarks, Applicant respectfully requests reconsideration and allowance of the pending claims.

I. Amendments to the Claims

Claim 13 is amended to recite that the pharmaceutical composition is administered once per day, that the composition comprises about 0.045 percent tazarotene as the sole active ingredient. Support for the amendments can be found, for example, in claims 20-23.

Claim 13 is further amended to recite that the composition is an oil-in-water emulsion lotion comprising an oil phase and an aqueous phase; that the oil phase comprises a dicarboxylic acid ester and a mineral oil at a total concentration of 10-12 percent; that the aqueous phase comprises water and 0.5-0.7 percent carbomer homopolymer; and that the composition further comprises a polymeric emulsifier at a concentration of 0.3-0.5 percent by weight of the composition. Support for the amendment can be found, for example, in claim 39.

Claim 18 is amended to recite light mineral oil. Support for the amendment can be found, for example, in claim 36.

Claims 17-22, 31, 36, and 39 are further amended to properly depend from claim 13. The amendments introduce no new matter in the application, and Applicant respectfully requests that the amendments be entered.

II. Rejection of Claims under 35 U.S.C. § 103

Claims 13-40 are rejected under 34 U.S.C. § 103 as allegedly obvious over Dow et al. (WO 2016/205001; "Dow") in view of Donello et al. (US 2012/0328670; "Donello"). To the extent that the rejection applies to the amended claims, Applicant respectfully traverses the rejection.

It is stated in the Office Action that Dow discloses, *inter alia*, a composition comprising halobetasol (a corticosteroid) and tazarotene (a retinoid), which is synergistically more

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efficacious that the combined efficacies of compositions each comprising only one of the active ingredients.[1] The Examiner notes Table 2 and Table 4 of Dow, stating that the amounts in the tables are the same amounts recited in instant claim 40.[2] The Examiner alleges that, although Dow does not disclose the treatment of acne, it would be obvious to combine the disclosure of Dow with the disclosure of Donello so as to arrive at the presently claimed invention. According to the Examiner:

> Donello teaches a composition of only (emphasis added) tazarotenic acid or a pharmaceutically acceptable salt, ester or amid thereof (claim 10). Donello teaches the treatment of skin disorders such as acne vulgaris with the administration of tazarotenic acid (claim 11-12).
>
> It would have been obvious to employ tazarotenic acid as the sole agent in the treatment of acne in view of Dow. One would have been motivated to employ tazarotenic acid because it is known that topically administered tazarotenic acid is effective in the treatment of skin disorders (e.g. psoriasis and acne) as disclosed by both Dow and Donello with a reasonable expectation of success absence evidence to the contrary.
>
> ...
>
> Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.[3]

III. Applicant Response

Applicant appreciates that the Examiner has considered various amendments and arguments prior to the submission of the present amendment. The present amendment is the first to be submitted by the undersigned representative, who has recently been granted Power of Attorney by Applicant. A review of the file history for this application shows that many allegations and rebuttals have been made regarding the propriety of the obviousness rejection, and whether or not the cited references support a *prima facie* case of obviousness. Applicant incorporates these prior arguments by reference. While not conceding these points, Applicant

[1] Office Action at pages 10-11.
[2] Office Action at page 13.
[3] Office Action at page 13.

believes that it would be beneficial at present to focus on the showing of unexpected results in the application that are evidence of non-obviousness and to confirm that the Examiner has considered these unexpected results.

According to MPEP § 2145, ***Office personnel should consider all rebuttal arguments and evidence presented by applicants***, and further that ***rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art.***

It is not clear that the Examiner has considered all of the evidence presented by Applicant. Applicant previously explained that the claimed method provides an unexpected combination of improved efficacy and tolerability, as evidenced by the data in the application. This evidence was presented in the application as originally filed on November 2, 2018, and this evidence was further discussed in amendments submitted on July 19, 2019; January 28, 2020; and June 26, 2020. Following these submissions, the Examiner issued Office Actions on October 28, 2019; February 27, 2020; and August 10, 2020. Each of these Office Actions set forth a "Response to Arguments," none of which acknowledged this data or the discussion related to this data.[4]

Applicant reiterates that the claimed method provides improved outcomes that could *not* be expected based on the cited references, as explained again below. Applicant respectfully requests that the Examiner consider this evidence as required by MPEP § 2145, confirm that the evidence has been considered, and allow the claims.

A. One of skill in the art would not have expected the surprising efficacy and tolerability of the claimed method.

The application describes a side-by-side comparison of acne treatment using tazarotene 0.045% lotion according to the present claims and TAZORAC 0.1% cream. The data in the application demonstrates the higher efficacy provided by administration of 0.045% tazarotene lotion according to the present claimed method, as compared to TAZORAC cream. For

[4] *See:* Final Rejection dated October 28, 2019 at page 3; Non-Final rejection dated February 27, 2020 at page 3; Final Rejection dated August 10, 2020 at pages 3-10.

Example, Table 6 in the application summarizes treatment success for 0.045% tazarotene lotion and 0.01% TAZORAC cream. Table 6 is reproduced below for ease of reference.

Table 6
Treatment % Success (Intention-To-Treat) at 12 Weeks

	Combined Placebo N=69	Composition A N=69	Tazorac® 0.1% Cream N=72
EGSS – Clear or Almost Clear	10.1%	18.8%	16.7%
Inflammatory Lesions			
Absolute Change	-14.0	-18.1	-16.8
% Change	-51.41%	-63.75%	-59.99%
Non-inflammatory Lesions			
Absolute Change	-13.1	-21.6	-20.3
% Change	-35.18%	-56.86%	-54.09%

The data in Table 6 shows that the improvement over placebo observed for 0.045% tazarotene lotion ("Composition A") was substantially higher than the improvement over placebo observed for 0.1% TAZORAC cream. Applicant notes that 18.8% of acne patients receiving Composition A reached an Evaluator's Global Severity Score (EGSS) equating to "clear" or "almost clear," whereas only 16.7% of patients receiving TAZORAC cream achieved this score. Applicant notes that this difference amounts to a **31.8% improvement** for Composition A, as compared to TAZORAC, over the combined placebo population in the study as outlined below.

Improvement over placebo: $\frac{(Composition\ A\ result - placebo\ result) - (TAZORAC\ result - placebo\ result)}{(TAZORAC\ result - placebo\ result)} \times 100\%$

$\frac{(18.8\% - 10.1\%) - (16.7\% - 10.1\%)}{(16.7\% - 10.1\%)} \times 100\%$

$= 31.8\%$

The *greater* efficacy over placebo provided by Composition A in the claimed method is particularly surprising when considering that the method employed *less than half* the tazarotene dose of TAZORAC. Applicant submits that the skilled artisan would *not* expect to increase the efficacy when decreasing the amount the active agent by over half. On the contrary, one of skill in the art would expect that decreasing the amount of tazarotene would decrease the efficacy of the method. Nothing in the cited references suggests otherwise. Indeed, nothing in the cited

references suggests the superior results provided by administering the claimed amount of tazarotene using the claimed vehicle in the claimed method.

Meanwhile, Table 8 of the application shows the marked improvement in tolerability provided by the use of tazarotene 0.045% lotion in the claimed method. Table 8 is reproduced below and tabulates the incidence of adverse events during treatment with tazarotene 0.045% lotion and TAZORAC 0.1% cream.

Table 8
Treatment Emergent Adverse Event Characteristics

	Combined Placebo	Composition A	Tazorac® 0.1% Cream
% Subjects Reporting Any Adverse Event	13.4%	14.7%	26.8%
% Subjects Reporting Any Serious Adverse Event	0%	0%	0%
% Subjects Discontinued Study Due to Adverse Event	0%	0%	1.4%

Table 8 shows that a dramatically higher tolerability was achieved using tazarotene 0.045% lotion than when using TAZORAC 0.1% cream. The irritation level observed for TAZORAC 0.1% cream was markedly higher than the irritation level observed for tazarotene 0.045% lotion when used per the presently claimed method. It can be seen from Table 8 that 26.8% of subjects receiving TAZORAC reported adverse events, wherein 14.7% of subjects receiving TAZORAC reported adverse events. This difference amounts to a 90.3% reduction (i.e., a **90.3% improvement**) in adverse events over the combined placebo population for Composition A, as compared to TAZORAC.

Improvement over placebo: $\frac{(Composition\ A\ result - placebo\ result) - (TAZORAC\ result - placebo\ result)}{(TAZORAC\ result - placebo\ result)} \times 100\%$

$\frac{(14.7\% - 13.4\%) - (26.8\% - 13.4\%)}{(26.8\% - 13.4\%)} \times 100\%$

= -90.3%

Applicant submits that one of skill in the art could ***not*** expect to decrease adverse events by 90.3% ***and*** increase efficacy by 31.8% by using a formulation with a decreased concentration of active agent, as recited in the present claims.

B. Greater than expected results of the claimed method are evidence of nonobviousness and are commensurate with the scope of the claims.

Applicant reiterates that one of skill in the art would *not* have expected greater efficacy and greater tolerability when using a composition having a lesser dose of tazarotene. MPEP § 716.02(a) explains that "greater than expected results are evidence of nonobviousness," and the claimed method provides greater than expected results. Applicant notes that Composition A contains the components and quantities recited in present claim 40, and is also closely embraced by claims 13, 17-19, 36, and 39. For at least these reasons, Applicant submits that the claims are *not* obvious over the cited references and respectfully requests that the rejection be withdrawn.

IV. Double Patenting Rejections

The claims are rejected on the grounds of non-statutory obviousness-type double patenting over claims in U.S. Patent Nos. 10,426,787 and 10,251,895, as well as over claims in co-pending Pat. Appl. No. 16/179,576.

The Examiner has not yet indicated that the pending claims are in condition for allowance. As such, the filing of a terminal disclaimer is premature. Applicant therefore respectfully requests, without acquiescing to the validity of these rejections, that the rejections be held in abeyance until the pending claims are in condition for allowance. At that time, Applicants will address the non-statutory double patenting rejections as necessary.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Except for the issue fees payable under 37 C.F.R. § 1.18, the Director is authorized to charge any additional fees during pendency of this application, including any required extension of time fees, or credit any overpayment to Deposit Account Number 20-1430. This paragraph is intended to be a constructive petition for extension of time in accordance with 37 C.F.R. § 1.136(a)(3).

If the Examiner believes a telephone conference would expedite prosecution of this application, please contact the undersigned at (415) 273-4310.

Respectfully submitted,



Andrew D. Presley
Registration No. 69,844

KILPATRICK TOWNSEND & STOCKTON LLP

74955372V.1

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/179,561	Filing Date 11/02/2018	☑ 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 $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ 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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	07/15/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 11	Minus	** 28	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0		x $480 =	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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ 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.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/ANGELA D JOHNSON/
*** 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.	

This collection of information is required by 37 CFR 1.16. 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, 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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IPR Petition - USP 11,311,482

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/179,561	11/02/2018	Arturo Angel	095920-00413US-1241000

CONFIRMATION NO. 1370

112120
Bausch Health / Kilpatrick Townsend & Stockton LLP
Mailstop: IP Docketing - 22
1100 Peachtree Street
Suite 2800
Atlanta, GA 30309

37 CFR 1.48(f)
ACKNOWLEDGEMENT LETTER

OC00000124979216

Date Mailed: 04/20/2021

NOTICE OF ACCEPTANCE OF REQUEST UNDER 37 CFR 1.48(f)

This is in response to the applicant's request under 37 CFR 1.48(f) submitted on 04/15/2021.

The request under 37 CFR 1.48(f) to correct the inventorship, to correct or update the name of an inventor, or to correct the order of names of joint inventors is accepted.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/rmohamed/

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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
16/179,561	11/02/2018	1627	2180	095920-00413US-1241000	23	2

CONFIRMATION NO. 1370

UPDATED FILING RECEIPT

112120
Bausch Health / Kilpatrick Townsend & Stockton LLP
Mailstop: IP Docketing - 22
1100 Peachtree Street
Suite 2800
Atlanta, GA 30309



Date Mailed: 04/20/2021

Receipt is acknowledged of this non-provisional utility 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 FIRST INVENTOR, 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 corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction 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 provided that the request is grantable.

Inventor(s)

Arturo Angel, Santa Rosa, CA;
Radhakrishnan Pillai, Santa Rosa, CA;

Applicant(s)

BAUSCH HEALTH US, LLC, Bridgewater, NJ;

Power of Attorney: The patent practitioners associated with Customer Number 112120

Domestic Priority data as claimed by applicant

This application is a CIP of 15/977,088 05/11/2018 ABN
which claims benefit of 62/505,421 05/12/2017

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

Title

TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

Preliminary Class

514

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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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.

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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.

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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NOT GRANTED

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/179,561	11/02/2018	Arturo Angel	095920-00413US-1241000

CONFIRMATION NO. 1370

112120
Bausch Health / Kilpatrick Townsend & Stockton LLP
Mailstop: IP Docketing - 22
1100 Peachtree Street
Suite 2800
Atlanta, GA 30309

POA ACCEPTANCE LETTER

OC000000124979133

Date Mailed: 04/20/2021

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/15/2021.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/rmohamed/

PTO/AIA/01 (06-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

■ United States application or PCT international application number 16/179,561 filed on November 2, 2018.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Arturo Angel Date (Optional): April 12, 2021

Signature: Arturo Angel

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 1 minute 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Acknowledgement Receipt	
EFS ID:	42468914
Application Number:	16179561
International Application Number:	
Confirmation Number:	1370
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Angel Arturo
Customer Number:	134756
Filer:	Andrew David Presley/Sharleen Lane
Filer Authorized By:	Andrew David Presley
Attorney Docket Number:	99336.000343
Receipt Date:	15-APR-2021
Filing Date:	02-NOV-2018
Time Stamp:	20:00:07
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	Oath or Declaration filed	095920-004130US_Declaration_Angel_This_version_has_SIGNATURE.pdf	132871 aad32479f81b46cff9f17c3b7d08d47759f2b5a2	no	1
Warnings:					

Padagis Ex. 1002
IPR Petition - USP 11,311,482

The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing	
Information:	
Total Files Size (in bytes):	132871

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.

Doc Code: R48.REQ
Document Description: Request under Rule 48 correcting inventorship

PTO/AIA/40 (04-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE
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.

REQUEST FOR CORRECTION IN A PATENT APPLICATION RELATING TO INVENTORSHIP OR AN INVENTOR NAME, OR ORDER OF NAMES, OTHER THAN IN A REISSUE APPLICATION (37 CFR 1.48)		
	Application Number	16/179,561
	Filing Date	November 2, 2018
	First Named Inventor	Arturo Angel
	Art Unit	1627
	Examiner Name	CRUZ, KATHRIEN ANN
	Practitioner Docket Number	095920-004130US-1241000

To: **Commissioner for Patents**
P.O. Box 1450
Alexandria, VA 22313-1450

Applicant hereby **requests that the inventorship be corrected or changed, or that the name of the inventor or a joint inventor, or the order of the names of joint inventors, be changed,** in the above-identified application. **Note**: 37 CFR 1.48 applies to any request to correct inventorship filed on or after September 16, 2012, regardless of the application filing date. **Do not submit this form after payment of the issue fee or if the application has been patented.** See 37 CFR 1.324 for correction of inventorship in a patent.

Please check the applicable box(es) below.

For a nonprovisional application:

☐ 1. This request is to correct or change the inventorship in a **nonprovisional** application (**under 37 CFR 1.48(a)**) and includes:

☐ An application data sheet (ADS) in accordance with 37 CFR 1.76(c) with the corrected or updated information shown with markings (*e.g.*, underlining for insertions, strikethrough for deletions). See the Manual of Patent Examining Procedure (MPEP) section 601.05(a) for information about filing an ADS in an application filed on/after September 16, 2012. For information about filing a Supplemental ADS in an application filed before September 16, 2012, see MPEP 601.05(b).

☐ The processing fee set forth in 37 CFR 1.17(i). $ _____

☐ An inventor is being added. An inventor's oath or declaration by any actual inventor who has not yet executed an oath or declaration is required (see 37 CFR 1.48(b)). See MPEP 602.01(a) for information about an inventor's oath or declaration for an application filed on/after September 16, 2012 (*e.g.*, form **PTO/AIA/01**). For information about an inventor's oath or declaration for an application filed before September 16, 2012 (*e.g.*, form **PTO/SB/01**), see MPEP 602.01(b).

☐ This request is being filed after the first Office action on the merits has been given or mailed (see 37 CFR 1.48(c) and 1.17(d)). Check one of the following:

☐ This request to correct or change the inventorship is due solely to the cancellation of claims in the application.

OR

☐ The fee set forth in 37 CFR 1.17(d) is due (in addition to the fee set forth in 37 CFR 1.17(i)). $ _____

This collection of information is required by 37 CFR 1.48. 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 1.11 and 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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IPR Petition - USP 11,311,482

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U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE
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REQUEST FOR CORRECTION IN A PATENT APPLICATION RELATING TO INVENTORSHIP OR AN INVENTOR NAME, OR ORDER OF NAMES, OTHER THAN IN A REISSUE APPLICATION (37 CFR 1.48)

■ 2. This request is to correct or update the name of the inventor or a joint inventor, or the order of names of joint inventors, in a **nonprovisional** application (**under 37 CFR 1.48(f)**) and includes:

■ An application data sheet in accordance with 37 CFR 1.76(c) identifying the complete inventive entity, including the corrected or updated name of the inventor, or the new order of names shown with markings (*e.g.*, underlining for insertions, strikethrough for deletions). See the MPEP 601.05(a) for information about filing an ADS in an application filed on/after September 16, 2012. For information about filing a Supplemental ADS in an application filed before September 16, 2012, see MPEP 601.05(b).

■ The processing fee set forth in 37 CFR 1.17(i). $ 140

For a provisional application:

☐ This request is to change or correct the inventorship, or correct or update the name of the inventor or a joint inventor, in a **provisional** application (**under 37 CFR 1.48(d)**) and includes:

☐ **Attached hereto** is a document that is signed by a party set forth in 37 CFR 1.33(b) and identifies each inventor by his or her legal name, in the preferred order. Note: the document may be an application data sheet in accordance with 37 CFR 1.76(c) that identifies the changes with markings (underlining for insertions, strikethrough for deletions).

☐ The processing fee set forth in 37 CFR 1.17(q). $ _____

Fee Payment Information:

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

■ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 20-1430.

■ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ Applicant*

■ attorney or agent of record
Registration number 69,844

☐ attorney or agent acting under 37 CFR 1.34
Registration number _____

Signature /Andrew Presley/

Typed or printed name Andrew D. Presley

Date April 12, 2021

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. *Juristic entities must be represented by a patent practitioner (See 37 CFR 1.31, applicable to any paper filed on or after September 16, 2012 that is presented on behalf of a juristic entity, regardless of application filing date). Submit multiple forms if more than one signature is required, see below**.

☐ ** Total of _____ forms are submitted.

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.

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IPR Petition - USP 11,311,482

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	~~99336.000293-CIP~~ 095920-004130US-1241000
	Application Number	16/179,561
Title of Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	~~Angel~~ Arturo		~~Arturo~~ Angel	

Residence Information (Select One) ● US Residency Non US Residency Active US Military Service

City	Santa Rosa	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	4953 Sheleen Court
Address 2	

City	Santa Rosa	State/Province	CA
Postal Code	95409	Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Radhakrishnan		Pillai	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

City	Santa Rosa	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	6787 Owl Hill Avenue
Address 2	

City	Santa Rosa	State/Province	CA
Postal Code	95409	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

PTO/AIA/14 (02-18)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	~~99336.000293-CIP~~095920-004130US-1241000
	Application Number	16/179,561
Title of Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES	

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	~~134756~~ 112120		
Email Address	~~patent@hselaw.com~~ ipefiling@kilpatricktownsend.com	Add Email	Remove Email

Application Information:

Title of the Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES		
Attorney Docket Number	~~99336.000293-CIP~~ 095920-004130US-1241000	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	10	**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	~~134756~~ 112120		

PTO/AIA/14 (02-18)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	~~99336.000293-CIP~~ 095920-004130US-1241000
	Application Number	16/179,561
Title of Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES	

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation in part of	15977088	2018-05-11
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
15977088	Claims benefit of provisional	62505421	2017-05-12

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	~~99336.000293-CIP~~ 095920-004130US-1241000
	Application Number	16/179,561
Title of Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

PTO/AIA/14 (02-18)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	~~99336.000293-CIP~~ 095920-004130US-1241000
	Application Number	16/179,561
Title of Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 — Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name: ~~Valeant Pharmaceuticals North America~~ BAUSCH HEALTH US, LLC

Mailing Address Information For Applicant:

Address 1	400 Somerset Corporate Boulevard		
Address 2			
City	Bridgewater	**State/Province**	NJ
Country	US	Postal Code	08807
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	~~99336.000293-CIP~~ 095920-004130US-1241000
	Application Number	16/179,561
Title of Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Andrew Presley/			Date (YYYY-MM-DD)	2021-04-12
First Name	Andrew D.	Last Name	Presley	Registration Number	69,844

Additional Signature may be generated within this form by selecting the Add button. Add

PTO/AIA/14 (02-18)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	~~99336.000293-CIP~~ 095920-004130US-1241000
	Application Number	16/179,561
Title of Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES	

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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.**

Electronic Patent Application Fee Transmittal	
Application Number:	16179561
Filing Date:	02-Nov-2018
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Angel Arturo
Filer:	Andrew David Presley/Sharleen Lane
Attorney Docket Number:	99336.000343

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**140**

Electronic Acknowledgement Receipt	
EFS ID:	42466417
Application Number:	16179561
International Application Number:	
Confirmation Number:	1370
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Angel Arturo
Customer Number:	134756
Filer:	Andrew David Presley/Sharleen Lane
Filer Authorized By:	Andrew David Presley
Attorney Docket Number:	99336.000343
Receipt Date:	15-APR-2021
Filing Date:	02-NOV-2018
Time Stamp:	16:32:26
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$140
RAM confirmation Number	E20214EG32472232
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Req to correct/update/change appl name until pay issue fee	095920-004130US_Rule46_changeApplicant.pdf	194122 2424b7aa599630c74d6c266cd5424a37b852356f	no	2
Warnings:					
Information:					
2	Assignee showing of ownership per 37 CFR 3.73	095920-004130US_Statement373.pdf	113572 3d148baaa2f91b280445090d77415c4070518df3	no	3
Warnings:					
Information:					
3	Power of Attorney	095920-004130US_POA82A_POA82B.pdf	261526 4ffcd808afc4ac2c31e165d48cb576b734faccec	no	2
Warnings:					
The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
Information:					
4	Oath or Declaration filed	095920-004130US_Declaration_Angel.pdf	171030 f37c07e3c5d3693f986a84da3b6d8fd46bc75b0b	no	2
Warnings:					
Information:					
5	Oath or Declaration filed	095920-004130US_Declaration_Pillai.pdf	986017 d6d3f31887e41ff722618b446eef39f7fadc007a	no	1
Warnings:					
The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
Information:					

6	Request under Rule 48 correcting inventorship	095920-004130US_Rule48_correctInventorName.pdf	1024904 54c7d574787e3ce8584fcc4bb557679dad6ba5b4	no	3
Warnings:					
Information:					
7	Application Data Sheet	095920-004130US_CorrectedADS.pdf	339141 f9561a83f9bc0eccac5d13501d4ffac03082195f	no	7
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
8	Fee Worksheet (SB06)	fee-info.pdf	30445 75585542199d20f1873102dc8c9ff4e4afe2ca6d	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	3120757		

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.

Doc Code: R46C.REQ
Document Description: Request under 37 CFR 1.46(c) to correct, update or change the applicant.

PTO/AIA/41 (04-15)
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U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE
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REQUEST TO CORRECT OR UPDATE THE NAME OF THE APPLICANT UNDER 37 CFR 1.46(c)(1), OR CHANGE THE APPLICANT UNDER 37 CFR 1.46(c)(2)
(FOR USE ONLY IN APPLICATIONS FILED ON OR AFTER SEPTEMBER 16, 2012)

Application Number	16/179,561
Filing Date	November 2, 2018
First Named Inventor	Arturo Angel
Art Unit	1627
Examiner Name	CRUZ, KATHRIEN ANN
Practitioner Docket Number	095920-004130US-1241000

To: Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Applicant hereby **requests that the name of the applicant be corrected or updated under 37 CFR 1.46(c)(1), or that the applicant be changed under 37 CFR 1.46(c)(2),** in the above-identified application. **Requests under 37 CFR 1.46(c)(1) or (c)(2) cannot be submitted after payment of the issue fee or if the application has been patented.**

Please check the applicable box(es) below.

☐ 1. This request is to **correct or update the name of the applicant** (**under 37 CFR 1.46(c)(1)**) and includes:

☐ An application data sheet (ADS) in accordance with 37 CFR 1.76(c) with the corrected or updated information shown with markings (*e.g.*, underlining for insertions, strikethrough for deletions). A Corrected Web-based ADS may be used.

Note: Requests under 37 CFR 1.46(c)(1) may be filed to correct typographical errors in the name of the § 1.46 applicant, or for updating the name of the § 1.46 applicant (*i.e.*, where there is no change in the applicant itself but just in the applicant's name). See the Manual of Patent Examining Procedure (MPEP) section 605.01.

■ 2. This request is to **change the applicant** (**under 37 CFR 1.46(c)(2)**) and includes:

■ An application data sheet (ADS) in accordance with 37 CFR 1.76(c) that identifies the changes with proper markings (underlining for insertions and strikethrough for deletions). A Corrected Web-based ADS may be used.

■ A Statement Under 37 CFR 3.73(c) (Form PTO/AIA/96 or equivalent). See MPEP 325.

I am the

☐ applicant* ■ attorney or agent of record Registration number 69,844 ☐ attorney or agent acting under 37 CFR 1.34 Registration number _____

Signature /Andrew Presley/

Typed or printed name Andrew D. Presley

Date April 12, 2021

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. *Juristic entities must be represented by a patent practitioner (See 37 CFR 1.31, applicable to any paper filed on or after September 16, 2012 that is presented on behalf of a juristic entity, regardless of application filing date). Submit multiple forms if more than one signature is required, see below**.

☐ ** Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.36. 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 1.11 and 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, 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Padagis Ex. 1002
IPR Petition - USP 11,311,482

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.

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IPR Petition - USP 11,311,482

PTO/AIA/96 (08-12)
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STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: BAUSCH HEALTH US, LLC

Application No./Patent No.: 16/179,561 Filed/Issue Date: November 2, 2018

Titled: TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

BAUSCH HEALTH US, LLC, a corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

   ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

   ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

A. ☑ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 055829, Frame 0113, or for which a copy thereof is attached.

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____

   The document was recorded in the United States Patent and Trademark Office at

   Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

   The document was recorded in the United States Patent and Trademark Office at

   Reel _____, Frame _____, or for which a copy thereof is attached.

This collection of information is required by 37 CFR 3.73(b). 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 1.11 and 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, 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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STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☑ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Andrew Presley/	April 12, 2021
Signature	Date
Andrew D. Presley	69,844
Printed or Typed Name	Title or Registration Number

[Page 2 of 2]

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.

Padagis Ex. 1002
IPR Petition - USP 11,311,482

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	16/179,561
Filing Date	November 2, 2018
First Named Inventor	Arturo Angel
Title	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
Art Unit	1627
Examiner Name	CRUZ, KATHRIEN ANN
Attorney Docket Number	095920-004130US-1241000

SIGNATURE of Applicant or Patent Practitioner

Signature	/Andrew Presley/	Date (Optional)	April 12, 2021
Name	Andrew D. Presley	Registration Number	69,844
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)	BAUSCH HEALTH US, LLC		

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 1.11 and 1.14. This collection is estimated to take 3 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, 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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Padagis Ex. 1002
IPR Petition - USP 11,311,482

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 112120

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☐ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box)

BAUSCH HEALTH US, LLC

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	/Suzanne L. Hamilton/	Date (Optional)	March 24, 2021
Name	Suzanne L. Hamilton		
Title	Sr. Legal IP Specialist and Authorized Signatory		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 1.11 and 1.14. This collection is estimated to take 3 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, 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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IPR Petition - USP 11,311,482

PTO/AIA/01 (06-12)
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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.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 16/179,561

filed on November 2, 2018.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Arturo Angel Date (Optional) :_____

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 1 minute 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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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.

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IPR Petition - USP 11,311,482

PTO/AIA/01 (06-12)
Approved for use through 11/30/2020 OMB 0651-0032
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This declaration is directed to:

- ☐ The attached application, or
- ☒ United States application or PCT international application number 16/179,561 filed on November 2, 2018.

The above-identified application was made or authorized to be made by me.

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LEGAL NAME OF INVENTOR

Inventor: Radhakrishnan Pillai Date (Optional): April 12, 2021

Signature: R Radhakrishnan

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 1 minute 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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Padagis Ex. 1002
IPR Petition - USP 11,311,482

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.
16/179,561	11/02/2018	Angel Arturo	99336.000343	1370

134756 7590 01/15/2021

HSE/Valeant
1600 Bausch & Lomb Place
Rochester, NY 14604

EXAMINER
CRUZ, KATHRIEN ANN

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
01/15/2021	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@hselaw.com

Notice of Panel Decision from Pre-Appeal Brief Review	Application No. 16/179,561	Applicant(s) Arturo et al.	
	Examiner Mark L Shibuya	Art Unit 1624	AIA (FITF) Status Yes

This is in response to the Pre-Appeal Brief Request for Review filed 10 December 2020 .

1. ☐ **Improper Request** - The Request is improper and a conference will not be held for the following reason(s):

☐ The Notice of Appeal has not been filed concurrent with the Pre-Appeal Brief Request.
☐ The request does not include reasons why a review is appropriate.
☐ A proposed amendment is included with the Pre-Appeal Brief request.
☐ Other: _____ .

The time period for filing a response continues to run from the receipt date of the Notice of Appeal or from the mail date of the last Office communication, if no Notice of Appeal has been received.

2. ☑ **Proceed to Board of Patent Appeals and Interferences** - A Pre-Appeal Brief conference has been held. The application remains under appeal because there is at least one actual issue for appeal. Applicant is required to submit an appeal brief in accordance with 37 CFR 41.37. The time period for filing an appeal brief will be reset to be one month from mailing this decision, or the balance of the two-month time period running from the receipt of the notice of appeal, whichever is greater. Further, the time period for filing of the appeal brief is extendible under 37 CFR 1.136 based upon the mail date of this decision or the receipt date of the notice of appeal, as applicable.

☑ The panel has determined the status of the claim(s) is as follows:
Claim(s) allowed: _____ .
Claim(s) objected to: _____ .
Claim(s) rejected: 13-40 .
Claim(s) withdrawn from consideration: _____ .

3. ☐ **Allowable application** - A conference has been held. The rejection is withdrawn and a Notice of Allowance will be mailed. Prosecution on the merits remains closed. No further action is required by applicant at this time.

4. ☐ **Reopen Prosecution** - A conference has been held. The rejection is withdrawn and a new Office action will be mailed. No further action is required by applicant at this time.

All participants:

(1) MARK L SHIBUYA .	(3) TQAS BENNETT CELSA .
(2) KATHRIEN CRUZ .	(4) _____ .

/MARK L SHIBUYA/
Supervisory Patent Examiner
Art Unit 1624

U.S. Patent and Trademark Office
PTOL-2297 (Rev. 02/11)

Part of Paper No. 20210112

Padagis Ex. 1002
IPR Petition - USP 11,311,482

Confirmation No.: 1370

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Angel, Arturo
Applicant:	Valeant Pharmaceuticals North America
Application No.:	16/179,561
Filed:	November 2, 2018
Examiner:	CRUZ, KATHRIEN ANN
Group/Art Unit:	1627
Atty. Docket No.:	99336.000343
Title:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

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

December 10, 2020

Dear Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicant requests review of the final rejection in the above identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. No more than five (5) pages of arguments are submitted herewith.

Fee-Charge Authorization

By way of precaution, the Commissioner is authorized to charge any fees or fee amounts not otherwise authorized but necessary for the consideration of this paper or the continued pendency of this application and to credit any overpayment to Deposit Account Number 03-3875 of Harter Secrest & Emery LLP. Please grant any extensions of time necessary for the filing of the Notice of Appeal and this Request.

PRE-APPEAL BRIEF REQUEST FOR REVIEW ARGUMENTS

I. Rejection of claims 13-40 under 35 U.S.C. § 103 as being unpatentable over WO 2016205001 and Donello (US 2012/0328670)

Applicant respectfully traverses this rejection with respect to the present claims because the combination of WO 2016205001 and Donello does not teach or suggest a method of treating acne vulgaris using a topical pharmaceutical composition meeting all of the combined limitations of independent claims 13 and 40. More particularly, the cited references are directed towards clearly distinct formulations or distinct uses, which based on the actual teachings of the references would not have been *prima facie* obvious to combine in a specific manner so as to result in the present claimed invention without the improper use of hindsight reconstruction based on Applicant's own teachings. In such regard, the Examiner in clear error fails to consider the actual teachings of such references relative to the claimed invention, as well as the examples presented in the application which demonstrate the surprising efficacy of the claimed invention, which further clearly overcomes any alleged *prima facie* case of obviousness.

I.1. The asserted references are directed towards distinct formulations or for distinct purposes, which would not have been prima facie obvious to combine based on the actual teachings of the cited references so as to result in the present claimed invention without the improper use of hindsight reconstruction based on Applicant's own teachings

While WO 2016205001 (alternatively referred to by the Examiner as "Dow") discloses an oil-in-water formulation comprising tazarotene at 0.045 wt% as a sole pharmaceutically active ingredient, the Examiner acknowledges it does not disclose use of the disclosed formulation for the treatment of acne. The Examiner asserts Donello teaches the treatment of acne vulgaris with the administration of tazarotenic acid (citing claims 11-12), and asserts that it would have been "obvious to employ tazarotenic acid as the sole agent in the treatment of acne in view of Dow," as one would have been motivated to do so "because it is known that topically administered tazanoic acid is effective in the treatment of skin disorders (e.g., psoriasis and acne) as disclosed by both Dow and Donello with a reasonable expectation of success absence evidence to the contrary." Final Rejection, page 13. The Examiner thus asserts that the motivation to employ the 0.045 wt% tazarotene oil-in-water emulsion formulation disclosed in WO 2016205001 in the treatment of acne is based on an alleged "reasonable expectation of success" based on both WO 2016205001 and Donello teaching use of tazarotene formulations for treatment of skin disorders, and Donello specifically teaching use of tazarotene for treatment of acne.

The rejection, however, in clear error fails to actually address Applicant's arguments that there would be no reasonable expectation of success for use of an oil-in-water emulsion formulation

containing the claimed concentration of tazarotene in the treatment of acne based on the actual teachings of WO 2016205001 and Donello, as Donello (which the Examiner relies upon for a teaching of the use of tazarotene for the treatment of acne) is instead specifically directed towards, and only actually demonstrates, use of microspheres comprising biodegradable polymer and tazarotene for reducing sebaceous gland size, while other non-microsphere based formulations (including vehicle alone, or Tazorac® gel formulation) were found to not be effective at significantly reducing sebaceous gland size (see, e.g., Fig. 2 and [0050] of Donello). As reduction of sebum is the only proposed effect for expected success in treating acne disclosed in Donello (see, e.g., [0016]), and as the only formulations disclosed in Donello which demonstrate significant reduction in sebaceous gland size are microparticle biodegradable polymer formulations as opposed to oil-in-water formulations as claimed (and to the contrary, other tazarotene formulations such as Tazorac® gel even at a higher concentration (0.1%) than that claimed in the present invention was found to not be effective at significantly reducing sebaceous gland size), **Donello thus clearly does not provide any evidence of any reasonable expectation of success for formulations other than the microsphere particle based formulations thereof for the treatment of acne.** The Examiner's proposed basis for obviousness based on a "reasonable expectation of success" for use of the formulation of WO 2016205001 in the treatment of acne based on Donello is thus clearly not supported by any actual teaching in Donello, but rather is entirely speculative in the absence of Applicant's own teachings.

The Examiner responds to Applicant's argument that Donello's use of formulations of microparticle biodegradable polymer formulations for the treatment of acne provides no reasonable expectation of success for use of other formulations (such as those of WO 2016205001) for the treatment of acne by again referring to WO 2016205001 as disclosing tazarotene oil-in-water emulsion formulations, and Donello clearly teaching that tazarotenic acid is useful for the treatment of acne, and again arguing that one would have a reasonable expectation of success "because it is in the same field of endeavor and both Dow and Donello employ the same active agent (e.g. tazarotenic acid), while Dow discloses psoriasis and Donello clearly discloses the treatment of acne (in which both are skin diseases), it would have been obvious to employ the treatment of acne to the teachings of Dow because it is known in the art that tazarotenic acid treats acne." Such arguments again in clear error fail to consider the actual teachings of Donello, i.e., that other formulations besides the specific microparticle biodegradable polymer formulations thereof were found to be not effective at significantly reducing sebaceous gland size as explained above, where reduction of sebum is the only proposed effect for expected success in treating acne disclosed in Donello. The Examiner's continued failure to consider the actual teachings of the cited reference which respect to support of any reasonable expectations of success is evidence of clear error in the asserted rejection.

While the Examiner attempts to further argue at page 8 of the Final Rejection that exemplary rationales (E)-(G) of the guidelines explained in MPEP 2141 and 2143 support a conclusion of obviousness for the instant claims, such argument is not well supported. In particular, with respect to (E) "Obvious to try ", the use of any particular formulation of WO 2016205001 has not been identified as one of a "finite number of identified, predictable solutions" in the cited art to any particular problem in Donello, but to the contrary Donello instead is directed towards a distinct solution to the problem addressed therein (i.e., use of a microparticle biodegradable polymer formulation), and actually teaches that other formulations did not obtain desired results. Rather than be "obvious to try," the proposed use of a distinct formulation relative to that actually taught by Donello would go against the actual teachings of Donello to use the distinct formulations thereof for the treatment of acne, and thus clearly not be *prima facie* obvious. With respect to (F) ("Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art"), the Examiner has not identified any relevant design incentives or market forces that would support obviousness of the present claimed invention, nor supported any finding that the proposed variation would have predictable results in the treatment of acne as claimed. Rather, Donello itself supports a conclusion that other formulations other than the disclosed microparticle biodegradable polymer formulations were found to not be effective. With respect to (G) ("Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention"), again the Examiner has not identified any such specific teaching, suggestion, or motivation that would be evident when considering the actual teachings of the cited references as explained above (rather than just stating generalities as to what is allegedly known in the art without consideration of such actual teachings).

Thus, in view of the clear lack of any reasonable expectation of success of the present claimed invention based on the actual teachings of Donello (which instead appears to teach the described microparticle biodegradable polymer formulations are required to obtain the aim result of reduction in sebaceous gland size, in comparison to ineffective results obtained for other tazarotene containing formulations), a *prima facie* case of obviousness has clearly not been established.

I.2. The present invention discloses results which in any event overcome the alleged prima facie case of obviousness

The asserted rejection is also in any event in further clear error, as the Examiner has failed to consider factual evidence submitted in the instant specification which clearly demonstrates an unexpected benefit of the claimed invention. Consistent with the rule that all evidence of nonobviousness must be considered when assessing patentability, the PTO must consider

comparative data in the specification in determining whether the claimed invention provides unexpected results. *In re Margolis*, 785 F.2d 1029, 1031, 228 USPQ 940, 941-42 (Fed. Cir. 1986). The Examiner has not articulated any reason why there would be reasonable expectation of success for the claimed use of the specific claimed oil-in-water tazarotene formulation for treatment of acne, wherein the tazarotene has been reduced to less than half the concentration of tazarotene in Tazorac® 0.1%, as required by the present jurisprudence and the MPEP guidance. In particular, the Examiner has not articulated any reason why there would be reasonable expectation of success for achieving better treatment efficacy in an oil-in-water tazarotene formulation when the tazarotene concentration is reduced to less than half of the concentration of tazarotene in Tazorac® 0.1%, while the cited reference relied upon for use of tazarotene in treating acne only demonstrates effectiveness of microsphere biodegradable particle formulations in reducing sebaceous gland size, and non-effectiveness of Tazorac® 0.1% formulations.

In contradistinction, the present inventors unexpectedly and surprisingly discovered that the presently claimed method of treating acne employing an oil-in-water emulsion composition having less than 0.05% tazarotene is more efficacious in treating acne than a commercial emulsion having 0.1% tazarotene, at least as measured by Evaluator's Global Severity Score ("EGSS") and reduction of inflammatory lesions. *In re Soni*, 34 U.S.P.Q.2d 1684, 1687 ("[T]hat which would have been surprising to a person of ordinary skill in a particular art would not have been obvious."). See Tables 6 and 7 of the present specification, as filed, which presents factual evidence for Composition A (having 0.045 wt% tazarotene in an oil-in-water formulation as identified in Table 2 of the specification) in accordance with the present claimed invention in comparison to placebo and 0.1 wt% tazarotene cream, which clearly demonstrates an unexpected benefit of the claimed invention. **Such demonstrated evidence of surprising results in fact constitutes "evidence to the contrary" with respect to the asserted obviousness rejection**. Thus, the asserted obviousness rejection, based on the distinct teachings of Donello in combination with WO 2016205001 and in consideration of all the evidence of record, clearly fails to establish obviousness. The Examiner's failure to consider such actual teachings of the cited references and demonstrated showing of surprising results in the present application represents clear error.

II. Rejections of claims 13-40 on the ground of nonstatutory double patenting

Claims 13-40 were rejected on the grounds of nonstatutory double patenting as being unpatentable over claims 1-10 of US 10,426,787 and claims 1-10 of US 10,251,895. The Examiner asserts the claims are not patentably distinct from each other because "both application recite the administration of tazarotene to treat acne," with the difference between the instant application and each of the '787 and the '895 patents is that the '787 and the '895 patents also recites halobetasol, but

the instant claims "do not preclude a combination therapy to treat acne," and that thus, the instant application and each of the '787 and '895 patents "possess significant overlapping scopes of invention." These rejections are in clear error, as the issue is not what the applications may or may not recite, but whether the instant claims would have been obvious from the claims of either of the '787 or '895 patents.

The claims of the '787 patent are specifically directed towards a method of treating psoriasis (not acne as alleged) employing a composition comprising tazarotene and halobetasol propionate as combined active agents, and the claims of the '895 patent are specifically directed towards a pharmaceutical composition for treating psoriasis comprising tazarotene and halobetasol propionate as combined active ingredients. The present application claims, conversely, are specifically directed towards a method of treating acne vulgaris employing a composition comprising tazarotene as the pharmaceutical active agent. Thus, instead of having "significant overlapping scopes of invention" as asserted by the Examiner, it is clear to one skilled in the art that the referenced patent claims and the instant application claims are instead clearly directed towards non-overlapping, mutually distinct claimed inventions, and accordingly would not have been obvious in view of each other.

III. Provisional rejection of claims 13-40 on the ground of nonstatutory double patenting

Claims 13-40 were provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 4, 6-12, and 24-28 of copending Application No. 16/179,576. As this is a provisional rejection, Applicant requests to defer filing of any required Terminal Disclaimer, or cancelling of corresponding claims in one of the applications, until otherwise allowable claims are indicated, as no claims have yet been indicated as otherwise being allowable.

Conclusion

As a proper *prima facie* case of obviousness has not been made, withdrawal of this rejection and allowance of the application is accordingly respectfully urged.

Respectfully submitted,

/Andrew J. Anderson/

Andrew J. Anderson, Reg. No. 33,564

HARTER SECREST & EMERY LLP
1600 Bausch & Lomb Place
Rochester, New York 14604-2711
Telephone: 585-231-1157

Electronic Patent Application Fee Transmittal	
Application Number:	16179561
Filing Date:	02-Nov-2018
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Angel Arturo
Filer:	Andrew James Anderson/Bethany Weber
Attorney Docket Number:	99336.000343

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
NOTICE OF APPEAL	1401	1	840	840
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Extension - 1 month with $0 paid	1251	1	220	220
Miscellaneous:				
		Total in USD ($)		**1060**

Electronic Acknowledgement Receipt	
EFS ID:	41352516
Application Number:	16179561
International Application Number:	
Confirmation Number:	1370
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Angel Arturo
Customer Number:	134756
Filer:	Andrew James Anderson/Bethany Weber
Filer Authorized By:	Andrew James Anderson
Attorney Docket Number:	99336.000343
Receipt Date:	10-DEC-2020
Filing Date:	02-NOV-2018
Time Stamp:	16:18:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$1060
RAM confirmation Number	E2020B0G18152794
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The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Notice of Appeal Filed	99336-343_Notice_of_Appeal.pdf	355145 935503465d12ed447903651c7087e119b23d0d8c	no	2
Warnings:					
Information:					
2	Pre-Brief Conference request	99336-343_PreAppealBriefRequest.pdf	254633 712436b21a416b0aeead4bcec5520da57e93c350	no	6
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	32704 af0e1ebf22729cc907df0488540153a7a10503d5	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	642482		

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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/AIA/31 (03-14)
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NOTICE OF APPEAL FROM THE EXAMINER TO THE PATENT TRIAL AND APPEAL BOARD

Docket Number (Optional): 99336.000343

I hereby certify that this correspondence is being facsimile transmitted to the USPTO, EFS-Web transmitted to the USPTO, or deposited with the United States Postal Service with sufficient postage in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, on Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____.

Signature _____

Typed or printed name _____

In re Application of: Valeant Pharmaceuticals International, Inc.

Application Number	Filed
16/179,561	November 2, 2018

For: TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

Art Unit	Examiner
1627	Cruz, Kathrien Ann

Applicant hereby **appeals** to the Patent Trial and Appeal Board from the last decision of the examiner.

The fee for this Notice of Appeal is (37 CFR 41.20(b)(1)) $ 840.00

☐ Applicant asserts small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by 50%, and the resulting fee is: $ _____

☐ Applicant certifies micro entity status. See 37 CFR 1.29. Therefore, the fee shown above is reduced by 75%, and the resulting fee is: $ _____
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 03-3875.

☑ Payment made via EFS-Web.

☑ A petition for an extension of time under 37 CFR 1.136(a) (PTO/AIA/22 or equivalent) is enclosed.
For extensions of time in reexamination proceedings, see 37 CFR 1.550.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant

☐ attorney or agent of record
Registration number _____

☑ attorney or agent acting under 37 CFR 1.34
Registration number 33,564

Signature /Andrew J. Anderson/

Typed or printed name Andrew J. Anderson

Telephone Number 585-231-1157

Date December 10, 2020

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☑ * Total of 1 forms are submitted.

This collection of information is required by 37 CFR 41.20(b)(1) and 41.31. 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 1.11, 1.14 and 41.6. 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, 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/179,561	11/02/2018	Angel Arturo	99336.000343	1370

134756 7590 08/10/2020

HSE/Valeant
1600 Bausch & Lomb Place
Rochester, NY 14604

EXAMINER
CRUZ, KATHRIEN ANN

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
08/10/2020	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@hselaw.com

Office Action Summary	**Application No.** 16/179,561	**Applicant(s)** Arturo et al.	
	Examiner KATHRIEN A CRUZ	**Art Unit** 1627	**AIA (FITF) Status** Yes

-- 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 MONTHS 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 6/25/2020.

☐ 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) 13-40 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) 13-40 is/are rejected.

8) ☐ Claim(s) _____ 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 _____ 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/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

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

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Upon careful consideration, the Final rejection dated 10/28/2020 is hereby vacated and a Non-Final Rejected is made below.

DETAILED ACTION

Claims 13-40 is pending.

Applicants response filed 6/25/2020 has been received and entered in the application.

Action Summary

Claims 13-40 are rejected under 35 U.S.C. 103 as being unpatentable over WO 2016205001 (WO 001) of record as disclosed in the IDS dated (7/19/2019) and Donello (U.S. Publication 2012/0328670) is maintained.

Claims 13-40 rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 10,426,787 is maintained.

Claims 13-40 rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 10,251,895 is maintained.

Claims 13-40 is provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4, 6-12, 24-28 of copending Application No. 16/179,576 is maintained.

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Response to Arguments

Applicant argues that Donello does not teach nor suggest a method of treating acne. This argument has been fully considered but has not been found persuasive. Dow teaches that the retinoid is present at a concentration below that which is presently utilized in topical formulations. For example, tazarotene or tazarotenic acid salt is included in a composition of the present invention at a positive concentration less than 0.05 wt%. Dow preferred embodiments, a topical pharmaceutical composition of the present invention is **an oil-in-water emulsion**. And Donello teaches a composition of only (emphasis added) tazarotenic acid or a pharmaceutically acceptable salt, ester or amid thereof (claim 10). Donello teaches the treatment of skin disorders such as acne vulgaris with the administration of tazarotenic acid. It would have been obvious to employ the teachings of Dow because it is known in the art that tazarotene or tazarotenic acid is useful in the treatment of acne with a reasonable expectation of success absence evidence to the contrary.

Applicants argues that the examiner does not articulate any reason why there would be a reasonable expectation of success for use of the specific oil-in-water. And asserts that the examiner has not address this argument. This argument has been fully considered but has not been found persuasive. Dow tazarotene or tazarotenic acid salt is included in a composition of the present invention at a positive concentration less than 0.05 wt%. (para 0032). Dow teaches that a topical pharmaceutical composition of the present invention is in the dosage form of gel, emulsion (including lotion, cream, and milk), shampoo, foam, suspension, liquid, spray, paste or ointment. In certain preferred embodiments, a topical pharmaceutical composition of the present invention is an oil-in-

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water emulsion, in which an internal oil phase is dispersed in a continuous aqueous phase. Alternatively, water-in-oil-in-water, water-in-oil and oil-in-water-in-oil emulsions are also contemplated. The emulsion may be a macroemulsion, a microemulsion, or a nanoemulsion. The only thing that Dow does not disclose acne. However, Donello teaches a composition of only (e.g. sole agent) of **tazarotenic acid to treat acne vulgaris** (claims 11-12). Donello was employ a means of demonstration that tazarotenic acid will treat acne alone (emphasis added). Therefore taking the cited art, it would have been obvious to one of ordinary skills to employ the teachings of Dow which discloses a oil-in-water with tazarotenic acid to treat acne because Donello clearly teaches that tazarotenic acid is useful in the treatment of acne.

Applicants argue that Donello clearly does not provide any evidence of any reasonable expectation of success for formulations for the treatment of acne. This argument has been fully considered but has not been found persuasive. Dow tazarotene or tazarotenic acid salt is included in a composition of the present invention at a positive concentration less than 0.05 wt%. (para 0032). Dow teaches that a topical pharmaceutical composition of the present invention is in the dosage form of gel, emulsion (including lotion, cream, and milk), shampoo, foam, suspension, liquid, spray, paste or ointment. In certain preferred embodiments, a topical pharmaceutical composition of the present invention is an oil-in-water emulsion, in which an internal oil phase is dispersed in a continuous aqueous phase. Alternatively, water-in-oil-in-water, water-in-oil and oil-in-water-in-oil emulsions are also contemplated. The emulsion may be a macroemulsion, a microemulsion, or a nanoemulsion. The only thing that Dow does not disclose acne. However, Donello teaches a composition of only (e.g. sole

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agent) of **tazarotenic acid to treat acne vulgaris** (claims 11-12). Donello was employ a means of demonstration that tazarotenic acid will treat acne alone (emphasis added). Therefore taking the cited art, it would have been obvious to one of ordinary skills to employ the teachings of Dow which discloses a oil-in-water with tazarotenic acid to treat acne because Donello clearly teaches that tazarotenic acid is useful in the treatment of acne.

Applicant argue that Donello formulations of microparticle biodegradable polymer formulations provides no reasonable expectation of success for use of other formulations. This argument the specific oil-in-water. And asserts that the examiner has not address this argument. This argument has been fully considered but has not been found persuasive. Dow tazarotene or tazarotenic acid salt is included in a composition of the present invention at a positive concentration less than 0.05 wt%. (para 0032). Dow teaches that a topical pharmaceutical composition of the present invention is in the dosage form of gel, emulsion (including lotion, cream, and milk), shampoo, foam, suspension, liquid, spray, paste or ointment. In certain preferred embodiments, a topical pharmaceutical composition of the present invention is an oil-in-water emulsion, in which an internal oil phase is dispersed in a continuous aqueous phase. Alternatively, water-in-oil-in-water, water-in-oil and oil-in-water-in-oil emulsions are also contemplated. The emulsion may be a macroemulsion, a microemulsion, or a nanoemulsion. The only thing that Dow does not disclose acne. However, Donello teaches a composition of only (e.g. sole agent) of **tazarotenic acid to treat acne vulgaris** (claims 11-12). Donello was employ a means of demonstration that tazarotenic acid will treat acne alone (emphasis added). Therefore taking the cited art, it would have been obvious to

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one of ordinary skills to employ the teachings of Dow which discloses a oil-in-water with tazarotenic acid to treat acne because Donello clearly teaches that tazarotenic acid is useful in the treatment of acne. Additionally, one would have a reasonable expectation of success because it is in the same field of endeavor and both Dow and Donello employ the same active agent (e.g. tazarotenic acid), while Dow disclose psoriasis and Donello clearly discloses the treatment of acne (in which both are skin diseases), it would have been obvious to employ the treatment of acne to the teachings of Dow because it is known in the art that tazarotenic acid treats acne.

Applicants argue again and in slightly varying ways that there is no reasonable expectation of success, however this simply is not true. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case,. Dow tazarotene or tazarotenic acid salt is included in a composition of the present invention at a positive concentration less than 0.05 wt%. (para 0032). Dow teaches that a topical pharmaceutical composition of the present invention is in the dosage form of gel, emulsion (including lotion, cream, and milk), shampoo, foam, suspension, liquid, spray, paste or ointment. In certain preferred embodiments, a topical pharmaceutical composition of the present invention is an oil-in-water emulsion, in which an internal oil phase is dispersed in a continuous aqueous phase. Alternatively, water-in-oil-in-water, water-in-oil and oil-in-water-in-oil emulsions are also contemplated. The emulsion may be a macroemulsion, a microemulsion, or a nanoemulsion. The only thing that Dow does not disclose acne. However, Donello

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teaches a composition of only (e.g. sole agent) of **tazarotenic acid to treat acne vulgaris** (claims 11-12). Donello was employ a means of demonstration that tazarotenic acid will treat acne alone (emphasis added). Therefore taking the cited art, it would have been obvious to one of ordinary skills to employ the teachings of Dow which discloses a oil-in-water with tazarotenic acid to treat acne because Donello clearly teaches that tazarotenic acid is useful in the treatment of acne. Additionally, one would have a reasonable expectation of success because it is in the same field of endeavor and both Dow and Donello employ the same active agent (e.g. tazarotenic acid), while Dow disclose psoriasis and Donello clearly discloses the treatment of acne (in which both are skin diseases), it would have been obvious to employ the treatment of acne to the teachings of Dow because it is known in the art that tazarotenic acid treats acne. The analysis that "should be made explicit" refers not to the teachings in the prior art of a motivation to combine, but to the court's analysis. . . . Under the flexible inquiry set forth by the Supreme Court, the district court therefore erred by failing to take account of 'the inferences and creative steps,' or even routine steps, that an inventor would employ and by failing to find a motivation to combine related pieces from the prior art." Ball Aerosol, 555 F.3d at 993, 89 USPQ2d at 1877. The Federal Circuit's directive in Ball Aerosol was addressed to a lower court, but it applies to Office personnel as well. When setting forth a rejection, Office personnel are to continue to make appropriate findings of fact as explained in MPEP § 2141 and § 2143, and must provide a reasoned explanation as to why the invention as claimed would have been obvious to a person of ordinary skill in the art at the time of the invention. This requirement for explanation remains even in situations in which Office personnel may properly rely on intangible

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realities such as common sense and ordinary ingenuity. Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; **(E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;**

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;

(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention (see MPEP 2143). In the instant claims E, F and G apply, it would have been obvious to one of ordinary skills to try because in the art to administer of tazarotenic acid to treat acne vulgaris. Thus, the many and various argument that there is no motivation to combine the art is moot in view supra.

Applicant's remarks constitute an analysis of Dow and Donello individually, without considering how the references were combined. Arguments lodged against the individual references in a piecemeal fashion without considering how all of the references were combined fails to be persuasive in establishing non-obviousness because it is the combined teachings that are the basis for a proper conclusion of obviousness, not each

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individual reference alone. In other words, it must be remembered that the references are relied upon in combination and are not meant to be considered separately. In fact, Applicant advocates an improper standard, i.e., that a reference applied under 35 U.S.C. 103(a) must explicitly teach the entire claimed invention in each single reference. This is the standard for anticipation under 35 U.S.C. 102, not obviousness under 35 U.S.C. 103(a). To properly conclude obviousness of an invention does not require the claimed invention to be expressly suggested in its entirety by any one single reference under 35 U.S.C. 103(a). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. Please see In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968) and In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant argue that obvious double patenting rejection over the the issue is not what the applications may or may not recite, but whether the instant claims would have been obvious from the claims of the '787 patent. The claims of the '787 patent are specifically directed towards a method of treating psoriasis (not acne as alleged) employing a composition comprising tazarotene and halobetasol propionate as combined active agents. While it is true that the '787 patent is treat psoriasis and the instant application is treating acne; however, both are skin disease and are treated with the very same active agent (e.g. tazarotenic acid). Therefore, both the instant application and the '787 patent possess overlapping scopes of inventions.

Applicant argue that obvious double patenting rejection over the issue is not what the applications may or may not recite, but whether the instant claims would have been

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obvious from the claims of the '895 patent. The claims of the '895 patent are specifically directed towards a method of treating psoriasis (not acne as alleged) employing a composition comprising tazarotene and halobetasol propionate as combined active agents. While it is true that the '895 patent is treat psoriasis and the instant application is treating acne; however, both are skin disease and are treated with the very same active agent (e.g. tazarotenic acid). Therefore, both the instant application and the '787 patent possess overlapping scopes of inventions.

Claim Rejections - 35 USC § 103

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

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-40 are rejected under 35 U.S.C. 103 as being unpatentable over Dow (WO 2016205001 (WO 001)) of record as disclosed in the IDS dated (7/19/2019) and Donello (U.S. Publication 2012/0328670) both are of record.

Dow teaches topical pharmaceutical compositions comprising a combination of active ingredients, and methods using the same, for treating psoriasis (para 0002). Dow teaches a composition comprising halobetasol (a corticosteroid) and tazarotene (a

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retinoid) is synergistically more efficacious than the combined efficacies (i.e., the sum of the efficacies) of compositions, each comprising only one of these active ingredients (pargra 0020). Dow teaches that the retinoid is present at a concentration below that which is presently utilized in topical formulations. For example, tazarotene or tazarotenic acid salt is included in a composition of the present invention at a positive concentration less than 0.05 wt%. (para 0032). Dow teaches the retinoid is present in the composition at a concentration in the range from about 0.001 to about 0.09 wt%, or from about 0.001 to about 0.08 wt%, or from about 0.001 to about 0.07 wt%, or from about 0.001 to about 0.06 wt%, or from about 0.01 to about 0.09 wt%, or from about 0.01 to about 0.08 wt%, or from about 0.01 to about 0.07 wt%, or from about 0.01 to about 0.06 wt%, or from about 0.001 to about 0.049 wt%, or from about 0.005 to about 0.045 wt%, or from about 0.005 to about 0.04 wt%, or from about 0.005 to about 0.03 wt%, or from about 0.005 to about 0.02 wt%, or from about 0.005 to about 0.01 wt%, or from about 0.01 to about 0.049 wt%, or from about 0.01 to about 0.045 wt%, or from about 0.02 to about 0.045 wt%, or from about 0.03 to about 0.045 wt%.(para 0033). Dow teaches that a topical pharmaceutical composition of the present invention is in the dosage form of gel, emulsion (including **lotion,** cream, and milk), shampoo, foam, suspension, liquid, spray, paste or ointment. In certain preferred embodiments, a topical pharmaceutical composition of the present invention is **an oil-in-water emulsion**, in which an internal oil phase is dispersed in a continuous aqueous phase. Alternatively, water-in-oil-in-water, water-in-oil and oil-in-water-in-oil emulsions are also contemplated. The emulsion may be a macroemulsion, a microemulsion, or a nanoemulsion. Also contemplated are other formulations in which an oil phase and a water phase coexist within the

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formulation, such as a multivesicular emulsion, which is not a true emulsion. Also contemplated is a liposomal dispersion in a gel, cream or other dosage form. Also contemplated are other formulations in which non-polar and polar liquid ingredients, with or without semipolar ingredients, coexist with the formulation (paragraph 0038).

Ingredient	Function	Concentration (wt%)			
		Range 1	Range 2	Range 3	Preferred embodiment
Halobetasol propionate	Class 1 Corticosteroid	0.001-0.04	0.005-0.03	0.005-0.02	0.01
Tazarotene	Retinoid	0.02-0.049	0.03-0.049	0.04-0.049	0.045
Diethyl sebacate	Liquid Oil & Solvent	1-5	2-4	2.5-3.5	2.97
Light mineral oil	Liquid Oil & Co-Solvent	5-15	5-10	7.5-8.5	8.03
Sorbitan monooleate	Surfactant/ Emulsifying Agent	0.01-1	0.02-0.5	0.05-0.2	0.1
Sorbitol solution, 70%	Humectant	5-15	7-12	10-11	10.7
Methyl paraben	Antimicrobial Preservative(1)	0.05-0.3	0.1-0.3	0.1-0.2	0.17
Propyl paraben	Antimicrobial Preservative(1)	0.01-0.1	0.01-0.05	0.02-0.04	0.03
Edetate disodium dihydrate	Chelating Agent(1)	0.02-0.1	0.02-0.7	0.03-0.06	0.05
Carbomer copolymer type B (e.g., Pemulen™ TR-1)	Emulsifying Agent	0.1-1	0.2-0.7	0.3-0.5	0.4
Carbomer homopolymer type A (e.g., Carbomer 981)	Thickener	0.2-1.5	0.3-1	0.5-0.7	0.6
Sodium hydroxide, 10% Solution	pH-adjusting Agent(1)	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5
Purified water	Carrier	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100

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(table 2 with specific amounts in table 4 (which are the same amounts as disclosed in instant claim 40)). Dow teaches in table 8-9 the topical administration up to 12 weeks.

Dow does not teach acne.

Donello teaches a composition of only (emphasis added) tazarotenic acid or a pharmaceutically acceptable salt, ester or amid thereof (claim 10). Donello teaches the treatment of skin disorders such as acne vulgaris with the administration of tazarotenic acid (claim 11-12).

It would have been obvious to employ tazarotenic acid as the sole agent in the treatment of acne in view of Dow. One would have been motivated to employ tazarotenic acide because it is known that topically administered tazarotenic acid is effective in the treatment of skin disorders (e.g. psoriasis and acne) as disclosed by both Dow and Donello with a reasonable expectation of success absence evidence to the contrary.

With regards the limitation "wherein the tazarotene or tazarotenic acid salt is dissolved in a liquid oil component of the emulsion", since it is known in the art that the composition is in an oil-in-water emulsion as disclose by Dow, it would have been obvious that in order to obtain the oil-in-water emulsion, the active agent would have been dissolved in an oil. Furthermore, the instant claims are drawn to a method of treating acne not a method of preparing said composition.

For these reasons, the claimed subject matter is deemed to fail to be patentably distinguishable over the state of the art as represented by the cited reference. The

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claims are therefore, properly rejected under 35 U.S.C. 103.In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*,

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686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 13-40 rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 10,426,787. Although the claims at

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issue are not identical, they are not patentably distinct from each other because both application recite the administration of tazarotene to treat acne. The difference between the instant application and the '787 patent is that the '787 also recites halobetasol, however the instant claims do not preclude a combination therapy to treat acne. Thus, the instant application and the '787 patent possess significant overlapping scopes of invention.

Claims 13-40 rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 10,251,895. Although the claims at issue are not identical, they are not patentably distinct from each other because both application recite the administration of tazarotene to treat acne. The difference between the instant application and the '895 patent is that the '895 also recites halobetasol, however the instant claims do not preclude a combination therapy to treat acne. Thus, the instant application and the '895 patent possess significant overlapping scopes of invention.

Claims 13-40 is provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4, 6-12, 24-28 of copending Application No. 16/179,576. Although the claims at issue are not identical, they are not patentably distinct from each other because both the instant claims and the '576 application recite a composition (tazarotene) for the treatment of acne. Taken that both applications disclose the same compound (tazarotene) to treat acne, one of ordinary skills in the art would recognize that both application possess significant overlapping scopes of invention with a reasonable expectation of success.

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This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Claims 13-40 is rejected.

No claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN ANN CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached on Monday - Thursday 8-6pm.

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Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. 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.

/KATHRIEN A CRUZ/
Primary Examiner, Art Unit 1627

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/179,561	Arturo et al.
	Examiner	Art Unit
	KATHRIEN A CRUZ	1627

CPC - Searched*		
Symbol	Date	Examiner

CPC Combination Sets - Searched*		
Symbol	Date	Examiner
A61K31/4436 OR A61K47/06 OR A61K47/14 OR A61K47/32 OR A61K47/34 OR A61K47/44 OR A61K9/0014 OR A61K9/06 OR A61K9/107 OR A61P17/00 OR A61P17/10	08/05/2020	kc

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	03/15/2019	kc
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	10/23/2019	kc
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	02/24/2020	kc
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	08/05/2020	kc
INVENTOR	08/05/2020	kc

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/179,561	Arturo et al.
	Examiner	Art Unit
	KATHRIEN A CRUZ	1627

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	11	"10426787"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/08/05 12:36
L2	3	((("ARTURO") near3 ("Angel")) and (("PILLAI") near3 ("Radhakrishnan"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/08/05 12:45
L3	3	L2	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/08/05 12:45
L4	10,103	tazarotene	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/08/05 12:45
L5	3,579	L4 and acne	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/08/05 12:45
L6	2,707	L5 and @py<"2017"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/08/05 12:45
L7	556	L6 and "acne vulgaris"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/08/05 12:45
L8	556	L7	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/08/05 12:45
L9	556	L8	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/08/05 12:45
L10	2	"20190133942".pn.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/08/05 12:45

L11	121,604	(A61K31/4436 OR A61K47/06 OR A61K47/14 OR A61K47/32 OR A61K47/34 OR A61K47/44 OR A61K9/0014 OR A61K9/06 OR A61K9/107 OR A61P17/00 OR A61P17/10).CPC.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/08/05 12:46
L12	60	L11 and "tazaroten"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/08/05 12:47
L13	6	l12 and acne	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/08/05 12:47

EAST Search History (Interference)

<This search history is empty>

8/5/2020 12:47:34 PM
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Confirmation No.: 1370

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Angel, Arturo
Applicant:	Valeant Pharmaceuticals North America
Application No.:	16/179,561
Filed:	November 2, 2018
Examiner:	CRUZ, KATHRIEN ANN
Group/Art Unit:	1627
Atty. Docket No.:	99336.000343
Title:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

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

June 25, 2020

Amendment

Dear Sir:

This Response is to the Non-Final Office Action dated February 27, 2020; the Applicant hereby amends the above-referenced application as follows:

Amendments to the Specification: none.

Amendments to the Claims: begin at page 2 of this paper.

Amendments to the Drawings: none.

Remarks/Arguments: begin at page 8 of this paper.

Appendix: none.

This Amendment is filed with a petition for, and fee payment of, a one-month extension to the shortened statutory period for reply recited in the above referenced Office Action. Should the undersigned representative be mistaken as to time or fee, please consider this petition for whatever extension of time is necessary to effect this Amendment and/or charge Deposit Account No. 03-3875 of Harter Secrest & Emery LLP for any required deficiency.

Amendments to the Claims

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

1-12. (Cancelled)

13. **(Previously presented)** A method of treating acne vulgaris, the method comprising topically applying a pharmaceutical composition to an affected area of a body of a subject suffering from acne vulgaris; wherein the composition comprises:

tazarotene or a pharmaceutically acceptable tazarotenic acid salt present in the composition at a positive concentration from about 0.01 to 0.049 percent by weight of the composition; and

a dermatologically acceptable oil-in-water emulsion vehicle; wherein said composition is an oil-in-water emulsion lotion.

14. **(Previously presented)** The method of claim 13, wherein the composition comprises tazarotene at a concentration of from about 0.03 to 0.049 percent by weight of the composition.

15. **(Previously presented)** The method of claim 13, wherein the composition comprises tazarotene at a concentration of about 0.045 percent by weight of the composition.

16. **(original)** The method of claim 13, wherein said emulsion comprises:

an aqueous phase comprising water, a carbomer homopolymer, and a polymeric emulsifier; and

an oil phase comprising at least one member selected from the group consisting of a dicarboxylic acid ester and a mineral oil.

17. **(original)** The method of claim 16, wherein the oil phase of the emulsion comprises diethyl sebacate.

18. **(original)** The method of claim 13, wherein the oil phase of the emulsion comprises diethyl sebacate and mineral oil.

19. **(original)** The method of claim 13, wherein the oil phase of the emulsion consists of diethyl sebacate and mineral oil.

20. **(original)** The method of claim 13, wherein said applying is carried out once per day for at least eight weeks.

21. **(original)** The method of claim 13, wherein said applying is carried out once per day for at least twelve weeks.

22. **(original)** The method of claim 13, wherein said applying is carried out once per day for twelve weeks.

23. **(original)** The method of claim 13, wherein the pharmaceutical composition contains the tazarotene or the tazarotenic acid salt as a sole active pharmaceutical ingredient.

24. **(Previously presented)** The method of claim 23, wherein the composition comprises tazarotene at 0.03 to 0.049 percent by weight of the composition.

25. **(Previously presented)** The method of claim 23, wherein the composition comprises tazarotene at about 0.045 percent by weight of the composition.

26. **(Previously presented)** The method of claim 25, wherein the tazarotene or tazarotenic acid salt is dissolved in a liquid oil component of the emulsion.

27. **(Previously presented)** The method of claim 25, wherein an oil phase of the emulsion comprises a liquid oil component comprising a dicarboxylic acid ester ("DCAE"), a monocarboxylic acid ester ("MCAE"), or combinations thereof.

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28. **(Previously presented)** The method of claim 25, wherein an oil phase of the emulsion comprises diethyl sebacate.

29. **(Previously presented)** The method of claim 25, wherein an aqueous phase of the emulsion comprises water and a carbomer homopolymer.

30. **(Previously presented)** The method of claim 25, wherein the composition has a pH of about 4 to about 6.

31. **(Previously presented)** The method of claim 13, wherein the tazarotene or tazarotenic acid salt is dissolved in a liquid oil component of the emulsion.

32. **(Previously presented)** The method of claim 13, wherein an oil phase of the emulsion comprises a liquid oil component comprising a dicarboxylic acid ester ("DCAE"), a monocarboxylic acid ester ("MCAE"), or combinations thereof.

33. **(Previously presented)** The method of claim 13, wherein an oil phase of the emulsion comprises diethyl sebacate.

34. **(Previously presented)** The method of claim 13, wherein an aqueous phase of the emulsion comprises water and a carbomer homopolymer.

35. **(Previously presented)** The method of claim 13, wherein the composition has a pH of about 4 to about 6.

36. **(Previously presented)** The method of claim 13, wherein the composition consists essentially of:

0.01 – 0.049 weight % tazarotene;

diethyl sebacate;

light mineral oil;

sorbitan monooleate;

sorbitol solution, 70%;

methylparaben;

propylparaben;

edetate disodium dihydrate;

carbomer polymer type B;

carbomer homopolymer type A;

sodium hydroxide;

purified water.

37. **(Previously presented)** The method of claim 13, wherein the composition consists essentially of:

0.02 – 0.049 weight % tazarotene;

1 - 5 weight % diethyl sebacate;

5 - 15 weight % light mineral oil;

0.01 - 1 weight % sorbitan monooleate;

5 - 15 weight % sorbitol solution, 70%;

0.05 - 0.3 weight % methylparaben;

0.01 – 0.1 weight % propylparaben;

0.02 – 0.1 weight % edetate disodium dihydrate;

0.1 - 1 weight % carbomer polymer type B;

0.2 – 1.5 weight % carbomer homopolymer type A;

sodium hydroxide, q.s. to pH 5.5 ±0.5; and

purified water, q.s. to 100 weight %.

38. **(Previously presented)** The method of claim 13, wherein the composition consists essentially of:

0.03 – 0.049 weight % tazarotene;

2 - 4 weight % diethyl sebacate;

5 - 10 weight % light mineral oil;

0.02 – 0.5 weight % sorbitan monooleate;

7 - 12 weight % sorbitol solution, 70%;

0.1 - 0.3 weight % methylparaben;

0.01 – 0.05 weight % propylparaben;

0.02 – 0.7 weight % edetate disodium dihydrate;

0.2 – 0.7 weight % carbomer polymer type B;

0.3 – 1 weight % carbomer homopolymer type A;

sodium hydroxide, q.s. to pH 5.5 ±0.5; and

purified water, q.s. to 100 weight %.

39. **(Previously presented)** The method of claim 13, wherein the composition consists essentially of:

0.04 – 0.049 weight % tazarotene;

2.5 – 3.5 weight % diethyl sebacate;

7.5 – 8.5 weight % light mineral oil;

0.05 – 0.2 weight % sorbitan monooleate;

10 - 11 weight % sorbitol solution, 70%;

0.1 - 0.2 weight % methylparaben;

0.02 – 0.04 weight % propylparaben;

0.03 – 0.06 weight % edetate disodium dihydrate;

0.3 – 0.05 weight % carbomer polymer type B;

0.5 – 0.7 weight % carbomer homopolymer type A;

sodium hydroxide, q.s. to pH 5.5 ±0.5; and

purified water, q.s. to 100 weight %.

40. **(Previously presented)** A method of treating acne vulgaris, the method comprising topically applying a pharmaceutical composition to an affected area of a body of a subject suffering from acne vulgaris; wherein the composition consists essentially of:

0.045 weight % tazarotene;

2.97 weight % diethyl sebacate;

8.03 weight % light mineral oil;

0.1 weight % sorbitan monooleate;

10.7 weight % sorbitol solution, 70%;

0.17 weight % methylparaben;

0.03 weight % propylparaben;

0.05 weight % edetate disodium dihydrate;

0.4 weight % carbomer polymer type B;

0.6 weight % carbomer homopolymer type A;

sodium hydroxide, q.s. to pH 5.5 ±0.5; and

purified water, q.s. to 100 weight %.

REMARKS/ARGUMENTS

In response to the Office Action of February 27, 2020, the present application has been carefully reviewed. Entry of the present amendment and reconsideration of the application are respectfully requested.

Status of the Claims

Claims 13-40 are rejected under 35 U.S.C. § 103 as being unpatentable over WO 2016205001 and Donello (US 2012/0328670).

Claims 13-40 are rejected on the grounds of nonstatutory double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 10,426,787.

Claims 13-40 are rejected on the grounds of nonstatutory double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 10,251,895.

Claims 13-40 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4, 6-12, 24-28 of copending Application No. 16/179,576.

Applicant respectfully traverses these rejections for the reasons set forth below.

Rejection of claims 13-40 under 35 U.S.C. § 103 as being unpatentable over WO 2016205001 and Donello (US 2012/0328670)

Applicant respectfully traverses this rejection with respect to the present claims because WO 2016205001 and Donello do not teach or suggest all of the combined limitations of independent claims 13 and 40. In such regard, the Examiner fails to consider the actual teachings of such references relative to the claimed invention, as well as the examples presented in the application which demonstrate the surprising efficacy of the claimed invention.

To demonstrate that a claim is obvious, the party asserting invalidity must present evidence that all limitations of the claim are taught or suggested in the prior art. *Fresenius USA, Inc. v. Baxter Int'l, Inc.* 582 F.3d 1288, 1296 (Fed. Cir. 2009). See also *Ex parte Reed* (BPAI, Jul. 14, 2009, Slip op., p. 7) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)) ("To establish

prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art."). In addition, "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." MPEP § 2143.03 (9th Ed., Rev. 08.2017, Jan. 2018, p. 2100-235) (quoting *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970).

Nowhere in either of WO 2016205001 or Donello is there teaching or suggestion of a method of treating acne with a composition comprising tazarotene in an oil-in-water emulsion at a tazarotene concentration of from about 0.01 to 0.049 percent by weight, as recited in independent claim 13, or more specifically treating acne with a composition consisting essentially of 0.045 percent by weight tazarotene and the further components as recited in independent claim 40. Thus, neither WO 2016205001 or Donello teach or suggest all of the limitations of the pending claims.

While WO 2016205001 discloses an oil-in-water formulation comprising tazarotene at 0.045 wt% as a sole pharmaceutically active ingredient, the Examiner acknowledges it does not disclose use of the disclosed formulations specifically for the treatment of acne. The Examiner asserts Donello teaches the treatment of acne vulgaris with the administration of tazarotenic acid (citing claims 11-12), and asserts that it would have been "obvious to employ tazarotenic acid as the sole agent in the treatment of acne in view of Dow," as one would have been motivated to do so because it is known that topically administered tazanoic acid is effective in the treatment of skin disorders (e.g., psoriasis and acne) as disclosed by both Dow and Donello with a reasonable expectation of success absence evidence to the contrary.

"To reject a claim based on [teaching, suggestion, or motivation] rationale, Office personnel must resolve the *Graham* factual inquiries. Then Office personnel must articulate the following:

(1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference . . .;

(2) a finding that there was reasonable expectation of success . . .."

MPEP § 2143 (9th Ed., Rev. 08.2017, Jan. 2018, p. 2100-230) (Emphasis added).

The Examiner appears to continue to assert that the motivation to employ the 0.045 wt% tazarotene oil-in-water emulsion formulation disclosed in WO 2016205001 in the treatment of acne is based on an alleged "reasonable expectation of success" based on both WO 2016205001 and Donello teaching use of tazarotene formulations for treatment of skin disorders, and Donello specifically teaching use of tazarotene for treatment of acne.

The rejection, however, fails to address Applicant's arguments that there would be no reasonable expectation of success for use of an oil-in-water emulsion formulation containing the claimed concentration of tazarotene in the treatment of acne based on the actual teachings of WO 2016205001 and Donello, as Donello is instead specifically directed towards, and only actually demonstrates, use of microspheres comprising biodegradable polymer and tazarotene for reducing sebaceous gland size, while other non-microsphere based formulations (including vehicle alone, or Tazorac® gel formulation) were found to not be effective at significantly reducing sebaceous gland size (see, e.g., Fig. 2 and [0050] of Donello). As reduction of sebum is the only proposed effect for expected success in treating acne disclosed in Donello (see, e.g., [0016]), and as the only formulations disclosed in Donello which demonstrate significant reduction in sebaceous gland size are microparticle biodegradable polymer formulations as opposed to oil-in-water formulations (and to the contrary, other tazarotene formulations such as formulations such as Tazorac® gel even at a higher concentration (0.1%) than that claimed in the present invention was found to not be effective at significantly reducing sebaceous gland size), **Donello thus clearly does not provide any evidence of any reasonable expectation of success for formulations other than the microsphere particle based formulations thereof for the treatment of acne.**

In the "Response to Arguments" section of the February 27, 2020 Office Action, the Examiner states "Applicant argues that Donello formulation does not significantly reduce sebaceous," and that this argument is not persuasive because "Applicant appears to incorporate limitation in which are not presented in the instant claims, no where does the claims recite a significant reduction of sebaceious, in fact the combination does work." Such statement, however, mischaracterizes Applicant's arguments as actually set forth above, which are based on

distinctions between the actual teachings of Donello and the present invention. Applicant does not simply argue that "Donello formulation does not significantly reduce sebaceous," but rather that Donello demonstrates that only the microparticle biodegradable polymer formulations thereof demonstrate significant reduction in sebaceous gland size, and that Donello thus provides no reasonable expectation of success for use of other formulations of tazarotene at treating acne. Such argument is based on what Donello might reasonably suggest to one skilled in the art based on the actual teachings thereof with respect to use of tazarotene for treatment of acne, and it is simply not relevant that the instant claims do not recite a significant reduction of sebaceous gland size. Rather, as this is the only basis for any expectation of success in the treatment of acne actually disclosed in Donello, and as Donello actually teaches that other tazarotene formulations (i.e., distinct from the microparticle biodegradable polymer formulations thereof such as formulations such as Tazorac® gel even at a higher concentration (0.1%) than that claimed in the present invention) were found to not be effective at significantly reducing sebaceous gland size, Donello itself does not teach or suggest that the present claimed method of treating acne "does work," but rather it is only Applicant's teachings which demonstrate such method works. It is clearly improper, however, to rely on Applicant's own teachings as the basis for an obviousness rejection. Rather, the actual teachings of Donello clearly do not provide any evidence of any reasonable expectation of success for formulations other than the microsphere particle based formulations thereof for the treatment of acne.

Thus, in view of the clear lack of any reasonable expectation of success of the present claimed invention based on the actual teachings of Donello (which instead appears to teach the described microparticle biodegradable polymer formulations are required to obtain the aim result of reduction in sebaceous gland size, in comparison to ineffective results obtained for other tazarotene containing formulations), a *prima facie* case of obviousness has clearly not been established.

Such rejection is also in any event in further clear error, as the Examiner has failed to consider factual evidence submitted in the instant specification which clearly demonstrates an unexpected benefit of the claimed invention. Consistent with the rule that all evidence of nonobviousness must be considered when assessing patentability, the PTO must

consider comparative data in the specification in determining whether the claimed invention provides unexpected results. *In re Margolis*, 785 F.2d 1029, 1031, 228 USPQ 940, 941-42 (Fed. Cir. 1986). More specifically, the Examiner has not articulated any reason why there would be reasonable expectation of success for the claimed use of the specific claimed oil-in-water tazarotene formulation for treatment of acne, wherein the tazarotene has been reduced to less than half the concentration of tazarotene in Tazorac® 0.1%, as required by the present jurisprudence and the MPEP guidance. *In re Kahn*, 441 F.3d 977, 987 (Fed. Cir. 2006) (A fact finder "must provide some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct. . . . [T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."); *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 418; 127 S.Ct. 1727, 1741 (2007) ("Rejection on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."). In particular, the Examiner has not articulated the reason why there would be reasonable expectation of success for achieving better treatment efficacy in an oil-in-water tazarotene formulation when the tazarotene concentration is reduced to less than half of the concentration of tazarotene in Tazorac® 0.1%, while the cited reference relied upon for use of tazarotene in treating acne only demonstrates effectiveness of microsphere biodegradable particle formulations in reducing sebaceous gland size, and non-effectiveness of Tazorac® 0.1% formulations.

In contradistinction, the present inventors unexpectedly and surprisingly discovered that the presently claimed method of treating acne employing an oil-in-water emulsion composition having less than 0.05% tazarotene is more efficacious in treating acne than a commercial emulsion having 0.1% tazarotene, at least as measured by Evaluator's Global Severity Score ("EGSS") and reduction of inflammatory lesions. *In re Soni*, 34 U.S.P.Q.2d 1684, 1687 ("[T]hat which would have been surprising to a person of ordinary skill in a particular art would not have been obvious."). See Tables 6 and 7 of the present specification, as filed, which presents factual evidence for Composition A (having 0.045 wt% tazarotene in an oil-in-water formulation as identified in Table 2 of the specification) in accordance with the present claimed invention in comparison to placebo and 0.1 wt% tazarotene cream, which clearly demonstrates an unexpected

benefit of the claimed invention. For the Examiner's convenience, Tables 6 and 7 are again reproduced immediately below.

TABLE 6

Treatment % Success (ITT) at 12 Weeks

	Combined Placebo N = 69	Composition A N = 69	Tazorac ® 0.1% Cream N = 72
EGSS - Clear or Almost Clear	10.1%	18.8%	16.7%
Inflammatory Lesions			
Absolute Change	−14.0	−18.1	−16.8
% Change	−51.41%	−63.75%	−59.99%
Non-inflammatory Lesions			
Absolute Change	−13.1	−21.6	−20.3
% Change	−35.18%	−56.86%	−54.09%

TABLE 7

Treatment % Success (PP)

	Combined Placebo N = 57	Composition A N = 54	Tazorac ® 0.1% Cream N = 56
EGSS - Clear or Almost Clear	12.3%	20.4%	16.1%
Inflammatory Lesions	−14.2	−18.3	−18.2
Non-inflammatory Lesions	−11.8	−20.8	−21.9

Since use of a composition having a tazarotene concentration less than half of the concentration of Tazorac® 0.1%, as required by independent claims 13 and 40, is surprisingly more efficacious in treating acne than a composition having the same concentration as Tazorac® 0.1%, the claimed invention is clearly nonobvious. **Such demonstrated evidence of surprising results in fact constitutes "evidence to the contrary" with respect to the asserted obviousness rejection**. Thus, the proposed obviousness rejection, based on the distinct teachings of Donello in combination with WO 2016205001 and in consideration of all the evidence of record, clearly fails to establish obviousness.

In the "Response to Arguments," the Examiner argues Applicant's arguments that no reason has been articulated why there would be a reasonable expectation of success for use of the specific

claimed oil-in-water emulsion [for treating acne] has been fully considered but is not found persuasive as WO 2016205001 teaches oil-in-water emulsion formulations comprising less than 0.05 wt% tazarotene, and that the only thing it does not disclose is treatment of acne, and that Donello was employed as a means of demonstrating that tazarotenic acid will treat acne alone. Such argument again **fails to consider the actual teachings of Donello**, which instead only teach that the microparticle biodegradable polymer formulations thereof demonstrate significant reduction in sebaceous gland size, and thus are predicted to be effective at treating acne, **as well failing to consider the demonstrated showing of unexpected results obtained for the disclosed examples in accordance with the present claimed invention**. To the contrary, the further actual teachings of Donello that other formulations of tazarotene were not found to be effective at reducing sebaceous gland size would appear to provide a clear lack of reasonable expectation of success for use of other formulations of tazarotene in treating acne in accordance with the present claimed invention, while the examples of the invention demonstrate the surprisingly more efficacious treatment of acne. The Examiner's failure to consider such actual teachings of the cited references and demonstrated showing of surprising results in the present application represents clear error in the asserted obviousness rejection.

Rejection of claims 13-40 on the ground of nonstatutory double patenting

Claims 13-40 were rejected on the grounds of nonstatutory double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 10,426,787. The Examiner asserts the claims are not patentably distinct from each other because "both application recite the administration of tazarotene to treat acne," with the difference between the instant application and the '787 patent is that the '787 patent also recites halobetasol, but the instant claims "do not preclude a combination therapy to treat acne," and that thus, the instant application and the '787 patent "possess significant overlapping scopes of invention." This rejection is respectfully traversed, as the issue is not what the applications may or may not recite, but whether the instant claims would have been obvious from the claims of the '787 patent. The claims of the '787 patent are specifically directed towards a method of treating psoriasis (not acne as alleged) employing a composition comprising tazarotene and halobetasol propionate as combined active agents, while

the present application claims are specifically directed towards a method of treating acne vulgaris employing a composition comprising tazarotene as the pharmaceutical active agent. Thus, instead of having "significant overlapping scopes of invention" as asserted by the Examiner, it is clear to one skilled in the art that such claims are instead clearly directed towards non-overlapping, mutually distinct inventions, and accordingly would not have been obvious in view of each other.

Claims 1, 4, 6-12 and 24-28 were rejected on the grounds of nonstatutory double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 10,251,895. The Examiner asserts the claims are not patentably distinct from each other because "both application recite the administration of tazarotene to treat acne," with the difference between the instant application and the '895 patent is that the '895 patent also recites halobetasol, but the instant claims "do not preclude a combination therapy to treat acne," and that thus, the instant application and the '895 patent possess significant overlapping scopes of invention." This rejection is respectfully traversed, as the issue is not what the applications may or may not recite, but whether the instant claims would have been obvious from the claims of the '895 patent. The claims of the '895 patent are specifically directed towards a pharmaceutical composition for treating psoriasis (not acne as alleged) comprising tazarotene and halobetasol propionate as combined active ingredients, while the present application claims are specifically directed towards a method of treating acne vulgaris employing a composition comprising tazarotene as the pharmaceutical active agent. Thus, instead of having "significant overlapping scopes of invention" as asserted by the Examiner, it is clear to one skilled in the art that such claims are instead clearly directed towards non-overlapping, mutually distinct inventions, and accordingly would not have been obvious in view of each other.

Claims 13-40 were provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 4, 6-12, and 24-28 of copending Application No. 16/179,576. As this is a provisional rejection, Applicant requests to defer filing of any required Terminal Disclaimer, or cancelling of corresponding claims in one of the applications, until

otherwise allowable claims are indicated, as no claims have yet been indicated as otherwise being allowable.

CONCLUSION

In view of the amendments and remarks having addressed all of the objections raised by the Examiner, reconsideration and allowance is courteously requested. Should the Examiner consider that additional amendments are necessary to place this application in condition for allowance, the favor is requested of a telephone call to the undersigned for the purposes of discussing such amendments.

Extension of Time

Applicant petitions for a one-month Extension of Time. The required fee accompanies this reply.

Precautionary Fee-Charge Authorization

By way of precaution, the Commissioner is authorized to charge any underpayment of fees or fee amounts not otherwise authorized but necessary for the consideration of this paper or the continued pendency of this application and to credit any overpayment to Deposit Account Number 03-3875 of Harter Secrest & Emery LLP.

Please grant any extensions of time necessary for the filing of this Amendment.

Respectfully submitted,

/Andrew J. Anderson/

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Electronic Patent Application Fee Transmittal	
Application Number:	16179561
Filing Date:	02-Nov-2018
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Angel Arturo
Filer:	Andrew James Anderson/Bethany Weber
Attorney Docket Number:	99336.000343
Filed as Large Entity	
Filing Fees for Utility under 35 USC 111(a)	

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($)
Extension - 1 month with $0 paid	1251	1	200	200
Miscellaneous:				
		Total in USD ($)		**200**

Electronic Acknowledgement Receipt	
EFS ID:	39828424
Application Number:	16179561
International Application Number:	
Confirmation Number:	1370
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Angel Arturo
Customer Number:	134756
Filer:	Andrew James Anderson/Bethany Weber
Filer Authorized By:	Andrew James Anderson
Attorney Docket Number:	99336.000343
Receipt Date:	25-JUN-2020
Filing Date:	02-NOV-2018
Time Stamp:	14:54:45
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$200
RAM confirmation Number	E20206OE54572738
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		99336-343_Response_to_OA.pdf	520290 af89e349bf95f7d8390f1c237ee1b4448f45f130	yes	16
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	7	
	Applicant summary of interview with examiner		8	16	
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	31118 df425ea55a47b9a97da2e8a936e0eb5a29600bc6	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	551408		

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
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.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/179,561	Filing Date 11/02/2018	☐ 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 $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ 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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	06/25/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 28	Minus	** 28	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0		x $460 =	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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ 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.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/DEIDRE C KING-WOODWARD/
*** 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.	

This collection of information is required by 37 CFR 1.16. 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, 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Padagis Ex. 1002
IPR Petition - USP 11,311,482

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/179,561	11/02/2018	Angel Arturo	99336.000343	1370

134756 7590 02/27/2020

HSE/Valeant
1600 Bausch & Lomb Place
Rochester, NY 14604

EXAMINER
CRUZ, KATHRIEN ANN

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
02/27/2020	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@hselaw.com

Office Action Summary	Application No. 16/179,561	Applicant(s) Arturo et al.	
	Examiner KATHRIEN A CRUZ	Art Unit 1627	AIA (FITF) Status Yes

-- 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 MONTHS 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 1/28/2020.

☐ 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) 13-40 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) 13-40 is/are rejected.

8) ☐ Claim(s) _____ 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 _____ 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/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

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

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Upon careful consideration, the Final rejection dated 10/28/2020 is hereby vacated and a Non-Final Rejected is made below.

DETAILED ACTION

Claims 13-40 is pending.

Applicants response filed 1/28/2020 has been received and entered in the application.

Action Summary

Claims 13-40 are rejected under 35 U.S.C. 103 as being unpatentable over WO 2016205001 (WO 001) of record as disclosed in the IDS dated (7/19/2019) and Donello (U.S. Publication 2012/0328670) is maintained.

Claims 1-23 is provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-23 of copending Application No. 15/977088 (reference application) is maintained in part (13-23 and newly added claims) is withdrawn.

Claims 1-23 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-23 of copending Application No. 16/179,576 (reference application) is withdrawn due to applicant's amendment of claims.

Padagis Ex. 1002
IPR Petition - USP 11,311,482

Response to Arguments

Applicant argues that Donello formulation does not significantly reduce sebaceous. This argument has been fully considered but has not been found persuasive. Applicants appear to incorporate limitation in which are not presented in the instant claims, no where does the claims recite a significant reduction of sebaceious, in fact the combination does work.

Applicants argues that the examiner does not articulate any reason why there would be a reasonable expectation of success for use of the specific oil-in-water. This argument has been fully considered but has not been found persuasive. Down tazarotene or tazarotenic acid salt is included in a composition of the present invention at a positive concentration less than 0.05 wt%. (para 0032). Dow teaches that a topical pharmaceutical composition of the present invention is in the dosage form of gel, emulsion (including lotion, cream, and milk), shampoo, foam, suspension, liquid, spray, paste or ointment. In certain preferred embodiments, a topical pharmaceutical composition of the present invention is an oil-in-water emulsion, in which an internal oil phase is dispersed in a continuous aqueous phase. Alternatively, water-in-oil-in-water, water-in-oil and oil-in-water-in-oil emulsions are also contemplated. The emulsion may be a macroemulsion, a microemulsion, or a nanoemulsion. The only thing that Dow does not disclose acne. However, Donello teaches a composition of only (e.g. sole agent) of tazarotenic acid to treat acne vulgaris (claims 11-12). Donello was employ a means of demonstration that tazarotenic acid will treat acne alone (emphasis added).

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Claim Rejections - 35 USC § 103

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

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-40 are rejected under 35 U.S.C. 103 as being unpatentable over WO 2016205001 (WO 001) of record as disclosed in the IDS dated (7/19/2019) and Donello (U.S. Publication 2012/0328670) both are of record.

Dow teaches topical pharmaceutical compositions comprising a combination of active ingredients, and methods using the same, for treating psoriasis (para 0002). Dow teaches a composition comprising halobetasol (a corticosteroid) and tazarotene (a retinoid) is synergistically more efficacious than the combined efficacies (i.e., the sum of the efficacies) of compositions, each comprising only one of these active ingredients (pargra 0020). Dow teaches that the retinoid is present at a concentration below that which is presently utilized in topical formulations. For example, tazarotene or tazarotenic acid salt is included in a composition of the present invention at a positive concentration less than 0.05 wt%. (para 0032). Dow teaches the retinoid is present in the composition at a concentration in the range from about 0.001 to about 0.09 wt%, or from about 0.001 to about 0.08 wt%, or from about 0.001 to about 0.07 wt%, or from about 0.001 to about 0.06 wt%, or from about 0.01 to about 0.09 wt%, or from about 0.01 to about 0.08 wt%, or from about 0.01 to about 0.07 wt%, or from about 0.01 to about 0.06 wt%, or from

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about 0.001 to about 0.049 wt%, or from about 0.005 to about 0.045 wt%, or from about 0.005 to about 0.04 wt%, or from about 0.005 to about 0.03 wt%, or from about 0.005 to about 0.02 wt%, or from about 0.005 to about 0.01 wt%, or from about 0.01 to about 0.049 wt%, or from about 0.01 to about 0.045 wt%, or from about 0.02 to about 0.045 wt%, or from about 0.03 to about 0.045 wt%.(para 0033). Dow teaches that a topical pharmaceutical composition of the present invention is in the dosage form of gel, emulsion (including **lotion,** cream, and milk), shampoo, foam, suspension, liquid, spray, paste or ointment. In certain preferred embodiments, a topical pharmaceutical composition of the present invention is **an oil-in-water emulsion**, in which an internal oil phase is dispersed in a continuous aqueous phase. Alternatively, water-in-oil-in-water, water-in-oil and oil-in-water-in-oil emulsions are also contemplated. The emulsion may be a macroemulsion, a microemulsion, or a nanoemulsion. Also contemplated are other formulations in which an oil phase and a water phase coexist within the formulation, such as a multivesicular emulsion, which is not a true emulsion. Also contemplated is a liposomal dispersion in a gel, cream or other dosage form. Also contemplated are other formulations in which non-polar and polar liquid ingredients, with or without semipolar ingredients, coexist with the formulation (paragraph 0038).

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Ingredient	Function	Concentration (wt%)			
		Range 1	Range 2	Range 3	Preferred embodiment
Halobetasol propionate	Class 1 Corticosteroid	0.001-0.04	0.005-0.03	0.005-0.02	0.01
Tazarotene	Retinoid	0.02-0.049	0.03-0.049	0.04-0.049	0.045
Diethyl sebacate	Liquid Oil & Solvent	1-5	2-4	2.5-3.5	2.97
Light mineral oil	Liquid Oil & Co-Solvent	5-15	5-10	7.5-8.5	8.03
Sorbitan monooleate	Surfactant/ Emulsifying Agent	0.01-1	0.02-0.5	0.05-0.2	0.1
Sorbitol solution, 70%	Humectant	5-15	7-12	10-11	10.7
Methyl paraben	Antimicrobial Preservative(1)	0.05-0.3	0.1-0.3	0.1-0.2	0.17
Propyl paraben	Antimicrobial Preservative(1)	0.01-0.1	0.01-0.05	0.02-0.04	0.03
Edetate disodium dihydrate	Chelating Agent(1)	0.02-0.1	0.02-0.7	0.03-0.06	0.05
Carbomer copolymer type B (e.g., Pemulen™ TR-1)	Emulsifying Agent	0.1-1	0.2-0.7	0.3-0.5	0.4
Carbomer homopolymer type A (e.g., Carbomer 981)	Thickener	0.2-1.5	0.3-1	0.5-0.7	0.6
Sodium hydroxide, 10% Solution	pH-adjusting Agent(1)	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5
Purified water	Carrier	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100

(table 2 with specific amounts in table 4 (which are the same amounts as disclosed in instant claim 40)). Dow teaches in table 8-9 the topical administration up to 12 weeks.

Dow does not teach acne.

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Donello teaches a composition of only (emphasis added) tazarotenic acid or a pharmaceutically acceptable salt, ester or amid thereof (claim 10). Donello teaches the treatment of skin disorders such as acne vulgaris with the administration of tazarotenic acid (claim 11-12).

It would have been obvious to employ tazarotenic acid as the sole agent in the treatment of acne in view of Dow. One would have been motivated to employ tazarotenic acide because it is known that topically administered tazarotenic acid is effective in the treatment of skin disorders (e.g. psoriasis and acne) as disclosed by both Dow and Donello with a reasonable expectation of success absence evidence to the contrary.

With regards the limitation "wherein the tazarotene or tazarotenic acid salt is dissolved in a liquid oil component of the emulsion", since it is known in the art that the composition is in an oil-in-water emulsion as disclose by Dow, it would have been obvious that in order to obtain the oil-in-water emulsion, the active agent would have been dissolved in an oil. Furthermore, the instant claims are drawn to a method of treating acne not a method of preparing said composition.

For these reasons, the claimed subject matter is deemed to fail to be patentably distinguishable over the state of the art as represented by the cited reference. The claims are therefore, properly rejected under 35 U.S.C. 103.In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

NEW REJECTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 13-40 rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 10,426,787. Although the claims at issue are not identical, they are not patentably distinct from each other because both application recite the administration of tazarotene to treat acne. The difference between

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the instant application and the '787 patent is that the '787 also recites halobetasol, however the instant claims do not preclude a combination therapy to treat acne. Thus, the instant application and the '787 patent possess significant overlapping scopes of invention.

Claims 13-40 rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 10,251,895. Although the claims at issue are not identical, they are not patentably distinct from each other because both application recite the administration of tazarotene to treat acne. The difference between the instant application and the '895 patent is that the '895 also recites halobetasol, however the instant claims do not preclude a combination therapy to treat acne. Thus, the instant application and the '895 patent possess significant overlapping scopes of invention.

Claims 13-40 is provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4, 6-12, 24-28 of copending Application No. 16/179,576. Although the claims at issue are not identical, they are not patentably distinct from each other because both the instant claims and the '576 application recite a composition (tazarotene) for the treatment of acne. Taken that both applications disclose the same compound (tazarotene) to treat acne, one of ordinary skills in the art would recognize that both application possess significant overlapping scopes of invention with a reasonable expectation of success.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

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Conclusion

Claims 13-40 is rejected.

No claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN ANN CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached on Monday - Thursday 8-6pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. 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

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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.

/KATHRIEN A CRUZ/
Primary Examiner, Art Unit 1627

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/179,561	Arturo et al.
	Examiner	Art Unit
	KATHRIEN A CRUZ	1627

CPC - Searched*		
Symbol	Date	Examiner

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	03/15/2019	kc
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	10/23/2019	kc
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	02/24/2020	kc

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	3	((("ARTURO") near3 ("Angel")) and (("PILLAI") near3 ("Radhakrishnan"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/02/24 14:31
L2	3	L1	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/02/24 14:31
L3	9754	tazarotene	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/02/24 14:34
L4	3471	L3 and acne	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/02/24 14:34
L5	2707	L4 and @py<"2017"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/02/24 14:34
L6	556	L5 and "acne vulgaris"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/02/24 14:34
L7	556	L6	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2020/02/24 14:34

EAST Search History (Interference)

<This search history is empty>

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PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/179,561	Filing Date 11/02/2018	☐ 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 $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ 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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	01/28/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 28	Minus	** 28	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0		x $460 =	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

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ 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.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/ANGELA D JOHNSON/
*** 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.	

This collection of information is required by 37 CFR 1.16. 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, 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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Confirmation No.: 1370

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Angel Arturo
Applicant:	Valeant Pharmaceuticals North America
Application No.:	16/179,561
Filed:	November 2, 2018
Examiner:	CRUZ, Kathrien Ann
Group/Art Unit:	1621
Atty. Docket No.:	99336.000343
Title:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

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

AMENDMENT AND RESPONSE TO OFFICE ACTION UNDER 37 C.F.R § 1.111

Dear Sir:

In response to the Office action dated October 28, 2019, please consider Applicant's amendments and remarks, as shown below.

Amendments to the Specification: none.

Amendments to the Claims begin at page 2 of this paper.

Amendments to the Drawings: none.

Remarks begin at page 8 of this paper.

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AMENDMENTS TO THE CLAIMS

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

1-12. (Cancelled)

13. **(Previously presented)** A method of treating acne vulgaris, the method comprising topically applying a pharmaceutical composition to an affected area of a body of a subject suffering from acne vulgaris; wherein the composition comprises:

tazarotene or a pharmaceutically acceptable tazarotenic acid salt present in the composition at a positive concentration from about 0.01 to 0.049 percent by weight of the composition; and

a dermatologically acceptable oil-in-water emulsion vehicle; wherein said composition is an oil-in-water emulsion lotion.

14. **(Previously presented)** The method of claim 13, wherein the composition comprises tazarotene at a concentration of from about 0.03 to 0.049 percent by weight of the composition.

15. **(Previously presented)** The method of claim 13, wherein the composition comprises tazarotene at a concentration of about 0.045 percent by weight of the composition.

16. **(original)** The method of claim 13, wherein said emulsion comprises:

an aqueous phase comprising water, a carbomer homopolymer, and a polymeric emulsifier; and

an oil phase comprising at least one member selected from the group consisting of a dicarboxylic acid ester and a mineral oil.

17. **(original)** The method of claim 16, wherein the oil phase of the emulsion comprises diethyl sebacate.

18. **(original)** The method of claim 13, wherein the oil phase of the emulsion comprises diethyl sebacate and mineral oil.

19. **(original)** The method of claim 13, wherein the oil phase of the emulsion consists of diethyl sebacate and mineral oil.

20. **(original)** The method of claim 13, wherein said applying is carried out once per day for at least eight weeks.

21. **(original)** The method of claim 13, wherein said applying is carried out once per day for at least twelve weeks.

22. **(original)** The method of claim 13, wherein said applying is carried out once per day for twelve weeks.

23. **(original)** The method of claim 13, wherein the pharmaceutical composition contains the tazarotene or the tazarotenic acid salt as a sole active pharmaceutical ingredient.

24. **(Previously presented)** The method of claim 23, wherein the composition comprises tazarotene at 0.03 to 0.049 percent by weight of the composition.

25. **(Previously presented)** The method of claim 23, wherein the composition comprises tazarotene at about 0.045 percent by weight of the composition.

26. **(Previously presented)** The method of claim 25, wherein the tazarotene or tazarotenic acid salt is dissolved in a liquid oil component of the emulsion.

27. **(Previously presented)** The method of claim 25, wherein an oil phase of the emulsion comprises a liquid oil component comprising a dicarboxylic acid ester ("DCAE"), a monocarboxylic acid ester ("MCAE"), or combinations thereof.

28. **(Previously presented)** The method of claim 25, wherein an oil phase of the emulsion comprises diethyl sebacate.

29. **(Previously presented)** The method of claim 25, wherein an aqueous phase of the emulsion comprises water and a carbomer homopolymer.

30. **(Previously presented)** The method of claim 25, wherein the composition has a pH of about 4 to about 6.

31. **(Previously presented)** The method of claim 13, wherein the tazarotene or tazarotenic acid salt is dissolved in a liquid oil component of the emulsion.

32. **(Previously presented)** The method of claim 13, wherein an oil phase of the emulsion comprises a liquid oil component comprising a dicarboxylic acid ester ("DCAE"), a monocarboxylic acid ester ("MCAE"), or combinations thereof.

33. **(Previously presented)** The method of claim 13, wherein an oil phase of the emulsion comprises diethyl sebacate.

34. **(Previously presented)** The method of claim 13, wherein an aqueous phase of the emulsion comprises water and a carbomer homopolymer.

35. **(Previously presented)** The method of claim 13, wherein the composition has a pH of about 4 to about 6.

36.**(Previously presented)** The method of claim 13, wherein the composition consists essentially of:

0.01 – 0.049 weight % tazarotene;

diethyl sebacate;

light mineral oil;

sorbitan monooleate;

sorbitol solution, 70%;

methylparaben;

propylparaben;

edetate disodium dihydrate;

carbomer polymer type B;

carbomer homopolymer type A;

sodium hydroxide;

purified water.

37.**(Previously presented)** The method of claim 13, wherein the composition consists essentially of:

0.02 – 0.049 weight % tazarotene;

1 - 5 weight % diethyl sebacate;

5 - 15 weight % light mineral oil;

0.01 - 1 weight % sorbitan monooleate;

5 - 15 weight % sorbitol solution, 70%;

0.05 - 0.3 weight % methylparaben;

0.01 – 0.1 weight % propylparaben;

0.02 – 0.1 weight % edetate disodium dihydrate;

0.1 - 1 weight % carbomer polymer type B;

0.2 – 1.5 weight % carbomer homopolymer type A;

sodium hydroxide, q.s. to pH 5.5 ±0.5; and

purified water, q.s. to 100 weight %.

38.**(Previously presented)** The method of claim 13, wherein the composition consists essentially of:

0.03 – 0.049 weight % tazarotene;

2 - 4 weight % diethyl sebacate;

5 - 10 weight % light mineral oil;

0.02 – 0.5 weight % sorbitan monooleate;

7 - 12 weight % sorbitol solution, 70%;

0.1 - 0.3 weight % methylparaben;

0.01 – 0.05 weight % propylparaben;

0.02 – 0.7 weight % edetate disodium dihydrate;

0.2 – 0.7 weight % carbomer polymer type B;

0.3 – 1 weight % carbomer homopolymer type A;

sodium hydroxide, q.s. to pH 5.5 ±0.5; and

purified water, q.s. to 100 weight %.

39.**(Previously presented)** The method of claim 13, wherein the composition consists essentially of:

0.04 – 0.049 weight % tazarotene;

2.5 – 3.5 weight % diethyl sebacate;

7.5 – 8.5 weight % light mineral oil;

0.05 – 0.2 weight % sorbitan monooleate;

10 - 11 weight % sorbitol solution, 70%;

0.1 - 0.2 weight % methylparaben;

0.02 – 0.04 weight % propylparaben;

0.03 – 0.06 weight % edetate disodium dihydrate;

0.3 – 0.05 weight % carbomer polymer type B;

0.5 – 0.7 weight % carbomer homopolymer type A;

sodium hydroxide, q.s. to pH 5.5 ±0.5; and

purified water, q.s. to 100 weight %.

40. **(Previously presented)** A method of treating acne vulgaris, the method comprising topically applying a pharmaceutical composition to an affected area of a body of a subject suffering from acne vulgaris; wherein the composition consists essentially of:

0.045 weight % tazarotene;

2.97 weight % diethyl sebacate;

8.03 weight % light mineral oil;

0.1 weight % sorbitan monooleate;

10.7 weight % sorbitol solution, 70%;

0.17 weight % methylparaben;

0.03 weight % propylparaben;

0.05 weight % edetate disodium dihydrate;

0.4 weight % carbomer polymer type B;

0.6 weight % carbomer homopolymer type A;

sodium hydroxide, q.s. to pH 5.5 ±0.5; and

purified water, q.s. to 100 weight %.

REMARKS

The Office action dated March 20, 2019 and the cited references have been carefully considered.

Claims 13-40 are currently pending. No new matter has been added. Reconsideration of the application is respectfully requested.

Status of the Claim

Claims 13-40 are rejected under 35 U.S.C. § 103 as being unpatentable over WO 2016205001 and Donello (US 2012/0328670).

Claims 13-40 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-23 of Application No. 15/977088.

Claims 13-40 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1, 4, 6-12, and 24-28 of copending Application No. 16/179,576.

Applicant respectfully traverses these rejections for the reasons set forth below.

Rejection of claims 13-40 under 35 U.S.C. § 103 as being unpatentable over WO 2016205001 and Donello (US 2012/0328670)

Applicant respectfully traverses this rejection with respect to the present claims because WO 2016205001 and Donello not teach or suggest all of the limitations of independent claims 13 and 40.

To demonstrate that a claim is obvious, the party asserting invalidity must present evidence that all limitations of the claim are taught or suggested in the prior art. *Fresenius USA, Inc. v. Baxter Int'l, Inc.* 582 F.3d 1288, 1296 (Fed. Cir. 2009). See also *Ex parte Reed* (BPAI, Jul. 14, 2009, Slip op., p. 7) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)) ("To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art."). In addition, "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." MPEP § 2143.03 (9th Ed., Rev. 08.2017, Jan. 2018, p. 2100-235) (quoting *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970).

Nowhere in either of WO 2016205001 or Donello is there teaching or suggestion of a method of treating acne with a composition comprising tazarotene in an oil-in-water emulsion at a tazarotene concentration of from about 0.01 to 0.049 percent by weight, as recited in the independent claim 13, or more specifically treating acne with a composition consisting essentially of 0.045 percent by weight tazarotene and the further components as recited in independent claim 40. Thus, neither WO 2016205001 or Donello teach or suggest all of the limitations of the pending claims.

While WO 2016205001 discloses an oil-in-water formulation comprising tazarotene at 0.045 wt% as a sole pharmaceutically active ingredient, the Examiner acknowledges it does not disclose use of the disclosed formulations specifically for the treatment of acne. The Examiner asserts Donello teaches the treatment of acne vulgaris with the administration of tazarotenic acid (citing claims 11-12), and asserts that it would have been obvious to employ tazarotenic acid as the sole agent in the treatment of acne in view of Dow, as one would have been motivated to do so because it is known that topically administered tazanoic acid is effective in the treatment of skin disorders (e.g., psoriasis and acne) as disclosed by both Dow and Donello with a reasonable expectation of success absence evidence to the contrary.

"To reject a claim based on [teaching, suggestion, or motivation] rationale, Office personnel must resolve the *Graham* factual inquiries. Then Office personnel must articulate the following:

(1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference . . .;

(2) a finding that there was reasonable expectation of success . . .."

MPEP § 2143 (9th Ed., Rev. 08.2017, Jan. 2018, p. 2100-230) (Emphasis added).

The Examiner appears to assert that the motivation to employ the 0.045 wt% tazarotene oil-in-water emulsion formulation disclosed in WO 2016205001 in the treatment of acne is based on an alleged "reasonable expectation of success" based on both WO 2016205001 and Donello teaching use of tazarotene formulations for treatment of skin disorders, and Donello specifically

teaching use of tazarotene for treatment of acne. Donello, however, is specifically directed towards, and only actually demonstrates, use of microspheres comprising biodegradable polymer and tazarotene for reducing sebaceous gland size, while other non-microsphere based formulations (including vehicle alone, or Tazorac® gel formulation) were not effective at significantly reducing sebaceous gland size (see, e.g., Fig. 2 and [0050] of Donello). As reduction of sebum is the only proposed effect for expected success in treating acne disclosed in Donello (see, e.g., [0016]), and as the only formulations disclosed in Donello which demonstrate significant reduction in sebaceous gland size are microparticle biodegradable polymer formulations as opposed to oil-in-water formulations (and to the contrary, as other tazarotene formulations such as formulations such as Tazorac® gel even at a higher concentration (0.1%) than that claimed in the present invention was found to not be effective at significantly reducing sebaceous gland size), there would be no reasonable expectation of success for use of an oil-in-water emulsion formulation containing the claimed concentration of tazarotene in the treatment of acne.

In view of the clear lack of any reasonable expectation of success of the present claimed invention based on the actual teachings of Donello (which instead appears to teach the described microparticle biodegradable polymer formulations are required to obtain the aim result of reduction in sebaceous gland size, in comparison to ineffective results obtained for other tazarotene containing formulations), a *prima facie* case of obviousness has clearly not been established. Further, such rejection is instead in clear error, as the Examiner has failed to consider factual evidence submitted in the instant specification which clearly demonstrates an unexpected benefit of the claimed invention. Consistent with the rule that all evidence of nonobviousness must be considered when assessing patentability, the PTO must consider comparative data in the specification in determining whether the claimed invention provides unexpected results. *In re Margolis*, 785 F.2d 1029, 1031, 228 USPQ 940, 941-42 (Fed. Cir. 1986).

More specifically, the Examiner has not articulated any reason why there would be reasonable expectation of success for use of the claimed use of the specific claimed oil-in-water tazarotene formulation for treatment of acne, wherein the tazarotene has been reduced to less than half the concentration of tazarotene in Tazorac® 0.1%, as required by the present

jurisprudence and the MPEP guidance. *In re Kahn*, 441 F.3d 977, 987 (Fed. Cir. 2006) (A fact finder "must provide some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct. . . . [T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."); *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 418; 127 S.Ct. 1727, 1741 (2007) ("Rejection on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."). In particular, the Examiner has not articulated the reason why there would be reasonable expectation of success for achieving better treatment efficacy in an oil-in-water tazarotene formulation when the tazarotene concentration is reduced to less than half of the concentration of tazarotene in Tazorac® 0.1%, while the cited reference relied upon for use of tazarotene in treating acne only demonstrates effectiveness of microsphere biodegradable particle formulations in reducing sebaceous gland size, and non-effectiveness of Tazorac® 0.1% formulations. To the contrary, the actual teachings of Donello would appear to provide a clear lack of reasonable expectation of success for the present claimed invention.

In contradistinction, the present inventors unexpectedly and surprisingly discovered that the presently claimed method of treating acne employing an oil-in-water emulsion composition having less than 0.05% tazarotene is more efficacious in treating acne than a commercial emulsion having 0.1% tazarotene, at least as measured by Evaluator's Global Severity Score ("EGSS") and reduction of inflammatory lesions. *In re Soni*, 34 U.S.P.Q.2d 1684, 1687 ("[T]hat which would have been surprising to a person of ordinary skill in a particular art would not have been obvious."). See Tables 6 and 7 of the present specification, as filed, which presents factual evidence for Composition A (having 0.045 wt% tazarotene in an oil-in-water formulation as identified in Table 2 of the specification) in accordance with the present claimed invention in comparison to placebo and 0.1 wt% tazarotene cream, which clearly demonstrates an unexpected benefit of the claimed invention. For the Examiner's convenience, Tables 6 and 7 are reproduced immediately below.

TABLE 6

Treatment % Success (ITT) at 12 Weeks

	Combined Placebo N = 69	Composition A N = 69	Tazorac ® 0.1% Cream N = 72
EGSS - Clear or Almost Clear	10.1%	18.8%	16.7%
Inflammatory Lesions			
Absolute Change	-14.0	-18.1	-16.8
% Change	-51.41%	-63.75%	-59.99%
Non-inflammatory Lesions			
Absolute Change	-13.1	-21.6	-20.3
% Change	-35.18%	-56.86%	-54.09%

TABLE 7

Treatment % Success (PP)

	Combined Placebo N = 57	Composition A N = 54	Tazorac ® 0.1% Cream N = 56
EGSS - Clear or Almost Clear	12.3%	20.4%	16.1%
Inflammatory Lesions	-14.2	-18.3	-18.2
Non-inflammatory Lesions	-11.8	-20.8	-21.9

Since use of a composition having a tazarotene concentration less than half of the concentration of Tazorac® 0.1%, as required by independent claims 13 and 40, is surprisingly more efficacious in treating acne than a composition having the same concentration as Tazorac® 0.1%, the claimed invention is clearly nonobvious. The proposed obviousness rejection, based on the distinct teachings of Donello in combination with WO 2016205001, clearly fails to establish obviousness.

Rejection of claims 13-40 on the ground of nonstatutory double patenting

Claims 13-40 were provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-23 of copending Application No. 15/977088. As Appl. No. 15/977088 is now abandoned, this provisional rejection is now moot.

Rejection of claims 13-40 under 35 U.S.C. § 101 over copending Application No. 16/179,576

Claims 13-40 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1, 4, 6-12, and 24-28 of copending Application No. 16/179,576.

Reconsideration of this rejection under 35 U.S.C. § 101 is respectfully urged, as the present application claims and those of Appl. No. 16/179,561 are not directed towards the same invention, as rather the instant claims are directed towards a method of treating acne vulgaris, while those of Appl. No. 16/179,576 are directed towards a specified composition. Accordingly this rejection under 35 U.S.C. § 101 is in clear error.

If the Examiner intends to modify this rejection to be a nonstatutory obviousness type provisional double patenting rejection, Applicant requests to defer filing of any required Terminal Disclaimer, or cancelling of corresponding claims in one of the applications, until otherwise allowable claims are indicated, as no claims have yet been indicated as otherwise being allowable.

Conclusion

In view of the foregoing, it is submitted that the claims are patentable and in condition for allowance. Allowance of the claims at an early date is solicited.

Precautionary Fee-Charge Authorization

By way of precaution, the Commissioner is authorized to charge any underpayment of fees or fee amounts not otherwise authorized but necessary for the consideration of this paper or the continued pendency of this application and to credit any overpayment to Deposit Account Number 03-3875 of Harter Secrest & Emery LLP.

Please grant any extensions of time necessary for the filing of this Amendment.

Respectfully submitted,

/Andrew J. Anderson/

Andrew J. Anderson, Reg. No. 33,564
Attorney for the Applicant
585-231-1157

Electronic Acknowledgement Receipt	
EFS ID:	38422761
Application Number:	16179561
International Application Number:	
Confirmation Number:	1370
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Angel Arturo
Customer Number:	134756
Filer:	Andrew James Anderson/Bethany Weber
Filer Authorized By:	Andrew James Anderson
Attorney Docket Number:	99336.000343
Receipt Date:	28-JAN-2020
Filing Date:	02-NOV-2018
Time Stamp:	16:13:31
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		99336-343_US_Response_JAN_2020.pdf	255969 4bb8c1a627a0b5e7be55cf4839a1f96f18cb71e0	yes	13

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	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response After Final Action	1	1
	Claims	2	7
	Applicant Arguments/Remarks Made in an Amendment	8	13
Warnings:			
Information:			
	Total Files Size (in bytes):	255969	

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.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/179,561	11/02/2018	Angel Arturo	99336.000343	1370

134756 7590 10/28/2019

HSE/Valeant
1600 Bausch & Lomb Place
Rochester, NY 14604

EXAMINER
CRUZ, KATHRIEN ANN

ART UNIT	PAPER NUMBER
1621	

NOTIFICATION DATE	DELIVERY MODE
10/28/2019	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@hselaw.com

Office Action Summary	**Application No.** 16/179,561	**Applicant(s)** Arturo et al.	
	Examiner KATHRIEN A CRUZ	**Art Unit** 1621	**AIA (FITF) Status** Yes

-- 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 MONTHS 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 7/19/2019.

☐ 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) 13-40 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) 13-40 is/are rejected.

8) ☐ Claim(s) _____ 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 _____ 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/08a and/or PTO/SB/08b) Paper No(s)/Mail Date 7/19/2019.

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

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

Claims 13-40 is pending.

Applicants response filed 7/19/2019 has been received and entered in the application.

Action Summary

Claims 1-6, 12-15, 20-23 are rejected under 35 U.S.C. 103 as being unpatentable over Fabior® (Tazarotene) Foam 0.1% [package insert]. Research Triangle Park, NC: Stiefel Laboratories, Inc; 2012 (Fabior) is withdrawn due to applicants amendment of claims.

Claims 8-11,16, 18 and 19 are rejected under 35 U.S.C. 103 as being unpatentable over Fabior in view of Singh et al., Dosage Forms: Non-Parenteral in Encyclopedia of Pharmaceutical Technology, 2002, Marcel Dekker (Singh)) is withdrawn due to applicants amendment of claims.

Claims 7 and 17 are are rejected under 35 U.S.C. 103 as being unpatentable over Fabior in view of Fiume et al., Int J Toxicol. 2012 Jul-Aug;31(4 Suppl):5S-76S (Fiume) is withdrawn due to applicants amendment of claims.

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Claims 1-23 is provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-23 of copending Application No. 15/977088 (reference application) is maintained in part (13-23 and newly added claims).

Claims 1-23 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-23 of copending Application No. 16/179,576 (reference application) is withdrawn due to applicant's amendment of claims.

Response to Arguments

Applicant's arguments with respect to claims 1-23 have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

Claim Rejections - 35 USC § 103

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

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-40 are rejected under 35 U.S.C. 103 as being unpatentable over WO 2016205001 (WO 001) of record as disclosed in the IDS dated (7/19/2019) and Donello (U.S. Publication 2012/0328670).

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Dow teaches topical pharmaceutical compositions comprising a combination of active ingredients, and methods using the same, for treating psoriasis (para 0002). Dow teaches a composition comprising halobetasol (a corticosteroid) and tazarotene (a retinoid) is synergistically more efficacious than the combined efficacies (i.e., the sum of the efficacies) of compositions, each comprising only one of these active ingredients (pargra 0020). Dow teaches that the retinoid is present at a concentration below that which is presently utilized in topical formulations. For example, tazarotene or tazarotenic acid salt is included in a composition of the present invention at a positive concentration less than 0.05 wt%. (para 0032). Dow teaches the retinoid is present in the composition at a concentration in the range from about 0.001 to about 0.09 wt%, or from about 0.001 to about 0.08 wt%, or from about 0.001 to about 0.07 wt%, or from about 0.001 to about 0.06 wt%, or from about 0.01 to about 0.09 wt%, or from about 0.01 to about 0.08 wt%, or from about 0.01 to about 0.07 wt%, or from about 0.01 to about 0.06 wt%, or from about 0.001 to about 0.049 wt%, or from about 0.005 to about 0.045 wt%, or from about 0.005 to about 0.04 wt%, or from about 0.005 to about 0.03 wt%, or from about 0.005 to about 0.02 wt%, or from about 0.005 to about 0.01 wt%, or from about 0.01 to about 0.049 wt%, or from about 0.01 to about 0.045 wt%, or from about 0.02 to about 0.045 wt%, or from about 0.03 to about 0.045 wt%.(para 0033). Dow teaches that a topical pharmaceutical composition of the present invention is in the dosage form of gel, emulsion (including **lotion,** cream, and milk), shampoo, foam, suspension, liquid, spray, paste or ointment. In certain preferred embodiments, a topical pharmaceutical composition of the present invention is **an oil-in-water emulsion**, in which an internal

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oil phase is dispersed in a continuous aqueous phase. Alternatively, water-in-oil-in-water, water-in-oil and oil-in-water-in-oil emulsions are also contemplated. The emulsion may be a macroemulsion, a microemulsion, or a nanoemulsion. Also contemplated are other formulations in which an oil phase and a water phase coexist within the formulation, such as a multivesicular emulsion, which is not a true emulsion. Also contemplated is a liposomal dispersion in a gel, cream or other dosage form. Also contemplated are other formulations in which non-polar and polar liquid ingredients, with or without semipolar ingredients, coexist with the formulation (paragraph 0038).

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Ingredient	Function	Concentration (wt%)			
		Range 1	Range 2	Range 3	Preferred embodiment
Halobetasol propionate	Class 1 Corticosteroid	0.001-0.04	0.005-0.03	0.005-0.02	0.01
Tazarotene	Retinoid	0.02-0.049	0.03-0.049	0.04-0.049	0.045
Diethyl sebacate	Liquid Oil & Solvent	1-5	2-4	2.5-3.5	2.97
Light mineral oil	Liquid Oil & Co-Solvent	5-15	5-10	7.5-8.5	8.03
Sorbitan monooleate	Surfactant/ Emulsifying Agent	0.01-1	0.02-0.5	0.05-0.2	0.1
Sorbitol solution, 70%	Humectant	5-15	7-12	10-11	10.7
Methyl paraben	Antimicrobial Preservative(1)	0.05-0.3	0.1-0.3	0.1-0.2	0.17
Propyl paraben	Antimicrobial Preservative(1)	0.01-0.1	0.01-0.05	0.02-0.04	0.03
Edetate disodium dihydrate	Chelating Agent(1)	0.02-0.1	0.02-0.7	0.03-0.06	0.05
Carbomer copolymer type B (e.g., Pemulen™ TR-1)	Emulsifying Agent	0.1-1	0.2-0.7	0.3-0.5	0.4
Carbomer homopolymer type A (e.g., Carbomer 981)	Thickener	0.2-1.5	0.3-1	0.5-0.7	0.6
Sodium hydroxide, 10% Solution	pH-adjusting Agent(1)	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5
Purified water	Carrier	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100

(table 2 with specific amounts in table 4 (which are the same amounts as disclosed in instant claim 40)). Dow teaches in table 8-9 the topical administration up to 12 weeks.

Dow does not teach acne.

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Donello teaches a composition of only (emphasis added) tazarotenic acid or a pharmaceutically acceptable salt, ester or amid thereof (claim 10). Donello teaches the treatment of skin disorders such as acne vulgaris with the administration of tazarotenic acid (claim 11-12).

It would have been obvious to employ tazarotenic acid as the sole agent in the treatment of acne in view of Dow. One would have been motivated to employ tazarotenic acide because it is known that topically administered tazarotenic acid is effective in the treatment of skin disorders (e.g. psoriasis and acne) as disclosed by both Dow and Donello with a reasonable expectation of success absence evidence to the contrary.

With regards the limitation "wherein the tazarotene or tazarotenic acid salt is dissolved in a liquid oil component of the emulsion", since it is known in the art that the composition is in an oil-in-water emulsion as disclose by Dow, it would have been obvious that in order to obtain the oil-in-water emulsion, the active agent would have been dissolved in an oil. Furthermore, the instant claims are drawn to a method of treating acne not a method of preparing said composition.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double

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patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets

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all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 13-40 is provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-23 of copending Application No. 15/977088 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because both the instant claims and the '088 application recite a composition (tazarotene) for the treatment of acne. Taken that both applications disclose the same compound (tazarotene) to treat acne, one of ordinary skills in the art would recognize that both application possess significant overlapping scopes of invention with a reasonable expectation of success.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

New Rejection

Claims 13-40 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4, 6-12, 24-28 of copending Application No. 16/179,576 (reference application).). Although the claims at issue are not identical, they are not patentably distinct from each other because both the instant claims and the '576 application recite a composition (tazarotene) for the treatment of acne (e.g. skin disease). Taken that both applications disclose the same compound (tazarotene) to treat acne, one of ordinary skills in the art would recognize that both application possess significant overlapping scopes of invention with a reasonable expectation of success.

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This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Claims 13-40 is rejected.

No claims are allowed.

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IPR Petition - USP 11,311,482

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN ANN CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached on Monday to Friday from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Melenie Gordon can be reached at telephone number (571) 272-8037. 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).

/KATHRIEN A CRUZ/
Primary Examiner, Art Unit 1621

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IPR Petition - USP 11,311,482

Notice of References Cited	Application/Control No. 16/179,561	Applicant(s)/Patent Under Reexamination Arturo et al.	
	Examiner KATHRIEN A CRUZ	Art Unit 1621	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20120328670-A1	12-2012	Donello; John E.	A61K9/0014	424/400
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/179,561	Arturo et al.
	Examiner	Art Unit
	KATHRIEN A CRUZ	1621

CPC - Searched*		
Symbol	Date	Examiner

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	03/15/2019	kc
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	10/23/2019	kc

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	3	"2013205001"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/10/23 12:24
L2	13	"6730308"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/10/23 12:24
L3	11	"8808716"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/10/23 12:26
L4	2	"20130205001"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/10/23 12:41
L5	3	"2013205001"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/10/23 12:42
L6	4	"2016205001"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/10/23 12:44
L7	2	"20160205001"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/10/23 12:44
L8	4	"2016205001"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/10/23 12:44
L9	8	"2016205001"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/10/23 12:47
L10	31	"8808716"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/10/23 13:32
L11	17	"10251895"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/10/23 13:32
L12	5	"20120129824"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/10/23 13:32
L13	2	"20140349981"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/10/23 13:32
L14	3	"20160367570"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/10/23 13:32

L15	8	"2016205001"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/10/23 13:32
L16	39	"1528238"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/10/23 13:32
L17	12	"2012087443"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/10/23 13:32
L18	3	((("ARTURO") near3 ("Angel")) and (("PILLAI") near3 ("Radhakrishnan"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/10/23 13:33
L19	3	L18	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/10/23 13:33
L20	9520	tazarotene	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/10/23 13:33
L21	3400	L20 and acne	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/10/23 13:33
L22	2707	L21 and @py<"2017"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/10/23 13:33
L23	556	L22 and "acne vulgaris"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/10/23 13:33
L24	556	L23	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/10/23 13:33

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

Application Number	16179561
Filing Date	2018-11-02
First Named Inventor	Arturo, Angel
Art Unit	1621
Examiner Name	CRUZ, Kathrien Ann
Attorney Docket Number	99336.000343

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	6730308	B1	2004-05-04	Sefton	
	2	8808716	B2	2014-08-19	Loupenok	
	3	10251895	B2	2019-04-09	Dow et al.	

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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
	1	20120129824	A1	2012-05-24	Angel et al.	
	2	20140349981	A1	2014-11-27	Evers et al.	
	3	20160367570	A1	2016-12-22	Dow et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /K.A.C/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Arturo, Angel
	Art Unit	1621
	Examiner Name	CRUZ, Kathrien Ann
	Attorney Docket Number	99336.000343

	4	20180360752	A1	2018-12-20	Arturo et al.	
	5	20190133943	A1	2019-05-09	Arturo et al.	
	6	20180177803	A1	2018-06-28	Dow et al.	

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FOREIGN PATENT DOCUMENTS Remove

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	2016/205001	WO	A1	2016-12-22	Dow et al.		
	2	1528328	CN	A	2004-09-15	Zheng et al.		☒
	3	2012/087443	WO	A1	2012-06-28	Angel et al.		☐
	4	2461/MUM/2009	IN		2012-03-30	Ghandi		☒
	5	2012/061630	WO	A2	2012-05-10	Jackson		☐
	6	0047211	WO		2000-08-17	Bershad et al.		☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16179561
	Filing Date	2018-11-02
	First Named Inventor	Arturo, Angel
	Art Unit	1621
	Examiner Name	CRUZ, Kathrien Ann
	Attorney Docket Number	99336.000343

	7	2004/058262	WO	A1	2004-07-15	Saoji et al.		☐
	8	2012/051614	WO	A2	2012-04-19	Kulesza et al.		☐
	9	1528313	CN	A	2004-09-15	Li		☒

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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]
	1	International Search Report and Written Opinion of PCT/US18/32359 of the International Searching Authority completed 17 July 2018 (10 pages).	
	2	Kircik, Leon H.: "Tretinoin microsphere gel pump 0.04% versus tazarotene cream 0.05% in the treatment of mild-to-moderate facial acne vulgaris.", Journal of Drugs in Dermatology: JDD, July 2009, Vol. 8, no. 7, pages 650-654.	
	3	Shalita A R et al: "Tazarotene gel is safe and effective in the treatment of acne vulgaris: a multicenter, double-blind, vehicle-controlled study.", Cutis, June 1999,Vol. 63, no. 6, pages 349-354.	
	4	Lebwohl et al.: "Duration of improvement in psoriasis after treatment with tazarotene 0.1% gel plus clobetasol propionate 0.05% ointment: comparison of maintenance treatments." International Journal of Dermatology (Jan 2001) Vol. 40, no. 1, pages 64-66 (XP009191230).	
	5	Dhawan et al.: "Tazarotene cream (0.1%) in combination with betamethasone valerate foam (0.12%) for plaque-type psoriasis", Journal of Drugs in Dermatology, New York NY, vol. 4, no. 2, 1 March 2005, pages 228-230 (XP009159245).	
	6	Tazorac® Brochure (ALLERGAN packaging insert, revised July/2017, 13 pages).	

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	Filing Date	2018-11-02
	First Named Inventor	Arturo, Angel
	Art Unit	1621
	Examiner Name	CRUZ, Kathrien Ann
	Attorney Docket Number	99336.000343

	7	International Search Report and Written Opinion of PCT/US16/035991 of the International Searching Authority completed 6 August 2016 (10 pages).	
	8	Hecker et al., In vitro compatibility of tazarotene with other topical treatments of psoriasis, pp 1008-1011, June 2000, Elsevier, US.	

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EXAMINER SIGNATURE

Examiner Signature	/KATHRIEN A CRUZ/	Date Considered	10/23/2019

*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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	Filing Date	2018-11-02
	First Named Inventor	Arturo, Angel
	Art Unit	1621
	Examiner Name	CRUZ, Kathrien Ann
	Attorney Docket Number	99336.000343

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	/Andrew J. Anderson/	Date (YYYY-MM-DD)	2019-07-19
Name/Print	Andrew J. Anderson	Registration Number	33564

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:

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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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /K.A.C/

PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/179,561	Filing Date 11/02/2018	☐ 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 $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $460 =	
☐ 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

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	07/19/2019							
	Total (37 CFR 1.16(i))	* 28	Minus	** 23	= 5		x $100 =	500
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0		x $460 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	500

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

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** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/CHRISTINE V MOORE/
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	16179561
Filing Date	2018-11-02
First Named Inventor	Arturo, Angel
Art Unit	1621
Examiner Name	CRUZ, Kathrien Ann
Attorney Docket Number	99336.000343

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	6730308	B1	2004-05-04	Sefton	
	2	8808716	B2	2014-08-19	Loupenok	
	3	10251895	B2	2019-04-09	Dow et al.	

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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
	1	20120129824	A1	2012-05-24	Angel et al.	
	2	20140349981	A1	2014-11-27	Evers et al.	
	3	20160367570	A1	2016-12-22	Dow et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16179561
	Filing Date	2018-11-02
	First Named Inventor	Arturo, Angel
	Art Unit	1621
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	Attorney Docket Number	99336.000343

	4	20180360752	A1	2018-12-20	Arturo et al.	
	5	20190133943	A1	2019-05-09	Arturo et al.	
	6	20180177803	A1	2018-06-28	Dow et al.	

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	1	2016/205001	WO	A1	2016-12-22	Dow et al.		
	2	1528328	CN	A	2004-09-15	Zheng et al.		☒
	3	2012/087443	WO	A1	2012-06-28	Angel et al.		☐
	4	2461/MUM/2009	IN		2012-03-30	Ghandi		☒
	5	2012/061630	WO	A2	2012-05-10	Jackson		☐
	6	0047211	WO		2000-08-17	Bershad et al.		☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16179561
	Filing Date	2018-11-02
	First Named Inventor	Arturo, Angel
	Art Unit	1621
	Examiner Name	CRUZ, Kathrien Ann
	Attorney Docket Number	99336.000343

	7	2004/058262	WO	A1	2004-07-15	Saoji et al.		☐
	8	2012/051614	WO	A2	2012-04-19	Kulesza et al.		☐
	9	1528313	CN	A	2004-09-15	Li		☒

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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	International Search Report and Written Opinion of PCT/US18/32359 of the International Searching Authority completed 17 July 2018 (10 pages).	
	2	Kircik, Leon H.: "Tretinoin microsphere gel pump 0.04% versus tazarotene cream 0.05% in the treatment of mild-to-moderate facial acne vulgaris.", Journal of Drugs in Dermatology: JDD, July 2009, Vol. 8, no. 7, pages 650-654.	
	3	Shalita A R et al: "Tazarotene gel is safe and effective in the treatment of acne vulgaris: a multicenter, double-blind, vehicle-controlled study.", Cutis, June 1999,Vol. 63, no. 6, pages 349-354.	
	4	Lebwohl et al.: "Duration of improvement in psoriasis after treatment with tazarotene 0.1% gel plus clobetasol propionate 0.05% ointment: comparison of maintenance treatments." International Journal of Dermatology (Jan 2001) Vol. 40, no. 1, pages 64-66 (XP009191230).	
	5	Dhawan et al.: "Tazarotene cream (0.1%) in combination with betamethasone valerate foam (0.12%) for plaque-type psoriasis", Journal of Drugs in Dermatology, New York NY, vol. 4, no. 2, 1 March 2005, pages 228-230 (XP009159245).	
	6	Tazorac® Brochure (ALLERGAN packaging insert, revised July/2017, 13 pages).	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16179561
	Filing Date	2018-11-02
	First Named Inventor	Arturo, Angel
	Art Unit	1621
	Examiner Name	CRUZ, Kathrien Ann
	Attorney Docket Number	99336.000343

	7	International Search Report and Written Opinion of PCT/US16/035991 of the International Searching Authority completed 6 August 2016 (10 pages).	
	8	Hecker et al., In vitro compatibility of tazarotene with other topical treatments of psoriasis, pp 1008-1011, June 2000, Elsevier, US.	

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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	16179561
	Filing Date	2018-11-02
	First Named Inventor	Arturo, Angel
	Art Unit	1621
	Examiner Name	CRUZ, Kathrien Ann
	Attorney Docket Number	99336.000343

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	/Andrew J. Anderson/	Date (YYYY-MM-DD)	2019-07-19
Name/Print	Andrew J. Anderson	Registration Number	33564

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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.

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Electronic Patent Application Fee Transmittal	
Application Number:	16179561
Filing Date:	02-Nov-2018
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Angel Arturo
Filer:	Andrew James Anderson/Michelle Seifert
Attorney Docket Number:	99336.000343
Filed as Large Entity	
Filing Fees for Utility under 35 USC 111(a)	

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:				

Padagis Ex. 1002
IPR Petition - USP 11,311,482

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 1 month with $0 paid	1251	1	200	200
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	240	240
		Total in USD ($)		**440**

Electronic Acknowledgement Receipt	
EFS ID:	36638877
Application Number:	16179561
International Application Number:	
Confirmation Number:	1370
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Angel Arturo
Customer Number:	134756
Filer:	Andrew James Anderson/Michelle Seifert
Filer Authorized By:	Andrew James Anderson
Attorney Docket Number:	99336.000343
Receipt Date:	19-JUL-2019
Filing Date:	02-NOV-2018
Time Stamp:	15:13:21
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$440
RAM confirmation Number	072219INTEFSW00001585033875
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		99336-343_US_Response_due_July_20_2019.pdf	262893 33035a5db507f2d43a55e81bf688690146d808b6	yes	15
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Applicant Arguments/Remarks Made in an Amendment		8	15	
	Claims		2	7	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	99336-343_IDS.pdf	1213607 20184028001330e098d1eba8ad8fc42d2fa7606a8	no	6
Warnings:					
Information:					
3	Foreign Reference	99336-293_FPD1_WO2016205001A1.pdf	1679775 9b0aae4fd48bd2295a9a019ed45998905059bdaa	no	52
Warnings:					
Information:					
4	Foreign Reference	99336-293_FPD2_CN1528328A.pdf	361319 734ee7dd6cd770466d4a56fe3c734dda0c674c75	no	8
Warnings:					
Information:					
5	Foreign Reference	99336-293_FPD2_CN1528328A-Translation.pdf	5980767 9b36cdb3b2d1aa3c792433323a98a5ae758c3361d	no	8

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Information:					
6	Foreign Reference	99336-293_FPD3_2012087443.pdf	1163087 b086b64ff54667ee2a86fac5c097710161902381	no	31
Warnings:					
Information:					
7	Foreign Reference	99336-293_FDP4_2461MUM2009.pdf	1836830 7d1353fca571fdf1660d21c1c4190409385305 63	no	31
Warnings:					
Information:					
8	Foreign Reference	99336-293_FDP4_2461MUM2009-translation.pdf	44634 4ce02013c87778b2e5bdb4d768e6e0b9ebf87e56	no	1
Warnings:					
Information:					
9	Foreign Reference	99336-293_FDP5_2012061630.pdf	2815487 559fa193e4c3eeb2dc9871f9350f15a04a3c87f5	no	56
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Information:					
10	Foreign Reference	99336-293_FDP6_0047211.pdf	475337 38e94536fe53d6fe6f8382c1f89844470ad1159b	no	12
Warnings:					
Information:					
11	Foreign Reference	99336-293_FDP7_2004058262.pdf	1780317 7a83c6dccbb32cb104af640402d90e0369983ed6	no	38
Warnings:					
Information:					
12	Foreign Reference	99336-293_FDP8_2012051614.pdf	1159643 79e1ac7e2e013a3b08db6113f533f81ded2fa560	no	25
Warnings:					
Information:					

13	Foreign Reference	99336-293_FDP9_CN1528313_with_translation.pdf	446556 5bc3efedf96dc94381d9156fc5a047ca65001e01	no	5
Warnings:					
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14	Non Patent Literature	99336-293_NPL1_ISR_WO.pdf	310431 52bef81fd0a3557d75f5a7f57dbb3c79a4a36c75	no	10
Warnings:					
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15	Non Patent Literature	99336-293_NPL2_Kircik.pdf	1663599 353fb479527bafddd29bdd891a4a03f9d5e40a0e	no	6
Warnings:					
Information:					
16	Non Patent Literature	99336-293_NPL3_Shalita_et_al.pdf	662350 7c8e62df66636040a119086091ebced9bf378f27	no	6
Warnings:					
Information:					
17	Non Patent Literature	99336-207_NPL4_Lebwohl.pdf	132751 fee2e3ad73ecb17d9b4919eea40e3a4fc0cf72e2	no	7
Warnings:					
Information:					
18	Non Patent Literature	99336-207_IDS_NPL5_Dhawan.pdf	4832185 ec927d9407db67ba9a7f26814c4c6f53e17647a1	no	3
Warnings:					
Information:					
19	Non Patent Literature	99336-207_NPL6_Tazorac.pdf	297701 f6a460be2d4b8556fdd1a3aaad42f96481a9e813	no	13
Warnings:					
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20	Non Patent Literature	99336-293_NPL7_ISR_WO_8-2016.pdf	335037 675c8d1f9fc956c95d12d416f0fe8d8a320722d8	no	10
Warnings:					
Information:					
21	Non Patent Literature	99336-293_NPL8_Hecker_et_al.pdf	289325 55c36a4bfb46755589ce40849 5f172d203bd010c	no	4
Warnings:					
Information:					
22	Fee Worksheet (SB06)	fee-info.pdf	32656 4074ed8dd39165ea284b92669307b564f0a8ecbb	no	2
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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.

REMARKS

The Office action dated March 20, 2019 and the cited references have been carefully considered.

Claims 1-12 are cancelled (without prejudice), and claim 13 is amended to more particularly specify wherein the composition applied in the claimed method is an oil-in-water emulsion (as supported, e.g., by the examples and original claims 4, 6-9, 16 and 17). New claims 24-40 are added, supported, e.g., by the examples and original claims 2 and 14, 3 and 15, 4, 6, 7, 8, and 12, and Table 2 of the specification. No new matter has been added. Entry of the present amendment and reconsideration of the application are respectfully requested.

Status of the Claim

Claims 1-6, 12-15, and 20-23 are rejected under 35 U.S.C. § 103 as being unpatentable over Fabior® (Tazarotene) Foam 0.1% package insert (hereinafter referred to as "Fabior® 0.1%").

Claims 8-11, 16, 18, and 19 are rejected under 35 U.S.C. § 103 as being unpatentable over Fabior® 0.1% in view of Singh et al. (Dosage Forms: Non-Parenteral in Encyclopedia of Pharmaceutical technology, 2002, Marcel Dekker; hereinafter referred to as "Singh").

Claims 7 and 17 are rejected under 35 U.S.C. § 103 as being unpatentable over Fabior® 0.1% in view of Fiume et al. (*Int. J. Toxicol.* (2012 July-August), 31(4 Suppl.):5S-76S; hereinafter referred to as "Fiume").

Claims 1-23 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-23 of copending Application No. 15/977088.

Claims 1-23 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-23 of copending Application No. 16/179,576.

Applicant respectfully traverses these rejections for the reasons set forth below.

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IPR Petition - USP 11,311,482

Rejection of claims 1-6, 12-15, and 20-23 under 35 U.S.C. § 103 as being unpatentable over Fabior® 0.1%

Claims 1-6, 12-15, and 20-23 are rejected under 35 U.S.C. § 103 as being unpatentable over Fabior® 0.1%. Applicant respectfully traverses this rejection with respect to the present amended claims because Fabior® 0.1% does not teach or suggest all of the limitations of independent claims 13 and 40.

To demonstrate that a claim is obvious, the party asserting invalidity must present evidence that all limitations of the claim are present in the prior art. *Fresenius USA, Inc. v. Baxter Int'l, Inc.* 582 F.3d 1288, 1296 (Fed. Cir. 2009). See also *Ex parte Reed* (BPAI, Jul. 14, 2009, Slip op., p. 7) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)) ("To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art."). In addition, "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." MPEP § 2143.03 (9th Ed., Rev. 08.2017, Jan. 2018, p. 2100-235) (quoting *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970).

Nowhere in Fabior® 0.1% is there teaching or suggestion of a method of treating acne with a composition comprising tazarotene in an oil-in-water emulsion at a tazarotene concentration of from about 0.01 to 0.049 percent by weight (less than half the concentration in Fabior® 0.1%), as recited in the independent claim 13, or more specifically 0.045 percent by weight as recited in independent claim 40. Thus, Fabior® 0.1% does not teach or suggest all of the limitations of the pending claims. Consequently, these claims are nonobvious over Fabior® 0.1%.

The Examiner admitted that Fabior® 0.1% does not teach the claimed concentration of tazarotene, but asserted that:

> "the amount of tazarotene in the disclosed composition is a result-effective parameter that will affect the pharmacological and pharmacokinetic properties of the final composition. In this manner, the amount of a specific ingredient in a composition is clearly a result-effective parameter that a person of ordinary skill in the art would routine optimize."

Office action, p. 3. Applicant respectfully traverses this rejection.

"To reject a claim based on [teaching, suggestion, or motivation] rationale, Office personnel must resolve the *Graham* factual inquiries. Then Office personnel must articulate the following:

(1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference . . .;

(2) a finding that there was reasonable expectation of success . . .."

MPEP § 2143 (9th Ed., Rev. 08.2017, Jan. 2018, p. 2100-230) (Emphasis added).

The Examiner appears to assert that the motivation to modify the tazarotene concentration is found in Fabior® 0.1% itself because the Examiner asserted that the amount of tazarotene in Fabior® 0.1% is a result-oriented parameter that a person of ordinary skill would routinely optimize. Office action, p. 3. The Examiner further states at page 5 of the Office action that "optimization of these parameters is a routine practice, and consequently, would be prima facie obvious, absent factual evidence demonstrating an unexpected benefit of the claimed invention. Such rejection is in clear error, as the Examiner has failed to consider factual evidence submitted in the specification which clearly does demonstrate an unexpected benefit of the claimed invention. Consistent with the rule that all evidence of nonobviousness must be considered when assessing patentability, the PTO must consider comparative data in the specification in determining whether the claimed invention provides unexpected results. *In re Margolis*, 785 F.2d 1029, 1031, 228 USPQ 940, 941-42 (Fed. Cir. 1986).

More specifically, the Examiner has not articulated any reason why there would be reasonable expectation of success for reducing the tazarotene to less than half the concentration of tazarotene in Fabior® 0.1% for use in treatment of acne, as required by the present jurisprudence and the MPEP guidance. *In re Kahn*, 441 F.3d 977, 987 (Fed. Cir. 2006) (A fact finder "must provide some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct. . . . [T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."); *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 418; 127 S.Ct. 1727, 1741 (2007) ("Rejection on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning

with some rational underpinning to support the legal conclusion of obviousness."). In particular, the Examiner has not articulated the reason why there would be reasonable expectation of success for achieving better treatment efficacy when the tazarotene concentration is reduced to less than half of the concentration of tazarotene in Fabior® 0.1%. On the other hand, a lack of reasonable expectation of success for the Examiner's proposed modification of Fabior® 0.1% is evidenced by the fact that the manufacture of Fabior® 0.1% has not produced a commercial tazarotene foam with less than 0.1% tazarotene.

In contradistinction, the present inventors unexpectedly and surprisingly discovered that the presently claimed method of treating acne employing an emulsion composition having less than 0.05% tazarotene is more efficacious in treating acne than a commercial emulsion having 0.1% tazarotene, at least as measured by Evaluator's Global Severity Score ("EGSS") and reduction of inflammatory lesions. *In re Soni*, 34 U.S.P.Q.2d 1684, 1687 ("[T]hat which would have been surprising to a person of ordinary skill in a particular art would not have been obvious."). See Tables 6 and 7 of the present specification, as filed, which presents factual evidence which clearly demonstrates an unexpected benefit of the claimed invention. For the Examiner's convenience, Tables 6 and 7 are reproduced immediately below.

TABLE 6

Treatment % Success (ITT) at 12 Weeks			
	Combined Placebo N = 69	Composition A N = 69	Tazorac ® 0.1% Cream N = 72
EGSS - Clear or Almost Clear	10.1%	18.8%	16.7%
Inflammatory Lesions			
Absolute Change	-14.0	-18.1	-16.8
% Change	-51.41%	-63.75%	-59.99%
Non-inflammatory Lesions			
Absolute Change	-13.1	-21.6	-20.3
% Change	-35.18%	-56.86%	-54.09%

TABLE 7

	Treatment % Success (ITP)		
	Combined Placebo N = 57	Composition A N = 54	Tazorac ® 0.1% Cream N = 56
EGSS - Clear or Almost Clear	12.3%	20.4%	16.1%
Inflammatory Lesions	-14.2	-18.3	-18.2
Non-inflammatory Lesions	-11.8	-20.8	-21.9

Since use of a composition having a tazarotene concentration less than half of the concentration of Fabior® 0.1%, as required by independent claims 13 and 40, is surprisingly more efficacious in treating acne than a composition having the same concentration as Fabior® 0.1%, the claimed invention is clearly nonobvious over Fabior® 0.1%.

Additionally in response to the Examiner's assertions that the claim limitation "as a sole active pharmaceutical ingredient" (present claims 23 and 24-30 dependent thereon) does not preclude additional active agents because the claim preamble "comprising" is open ended, such further comments are additionally in clear error. While the use of "comprising" in the preamble may initially signal that the entire claim is presumptively open-ended, any such initial presumption is clearly overcome with respect to the number of active agents permitted in these claims by use of the subsequent expressly stated limitation that tazarotene is a sole active pharmaceutical ingredient in such claims.

Rejection of claims 8-11, 16, 18, and 19 under 35 U.S.C. § 103 as being unpatentable over Fabior® 0.1% in view of Singh

Claims 8-11, 16, 18, and 19 are rejected under 35 U.S.C. § 103 as being unpatentable over Fabior® 0.1% in view of Singh. Applicant respectfully traverses this rejection with respect to the present amended claims because the combination of Fabior® 0.1% and Singh does not teach or suggest all of the limitations of each of remaining claims 16, 18 and 19. Moreover, the combination of Fabior® 0.1% and Singh does not provide teaching, suggestion, or motivation to reduce the tazarotene to from about 0.01 to 0.049 percent by weight in a composition applied to treat acne with reasonable expectation of better efficacy than applying a composition having 0.1% tazarotene as demonstrated in the present application.

As presented above, Fabior® 0.1% does not teach or suggest use of any tazarotene composition having from about 0.01 to 0.049 percent by weight for any application. Adding Singh to show disclosure of carbomers still does not show that the combination of Fabior® 0.1% and Singh teaches or suggests use of any tazarotene composition having from about 0.01 to 0.049 percent by weight. In other words, the combination of Fabior® 0.1% and Singh still does not teach or suggest all of the limitations of each of claims 16, 18, and 19. Therefore, these claims are nonobvious over Fabior® 0.1% in view of Singh.

Moreover, as presented above, a claimed composition having less than half of the tazarotene concentration of Fabior® 0.1% was shown surprisingly to have better efficacy in treating acne than a composition having 0.1% tazarotene. Adding Singh merely to show disclosure of carbomers still does not negate this fact. Since there is nothing in the combination of Fabior® 0.1% and Singh that suggests that reducing Fabior® 0.1%'s tazarotene concentration would result in better efficacy in treating acne with any reasonable expectation of success, the present claimed invention is further nonobvious over Fabior® 0.1% in view of Singh.

Rejection of claims 7 and 17 under 35 U.S.C. § 103 as being unpatentable over Fabior® 0.1% in view of Fiume

Claims 7 and 17 are rejected under 35 U.S.C. § 103 as being unpatentable over Fabior® 0.1% in view of Fiume. Applicant respectfully traverses this rejection because the combination of Fabior® 0.1% and Fiume does not teach or suggest all of the limitations of remaining claim 17. Moreover, the combination of Fabior® 0.1% and Fiume does not provide teaching, suggestion, or motivation to reduce the tazarotene to from about 0.01 to 0.049 percent by weight in a composition applied to treat acne with reasonable expectation of better efficacy than applying a composition having 0.1% tazarotene.

As presented above, Fabior® 0.1% does not teach or suggest use of any tazarotene composition having from about 0.01 to 0.049 percent by weight for any application. Adding Fiume merely to show disclosure of diethyl sebacate still does not show that the combination of Fabior® 0.1% and Fiume teaches or suggests use of any tazarotene composition having from about 0.01 to 0.049 percent by weight. In other words, the combination of Fabior® 0.1% and

Fiume still does not teach or suggest all of the limitations of claim 7. Therefore, this claim is nonobvious over Fabior® 0.1% in view of Fiume.

Moreover, as presented above, a claimed composition having less than half of the tazarotene concentration of Fabior® 0.1% was shown surprisingly to have better efficacy in treating acne than a composition having 0.1% tazarotene. Adding Fiume to show disclosure of diethyl sebacate still does not negate this fact. Since there is nothing in the combination of Fabior® 0.1% and Fiume that suggests that reducing Fabior® 0.1%'s tazarotene concentration would result in better efficacy in treating acne with any reasonable expectation of success, the present claimed invention is further nonobvious over Fabior® 0.1% in view of Fiume.

Rejection of claims 1-23 on the ground of nonstatutory double patenting

Claims 1-23 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-23 of copending Application No. 15/977088. As this is a provisional rejection, and as no claims have yet been indicated as otherwise being allowable, Applicant requests to defer filing of any required Terminal Disclaimer, or cancelling of corresponding claims in one of the applications, until otherwise allowable claims are indicated.

Rejection of claims 1-23 under 35 U.S.C. § 101 over copending Application No. 16/179,576

Claims 1-23 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-23 of copending Application No. 16/179,576. Reconsideration of this provisional rejection is respectfully urged in view of the amendments to the claims in each of such applications.

Conclusion

Since Fabior® 0.1% or its combination with Singh or Fiume does not teach or suggest all of the limitations of each of pending claims 13-40, a *prima facie* case of obviousness of the present claims over Fabior® 0.1%, or its combination with Singh or Fiume, has not been established. Alternatively, since evidence has been presented in the application that the claimed method of treating acne by applying a composition having less than half of Fabior® 0.1%'s tarazotene concentration surprisingly had better efficacy than applying a composition having Fabior® 0.1%'s tazarotene concentration, such evidence of unexpected results clearly overcome

any alleged case of *prima facie* obviousness of the claimed invention over Fabior® 0.1% or its combination with Singh or Fiume.

In view of the foregoing, it is submitted that the claims are patentable and in condition for allowance. Allowance of the claims at an early date is solicited.

Precautionary Fee-Charge Authorization

By way of precaution, the Commissioner is authorized to charge any underpayment of fees or fee amounts not otherwise authorized but necessary for the consideration of this paper or the continued pendency of this application and to credit any overpayment to Deposit Account Number 03-3875 of Harter Secrest & Emery LLP.

Please grant any extensions of time necessary for the filing of this Amendment.

Respectfully submitted,

/Andrew J. Anderson/

Andrew J. Anderson, Reg. No. 33,564

Attorney for the Applicant
585-231-1157

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AMENDMENTS TO THE CLAIMS

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

1-12. (Cancelled)

13. **(currently amended)** A method of treating acne vulgaris, the method comprising topically applying a pharmaceutical composition to an affected area of a body of a subject suffering from acne vulgaris; wherein the composition comprises:

tazarotene or a pharmaceutically acceptable tazarotenic acid salt present in the composition at a positive concentration from about 0.01 to 0.049 percent by weight of the composition; and

a dermatologically acceptable oil-in-water emulsion vehicle; wherein said composition is an oil-in-water emulsion lotion.

14. **(currently amended)** The method of claim 13, ~~comprising~~ wherein the composition comprises tazarotene at a concentration of from about 0.03 to 0.049 percent by weight of the composition.

15. **(currently amended)** The method of claim 13, ~~comprising~~ wherein the composition comprises tazarotene at a concentration of about 0.045 percent by weight of the composition.

16. **(original)** The method of claim 13, wherein said emulsion comprises:

an aqueous phase comprising water, a carbomer homopolymer, and a polymeric emulsifier; and

an oil phase comprising at least one member selected from the group consisting of a dicarboxylic acid ester and a mineral oil.

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17. **(original)** The method of claim 16, wherein the oil phase of the emulsion comprises diethyl sebacate.

18. **(original)** The method of claim 13, wherein the oil phase of the emulsion comprises diethyl sebacate and mineral oil.

19. **(original)** The method of claim 13, wherein the oil phase of the emulsion consists of diethyl sebacate and mineral oil.

20. **(original)** The method of claim 13, wherein said applying is carried out once per day for at least eight weeks.

21. **(original)** The method of claim 13, wherein said applying is carried out once per day for at least twelve weeks.

22. **(original)** The method of claim 13, wherein said applying is carried out once per day for twelve weeks.

23. **(original)** The method of claim 13, wherein the pharmaceutical composition contains the tazarotene or the tazarotenic acid salt as a sole active pharmaceutical ingredient.

24. **(New)** The method of claim 23, wherein the composition comprises tazarotene at 0.03 to 0.049 percent by weight of the composition.

25. **(New)** The method of claim 23, wherein the composition comprises tazarotene at about 0.045 percent by weight of the composition.

26. **(New)** The method of claim 25, wherein the tazarotene or tazarotenic acid salt is dissolved in a liquid oil component of the emulsion.

27. **(New)** The method of claim 25, wherein an oil phase of the emulsion comprises a liquid oil component comprising a dicarboxylic acid ester ("DCAE"), a monocarboxylic acid ester ("MCAE"), or combinations thereof.

28. **(New)** The method of claim 25, wherein an oil phase of the emulsion comprises diethyl sebacate.

29. **(New)** The method of claim 25, wherein an aqueous phase of the emulsion comprises water and a carbomer homopolymer.

30. **(New)** The method of claim 25, wherein the composition has a pH of about 4 to about 6.

31. **(New)** The method of claim 13, wherein the tazarotene or tazarotenic acid salt is dissolved in a liquid oil component of the emulsion.

32. **(New)** The method of claim 13, wherein an oil phase of the emulsion comprises a liquid oil component comprising a dicarboxylic acid ester ("DCAE"), a monocarboxylic acid ester ("MCAE"), or combinations thereof.

33. **(New)** The method of claim 13, wherein an oil phase of the emulsion comprises diethyl sebacate.

34. **(New)** The method of claim 13, wherein an aqueous phase of the emulsion comprises water and a carbomer homopolymer.

35. **(New)** The method of claim 13, wherein the composition has a pH of about 4 to about 6.

36.**(New)** The method of claim 13, wherein the composition consists essentially of:

0.01 – 0.049 weight % tazarotene;

diethyl sebacate;

light mineral oil;

sorbitan monooleate;

sorbitol solution, 70%;

methylparaben;

propylparaben;

edetate disodium dihydrate;

carbomer polymer type B;

carbomer homopolymer type A;

sodium hydroxide;

purified water.

37.**(New)** The method of claim 13, wherein the composition consists essentially of:

0.02 – 0.049 weight % tazarotene;

1 - 5 weight % diethyl sebacate;

5 - 15 weight % light mineral oil;

0.01 - 1 weight % sorbitan monooleate;

5 - 15 weight % sorbitol solution, 70%;

0.05 - 0.3 weight % methylparaben;

0.01 – 0.1 weight % propylparaben;

0.02 – 0.1 weight % edetate disodium dihydrate;

0.1 - 1 weight % carbomer polymer type B;

0.2 – 1.5 weight % carbomer homopolymer type A;

sodium hydroxide, q.s. to pH 5.5 ±0.5; and

purified water, q.s. to 100 weight %.

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38.**(New)** The method of claim 13, wherein the composition consists essentially of:

0.03 – 0.049 weight % tazarotene;

2 - 4 weight % diethyl sebacate;

5 - 10 weight % light mineral oil;

0.02 – 0.5 weight % sorbitan monooleate;

7 - 12 weight % sorbitol solution, 70%;

0.1 - 0.3 weight % methylparaben;

0.01 – 0.05 weight % propylparaben;

0.02 – 0.7 weight % edetate disodium dihydrate;

0.2 – 0.7 weight % carbomer polymer type B;

0.3 – 1 weight % carbomer homopolymer type A;

sodium hydroxide, q.s. to pH 5.5 ±0.5; and

purified water, q.s. to 100 weight %.

39.**(New)** The method of claim 13, wherein the composition consists essentially of:

0.04 – 0.049 weight % tazarotene;

2.5 – 3.5 weight % diethyl sebacate;

7.5 – 8.5 weight % light mineral oil;

0.05 – 0.2 weight % sorbitan monooleate;

10 - 11 weight % sorbitol solution, 70%;

0.1 - 0.2 weight % methylparaben;

0.02 – 0.04 weight % propylparaben;

0.03 – 0.06 weight % edetate disodium dihydrate;

0.3 – 0.05 weight % carbomer polymer type B;

0.5 – 0.7 weight % carbomer homopolymer type A;

sodium hydroxide, q.s. to pH 5.5 ±0.5; and

purified water, q.s. to 100 weight %.

40. **(New)** A method of treating acne vulgaris, the method comprising topically applying a pharmaceutical composition to an affected area of a body of a subject suffering from acne vulgaris; wherein the composition consists essentially of:

0.045 weight % tazarotene;

2.97 weight % diethyl sebacate;

8.03 weight % light mineral oil;

0.1 weight % sorbitan monooleate;

10.7 weight % sorbitol solution, 70%;

0.17 weight % methylparaben;

0.03 weight % propylparaben;

0.05 weight % edetate disodium dihydrate;

0.4 weight % carbomer polymer type B;

0.6 weight % carbomer homopolymer type A;

sodium hydroxide, q.s. to pH 5.5 ±0.5; and

purified water, q.s. to 100 weight %.

Detail

APPLICATION NUMBER	2461/MUM/2009
APPLICANT NAME	LYKA LABS LIMITED
DATE OF FILING	22/10/2009 16:15:56
E-MAIL	gopanair@gnaipr.net
PRIORITY DATE	NA
TITLE OF INVENTION	"TOPICAL FORMULATION CONTAINING HALOBETASOL PROPIONATE AND TAZAROTENE"
PUBLICATION DATE (U/S 11A)	30/03/2012

Application Status

Status	Application Published

Department of Industrial Policy and Promotion
Government of India

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CBR संख्या 12278 दि. 21-10-2010
के रूप में प्राप्त हुए

FORM 2

THE PATENTS ACT 1970

(39 of 1970)

&

The Patents Rules, 2003

COMPLETE SPECIFICATION

(See section 10 and rule 13)

अनन्तिम विनिर्देश के पश्चात संपूर्ण विनिर्देश
21 OCT 2010 फाइल किया गया।
COMPLETE AFTER PROVISIONAL
SPECIFICATION FILED ON 21 OCT 2010

1. TITLE OF THE INVENTION:

"TOPICAL FORMULATION CONTAINING HALOBETASOL PROPIONATE AND TAZAROTENE"

2. APPLICANT:

(a) NAME: Lyka Labs Limited.

(b) NATIONALITY: Indian Company incorporated under the Indian Companies Act, 1956

(c) ADDRESS: 101, Shivshakti Industrial Estate, Andheri-Kurla Road, Andheri (East), Mumbai 400059, Maharashtra, India.

3. PREAMBLE TO THE DESCRIPTION:

The following specification particularly describes the invention and the manner in which it is to be performed:

DUPLICATE

2461 | मुंबई/MUM/2009

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TECHNICAL FIELD OF INVENTION:

The present invention relates to a topical pharmaceutical composition comprising combination of therapeutically effective amount of high potency corticosteroid such as Halobetasol propionate and retinoid such as Tazarotene, useful for the treatment of different types of psoriasis such as Plaque Psoriasis, Guttate Psoriasis, Seborrheic Psoriasis, Palmoplantar Psoriasis, Pustular Psoriasis, Palmoplantar Pustulosis or Acropustulosis Erythrodermic Psoriasis, Inverse Psoriasis or Flexural Psoriasis. The invention further relates to process for preparation thereof.

BACKGROUND OF THE INVENTION:

Proliferative skin diseases are widespread throughout the world and afflict millions of humans. The expression "proliferative skin diseases" means benign and malignant proliferative skin diseases which are characterized by accelerated cell division in the epidermis, dermis or appendages thereto, associated with incomplete tissue *differentiation. Such diseases includes psoriasis, atopic dermatitis, non-specific* dermatitis, primary irritant contact dermatitis, allergic contact dermatitis, basal and squamous cell carcinomas of the skin, lamellar ichthyosis, epidermolytic hyperkeratosis, premalignant sun induced keratosis, non-malignant kertosis, acne and seborrheic dermatitis in humans.

Among other proliferative skin diseases; psoriasis is a chronic skin disorder that affects 2 4% of the population world-wide.

As psoriasis is a nonfatal disease, its profound impact on the overall quantity of life and well-being is often underestimated. It has a significant effect on the physical, social, psychological and financial avenues of life and an early and aggressive treatment is required to prevent disease progression.

Many patients require life-long treatments for repeated relapses. Treatments for psoriasis have thus far included topicals (including anthralin), steroids, vitamin D, analogues and retinoids, such as tazarotene and other forms of treatment include systemic

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immunosuppressant such as methotrexate and cyclosporin, phototherapy such as broad and narrow-band ultraviolet Type B (UVB) and Goeckerman treatment, which is a combination of tar and UVB therapy. Recently a new class of drugs, the biologics, has also been approved for the treatment of psoriasis.

Though monotherapies are effective for the treatment of psoriasis, evidences are accumulating that combining topical retinoid, specifically Tazarotene with other established antipsoriatic therapies result in enhanced efficacy and reduced adverse events. In particular, concomitant use of topical Tazarotene with a mid-potency or high-potency corticosteroid in the treatment of psoriatic plaques enhances efficacy and reduces the risk of corticosteroid skin atrophy. The results of completed Phase III clinical trials of this agent indicate a beneficial effect in moderate to severe plaque psoriasis.

Retinol have been defined narrowly as comprising vitamin A (retinol) and its derivatives, such as vitamin A aldehyde (retinal) and vitamin A acid (retinoic acid), which are metabolites of natural vitamin A. However, subsequent research has resulted in a larger class of chemical compounds that are termed retinoids because they have biological actions similar to the parent vitamin A, even though there may be great structural dissimilarities. Thus, Retinol (Vitamin A) is an organic molecule that is not synthesized in the body; therefore, it must be obtained from the diet, as either preformed retinol or its precursor beta carotene, which is then converted *in vivo* into retinol.

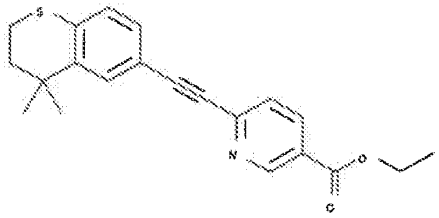
Further, Retinol binds to several retinoic acid receptors in the nucleus, including α, β and γ *with receptor γ being the predominant in human epidermis. Tazarotene is a vitamin A* derivative that is converted *in vivo* into its active agent, Tazarotene acid, which binds to all three retinoic acid receptors with particularly increased selectivity for receptors β and γ. It has little affinity for the retinoic X receptors.

Tazarotene is mainly used for the treatment of psoriasis, acne vulgaris and sun damaged skin (photodamage). Tazarotene induces the expression of tazarotene-induced gene 3 (TIG3), a tumor suppressor gene. In psoriasis, Tazarotene acid normalizes abnormal keratinocyte differentiation, decreases expression of inflammatory markers and reduces keratinocyte hyperproliferation. Thus, it is very useful as an anti-psoriatic agent.

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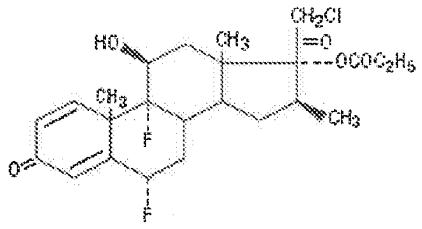
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Chemically, Tazarotene is ethyl 6-[2-(4,4-dimethyl-3,4 dihydro 2*H* 1 benzothiopyran 6-yl)ethynyl]pyridine-3-carboxylate It has the following structural formula:



Further, like other topical corticosteroids, Halobetasol propionate has anti-inflammatory, antipruritic and vasoconstrictive actions. The mechanism of the anti-inflammatory activity of the topical corticosteroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A_2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A_2.

Chemically, Halobetasol propionate is 21-chloro-6α, 9 difluoro 11β, 17 dihydroxy 16β methylpregna-1, 4 diene-3 20-dione, 17-propionate, $C_{25}H_{31}ClF_2O_5$. It has the following structural formula:



Moreover, methods for the treatment of inflammatory dermatoses by administering topical compositions comprising a corticosteroid such as clobetasol propionate, triamcinolone acetonide and hydrocortisone along with a retinoid such as tretinoin in amounts which are effective for treating the dermatoses is disclosed in US5998395.

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US2004192662 provides a method for treating proliferative skin diseases comprising the administration of an effective amount of Tazarotene and an effective amount of a corticosteroid (mometasone furoate and fluocinolone acetonide) useful for treating psoriasis.

Indian Patent Application No.1741/MUM/2007 (corresponding PCT Publication no WO2009063491) relates to process for preparation of topical compositions comprising arbutin, corticosteroid (triamcinolone or desonide), retinoid (tretinoin) and optionally a sun protection factor (SPF) for the treatment of skin diseases includes melasma, ephelides, post inflammatory hyperpigmentation, dermal blemishes, non-congenital hyperpigmentation, and solar lentigo.

An article titled "In vitro compatibility of tazarotene with other topical treatments of psoriasis" by Hecker D, Worsley J, Yueh G, Lebwohl M., discloses the compatibility of tazarotene gel with 15 other topical steroids of different potencies, used in the treatment of psoriasis.

An article titled "Tazarotene 0.1% gel plus corticosteroid cream in the treatment of plaque psoriasis" by Lebwohl et al discloses a combination of 0.1% tazarotene gel with either placebo, low potency steroid (0.01% fluocinolone acetonide cream), mid-potency steroid (0.1% mometasone furoate cream) or high-potency steroid (0.05% fluocinonide cream). The said article illustrated that 0.1% Tazarotene gel once-daily in combination with once-daily application of mid- or high-potency topical steroid achieved a significantly greater reduction in scaling, erythema and overall lesion severity than tazarotene once-daily with placebo. Similar studies by Tanghetti et al. and Gollnick et al. confirmed that the use of mid- and high-potency steroids can enhance the efficacy of tazarotene in significantly improving psoriasis.

An article titled "The efficacy of topical tazarotene monotherapy and combination therapies in psoriasis" by John Koo et al discloses tazarotene in combination with 0.05% diflorasone diacetate which gives reduction of 28% in the epidermal thickness. Further, tazarotene significantly reduced epidermal atrophy induced by 0.05% diflorasone diacetate.

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An article titled "Evaluating the potential clinical benefits of switching patients with plaque psoriasis from calcipotriene to tazarotene treatment" by Coynik D compare the effects of 0.1% tazarotene gel combined with a topical corticosteroid to calcipotriene combined with a topical corticosteroid. The authors concluded that switching patients from calcipotriene to tazarotene could increase efficacy and patient satisfaction.

Thus, in light of above; though there are prior arts describing corticosteroids and retinoids in combination, none of them has specifically evaluated the benefits and effect of the combination comprising Halobetasol propionate and Tazarotene simultaneously.

Accordingly, the present invention discloses an effective combination comprising Halobetasol propionate and Tazarotene useful for treating different types of psoriasis such as Plaque Psoriasis, Guttate Psoriasis, Seborrheic Psoriasis, Palmoplantar Psoriasis, Pustular Psoriasis, Palmoplantar Pustulosis or Acropustulosis Erythrodermic Psoriasis, Inverse Psoriasis or Flexural Psoriasis. Though these two drugs have entirely different modes of action and when combined in a single formulation, have synergistic effects which lead to more rapid clearing and are notably effective for types of psoriasis which have not responded to either corticosteroids or retinoids alone.

OBJECT OF THE INVENTION:

The main object of the current invention is to provide the topical composition comprising Halobetasol propionate and Tazarotene, useful for the treatment of different types of psoriasis such as Plaque Psoriasis, Guttate Psoriasis, Seborrheic Psoriasis, Palmoplantar Psoriasis, Pustular Psoriasis, Palmoplantar Pustulosis or Acropustulosis Erythrodermic Psoriasis, Inverse Psoriasis or Flexural Psoriasis and process for preparation thereof.

SUMMARY OF THE INVENTION:

In accordance with the above objective, the present invention discloses topical composition comprising of high potency corticosteroid such as Halobetasol propionate and retinoid such as Tazarotene having synergistic effect against different types of

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psoriasis such as Plaque Psoriasis, Guttate Psoriasis, Seborrheic Psoriasis, Palmoplantar Psoriasis, Pustular Psoriasis, Palmoplantar Pustulosis or Acropustulosis Erythrodermic Psoriasis, Inverse Psoriasis or Flexural Psoriasis.

In further aspect, the present invention provides a process for preparation of said composition.

In yet another aspect, the present invention provides the said combination in different dosage forms such as cream, ointment, gel or lotion.

DETAILED DESCRIPTION OF THE INVENTION:

The invention will now be described in detail in connection with certain preferred and optional embodiments, so that various aspects thereof may be more fully understood and appreciated.

The present invention describes a topical composition for the treatment of different types of psoriasis such as Plaque Psoriasis, Guttate Psoriasis, Seborrheic Psoriasis, Palmoplantar Psoriasis, Pustular Psoriasis, Palmoplantar Pustulosis or Acropustulosis Erythrodermic Psoriasis, Inverse Psoriasis or Flexural Psoriasis which comprises of Halobetasol propionate a synthetic corticosteroid and Tazarotene a retinoid in the form of cream, ointment, gel or lotion.

The term "topical" as employed herein relates to the use of the active ingredient incorporated in a suitable pharmaceutical carrier, and applied at the site of the disease for exertion of local action.

More particularly, the present invention provides the topical composition comprising therapeutically effective amount of Halobetasol propionate and Tazarotene along with pharmaceutically acceptable excipients.

In one of the embodiment, the topical cream/ointment formulation comprises Halobetasol propionate (0.025 to 0.05% w/w) and Tazarotene (0.05 to 0.1% w/w) along with the

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pharmaceutical excipients selected from the group comprising of ointment/cream base like waxes, preservatives, antioxidants, buffering agent, chelating agent, penetration enhancer, surfactant, solubilizer, emulsifier and combinations thereof .

According to the embodiment, the topical cream of Halobetasol propionate and Tazarotene, is prepared using excipients selected from the group consisting of Cetostearyl alcohol, Cetomacrogol 1000, Light liquid paraffin, White soft paraffin, Chlorocresol, Butylated hydroxy toluene, Propylene glycol, Hexylene glycol, Disodium EDTA and Citric acid.

According to another embodiment, the ointment of Halobetasol propionate and Tazarotene is prepared using excipients selected from the group consisting of Butylated hydroxy toluene, Sorbitan sesquioleate, Propylene glycol, Hexylene glycol, White soft paraffin, White bees wax, Cetyl alcohol, Lanolin anhydrous and Liquid paraffin.

According to the invention, the topical composition of Halobetasol propionate and Tazarotene is in the form of cream that can be prepared by melting oil base excipients, emulsifier and optionally antioxidant; followed by dissolving chelating agent in sufficient quantity of purified water; mixing oil phase and water phase under stirring for the emulsion formation at 60-70°C; this is followed by adding preservatives dissolved in solubilizer, penetration enhancer, etc.; followed by cooling and stirring, till stable cream formation takes place. Active ingredient dissolved in Solubilizer can be added before cream formation or while the cream formation is taking place.

According to the invention, the topical composition of Halobetasol propionate and Tazarotene . is in the form of ointment that can be prepared by melting ointment base excipients and mixing surfactant to ointment base; adding active ingredient either by dissolving or suspending in solubilizer under constant stirring; cooling and stirring the till ointment formation takes place.

In further embodiment, the topical gel/lotion formulation comprises Halobetasol propionate (0.025 to 0.05% w/w) and Tazarotene (0.05 to 0.1% w/w) along with pharmaceutical excipients selected from the group comprising oil base, preservatives,

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antioxidants, buffering agent, chelating agent, penetration enhancer, co-solvent, Carbopol, pH adjuster along with vehicle, surfactant, solubilizer, emulsifier and combinations thereof.

Further, the gel of Halobetasol propionate and Tazarotene is prepared using excipients selected from the group consisting of Carbopol 980, Carbopol 940; Hydroxy Propyl Cellulose, Disodium EDTA, Banzyl Alcohol ,Chlorocresol, Butylated Hydroxytoluenen, Ascorbic Acid, Sodium Sulphide, Sodium Metabisulphite, Propylene glycol, Citric acid, Sodium Citrate, Triethanolamine, Sodium Hydroxide, Diethanolamine, Purified Water and Isopropyl alcohol.

According to the present invention, the topical composition of Halobetasol and Tazarotene is in the form of gel that can be prepared by soaking carbopol 980 slurry in sufficient quantity of purified water; dissolving chelating agent in sufficient quantity of purified water and adding to carbopol slurry; adding active ingredients and preservative dissolving or dispersing in solubilizer; this is followed by adding Isopropyl alcohol under stirring; checking the pH and adjusting the pH around 4.0 to 6.0 with 20% triethanolamine (TEA) or Diethanolamine or sodium hydroxide solution, till gel formation takes place.

According to another preferred embodiment, the lotion of Halobetasol propionate and Tazarotene is prepared using excipients selected from the group consisting of Cetyl alcohol, Sodium Lauryl Sulphate, Propylene glycol, Polyethylene Glycol 400, White soft paraffin, Butylated Hydroxytoluene, Methyl paraben, Propyl paraben and Chlorocresol.

Further, the topical composition of Halobetasol and Tazarotene in the form of lotion is prepared by melting emulsifier, oil base and preservatives and optionally antioxidant by heating at 70-80°C; mixing oil phase and water phase under stirring for the emulsion formation at 60-70°C; followed by adding surfactant etc. for the stable lotion formation. Active ingredient dissolved in solubilizer can be added before emulsion formation or while the emulsion formation is taking place.

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Alternately, lotion can be prepared by dissolving Halobetasol in hot Propylene Glycol and dissolving Tazarotene in Propylene glycol in separate beakers. Simultaneously, dissolving Butylated Hydroxy Toluene in PEG 400; and then adding all the solutions into one vessel followed by mixing, till clear solution is obtained and making up the volume with propylene glycol or PEG 400.

The invention is further illustrated by following non-limiting examples of this combination product:

EXAMPLES:

Example 1:

Composition for the Preparation of Cream:

	Ingredients	Concentration % w/w
Active Ingredients	Halobetasol propionate	0.025 - 0.05%
	Tazarotene	0.05 0.1%
Emulsifiers	Cetostearyl alcohol	4.2 7.8%
	Cetomacrogol 1000	1.05 - 1.95%
Oil Base	Light Liquid Paraffin	2.8 - 5.2%
	White soft Paraffin	2.8 - 5.2%
Penetration enhancers/ solubilizer	Propylene glycol	6.3 - 10.2%
	Hexylene glycol	7 - 13%
Antioxidant	Butylated Hydroxy Toluene	0.01 0.025%
Chelating agent	Disodium EDTA	0.007 - 0.013%
Preservative	Chlorocresol	0.07 - 0.13%
Vehicle	Water	q.s

Process for preparing Cream formulation is as follows:

1) Melting oil base excipients, emulsifier and optionally antioxidant;
2) dissolving chelating agent in sufficient quantity of purified water;
3) mixing oil phase and water phase under stirring for the emulsion formation at 60°-70°C;

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4) dissolving or dispersing active ingredients in solubilizer and adding to bulk of step 3;

5) dissolving preservative in Solubilizer and adding it to bulk of step 4 under stirring;

6) cooling and stirring of the bulk till cream formation takes place; and

7) adjusting the weight with purified water.

Example 2:

Composition for the Preparation of Ointment:

	Ingredients	Concentration % w/w
Active Ingredients	Halobetasol propionate	0.025 - 0.05%
	Tazarotene	0.05 - 0.1%
Solubilizers	Hexylene glycol	7 - 13%
	Propylene glycol	7 - 13%
Ointment base	White Soft Paraffin	54.95 - 90%
	White Beeswax	21 - 39 %
Surfactant	Sorbitan Sesquioleate	0.105 - 0.195%

Process for preparing Ointment formulation is as follows:

1) Melting ointment base excipients and mixing surfactant to ointment base;

2) adding active ingredients to bulk (melted ointment base) either by dissolving or dispersing in solubilizer under constant stirring; and

3) cooling and stirring the bulk till ointment formation takes place.

Example 3:

Composition for the Preparation of Lotion:

	Ingredients	Concentration % w/v
Active Ingredients	Halobetasol propionate	0.025 - 0.05%
	Tazarotene	0.05 0.1%
Oil base	White Soft Paraffin	0.525 - 0.975%
Emulsifier	Cetyl Alcohol	1.33 - 2.47%
Solubilizer	Propylene Glycol	5.25 - 9.75%
Antioxidant	Butylated Hydroxy Toluene	0.01 - 0.025%
Preservatives	Methyl Paraben	0.245 - 0.455%

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	Propyl Paraben	0.035 - 0.065%
Surfactant	Sodium Lauryl Sulphate	0.21 - 0.39%
Vehicle	Water	q.s

Process for preparing Lotion formulation is as follows:

1) Melting emulsifier, oil base, and preservatives and optionally antioxidant by heating at 70-80°C;
2) mixing oil phase and sufficient water phase under stirring for the emulsion formation at 60°-70°C;
3) dissolving or dispersing active ingredients in solubilizer;
4) adding active drug either before emulsion formation or during emulsion formation;
5) dissolving surfactant in sufficient purified water and then adding to bulk;
6) cooling and stirring the bulk till lotion formation takes place and then making up the volume.

Alternate composition for the Preparation of Lotion:

	Ingredients	Concentration % w/v
Active Ingredients	Halobetasol propionate	0.025 - 0.05%
	Tazarotene	0.05 - 0.1%
Solubilizer	PEG 400	40.25 - 74.75%
Antioxidant	Butylated Hydroxy Toluene	0.014 - 0.026%
Solubilizer	Propylene Glycol	q.s

Alternate process for preparing Lotion formulation is as follows:

1) Dissolving Halobetasol in hot Propylene Glycol;
2) In a separate beaker dissolving Tazarotene in Propylene glycol;
3) dissolving Butylated hydroxy toluene in PEG 400;
4) adding all the solutions into one vessel, mixing well till clear solution is obtained and making up the volume with propylene glycol or PEG 400

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Example 4:

Composition for the Preparation of Gel:

	Ingredients	Concentration % w/w
Active Ingredients	Halobetasol propionate	0.025 - 0.05%
	Tazarotene	0.05 - 0.1%
Gelling agent	Carbopol 980	0.595 - 1.105%
Chelating agent	Disodium EDTA	0.035 - 0.065%
Penetration Enhancer/Solubilizer	Propylene Glycol	21 - 39%
Preservative	Benzyl Alcohol	0.3 - 1.3%
Vehicle	Isopropyl Alcohol	7 - 13%
Vehicle	Water	q.s
pH adjusting agent	TEA 20% solution	q.s

Process for preparing Gel formulation is as follows:

1) Preparing carbopol 980 slurry in sufficient quantity of purified water;
2) dissolving chelating agent in sufficient quantity of purified water and adding to carbopol slurry of step 1;
3) dissolving Halobetasol propionate in solubilizer and adding to bulk of step 2;
4) dissolving Tazarotene in Benzyl alcohol and adding to bulk of step 3;
5) adding Isopropyl alcohol to the bulk of step 4 under stirring;
6) checking the pH and adjusting pH with 20% pH adjusting agent about 4.0 to 6.0 till gel formation takes place;
7) adjusting the final weight with purified water and mixing well.

Overages of Halobetasol propionate and Tazarotene can be added for the long term stability purpose.

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STABILITY DATA:

Stability study of the product is carried out as per ICH guideline for 6 months at accelerated condition of 40°C / 75% RH and real time condition of 30°C / 65%RH. Product is stable.

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We Claim,

1. A topical pharmaceutical composition comprising Halobetasol propionate and Tazarotene in therapeutically effective amounts along with pharmaceutically acceptable excipients; useful for the treatment of different types of psoriasis such as Plaque Psoriasis, Guttate Psoriasis, Seborrheic Psoriasis, Palmoplantar Psoriasis, Pustular Psoriasis, Palmoplantar Pustulosis or Acropustulosis Erythrodermic Psoriasis, Inverse Psoriasis or Flexural Psoriasis.

2. The topical pharmaceutical composition as claimed in claim 1, wherein the Halobetasol propionate is present in an amount of 0.025 to 0.05%.

3. The topical pharmaceutical composition as claimed in claim 1, wherein the Tazaroten is present in an amount of 0.05 to 0.1%.

4. The topical pharmaceutical composition as claimed in claim 1, wherein the composition is in the form of cream, ointment, gel or lotion.

5. The topical pharmaceutical composition as claimed in claim 4, wherein the cream formulation contains pharmaceutically acceptable excipients selected from the group consisting of Cetostearyl alcohol, Cetomacrogol 1000, Light liquid paraffin White soft paraffin, Chlorocresol, Butylated hydroxy toluene, Propylene glycol, Hexylene glycol, Disodium EDTA and Citric acid.

6. The topical pharmaceutical composition as claimed in claim 4, wherein the ointment contains pharmaceutically acceptable excipients selected from the group consisting of Butylated hydroxy toluene, Sorbitan sesquioleate, Propylene glycol, Hexylene glycol, White soft paraffin, White bees wax, Cetyl alcohol, Lanolin anhydrous and Liquid paraffin.

7. The topical pharmaceutical composition as claimed in claim 4, wherein the gel formulation contains pharmaceutically acceptable excipients selected from the group consisting of Carbopol 980, Carbopol 940; Hydroxy propyl cellulose,

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Disodium EDTA, Banzyl Alcohol, Chlorocresol, Butylated Hydroxytoluenen, Ascorbic acid, Sodium sulphide, Sodium metabisulphite, Propylene glycol, Citric acid, Sodium citrate, Triethanolamine, Sodium hydroxide, Diethanolamine, Purified water and Isopropyl alcohol.

8. The topical pharmaceutical composition as claimed in claim 4, wherein the lotion contains pharmaceutically acceptable excipients selected from the group consisting of Cetyl alcohol, Sodium lauryl sulphate, Propylene glycol, Polyethylene Glycol 400, White soft paraffin, Butylated Hydroxytoluene, Methyl paraben, Propyl paraben and Chlorocresol.

9. The topical pharmaceutical composition as claimed in any one of the claims 1 to 4, wherein the cream formulation is prepared by,

a) Melting oil base excipients, emulsifier and optionally antioxidant;
b) dissolving chelating agent in sufficient quantity of purified water;
c) mixing oil phase and water phase under stirring for the emulsion formation at 60°-70°C;
d) dissolving or dispersing active ingredients in solubilizer and adding to bulk of step (c);
e) dissolving preservative in Solubilizer and adding it to bulk of step (d) under stirring;
f) cooling and stirring of the bulk till cream formation takes place; and
g) adjusting the weight with purified water.

10. The topical pharmaceutical composition as claimed in any one of the claims 1 to 4, wherein the ointment is prepared by,

a) Melting ointment base excipients and mixing surfactant to ointment base;
b) adding active ingredients to bulk (melted ointment base) either by dissolving or dispersing in solubilizer under constant stirring; and
c) cooling and stirring the bulk till ointment formation takes place.

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11. The topical pharmaceutical composition as claimed in any one of the claims 1 to 4, wherein the gel formulation is prepared by,

a) Preparing carbopol 980 slurry in sufficient quantity of purified water;

b) dissolving chelating agent in sufficient quantity of purified water and adding to carbopol slurry of step (a);

c) dissolving Halobetasol propionate in solubilizer and adding to bulk of step (b);

d) dissolving Tazarotene in Benzyl alcohol and adding to bulk of step (c);

e) adding IPA to the bulk of step (d) under stirring;

f) checking the pH and adjusting pH with 20% pH adjusting agent about 4.0 to 6.0 till gel formation takes place;

g) adjusting the final weight with purified water and mixing well.

12. The topical pharmaceutical composition as claimed in any one of the claims 1 to 4, wherein the lotion is prepared by,

a) Melting emulsifier, oil base, preservatives and optionally antioxidant by heating at 70-80°C;

b) mixing oil phase and sufficient water phase under stirring for the emulsion formation at 60°-70°C;

c) dissolving or dispersing active ingredients in solubilizer;

d) adding active drug either before emulsion formation or during emulsion formation;

e) dissolving surfactant in sufficient purified water and then adding to bulk;

f) cooling and stirring the bulk till lotion formation takes place and then making up the volume.

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13. The topical pharmaceutical composition as claimed in any one of the claims 1 to 4, wherein the lotion is alternately prepared by,

a) Dissolving Halobetasol in hot Propylene glycol;

b) In a separate beaker dissolving Tazarotene in Propylene glycol;

c) dissolving Butylated hydroxy toluene in PEG 400;

d) adding all the solutions into one vessel and mix well till clear solution is obtained and making up the volume with propylene glycol or PEG 400

Dated this 21st day of October, 2010

P. Aruna Sree

Dr. P. Aruna Sree
(Regn.No.: IN/PA 998)
Agent for the Applicant

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ABSTRACT:

The invention disclosed herein is a topical pharmaceutical composition comprising combination of Halobetasol propionate and Tazarotene along with pharmaceutically acceptable excipients, useful for the treatment of different types of psoriasis and also discloses the process for preparation thereof.

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TECHNICAL FIELD OF INVENTION:

The present invention relates to topical pharmaceutical composition comprising therapeutic amount of high potency corticosteroid Halobetasol propionate along with retinoid Tazarotene for the treatment of different types of psoriasis such as Plaque Psoriasis, Guttate Psoriasis, Seborrheic Psoriasis, Palmoplantar Psoriasis, Pustular Psoriasis, Palmoplantar Pustulosis or Acropustulosis Erythrodermic Psoriasis, Inverse Psoriasis or Flexural Psoriasis. The said topical pharmaceutical formulation is in the form of cream, ointment, gel or lotion. The invention further relates to process for preparation thereof.

BACKGROUND OF THE INVENTION:

Proliferative skin diseases are widespread throughout the world and afflict millions of humans. The expression "proliferative skin diseases" means benign and malignant *proliferative skin diseases which are characterized by accelerated cell division in the* epidermis, dermis or appendages thereto, associated with incomplete tissue differentiation. Such diseases includes psoriasis, atopic dermatitis, non-specific dermatitis, primary irritant contact dermatitis, allergic contact dermatitis, basal and squamous cell carcinomas of the skin, lamellar ichthyosis, epidermolytic hyperkeratosis, premalignant sun induced keratosis, non-malignant kertosis, acne and seborrheic dermatitis in humans.

Among other proliferative skin diseases; psoriasis is a chronic skin disorder that affects ~2-4% of the population world-wide.

As psoriasis is a nonfatal disease, its profound impact on the overall quantity of life and well-being is often underestimated. It has a significant effect on the physical, social, psychological and financial avenues of life and an early and aggressive treatment is required to prevent disease progression.

There is currently no cure for psoriasis. Many patients require life-long treatments for repeated relapses. Treatments for psoriasis have thus far included topicals (including

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anthralin), steroids, vitamin D, analogues and retinoids, such as tazarotene and other forms of treatment include systemic immunosuppressant such as methotrexate and cyclosporin, phototherapy such as broad and narrow-band ultraviolet Type B (UVB) and Goeckerman treatment, which is a combination of tar and UVB therapy. Recently a new class of drugs, the biologics, has also been approved for the treatment of psoriasis.

Though monotherapies are effective for the treatment of psoriasis, evidences are accumulating that combining topical retinoid, specifically Tazarotene with other established antipsoriatic therapies result in enhanced efficacy and reduced adverse events. In particular, concomitant use of topical Tazarotene with a mid-potency or high-potency corticosteroid in the treatment of psoriatic plaques enhances efficacy and reduces the risk of corticosteroid skin atrophy. The results of completed Phase III clinical trials of this agent indicate a beneficial effect in moderate to severe plaque psoriasis.

Retinol have been defined narrowly as comprising vitamin A (retinol) and its derivatives, such as vitamin A aldehyde (retinal) and vitamin A acid (retinoic acid), which are metabolites of natural vitamin A. However, subsequent research has resulted in a larger class of chemical compounds that are termed retinoids because they have biological actions similar to the parent vitamin A, even though there may be great structural dissimilarities. Thus, Retinol (Vitamin A) is an organic molecule that is not synthesized in the body; therefore, it must be obtained from the diet, as either preformed retinol or its precursor beta carotene, which is then converted *in vivo* into retinol.

Further, Retinol binds to several retinoic acid receptors in the nucleus, including α, β and γ with receptor γ being the predominant in human epidermis. Tazarotene is a vitamin A derivative that is converted *in vivo* into its active agent, Tazarotene acid, which binds to all three retinoic acid receptors with particularly increased selectivity for receptors β and γ. It has little affinity for the retinoic X receptors.

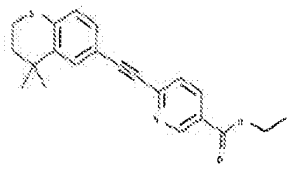
Tazarotene is mainly used for the treatment of psoriasis, acne vulgaris and sun damaged skin (photodamage). Tazarotene induces the expression of tazarotene-induced gene 3 (TIG3), a tumor suppressor gene. In psoriasis, Tazarotene acid normalizes abnormal

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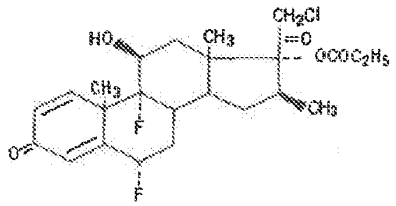
keratinocyte differentiation, decreases expression of inflammatory markers and reduces keratinocyte hyperproliferation. Thus, it is very useful as an anti-psoriatic agent.

Chemically, Tazarotene is ethyl 6-[2-(4,4-dimethyl-3,4-dihydro-2*H*-1-benzothiopyran-6-yl)ethynyl]pyridine-3-carboxylate It has the following structural formula:



Further, like other topical corticosteroids, Halobetasol propionate has anti-inflammatory, antipruritic and vasoconstrictive actions. The mechanism of the anti-inflammatory activity of the topical corticosteroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A_2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A_2.

Chemically, Halobetasol propionate is 21-chloro-6α, 9-difluoro-11β, 17-dihydroxy-16β-methylpregna-1, 4-diene-3-20-dione, 17-propionate, $C_{25}H_{31}ClF_2O_5$. It has the following structural formula:



Moreover, methods for the treatment of inflammatory dermatoses by administering topical compositions comprising a corticosteroid such as clobetasol propionate, triamcinolone acetonide and hydrocortisone along with a retinoid such as tretinoin in amounts which are effective for treating the dermatoses is disclosed in US5998395.

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US2004192662 provides a method for treating proliferative skin diseases comprising the administration of an effective amount of Tazarotene and an effective amount of a corticosteroid (mometasone furoate and fluocinolone acetonide) useful for treating psoriasis.

Indian Patent Application No.1741/MUM/2007 (corresponding PCT Publication no WO2009063491) relates to process for preparation of topical compositions comprising arbutin, corticosteroid (triamcinolone or desonide), retinoid (tretinoin) and optionally a sun protection factor (SPF) for the treatment of skin diseases includes melasma, ephelides, post inflammatory hyperpigmentation, dermal blemishes, non-congenital hyperpigmentation, and solar lentigo.

An article titled "In vitro compatibility of tazarotene with other topical treatments of psoriasis" by Hecker D, Worsley J, Yueh G, Lebwohl M., discloses the compatibility of tazarotene gel with 15 other topical steroids of different potencies, used in the treatment of psoriasis.

Thus in light of above; though there are prior arts describing corticosteroids and retinoids in combination, none of them specifically evaluated the effect of the combination comprising Halobetasol propionate and Tazarotene simultaneously.

Accordingly, the present invention discloses an effective combination comprising Halobetasol propionate and Tazarotene useful for different types treating psoriasis such as Plaque Psoriasis, Guttate Psoriasis, Seborrheic Psoriasis, Palmoplantar Psoriasis, Pustular Psoriasis, Palmoplantar Pustulosis or Acropustulosis Erythrodermic Psoriasis, Inverse Psoriasis or Flexural Psoriasis. Though these two drugs have entirely different modes of action and when combined in a single formulation, have synergistic effects which lead to more rapid clearing and are notably effective for types of psoriasis which have not responded to either corticosteroids or retinoids alone.

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OBJECT OF THE INVENTION:

The main object of the current invention is to provide the topical composition comprising Halobetasol propionate with Tazarotene in the form of cream, ointment, gel and lotion which is useful for the treatment of different types of psoriasis such as Plaque Psoriasis, Guttate Psoriasis, Seborrheic Psoriasis, Palmoplantar Psoriasis, Pustular Psoriasis, Palmoplantar Pustulosis or Acropustulosis Erythrodermic Psoriasis, Inverse Psoriasis or Flexural Psoriasis.

Another object of the present invention is to provide the process for preparation of said topical composition in the form of cream, ointment, gel and lotion.

SUMMARY OF THE INVENTION:

The present invention discloses the topical composition containing high potency corticosteroid Halobetasol propionate along with retinoid Tazarotene in the form of cream. ointment, gel and lotion having synergistic effect against for the treatment of different types of psoriasis such as Plaque Psoriasis, Guttate Psoriasis, Seborrheic Psoriasis, Palmoplantar Psoriasis, Pustular Psoriasis, Palmoplantar Pustulosis or Acropustulosis Erythrodermic Psoriasis, Inverse Psoriasis or Flexural Psoriasis. The invention further relates to the process for preparation thereof.

DETAILED DESCRIPTION OF THE INVENTION:

The invention will now be described in detail in connection with certain preferred and optional embodiments, so that various aspects thereof may be more fully understood and appreciated.

The present invention describes topical composition for the treatment of different types of psoriasis such as Plaque Psoriasis, Guttate Psoriasis, Seborrheic Psoriasis, Palmoplantar Psoriasis, Pustular Psoriasis, Palmoplantar Pustulosis or Acropustulosis Erythrodermic Psoriasis, Inverse Psoriasis or Flexural Psoriasis which comprises of Halobetasol

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propionate a synthetic corticosteroid with Tazarotene a retinoid in the form of cream, ointment, gel and lotion, useful for the treatment of psoriasis with bacterial infection.

The term "topical" as employed herein relates to the use of the active ingredient incorporated in a suitable pharmaceutical carrier, and applied at the site of the disease for exertion of local action.

In accordance to the above objectives, the present invention provides the topical composition which comprises therapeutically effective amount of Halobetasol propionate with Tazarotene along with pharmaceutically accepted excipients.

In one of the embodiment, the topical cream/ointment formulation comprises Halobetasol propionate (0.05% w/w) and Tazarotene (0.05 to 0.1% w/w) along with the pharmaceutical excipients selected from the group comprising of ointment/cream base like waxes, preservatives, antioxidants, buffering agent, chelating agent, penetration enhancer, surfactant, solubilizer, emulsifier and combinations thereof .

According to the embodiment, the topical cream of Halobetasol propionate and Tazarotene, is prepared using excipients selected from the group consisting of Cetostearyl alcohol, Cetomacrogol 1000, microcrystalline wax, Light liquid paraffin White soft paraffin, Chlorocresol, Butylated Hydroxy Toluene, Propylene glycol, Disodium EDTA and Citric acid.

According to another embodiment, the ointment of Halobetasol propionate and Tazarotene is prepared using excipients selected from the group consisting of Butylated hydroxy Toluene, Sorbitan Sesquioleate, Propylene glycol, White soft paraffin, White bees wax, Cetyl alcohol, Lanolin anhydrous and Liquid paraffin.

According to the invention, the topical composition of Halobetasol propionate with Tazarotene is in the form of cream that can be prepared by mixing oil phase and water phase under stirring for the emulsion formation at 60-70°C, this is followed by cooling till cream formation takes place followed by adding preservatives, penetration enhancer,

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antifoaming agent etc for the stable cream formation. Active ingredient can be added before cream formation or while the cream formation is taking place.

According to the invention, the topical composition of Halobetasol propionate with Tazarotene is in the form of ointment that can be prepared by melting and mixing the oil base excipients, active ingredient is either dissolved or suspended in oil base and added under constant stirring, followed by adding penetration enhancer, surfactant, antioxidant, etc.

In further embodiment, the topical gel formulation comprises Halobetasol propionate (0.05% w/w) and Tazarotene (0.05 to 0.1% w/w) along with pharmaceutical excipients selected from the group comprising oil base, preservatives, antioxidants, buffering agent, chelating agent, penetration enhancer, co-solvent, Carbopol, pH adjuster along with vehicle, surfactant, solubilizer, emulsifier and combinations thereof.

According to another preferred embodiment, the lotion of Halobetasol propionate and Tazarotene is prepared using excipients selected from the group consisting of Cetyl alcohol, Sodium Lauryl Sulphate, Propylene glycol, White soft paraffin and Chlorocresol.

According to another preferred embodiment, the gel of Halobetasol propionate and Tazarotene is prepared using excipients selected from the group consisting of Carbopol 980, Carbopol 940; Hydroxy Propyl Cellulose, Disodium EDTA, Chlorocresol, Ascorbic Acid, Sodium Sulphide, Sodium Metabisulphite, Propylene glycol, Citric acid, Sodium Citrate, Triethanolamine, Sodium Hydroxide, Diethanolamine, Purified Water and IPA

According to the invention, the topical composition of Halobetasol with Tazarotene is in the form of lotion that can be prepared by mixing oil phase and water phase under stirring for the emulsion formation at 60-70°C, followed by adding preservatives, penetration enhancer, antifoaming agent etc for the stable lotion formation. Active ingredient can be added before emulsion formation or while the emulsion formation is taking place.

Alternately, lotion can be prepared by dissolving Halobetasol in hot Propylene Glycol and dissolving Tazarotene in Propylene glycol in separate beakers. Simultaneously, dissolving

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Butylated Hydroxy Toluene in PEG 400; and then adding all the solutions into one vessel followed by mixing, till clear solution is obtained.

According to the invention, the topical composition of Halobetasol with Tazarotene is in the form of gel that can be prepared by soaking carbopol in purified water overnight. Active drugs can be dissolved in co-solvent such as Propylene Glycol and added to carbopol gel and mixed properly, then by adjusting pH with triethanolamine (TEA) or Diethanolamine or sodium hydroxide solution. Other inactives can be added to product.

The invention is further illustrated by following non-limiting examples of this combination product:

EXAMPLES:

Example 1:

Composition for the Preparation of Cream:

	Ingredients	Concentration
Active Ingredients	Halobetasol propionate	0.05% w/w
	Tazarotene	0.1 % w/w
Emulsifiers	Cetostearyl alcohol	4.2-7.8 %
	Cetomacrogol 1000	1.05-1.95 %
Oil Base	Light Liquid Paraffin	2.8-5.2 %
	White soft Paraffin	2.8-5.2 %
Penetration enhancers	Propylene glycol	6.3-10.2 %
	Hexylene glycol	7-13 %
Antioxidant	Butylated Hydroxy Toluene	0.01-.025%
Chelating agent	Disodium EDTA	0.007-0.013 %
Preservative	Chlorocresol	0.07-0.13 %
Vehicle	Water	q.s

Process for preparing cream formulation is as follows:

1) Melting oil base excipients, emulsifier and antioxidant;
2) Dissolving, chelating agent in sufficient quantity of purified water;

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3) Mixing oil phase and water phase under stirring for the emulsion formation at 60°-70°C
4) Dissolving or dispersing active ingredients in Solubilizer and adding to bulk of step 3. Adding preservative to bulk of step 4 under stirring;
5) Cooling and stirring of the bulk till cream formation takes place; and
6) Adjusting the weight with purified water

Example 2:

Composition for the Preparation of Ointment:

	Ingredients	Concentration
Active Ingredients	Halobetasol propionate	0.05% w/w
	Tazarotene	0.05 to 0.1% w/w
Solubilizers	Hexylene glycol	7-13 %
	Propylene glycol	7-13 %
Ointment base	White Soft Paraffin	54.95-90 %
Surfactant	Sorbitan Sesquioleate	0.105-0.195 %
	White Beeswax	21-39 %

Process for preparing ointment formulation is as follows:

1) Melting ointment base excipients and mixing surfactant to ointment base;
2) Adding active ingredients to bulk (melted ointment base) either by dissolving or dispersing in solubilizer; and
3) Cooling and stirring the bulk till ointment formation takes place.

Example 3:

Composition for the Preparation of Lotion:

	Ingredients	Concentration
Active Ingredients	Halobetasol propionate	0.05% w/w
	Tazarotene	0.05 to 0.1% w/w
Oil base	White Soft Paraffin	0.525-0.975 %
Emulsifier	Cetyl Alcohol	1.33-2.47 %
Solubilizer	Propylene Glycol	5.25-9.75 %

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Antioxidant	Butylated Hydroxy Toluene	0.01-.025%
Preservatives	Methyl Paraben	0.245-0.455 %
	Propyl Paraben	0.035-0.065 %
Surfactant	Sodium Lauryl Sulphate	0.21-0.39 %
Vehicle	Water	q.s

Process for preparing lotion formulation is as follows:

1) Melting emulsifier, oil base and preservatives by heating at 70-80°C;
2) Mixing oil phase and sufficient water phase under stirring for the emulsion formation at 60°-70°C;
3) Dissolving or dispersing active ingredients in Solubilizer;
4) Adding active drug either before emulsion formation or during emulsion Formation;
5) Dissolving surfactant in sufficient purified water and then adding to bulk;
6) Cooling and stirring the bulk till lotion formation takes place and then making up the volume.

Alternate composition for the Preparation of Lotion:

	Ingredients	**Concentration**
Active Ingredients	Halobetasol propionate	0.025-0.05 %
	Tazarotene	0.05-0.1 %
Solubilizer	PEG 400	40.25-74.75 %
Antioxidant	Butylated Hydroxy Toluene	0.014-0.026 %
Solubilizer	Propylene Glycol	q.s

Alternate process for preparing lotion formulation is as follows:

1) Dissolve Halobetasol in hot Propylene Glycol.
2) In a separate beaker dissolve Tazarotene in Propylene glycol.
3) Dissolve Butylated Hydroxy Toluene in PEG 400.
4) Add all the solutions into one vessel and mix well till clear

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Example 4:

Composition for the Preparation of Gel:

	Ingredients	Concentration
Active Ingredients	Halobetasol propionate	0.05% w/w
	Tazarotene	0.05 % w/w
Gelling agent	Carbopol 980	0.595-1.105 %
Chelating agent	Disodium EDTA	0.035-0.065 %
Penetration Enhancer/Solubilizer	Propylene Glycol	21-39 %
Antioxidant	Butylated Hydroxy Toluene	0.014-0.026 %
	Benzyl Alcohol	0.3-1.3 %
Vehicle	Iso Propyl Alcohol	7-13 %
Vehicle	Water	q.s
pH adjusting agent	TEA 20% solution	q.s

Process for preparing gel formulation is as follows:

1) Preparing carbopol 980 slurry in sufficient quantity of purified water.
2) Dissolving chelating agent and buffering agent in sufficient quantity of purified water and adding to carbopol slurry of step 1
3) Dissolving or dispersing active ingredients and preservative in Solubilizer and adding to bulk of step 2
4) Adding IPA to the bulk of step 3 under stirring
5) Checking the pH and adjusting pH with 20% pH adjusting agent about 4.0 to 6.0 till gel formation takes place.
6) Adjusting the final weight with purified water and mixing well.

Averages of Halobetasol propionate and Tazarotene can be added for the long term stability purpose.

Dated this the 22nd day of October, 2009

Dr. Gopakumar G. Nair
Regn. No.: IN/PA 509
Agent for the Applicant

12

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L3 ANSWER 1 OF 1 CAPLUS COPYRIGHT 2016 ACS on STN

ACCESSION NUMBER: 2012:481417 CAPLUS Full-text

DOCUMENT NUMBER: 157:209393

TITLE: Topical formulations containing halobetasol propionate and tazarotene

INVENTOR(S): Gandhi, Narendra Ishwarlal; Samant, Rajan Shantaram

PATENT ASSIGNEE(S): Lyka Labs Limited, India

SOURCE: Indian Pat. Appl., 33pp.
CODEN: INXXBQ

DOCUMENT TYPE: Patent

LANGUAGE: English

FAMILY ACC. NUM. COUNT: 1

PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
IN 2009MU02461	A	20120330	IN 2009-MU2461	20091022

PRIORITY APPLN. INFO.: IN 2009-MU2461 20091022

AB The invention disclosed herein is a topical pharmaceutical composition comprising combination of halobetasol propionate and tazarotene along with pharmaceutically acceptable excipients, useful for the treatment of different types of psoriasis and also discloses the process for preparation thereof. Thus, an ointment contained halobetasol propionate 0.025-0.05, tazarotene 0.05-0.1, hexylene glycol 7-13, propylene glycol 7-13, white soft paraffin 54.95-90, white beeswax 21-39, and sorbitan sesquioleate 0.105-0.195%.

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Confirmation No.: 1370

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Angel Arturo
Applicant:	Valeant Pharmaceuticals North America
Application No.:	16/179,561
Filed:	November 2, 2018
Examiner:	CRUZ, Kathrien Ann
Group/Art Unit:	1621
Atty. Docket No.:	99336.000343
Title:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

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

AMENDMENT AND RESPONSE TO OFFICE ACTION UNDER 37 C.F.R § 1.111

Dear Sir:

In response to the Office action dated March 20, 2019, please consider Applicant's amendments and remarks, as shown below.

Amendments to the Specification: none.

Amendments to the Claims begin at page 2 of this paper.

Amendments to the Drawings: none.

Remarks begin at page 8 of this paper.

A petition for a one-month extension of time is included herewith. Should the undersigned representative be mistaken as to time or fee, please charge Deposit Account No. 03-3875 of Harter Secrest & Emery LLP for any required fees.

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UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/179,561	11/02/2018	Angel Arturo	99336.000343

CONFIRMATION NO. 1370

134756
HSE/Valeant
1600 Bausch & Lomb Place
Rochester, NY 14604

PUBLICATION NOTICE

OC000000108046205

Title:TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

Publication No.US-2019-0133942-A1
Publication Date:05/09/2019

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/179,561	11/02/2018	Angel Arturo	99336.000293-CIP	1370

134756 7590 03/20/2019

HSE/Valeant
1600 Bausch & Lomb Place
Rochester, NY 14604

EXAMINER	
CRUZ, KATHRIEN ANN	

ART UNIT	PAPER NUMBER
1621	

NOTIFICATION DATE	DELIVERY MODE
03/20/2019	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@hselaw.com

Office Action Summary	Application No. 16/179,561	Applicant(s) Arturo et al.	
	Examiner KATHRIEN A CRUZ	Art Unit 1621	AIA (FITF) Status Yes

-- 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 MONTHS 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 11/02/2018.

☐ 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) 1-23 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) 1-23 is/are rejected.

8) ☐ Claim(s) _____ 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 _____ 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/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

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

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

DETAILED ACTION

Claims 1-23 is pending.

Claim Rejections - 35 USC § 103

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

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 12-15, 20-23 are rejected under 35 U.S.C. 103 as being unpatentable over Fabior® (Tazarotene) Foam 0.1% [package insert]. Research Triangle Park, NC: Stiefel Laboratories, Inc; 2012 (Fabior).

Fabior Foam contains tazarotene, 1 mg/g in aqueous-based white to off-white foam vehicle consisting of butylated hydroxytoluene, ceteareth-12, citric acid anhydrous,

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diisopropyl adipate, light mineral oil, potassium citrate monohydrate, potassium sorbate, purified water, and sorbic acid.

The difference between Fabior and the claimed formulaton is that Fabior does not teach the invention with particularity so as to amount to anticipation (See M.P.E.P. § 2131: "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).). However, based on the above, Fabior teaches the elements of the claimed invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill (the prior art reference teaches or suggests all the claim limitations with a reasonable expectation of success. See M.P.E.P. § 2143).

Fabior may not teach the recited effective amounts of tazarotene. However, the amount of tazarotene in the disclosed composition is a result-effective parameter that will affect the pharmacological and pharmacokinetic properties of the final composition. In this manner, the amount of a specific ingredient in a composition is clearly a result-effective parameter that a person of ordinary skill in the art would routinely optimize.

Specifically, it would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve a desired results. For any compound, the therapeutically effective dose can be estimated

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initially either in cell culture assays or in animal models, usually rats, rabbits, dogs, or pigs. The animal model also can be used to determine the appropriate concentration range and route of administration. Such information can then be used to determine useful doses and routes for administration in humans.

Therapeutic efficacy and toxicity, e.g., ED_{50} (the dose therapeutically effective in 50% of the population) and LD_{50} (the dose lethal to 50% of the population), can be determined by standard pharmaceutical procedures in cell cultures or experimental animals. The dose ratio of toxic to therapeutic effects is the therapeutic index, and it can be expressed as the ratio, $LD_{50}/ED_{5}o$. Pharmaceutical compositions which exhibit large therapeutic indices are preferred. The data obtained from cell culture assays and animal studies is used in formulating a range of dosage for human use. The dosage contained in such compositions is preferably within a range of circulating concentrations that include the ED_{50} with little or no toxicity. The dosage varies within this range depending upon the dosage form employed, sensitivity of the patient, and the route of administration. The exact dosage will be determined by the practitioner, in light of factors related to the subject that requires treatment. Dosage and administration are adjusted to provide sufficient levels of the active ingredient or to maintain the desired effect. Factors which can be taken into account include the severity of the disease state, general health of the subject, age, weight, and gender of the subject, diet, time and frequency of administration, drug combination(s), reaction sensitivities, and tolerance/response to therapy. Long-acting pharmaceutical compositions can be administered once or twice daily every 3 to 4 days, every week, or once every two weeks depending on the half-life and clearance rate of the particular formulation.

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Normal dosage amounts can vary from micrograms to 100,000 micrograms, up to a maximum total dose, depending upon the route of administration. Guidance as to particular dosages and methods of delivery is provided in the literature and generally available to practitioners in the art.

In this way, optimization of these parameters is a routine practice, and consequently, would be prima facie obvious, absent factual evidence demonstrating an unexpected benefit of the claimed amount(s).

With regards to the claim limitation of “as a sole active pharmaceutical ingredient” (claim 23), the claims recite “comprising” and “contains” which is open ended claim language which does not precluded additional active agents. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term ‘comprising,’ the terms ‘containing’ and ‘mixture’ are open-ended."). *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition ‘comprising’ in a method claim indicates that the claim is open-ended and allows for additional steps."); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves

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"the claim open for the inclusion of unspecified ingredients even in major amounts"). In *Gillette Co. v. Energizer Holdings Inc.*, 405 F.3d 1367, 1371-73, 74 USPQ2d 1586, 1589-91 (Fed. Cir. 2005), the court held that a claim to "a safety razor blade unit comprising a guard, a cap, and a group of first, second, and third blades" encompasses razors with more than three blades because the transitional phrase "comprising" in the preamble and the phrase "group of" are presumptively open-ended. "The word 'comprising' transitioning from the preamble to the body signals that the entire claim is presumptively open-ended." *Id.* In contrast, the court noted the phrase "group consisting of" is a closed term, which is often used in claim drafting to signal a "Markush group" that is by its nature closed. *Id.* The court also emphasized that reference to "first," "second," and "third" blades in the claim was not used to show a serial or numerical limitation but instead was used to distinguish or identify the various members of the group. *Id.*

Claims 8-11,16, 18 and 19 are rejected under 35 U.S.C. 103 as being unpatentable over Fabior in view of Singh et al., Dosage Forms: Non-Parenteral in Encyclopedia of Pharmaceutical Technology, 2002, Marcel Dekker (Singh))

Fabior may fail to explicitly teach those formulations comprising which are lotions and creams, or those comprising carbomers (thickening agents), as covered by the rejected claims. However, it id for that proposition that the examiner joins Singh, which teaches these formulations with the recited carbomers (polycarylates):

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SEMISOLID DOSAGE FORMS

Ointments, creams, and pastes are semisolid dosage forms intended for topical application. They may be applied to the skin, used nasally, rectally, and vaginally. Most of them contain some form of medicament. Medicated ointments are semi-solid preparations intended for application to skin or mucous membranes. Nonmedicated ointments are used as protectants, lubricants, and emollients. Ointment bases used for ointment preparation are of four types, hydrocarbon bases, absorption bases, water-removable bases, and water-soluble bases. Hydrocarbon bases have emollient properties and are effective as occlusive dressings (e.g., Petrolatum, USP). Absorption bases permit the incorporation of aqueous solutions to form w/o emulsions (e.g., hydrophilic petrolatum and lanolin). Water-removable bases are also o/w emulsions and are water washable (e.g., hydrophilic ointment). Water-soluble bases have no oleaginous component and are referred to as *greaseless* water-washable bases (e.g., polyethylene glycol ointment). The potential for absorption depends on the choice of the bases, and intended use of the medicament. Appropriate selection of ointment bases is important for dermal therapy. Ointments for rectal preparation (e.g., Tronolane® ointment for hemorrhoidal analgesia) and vaginal preparations (e.g., Mycelex-7® ointment as antifungal) are available in the market. Creams are semisolid emulsions with one or more medicinal agents intended for external use. The so called *vanishing creams* are o/w emulsions with stearic acid and cold creams are w/o emulsions with an oily base. Creams spread more easily than ointments and are preferred by some patients. Gels are semisolid systems with dispersions of small or large molecules in an aqueous vehicle with a gelling agent e.g., high molecular weight Carbopols® that are cross-linked polyacrylic acid. Some

In this way, those of ordinary skill could have applied the recited formulations to tazarotene in a predictable fashion for the purposes of obtaining a topical drug product. Specifically, Fabior teaches that tazarotene is a drug for acne. Singh is added for the proposition that creams, lotions and gels comprising additives such as carbomers (i.e., polyacrylates) are applicable to topical skin formulations. Since Singh teaches that the particular known technique of using the recited formulations for skin was recognized as part of the ordinary capabilities of one skilled in the art, those of ordinary skill would have recognized that applying the known technique to tazarotene would have yielded

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predictable results. Accordingly, formulating tazarotene in the recited formulations, such as creams, lotions and gels, would have been prima facie obvious.

Claims 7 and 17 are are rejected under 35 U.S.C. 103 as being unpatentable over Fabior in view of Fiume et al., Int J Toxicol. 2012 Jul-Aug;31(4 Suppl):5S-76S (Fiume).

The rejected claims cover using diethyl sebacate (DS) instead of diisopropyl adipate. However, substitution of one emollient, or penetration enhancer for another is well within the purview of ordinary skill, see MPEP 2144.06.

Nonetheless, DS is a known and well-characterized emollient and commonly used, See Fiume:

Diethyl Sebacate 110-40-7	Diethyl Sebacate is the diester of ethyl alcohol and Sebacic Acid	Fragrance Ingredients; Plasticizers; Skin-Conditioning Agents - Emollient; Solvents	

See page 10S, for example.

Therefore, those of oridianry skill could have used DS in the formulation of Fabior as an emollient and penetration enhancer, with a reasonable expectation of success, and in this manner, using DS in a topical formulation would have been prima facie obvious, in the absence of any unexpected benefit.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may

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be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-23 is provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-23 of copending Application No. 15/977088 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because both the instant claims and the '088 application recite a composition (tazarotene) for the treatment of acne. This difference is that the '088 recite "wherein the composition is an oil-in-water emulsion" and the instant application is a lotion as well as the concentration of tazarotene. Taken that both applications disclose the same compound (tazarotene) to treat acne, one of ordinary skills in the art would recognize that both application possess significant overlapping scopes of invention with a reasonable expectation of success.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S.

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186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the claims that are directed to the same invention so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-23 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-23 of copending Application No. 16/179,576 (reference application). This is a provisional statutory double patenting rejection since the claims directed to the same invention have not in fact been patented.

Conclusion

Claims 1-23 is rejected.

No claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN ANN CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached on Monday to Friday from 9 a.m. to 5 p.m.

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IPR Petition - USP 11,311,482

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Melenie Gordon can be reached at telephone number (571) 272-8037. 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).

/KATHRIEN A CRUZ/
Primary Examiner, Art Unit 1621

Padagis Ex. 1002
IPR Petition - USP 11,311,482

Notice of References Cited	Application/Control No. 16/179,561	Applicant(s)/Patent Under Reexamination Arturo et al.	
	Examiner KATHRIEN A CRUZ	Art Unit 1621	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
	A					
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Fabior® (Tazarotene) Foam 0.1% [package insert]. Research Triangle Park, NC: Stiefel Laboratories, Inc; 2012 (Year: 2012)
	V	Singh et al., Dosage Forms: Non-Parenteral in Encyclopedia of Pharmaceutical Technology, 2002, Marcel Dekker (Year: 2002)
	W	Fiume et al., Int J Toxicol. 2012 Jul-Aug;31(4 Suppl):5S-76S
	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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/179,561	Arturo et al.
	Examiner	Art Unit
	KATHRIEN A CRUZ	1621

CPC - Searched*		
Symbol	Date	Examiner

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
EAST (US-PGPUB, USPAT, USOCR, FPRS, EPO, JPO, DERWENT, IBM_TDB)	03/15/2019	kc

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	61	((("ARTURO") near3 ("Angel")) OR (("PILLAI") near3 ("Radhakrishnan"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/03/15 16:09
L2	1	((("ARTURO") near3 ("Angel")) and (("PILLAI") near3 ("Radhakrishnan"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/03/15 16:10
L3	9070	tazarotene	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/03/15 16:11
L4	3253	l3 and acne	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/03/15 16:11
L5	2707	l4 and @py<"2017"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/03/15 16:12
L6	556	l5 and "acne vulgaris"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	OFF	2019/03/15 16:12

3/15/2019 4:14:38 PM
C:\Users\kcruz\Documents\EAST\Workspaces\16179561.wsp

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/179,561	11/02/2018	Angel Arturo	99336.000293-CIP

CONFIRMATION NO. 1370

134756
HSE/Valeant
1600 Bausch & Lomb Place
Rochester, NY 14604

INFORMAL NOTICE

OC0000010545193 6

Date Mailed: 01/31/2019

INFORMATIONAL NOTICE TO APPLICANT

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
  Angel Arturo
  Radhakrishnan Pillai

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/dgela/

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 16/179,561

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	300
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	660
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	760
TOTAL CLAIMS (37 CFR 1.16(i))	23 minus 20 =	* 3			OR	x 100 =	300
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*				x 460 =	0.00
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	2020

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.

Padagis Ex. 1002
IPR Petition - USP 11,311,482

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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
16/179,561	11/02/2018	1629	2180	99336.000293-CIP	23	2

CONFIRMATION NO. 1370

UPDATED FILING RECEIPT

134756
HSE/Valeant
1600 Bausch & Lomb Place
Rochester, NY 14604

OC000000103451935

Date Mailed: 01/31/2019

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**

Inventor(s)

Angel Arturo, Santa Rosa, CA;
Radhakrishnan Pillai, Santa Rosa, CA;

Applicant(s)

Valeant Pharmaceuticals North America, Bridgewater, NJ;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CIP of 15/977,088 05/11/2018
which claims benefit of 62/505,421 05/12/2017

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 11/23/2018

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/179,561**

Projected Publication Date: 05/09/2019

Non-Publication Request: No

Early Publication Request: No
Title

TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

Preliminary Class

514

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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 (1-866-999-4258).

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).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

Confirmation No.: 1370

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Arturo, Angel
Applicant:	Valeant Pharmaceuticals North America
Application No.:	16/179,561
Filed:	November 2, 2018
Examiner:	tbd
Group/Art Unit:	tbd
Atty. Docket No.:	99336.000343
Title:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

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

January 28, 2019

Response to the Notice to File Corrected Application Papers
and
Preliminary Amendment

Dear Sir:

This Response is to the Notice to File Corrected Application Papers dated November 26, 2018; the Applicant hereby amends the above-referenced application as follows:

Amendments to the Specification: begin at page 2 of this paper.

Amendments to the Claims: none.

Amendments to the Drawings: none.

Remarks/Arguments: begin at page 3 of this paper.

Appendix: Substitute Specification (marked-up); Substitute Specification (clean copy).

Amendments to the Specification

Please replace the original Specification with the attached Substitute Specification in accordance with 37 CFR 1.125, which has been formatted as provided by 37 CFR 1.77(b). No new matter has been as added to the Substitute Specification.

ATTACHMENTS:

1. A Substitute Specification (excluding the claims) with markings showing all the changes relative to the immediate prior version of the specification of record.
2. A clean version (without markings) of the same Substitute Specification.

REMARKS/ARGUMENTS

In response to the Notice to File Corrected Application Papers dated November 26, 2018, the present application has been carefully reviewed and amended.

A Substitute Specification is submitted wherein original paragraphs [0021], [0022], and [0062] have been amended consistent with the originally submitted drawings, which are properly numbered. No new matter has been as added to the Substitute Specification. Entry of the present amendment is accordingly respectfully requested in response to the Notice to File Corrected Application Papers.

CONCLUSION

Should the Examiner consider that additional amendments are necessary to place this application in condition for allowance, the favor is requested of a telephone call to the undersigned for the purposes of discussing such amendments.

Precautionary Fee-Charge Authorization

By way of precaution, the Commissioner is authorized to charge any underpayment of fees or fee amounts not otherwise authorized but necessary for the consideration of this paper or the continued pendency of this application and to credit any overpayment to Deposit Account Number 03-3875 of Harter Secrest & Emery LLP.

Please grant any extensions of time necessary for the filing of this Amendment.

Respectfully submitted,

/Andrew J. Anderson/

Andrew J. Anderson, Reg. No. 33,564
Customer Number **23387**
HARTER SECREST & EMERY LLP
1600 Bausch & Lomb Place
Rochester, New York 14604-2711
Telephone: 585-231-1157
Fax: 585-232-2152
Email: aanderson@hselaw.com

P05877-2-C1

TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part application of U.S. Patent Application No. 15/977,088, filed May 11, 2018, which claims priority to U.S. Provisional Patent 62/505,421, filed May 12, 2017.

BACKGROUND

[0002] The present invention relates to topical compositions and methods for treating skin diseases such as acne and psoriasis. In particular, this invention relates to topical pharmaceutical compositions comprising tazarotene or a pharmaceutically acceptable tazarotenic acid salt, in an oil-in-water emulsion vehicle, for treating skin diseases.

[0003] The retinoid tazarotene has been commercially available and has been used to treat acne and psoriasis topically. However, tazarotene may cause significant local skin irritation, especially early in the first through fourth weeks of therapy, thus limiting its use for a prolonged period because many patients stop treatment due to skin irritation. The need exists for more effective and safer topical medicaments with reduced adverse effects for the management of acne, psoriasis and other skin diseases.

SUMMARY OF THE INVENTION

[0004] In general, the present invention provides topical compositions and methods for treating skin diseases such as acne and psoriasis.

[0005] In one aspect, this invention provides a topical pharmaceutical composition for treating skin diseases, including acne and psoriasis, comprising: tazarotene or a pharmaceutically acceptable tazarotenic acid salt present in the composition at a positive concentration of less than 0.050 percent by weight of the composition; and a dermatologically acceptable oil-in-water emulsion vehicle.

[0006] In another aspect, this invention provides a method of treating skin diseases, including acne and psoriasis, comprising topically applying a pharmaceutical composition to an affected area of a body of a subject suffering from the skin disease, wherein the composition comprises: tazarotene or a pharmaceutically acceptable tazarotenic acid salt present in the composition at a positive concentration of less than 0.050 percent by weight of the composition; and a dermatologically acceptable oil-in-water emulsion vehicle.

[0007] According to other aspects, the topical pharmaceutical composition may comprise tazarotene or the salt thereof at 0.01 to 0.049 percent by weight of the composition, or at about 0.045 percent by weight of the composition.

[0008] According to another aspect, the tazarotene or tazarotenic acid salt may be dissolved in a liquid oil component of the emulsion.

[0009] According to another aspect, the topical pharmaceutical composition may contain the tazarotene or the tazarotenic acid salt as a sole active pharmaceutical ingredient.

[0010] According to various aspects, the oil phase of the emulsion may comprise a liquid oil component comprising a DCAE, a MCAE, or combinations thereof. In other aspects, the oil phase includes diethyl sebacate as the DCAE.

[0011] According to other aspects, the aqueous phase of the emulsion may comprise water and a carbomer homopolymer.

[0012] According to another aspect, the topical pharmaceutical composition may comprise: an aqueous phase comprising water, a carbomer homopolymer, and a polymeric emulsifier; an oil phase comprising at least one member selected from the group consisting of a dicarboxylic acid ester and a mineral oil, and the tazarotene or the tazarotenic acid salt. According to other aspects, the aqueous phase may further comprise a humectant or a preservative, such as at least one member selected from the group consisting of methylparaben, propylparaben and sorbitol.

[0013] According to other aspects, the topical pharmaceutical composition may have the form of a lotion, or of a cream.

[0014] According to another aspect, the topical pharmaceutical composition may have a pH of about 4 to about 6.

[0015] For the methods of this invention, the step of applying may be carried out once per day for at least eight weeks. According to one aspect, the applying is carried out once per day for at least twelve weeks.

[0016] According to other aspects, the composition may be applied is to an affected area of a body of a subject suffering from acne vulgaris in order to treat that condition.

[0017] Other features and advantages of the present invention will become apparent from the accompanying drawings and the following detailed description and claims.

BRIEF DESCRIPTION OF THE FIGURES

[0018] Figure 1 is a graph of EGSS by visit.

[0019] Figure 2 is a graph of change in inflammatory lesions from baseline.

[0020] Figure 3 is a graph of change in non-inflammatory lesions from baseline.

[0021] Figures 4A, 4B, and 4C are graphs of cutaneous tolerability to burning, stinging, and itching, respectively.

[0022] Figures 5A, 5B, 5C, and 5D are ~~includes~~ graphs of cutaneous safety assessed by scaling, erythema, hypo-pigmentation, and hyper-pigmentation, respectively.

DETAILED DESCRIPTION OF THE INVENTION

[0023] In general, the present invention provides topical compositions and methods for treating skin diseases, including acne and psoriasis.

[0024] Throughout this disclosure, unless otherwise indicated, the concentration of an ingredient of the composition is in percent by weight of the total composition.

[0025] In one aspect, the topical pharmaceutical composition comprises tazarotene, or a pharmaceutically acceptable salt of tazarotenic acid, at a concentration below that which is presently utilized in topical formulations. For example, tazarotene or the tazarotenic acid salt is included in a composition at a positive concentration less than 0.05 wt%.

[0026] In certain embodiments of the present invention, tazarotene or the tazarotenic acid salt is present in the composition at a positive concentration of less than 0.05% based on the weight of the composition ("wt%"). For example, this component is present in the range from about 0.01 to about 0.049 wt%, or from about 0.01 to about 0.045 wt%, or from about 0.02 to about 0.045 wt%, or from about 0.03 to about 0.045 wt%, or at about 0.045 wt%. Specific concentrations of this component may be 0.01 wt%, 0.015 wt%, 0.02 wt%, 0.025 wt%, 0.03 wt% 0.035 wt%, 0.04 wt%, and 0.045 wt%.

[0027] In one aspect, the topical pharmaceutical composition comprises an oil-in-water emulsion as a carrier vehicle, in which an internal oil phase is dispersed in a continuous aqueous phase. The emulsion may be a macroemulsion, a microemulsion, or a nanoemulsion. The composition may have the dosage form of gel, lotion, or cream, or ointment, or liquid, or oil, or spray or foam.

[0028] In addition to the tazarotene active ingredient, the composition of the present invention may comprise one or more dermatologically acceptable

excipients, such as liquid oils, waxes viscosity-modifying agents, thickening agents, gelling agents, alcohols, surfactants, chelating agents, buffers, preservatives, humectants, emollients, stabilizers, diluents, dispersing agents, emulsifiers, wetting agents, stabilizers, pH adjusters, solvents or cosolvents.

[0029] The composition of the invention may desirably contain a thickening agent to provide viscosity so that the formulation may be provided in the form of a gel, lotion, cream, or ointment. The thickening agent may be miscible or soluble in an aqueous fluid. Non-limiting examples of suitable thickening agents include acacia, alginic acid and its salts, hyaluronic acid and its salts, carbomers (also known as carboxy vinyl polymers, which are cross-linked polyacrylic acid), carboxymethylcellulose, ethylcellulose, gelatin, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methylcellulose, poloxamers, polyvinylpyrrolidone, polyvinyl alcohol, tragacanth, xanthan gum, magnesium aluminum silicate, and bentonite. The thickening agent may also reside in the oil or lipophilic portion of the formulation. Examples of suitable lipophilic thickening agents include cetyl alcohol, stearyl alcohol, glyceryl stearate, white beeswax, microcrystalline wax, hydrogenated polyisobutane polymers, and emulsifying wax.

[0030] A suitable group of thickening agents is carbomers, such as Carbopol® and polycarbophil (The Lubrizol Corporation, Wickliffe, Ohio). Carbopol® homopolymers are polymers of acrylic acid crosslinked with allyl sucrose or allylpentaerythritol. Carbopol® copolymers are polymers of acrylic acid and C_{10}-C_{30} alkyl acrylate crosslinked with allylpentaerythritol. Carbopol® interpolymers are

carbomer homopolymers or copolymers that contain a block copolymer of polyethylene glycol and a long chain alkyl acid ester. Noveon® polycarbophil is a polymer of acrylic acid crosslinked with divinyl glycol.

[0031] A surfactant or emulsifier is optionally included, if desired or required. Pharmaceutically acceptable anionic, cationic, or non-ionic surfactants may be included in a composition of the present invention. Non-ionic surfactants are preferred. Non-limiting examples of non-ionic surfactants are Octoxynol (also known as Macrogol tetramethylbutylphenyl ether, octylphenoxy polyethoxyethanol, or polyoxyethylene octylphenyl ether), such as Octoxynol 1, 3, 5, 8, 9, 10, 12, 13, 16, 30, 40, 70 (wherein the number indicates the number of repeating oxyethylene units), or other Octoxynols that comprise different numbers of repeating units of oxyethylene in the side chain, sorbitan esters (such as sorbitan monooleate and sorbitan monostearate, commonly known by their trade names Span 80 and Span 60), polysorbates (such as polysorbate 80 (polyoxyethylene sorbitan monooleate), polysorbate 60 (polyoxyethylene sorbitan monostearate), polysorbate 20 (polyoxyethylene sorbitan monolaurate), commonly known by their trade names of Tween® 80, Tween® 60, Tween® 20), poloxamers (synthetic block polymers of ethylene oxide and propylene oxide, such as those commonly known by their trade names of Pluronic®; e.g., Pluronic® F127 or Pluronic® F108), or poloxamines (synthetic block polymers of ethylene oxide and propylene oxide attached to ethylene diamine, such as those commonly known by their trade names of Tetronic®; e.g., Tetronic® 1508 or Tetronic® 908, etc.), other nonionic surfactants such as Brij® (polyoxyethylene alkyl ether having a formula of CH_3–$(CH_2)_{10-16}$–(O-

$C_2H_4)_{1-25}$–OH), Myrj® (stearic acid esterified with polyoxyethylene having 40-100 repeating oxyethylene units), and long chain fatty alcohols (e.g., oleyl alcohol, stearyl alcohol, myristyl alcohol, docosahexaenoyl alcohol, etc.) with carbon chains having about 12 or more carbon atoms (e.g., such as from about 12 to about 24 carbon atoms).

[0032] In addition, polymeric emulsifiers such as those known under the trade name Pemulen™ (The Lubrizol Corporation, Wickliffe, Ohio) may be used. These are polymers of acrylic acid, modified by long chain (C_{10}-C_{30}) alkyl acrylates, and crosslinked with allylpentaerythritol.

[0033] An anionic emulsifier may be used, such as sodium or potassium oleate, triethanolamine stearate, sodium lauryl sulfate, sodium dioctyl sulfosuccinate, and sodium docusate. Less preferred are cationic emulsifiers such as quaternary ammonium salts. Still other emulsifiers include glyceryl monostearate, polyoxyethylene monooleate, polyoxyethylene monostearate, polyoxyethylene monolaurate, potassium oleate, sodium lauryl sulfate, sodium oleate, sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, sorbitan trioleate, triethanolamine oleate, polyoxyethylene sorbitan monolaurate, polyoxyethylene sorbitan monopalmitate, polyoxyethylene sorbitan monostearate, polyoxyethylene sorbitan tristearate, polyoxyethylene sorbitan monooleate, and polyoxyethylene sorbitan trioleate.

[0034] The formulation desirably contains a dermatologically acceptable humectant such as glycerin, sorbitol, hexylene glycol, propylene glycol, or urea. In

addition, the formulation may contain an emollient such as petrolatum, lanolin, mineral oil, light mineral oil, stearic acid, cyclomethicone, or dimethicone. Chelating agents such as EDTA and citric acid and their salts may be included in a formulation of the present invention.

[0035] The liquid oil component of the composition includes one or more materials that are practically insoluble or insoluble in water and which are liquid at room temperature. For example, in one embodiment, the liquid oil component of the composition includes one or more materials that are practically insoluble or insoluble in water and which are liquid at room temperature of 22 °C. The liquid oil component may be selected from one or more ingredients from the group consisting of dicarboxylic acid esters ("DCAE"), monocarboxylic acid esters ("MCAE"), fish-liver oil, long-chain triglycerides (wherein each side chain has 14-18 carbons, such as peanut oil, sesame oil, coconut oil, sunflower oil, corn oil, olive oil, cotton seed oil, or derivatives thereof), propylene glycol diesters, medium-chain triglycerides (such as those wherein each side chains has 8-10 carbons; e.g., capric/caprylic acid triglycerides), hydrocarbons like mineral oil, light mineral oil, squalene, and squalane, fatty alcohols (such as octyldodecanol and isostearyl alcohol), and fatty acids (such as isostearic acid and oleic acid).

[0036] In some embodiments, the liquid oil component comprises a dicarboxylic acid ester and light mineral oil. In some other embodiments, the liquid oil component comprises one or more long-chain triglycerides.

[0037] The formulation may include other lipophilic liquids in an amount that is sufficient to be miscible with the dicarboxylic acid ester and/or monocarboxylic acid ester. The lipophilic liquid may be an emollient such as lanolin oil, mineral oil, light mineral oil, isostearic acid, squalene, octyldodecanol, fractionated coconut oil, cyclomethicone, or dimethicone.

[0038] In addition to the liquid oil component, the formulation may contain water insoluble or practically insoluble ingredients that are not liquid at room temperature, but are soluble in the liquid oil component.

[0039] A DCAE that is suitable for the present invention has the formula $R_1OOC\text{-}(CH_2)_n\text{-}COOR_2$, wherein R_1 and R_2 are alkyl groups containing between 1 and 4 carbons or aryl groups and may be the same or may be different and wherein $(CH_2)_n$ is a straight or branched chain and n is between 1 and 12. Examples of DCAEs containing one or more aryl groups are dibenzyl esters of dicarboxylic acids. A preferred dicarboxylic acid ester is diethyl sebacate, which has the formula $CH_3CH_2OOC\text{-}(CH_2)_8\text{-}COOCH_2CH_3$. Examples of other suitable dicarboxylic acid esters (where R_1 and R_2 are the same) are dimethyl, diethyl, dipropyl, diisopropyl, dibutyl and diisobutyl esters such as oxalate, malate, succinate, glutarate, adipate, pimelate, suberate, and azalate. Examples of suitable dicarboxylic acid esters (where R_1 is different from R_2) are methyl ethyl, methyl propyl, methyl butyl, methyl isopropyl, ethyl propyl, ethyl butyl, ethyl isopropyl, and propyl butyl esters such as oxalate, malate, succinate, glutarate, adipate, pimelate, suberate, azalate, and sebacate.

[0040] In some aspects, diethyl sebacate is included at 0.1 to 20 wt%, or at 0.5 to 10 wt%, or at 2 to 4 wt% of the weight of the composition.

[0041] Alternatively, or in combination with the DCAE, the formulation may contain a MCAE. The MCAE that is suitable for the present invention has the formula CH_3-$(CH_2)_n$-$COOR_1$, wherein R_1 is an alkyl group containing between 1 and 4 carbons or an aryl group, and wherein $(CH_2)_n$ is straight or branched chain and n is between 1 and 12. Examples of such monocarboxylic acid esters include methyl, ethyl, propyl, isopropyl, butyl, or an aryl such as benzyl formate, acetate, propionate, butyrate, valerate, laurate, myristate, palmitate, and stearate. Examples of preferred monocarboxylic acid esters are isopropyl palmitate and isopropyl myristate.

[0042] The liquid oil phase may beneficially be used to dissolve one or more of the active ingredients within the emulsion. In one embodiment the tazarotene component is dissolved in the liquid oil phase within the formulation at room temperature. In another embodiment the tazarotene component is suspended within the formulation at room temperature. In the case wherein the tazarotene component is suspended in the formulation, this suspended active ingredient may be micronized, namely that the mean particle size is preferably about 25 microns in diameter or less.

[0043] In one aspect, a composition of the present invention comprises the ingredients at the concentrations shown in Table 1.

Table 1

Compositions of the Present Invention for Treating Skin Diseases

Ingredient	Concentration (wt%)		
	Range 1	Range 2	Range 3
Tazarotene or Tazarotenic Acid Compound	0.01-0.049	0.02-0.045	0.03-0.045
Emollient, Solvent, and/or Thickener	0.5-40	1-25	2-20
Emulsifier	0.25-10	0.5-7	1-5
Humectant	0-15	2-12	3-10
Polymeric Thickener	0.05-2	0.1-1.5	0.3-1
Pharmaceutical Aids	q.s.	q.s.	q.s.
Purified water	q.s. to 100	q.s. to 100	q.s. to 100

[0044] Non-limiting examples of compositions of the present invention are shown in Table 2.

Table 2

Some Emulsion Compositions of the Present Invention for Treating Acne

Ingredient	Function	Concentration (wt%)			
		Range 1	Range 2	Range 3	Composition A
Tazarotene	Retinoid	0.02-0.049	0.03-0.049	0.04-0.049	0.045
Diethyl sebacate	Liquid Oil & Solvent	1-5	2-4	2.5-3.5	2.97
Light mineral oil	Liquid Oil & Co-Solvent	5-15	5-10	7.5-8.5	8.03
Sorbitan monooleate	Surfactant/ Emulsifying Agent	0.01-1	0.02-0.5	0.05-0.2	0.1
Sorbitol solution, 70%	Humectant	5-15	7-12	10-11	10.7
Methyl paraben	Antimicrobial Preservative(1)	0.05-0.3	0.1-0.3	0.1-0.2	0.17
Propyl paraben	Antimicrobial Preservative(1)	0.01-0.1	0.01-0.05	0.02-0.04	0.03
Edetate disodium dihydrate	Chelating Agent(1)	0.02-0.1	0.02-0.7	0.03-0.06	0.05
Carbomer copolymer type B (e.g., Pemulen™ TR-1)	Emulsifying Agent	0.1-1	0.2-0.7	0.3-0.5	0.4
Carbomer homopolymer type A (e.g., Carbomer 981)	Thickener	0.2-1.5	0.3-1	0.5-0.7	0.6
Sodium hydroxide, 10% Solution	pH-adjusting Agent(1)	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5
Purified water	Carrier	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100

Note: (1) These ingredients are broadly classified as Pharmaceutical Aids.

[0045] A lotion having a composition as shown Composition A of Table 2 may be prepared as follows.

[0046] A separate aqueous phase is made. In a manufacturing vessel equipped with a mixing implement (such as a propeller) and temperature control, purified

water and disodium edetate dihydrate are combined and the mixture is agitated until a clear solution is achieved. Sorbitol, methylparaben, and propylparaben are then added to the mixture. The mixture is continuously mixed and heated to approximately 75 °C. The mixture is agitated until a solution is obtained. The mixture is then removed from the heat source and allowed to cool to below 40 °C with continued mixing. With continuous mixing, Carbopol® 981 and Pemulen™ TR-1 carbomers are added to the mixture and dispersed. Mixing continues until the two carbomers are fully dispersed and hydrated.

[0047] A separate oil phase is made. In a vessel equipped with a mixing implement such as a propeller, diethyl sebacate, and tazarotene are combined. The mixture is agitated until a solution is achieved. With continuous mixing, light mineral oil and sorbitan monooleate are added. Mixing is continued until a solution is obtained.

[0048] In a separate vessel, an approximate 2.5 N solution of sodium hydroxide is prepared.

[0049] With high speed mixing, the oil phase containing the active ingredient (tazarotene) is added to the aqueous phase. Mixing is continued until a homogeneous emulsion is obtained. Mixing speed is decreased and mixing continued for an additional time of 10 minutes to 1 hour. With continuous mixing, an appropriate amount of the sodium hydroxide solution is added incrementally to obtain a pH of 5.5 ± 0.5. Mixing continues further until a homogeneous lotion is obtained, such as for 30 minutes to 3 hours.

[0050] A first clinical study in acne patients was conducted to compare the efficacy of a composition of the present invention containing tazarotene (the "Composition A" lotion of Table 2).

[0051] A first placebo ("Lotion Placebo") corresponded to and had a similar viscosity as Composition A but lacked tazarotene. A second placebo ("Cream Placebo") corresponded to the Lotion Placebo but employed carbomer homopolymer type C in place of carbomer homopolymer type A to yield a higher viscosity emulsion with a viscosity similar to 0.1% tazarotene cream employed in the study. This allows for better blinding of the test formulations and control of the clinical study. In the following results, data for Lotion Placebo and Cream Placebo may be combined and reported as "Combined Placebo".

[0052] Additionally, commercially available 0.1% tazarotene cream (Tazorac® 0.1% cream) was employed in this clinical study for comparison purposes.

[0053] A double blind, multi-site, randomized clinical study was conducted on patients suffering from acne vulgaris, whereby neither the acne patient nor the investigator knew the identity of the test composition assigned. 210 patients were randomized to receive either Composition A lotion, Tazorac® 0.1% cream, Placebo Lotion and Placebo Cream at a 2:2:1:1 randomization:

69 subjects "Composition A lotion"

72 subjects "Tazorac® 0.1% cream"

34 subjects "Lotion Placebo"

35 subjects "Cream Placebo".

[0054] Primary inclusion criteria were moderate to severe acne, inflammatory lesion count of at least 20 but no more than 40, and non-inflammatory lesion count of at least 20 but no more than 100. The blindly labeled lotions were applied to the affected area once daily for twelve weeks, with assessments at 2 weeks, 4 weeks, 8 weeks and 12 weeks.

[0055] The investigator monitored the efficacy at each study visit by assessing the treatable area, determining the Evaluator's Global Severity Score (EGSS), and determining the grade of improvement. EGSS included the following grades:

Clear = 0; Almost Clear = 1; Mild = 2; Moderate = 3; Severe = 4.

[0056] Clinical Efficacy was determined primarily based on the percentage of subjects who were treatment successes at 12 weeks. To be judged as a treatment success, as reported in Tables 4, 6, and 7, subjects had to show at least two-grade improvement from the baseline and EGSS score equating to "clear" or "almost clear". Also, the numbers of inflammatory and non-inflammatory lesions were assessed.

[0057] Table 3 reports Baseline Characteristics.

Table 3
Baseline Characteristics –
Inflammatory Lesions and Non-inflammatory lesions

	Combined Placebo N=69	Composition A N=69	Tazorac® 0.1% Cream N=72
Inflammatory Lesions Mean (SD) Median	 27.2 (5.49) 26.0	 28.3 (6.0) 27.0	 27.3 (5.95) 26.0
Non-inflammatory Lesions Mean (SD) Median	 36.6 (13.17) 34.0	 37.6 (14.70) 34.0	 36.6 (13.31) 34.0

[0058] Table 4 reports treatment % success on an intention-to-treat (ITT) basis.

Table 4
EGSS (Clear or Almost Clear) by Visit (ITT)

	Combined Placebo N=69	Composition A N=69	Tazorac® 0.1% Cream N=72
Week 2	0%	0%	0%
Week 4	0%	1.4%	1.4%
Week 8	4.3%	7.2%	5.6%
Week 12	10.1%	18.8%	16.7%

[0059] Table 5 reports absolute change in inflammatory lesions from baseline. Change in inflammatory and non-inflammatory lesions from baseline is reported in Figures 2 and 3.

Table 5
Inflammatory Lesions by Visit
Absolute Change from Baseline

	Combined Placebo N=69	Composition A N=69	Tazorac® 0.1% Cream N=72
Week 2	-4.7	-2.9	-2.4
Week 4	-7.2	-5.8	-7.8
Week 8	-10.9	-13.2	-12.0
Week 12	-14.0	-18.1	-16.8

[0060] Table 6 reports treatment % success for primary efficacy on an intention-to-treat basis for EGSS at week 12. For EGSS, to be judged as a treatment success, subjects had to show at least two-grade improvement from the baseline and EGSS score equating to "clear" or "almost clear". For inflammatory and non-inflammatory lesions, absolute change from baseline to week 12 in mean inflammatory and non-inflammatory counts is reported.

Table 6
Treatment % Success (ITT) at 12 Weeks

	Combined Placebo N=69	Composition A N=69	Tazorac® 0.1% Cream N=72
EGSS – Clear or Almost Clear	10.1%	18.8%	16.7%
Inflammatory Lesions Absolute Change % Change	 -14.0 -51.41%	 -18.1 -63.75%	 -16.8 -59.99%
Non-inflammatory Lesions Absolute Change % Change	 -13.1 -35.18%	 -21.6 -56.86%	 -20.3 -54.09%

[0061] Table 7 reports treatment % success on a per-protocol basis for EGSS. For lesions, absolute change from baseline to Week 12 in mean inflammatory and non-inflammatory counts is reported.

Table 7
Treatment % Success (PP)

	Combined Placebo N=57	Composition A N=54	Tazorac® 0.1% Cream N=56
EGSS – Clear or Almost Clear	12.3%	20.4%	16.1%
Inflammatory Lesions	-14.2	-18.3	-18.2
Non-inflammatory Lesions	-11.8	-20.8	-21.9

[0062] The compositions were tested for cutaneous safety and tolerability. Cutaneous tolerability was assessed by burning, stinging or itching reported by the subjects. This data is summarized in Figures 4A, 4B, and 4C. Cutaneous safety was assessed by scaling, erythema, hypo-pigmentation and hyper-pigmentations as evaluated by the investigator. This data is summarized in Figures 5A, 5B, 5C, and 5D.

[0063] Table 8 reports treatment emergent adverse event characteristics.

Table 8
Treatment Emergent Adverse Event Characteristics

	Combined Placebo	Composition A	Tazorac® 0.1% Cream
% Subjects Reporting Any Adverse Event	13.4%	14.7%	26.8%
% Subjects Reporting Any Serious Adverse Event	0%	0%	0%
% Subjects Discontinued Study Due to Adverse Event	0%	0%	1.4%

[0064] Notably, this clinical study showed that Composition A, containing less than half of the tazarotene active ingredient, had a numerically better efficacy than the Tazorac® 0.1% Cream. Also, the adverse event profile was lower for Composition A than for Tazorac® 0.1% Cream.

[0065] In another aspect, the present invention provides a method for treating acne. The method comprises topically applying to an affected area of the body of a subject suffering from acne any one of the compositions of the present invention, as disclosed herein, one or more times per day for a period of time sufficient to treat such acne. For example, such a period of time may be 1 to 30 days or longer as needed For example, such a period of time may be one week, two weeks, four weeks, eight weeks, twelve weeks, or longer as needed. For example, a composition of the present invention is applied topically to affected areas of the body once per day for 7-14 days. Alternatively, it may be applied two or three times per day for 7-14 days. Alternatively, it may be applied once per day for one week to six months. For example, it may be applied once per day for two weeks, four weeks, eight weeks, or twelve weeks. In one embodiment, the treatment may be stopped for 1-7 days (e.g., 2, 3, 4, 5, 6, or 7 days) after an extended treatment period before it is resumed for another extended treatment period. Such an extended period may be 7 days, 7-14 days, 7-21 days, 7-30 days, or longer before more treatment is needed or desired.

[0066] In yet another aspect, the present invention provides a method of treating acne topically with any of the pharmaceutical compositions of this invention, wherein the composition is applied once daily for more than 2 weeks, such as 4

weeks, for 6 weeks, for 8 weeks or for 12 weeks, without any serious adverse events, and/or with an improved adverse event profile compared to 0.1% tazarotene cream.

[0067] In yet another aspect, the present invention provides a method of treating acne topically with any of the pharmaceutical compositions of this invention, wherein the composition is applied once daily for 12 weeks, and has better clinical efficacy and a lower adverse event profile as compared to commercial compositions containing 0.1% tazarotene.

[0068] Two larger clinical studies (Studies 301 and 302) in acne patients were conducted to compare the efficacy of a composition of the present invention containing tazarotene (the "Composition A" Lotion of Table 2) to that of a placebo that was the vehicle of Composition A (i.e., without the active ingredient tazarotene).

[0069] These studies were phase-3, multi-center, randomized, double-blind, vehicle-controlled, two-arm, parallel group studies comparing the safety and efficacy of Composition A ("IDP-123 Lotion" or "Composition A Lotion") and IDP-123 vehicle lotion ("Placebo Lotion") in the treatment of acne vulgaris. Neither the acne patient nor the investigator knew the identity of the test composition assigned.

[0070] In the first study (Study 301), 813 patients were randomized to receive either Composition A Lotion or Placebo Lotion, as follows.

402 subjects receiving "Composition A Lotion,"

411 subjects receiving "Placebo Lotion."

[0071] In the second study (Study 302), 801 patients were randomized to receive either Composition A Lotion or Placebo Lotion, as follows.

397 subjects receiving "Composition A Lotion,"

404 subjects receiving "Placebo Lotion."

[0072] Primary inclusion criteria were moderate to severe acne, inflammatory lesion count of at least 20 but no more than 50, and non-inflammatory lesion count of at least 25 but no more than 100. The blindly labeled lotions were applied to the affected facial area once daily for twelve weeks, with assessments at 2 weeks, 4 weeks, 8 weeks and 12 weeks.

[0073] The investigator monitored the efficacy at each study visit by assessing the treatable area, determining the Evaluator's Global Severity Score ("EGSS"), and determining the grade of improvement. EGSS included the following grades:

Clear = 0; Almost Clear = 1; Mild = 2; Moderate = 3; Severe = 4.

[0074] Clinical Efficacy was determined primarily based on: (1) superiority in absolute change from baseline to week 12 in mean inflammatory counts; (2) superiority in absolute change from baseline to week 12 in mean non-inflammatory counts; and (3) percentage of subjects who achieve at least a two-grade reduction from baseline and are "Clear" or "Almost Clear" at week 12 in the EGSS.

[0075] Table 9 reports Baseline Characteristics.

Table 9

Subject Baseline Characteristics –
Inflammatory Lesions and Non-inflammatory Lesion Counts

	Study 301		Study 302	
	Composition A Lotion N=402[(1)]	Placebo Lotion N=411[(1)]	Composition A Lotion N=397[(1)]	Placebo Lotion N=404[(1)]
Inflammatory Lesions Mean (SD) Median	28.5(7.04) 26.0	28.1 (7.04) 26.0	28.0 (7.32) 26.0	27.9 (7.10) 26.0
Non-inflammatory Lesions Mean (SD) Median	41.1 (15.67) 36.0	40.7 (16.29) 34.0	41.8 (17.87) 36.0	40.6 (16.31) 35.0

[0076] Table 10 reports treatment % success at week 12 on an intention-to-treat (ITT) basis.

Table 10
EGSS (Clear or Almost Clear) at Week 12 (ITT)

	Study 301		Study 302	
	Composition A Lotion N=402	Placebo Lotion N=411	Composition A Lotion N=397	Placebo Lotion N=404
Week 12	25.5% (p<0.001)	13.0%	29.6% (p<0.001)	17.3

[0077] Table 11 reports absolute changes in inflammatory and non-inflammatory lesions from baseline at week 12.

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Table 11
Inflammatory and Non-Inflammatory Lesions
Absolute Changes from Baseline at Week 12

	Study 301		Study 302	
	Composition A Lotion N=402	Placebo Lotion N=411	Composition A Lotion N=397	Placebo Lotion N=404
Inflammatory Lesions	-15.6 (p<0.001)	-12.4	-16.7 (p<0.001)	-13.4
Non-inflammatory Lesions	-21.0 (p<0.001)	-16.4	-24.6 (p<0.001)	-16.6

[0078] Table 12 reports assessment of treatment success on a per-protocol basis for EGSS. For lesions, absolute changes from baseline to week 12 in mean inflammatory and non-inflammatory counts are reported.

Table 12

Treatment Success (Per-Protocol Basis)

	Study 301		Study 302	
	Composition A Lotion N=402	Placebo Lotion N=411	Composition A Lotion N=397	Placebo Lotion N=404
EGSS – Clear or Almost Clear	26.8%	14.4%	30.6%	18.3%
Inflammatory Lesions	-15.8	-12.4	-16.4	-13.4
Non-inflammatory Lesions	-21.3	-16.3	-24.1	-15.4

[0079] The compositions were tested for cutaneous safety and tolerability. Cutaneous tolerability was assessed by itching, burning, or stinging reported by the subjects. Cutaneous safety was assessed by scaling, erythema, hypo-pigmentation, and hyper-pigmentations, as evaluated by the investigator.

[0080] Table 13 shows the number of subjects reporting moderate or severe itching, burning, or stinging; or being observed to have moderate or severe scaling, erythyma, hypopigmentation, or hyperpigmentation. In general, the reported numbers of these conditions are similar between those subjects using Composition A Lotion and Placebo Lotion.

Table 13

Cutaneous Safety and Tolerability

	Study 301		Study 302	
	Composition A Lotion N=387	Placebo Lotion N=392	Composition A Lotion N=392	Placebo Lotion N=399
Scaling				
Moderate	4	2	6	1
Severe	0	0	1	0
Erythema				
Moderate	7	8	13	6
Severe	0	0	1	0
Hypopigmentation				
Moderate	1	1	0	0
Severe	0	0	0	0
Hyperpigmentation				
Moderate	7	9	8	17
Severe	1	2	0	1
Itching				
Moderate	4	2	4	4
Severe	0	0	0	0
Burning				
Moderate	2	0	5	0
Severe	0	0	2	0
Stinging				
Moderate	1	1	3	0
Severe	0	0	1	0

[0081] Table 13 reports treatment emergent adverse event characteristics.

Table 13

Treatment Emergent Adverse Event Characteristics

	Study 301		Study 302	
	Composition A Lotion N=392(1)	Placebo Lotion N=399(1)	Composition A Lotion N=387(1)	Placebo Lotion N=392(1)
% Subjects Reporting Any Adverse Event	25.5%	19.5%	28.2%	18.6%
% Subjects Reporting Any Serious Adverse Event	0.8%	0.8%	0.3%	0.3%
% Subjects Discontinued Study Due to Adverse Event	3.1%	0.5%	2.6%	0.5%

Note: (1) safety population, which comprises all randomized subjects who were presumed to have used the study drug at least once and who provided at least one post-baseline safety evaluation.

[0082] Notably, these clinical studies showed that the percentages of subjects reporting any serious adverse event for Composition A are no higher than those for the Placebo Lotion, indicating the excellent safety of Composition A.

[0083] The treatment success, as measured by investigator's global assessment of Composition A Lotion (denoted as "EGSS" above) and some commercial products containing a retinoid (as gleaned from their package inserts) is shown in Table 14.

Table 14

Comparison of Treatment Success of Various Products Containing a Retinoid

		Number of Subjects	Treatment Success (%)
Tazarotene Products	Composition A Lotion, 0.045% tazarotene	402	25.5
		397	29.6
	Tazorac Cream, 0.1% tazarotene	218	18
		206	20
	Fabior Foam, 0.1% tazarotene	371	29
		373	28
Tretinoin Products	Altreno Lotion, 0.05% tretinoin	406	16.5
		413	19.8
	Atralin Gel, 0.05% tretinoin	375	21
		299	23
Adapalene Products	Adapalene Gel, 0.3%	258	21
	Adapalene Gel, 0.1%	261	16
	Adapalene Lotion, 0.1%	533	26.3
		535	24.1
	Epiduo Gel, 0.1% adapalene/2.5% benzoyl peroxide	149	21.5
		415	30.1
	0.1% Adapalene in Epiduo vehicle	148	12.2
		420	19.8

[0084] Surprisingly, Composition A Lotion achieved at least similar or higher success rate than other products that contain at least twice the concentration of the active ingredient.

[0085] In another aspect, the present invention provides a method for treating acne vulgaris (acne). The method comprises topically applying to an affected area of the body of a subject suffering from acne any one of the compositions of the present invention, as disclosed herein, one or more (such as 1, 2, 3, or more) times per day for a period of time sufficient to treat such acne vulgaris. For example, such a period of time may be 1 to 30 days or longer as needed. For example, such a period of time may be one week, two weeks, four weeks, eight weeks, twelve weeks, or longer as needed. For example, a composition of the present invention is applied topically to affected areas of the body once per day for 7-14 days.

Alternatively, it may be applied two or three times per day for 7-14 days. Alternatively, it may be applied once per day for one week to six months. For example, it may be applied once per day for two weeks, four weeks, eight weeks, or twelve weeks. In one embodiment, the treatment may be stopped for 1-7 days (e.g., 2, 3, 4, 5, 6, or 7 days) after an extended treatment period before it is resumed for another extended treatment period. Such an extended period may be 7 days, 7-14 days, 7-21 days, 7-30 days, or longer before more treatment is needed or desired.

[0086] In yet another aspect, the present invention provides a method of treating acne vulgaris topically with any of the pharmaceutical compositions of this invention, wherein the composition is applied once daily for more than 2 weeks, such as 4 weeks, for 6 weeks, for 8 weeks or for 12 weeks, without any serious adverse events, and/or with an improved adverse event profile compared to 0.1% tazarotene cream.

[0087] In yet another aspect, the present invention provides a method of treating acne vulgaris topically with any of the pharmaceutical compositions of this invention, wherein the composition is applied once daily for 12 weeks, and has better clinical efficacy and a lower adverse event profile as compared to commercial compositions containing 0.1% tazarotene (Tazorac® Cream).

[0088] While the present disclosure shows and describes a number of exemplary embodiments, it will be manifest to those skilled in the art that various further modifications may be made without departing from the spirit and scope of

the underlying inventive concept and that the same is not limited to particular compositions, processes, methods, or structures herein shown and described.

P05877-2-C1

TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part application of U.S. Patent Application No. 15/977,088, filed May 11, 2018, which claims priority to U.S. Provisional Patent 62/505,421, filed May 12, 2017.

BACKGROUND

[0002] The present invention relates to topical compositions and methods for treating skin diseases such as acne and psoriasis. In particular, this invention relates to topical pharmaceutical compositions comprising tazarotene or a pharmaceutically acceptable tazarotenic acid salt, in an oil-in-water emulsion vehicle, for treating skin diseases.

[0003] The retinoid tazarotene has been commercially available and has been used to treat acne and psoriasis topically. However, tazarotene may cause significant local skin irritation, especially early in the first through fourth weeks of therapy, thus limiting its use for a prolonged period because many patients stop treatment due to skin irritation. The need exists for more effective and safer topical medicaments with reduced adverse effects for the management of acne, psoriasis and other skin diseases.

SUMMARY OF THE INVENTION

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[0004] In general, the present invention provides topical compositions and methods for treating skin diseases such as acne and psoriasis.

[0005] In one aspect, this invention provides a topical pharmaceutical composition for treating skin diseases, including acne and psoriasis, comprising: tazarotene or a pharmaceutically acceptable tazarotenic acid salt present in the composition at a positive concentration of less than 0.050 percent by weight of the composition; and a dermatologically acceptable oil-in-water emulsion vehicle.

[0006] In another aspect, this invention provides a method of treating skin diseases, including acne and psoriasis, comprising topically applying a pharmaceutical composition to an affected area of a body of a subject suffering from the skin disease, wherein the composition comprises: tazarotene or a pharmaceutically acceptable tazarotenic acid salt present in the composition at a positive concentration of less than 0.050 percent by weight of the composition; and a dermatologically acceptable oil-in-water emulsion vehicle.

[0007] According to other aspects, the topical pharmaceutical composition may comprise tazarotene or the salt thereof at 0.01 to 0.049 percent by weight of the composition, or at about 0.045 percent by weight of the composition.

[0008] According to another aspect, the tazarotene or tazarotenic acid salt may be dissolved in a liquid oil component of the emulsion.

[0009] According to another aspect, the topical pharmaceutical composition may contain the tazarotene or the tazarotenic acid salt as a sole active pharmaceutical ingredient.

[0010] According to various aspects, the oil phase of the emulsion may comprise a liquid oil component comprising a DCAE, a MCAE, or combinations thereof. In other aspects, the oil phase includes diethyl sebacate as the DCAE.

[0011] According to other aspects, the aqueous phase of the emulsion may comprise water and a carbomer homopolymer.

[0012] According to another aspect, the topical pharmaceutical composition may comprise: an aqueous phase comprising water, a carbomer homopolymer, and a polymeric emulsifier; an oil phase comprising at least one member selected from the group consisting of a dicarboxylic acid ester and a mineral oil, and the tazarotene or the tazarotenic acid salt. According to other aspects, the aqueous phase may further comprise a humectant or a preservative, such as at least one member selected from the group consisting of methylparaben, propylparaben and sorbitol.

[0013] According to other aspects, the topical pharmaceutical composition may have the form of a lotion, or of a cream.

[0014] According to another aspect, the topical pharmaceutical composition may have a pH of about 4 to about 6.

[0015] For the methods of this invention, the step of applying may be carried out once per day for at least eight weeks. According to one aspect, the applying is carried out once per day for at least twelve weeks.

[0016] According to other aspects, the composition may be applied is to an affected area of a body of a subject suffering from acne vulgaris in order to treat that condition.

[0017] Other features and advantages of the present invention will become apparent from the accompanying drawings and the following detailed description and claims.

BRIEF DESCRIPTION OF THE FIGURES

[0018] Figure 1 is a graph of EGSS by visit.

[0019] Figure 2 is a graph of change in inflammatory lesions from baseline.

[0020] Figure 3 is a graph of change in non-inflammatory lesions from baseline.

[0021] Figures 4A, 4B, and 4C are graphs of cutaneous tolerability to burning, stinging, and itching, respectively.

[0022] Figures 5A, 5B, 5C, and 5D are graphs of cutaneous safety assessed by scaling, erythema, hypo-pigmentation, and hyper-pigmentation, respectively.

DETAILED DESCRIPTION OF THE INVENTION

[0023] In general, the present invention provides topical compositions and methods for treating skin diseases, including acne and psoriasis.

[0024] Throughout this disclosure, unless otherwise indicated, the concentration of an ingredient of the composition is in percent by weight of the total composition.

[0025] In one aspect, the topical pharmaceutical composition comprises tazarotene, or a pharmaceutically acceptable salt of tazarotenic acid, at a concentration below that which is presently utilized in topical formulations. For example, tazarotene or the tazarotenic acid salt is included in a composition at a positive concentration less than 0.05 wt%.

[0026] In certain embodiments of the present invention, tazarotene or the tazarotenic acid salt is present in the composition at a positive concentration of less than 0.05% based on the weight of the composition ("wt%"). For example, this component is present in the range from about 0.01 to about 0.049 wt%, or from about 0.01 to about 0.045 wt%, or from about 0.02 to about 0.045 wt%, or from about 0.03 to about 0.045 wt%, or at about 0.045 wt%. Specific concentrations of this component may be 0.01 wt%, 0.015 wt%, 0.02 wt%, 0.025 wt%, 0.03 wt% 0.035 wt%, 0.04 wt%, and 0.045 wt%.

[0027] In one aspect, the topical pharmaceutical composition comprises an oil-in-water emulsion as a carrier vehicle, in which an internal oil phase is dispersed in a continuous aqueous phase. The emulsion may be a macroemulsion, a microemulsion, or a nanoemulsion. The composition may have the dosage form of gel, lotion, or cream, or ointment, or liquid, or oil, or spray or foam.

[0028] In addition to the tazarotene active ingredient, the composition of the present invention may comprise one or more dermatologically acceptable

excipients, such as liquid oils, waxes viscosity-modifying agents, thickening agents, gelling agents, alcohols, surfactants, chelating agents, buffers, preservatives, humectants, emollients, stabilizers, diluents, dispersing agents, emulsifiers, wetting agents, stabilizers, pH adjusters, solvents or cosolvents.

[0029] The composition of the invention may desirably contain a thickening agent to provide viscosity so that the formulation may be provided in the form of a gel, lotion, cream, or ointment. The thickening agent may be miscible or soluble in an aqueous fluid. Non-limiting examples of suitable thickening agents include acacia, alginic acid and its salts, hyaluronic acid and its salts, carbomers (also known as carboxy vinyl polymers, which are cross-linked polyacrylic acid), carboxymethylcellulose, ethylcellulose, gelatin, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methylcellulose, poloxamers, polyvinylpyrrolidone, polyvinyl alcohol, tragacanth, xanthan gum, magnesium aluminum silicate, and bentonite. The thickening agent may also reside in the oil or lipophilic portion of the formulation. Examples of suitable lipophilic thickening agents include cetyl alcohol, stearyl alcohol, glyceryl stearate, white beeswax, microcrystalline wax, hydrogenated polyisobutane polymers, and emulsifying wax.

[0030] A suitable group of thickening agents is carbomers, such as Carbopol® and polycarbophil (The Lubrizol Corporation, Wickliffe, Ohio). Carbopol® homopolymers are polymers of acrylic acid crosslinked with allyl sucrose or allylpentaerythritol. Carbopol® copolymers are polymers of acrylic acid and C_{10}-C_{30} alkyl acrylate crosslinked with allylpentaerythritol. Carbopol® interpolymers are

carbomer homopolymers or copolymers that contain a block copolymer of polyethylene glycol and a long chain alkyl acid ester. Noveon® polycarbophil is a polymer of acrylic acid crosslinked with divinyl glycol.

[0031] A surfactant or emulsifier is optionally included, if desired or required. Pharmaceutically acceptable anionic, cationic, or non-ionic surfactants may be included in a composition of the present invention. Non-ionic surfactants are preferred. Non-limiting examples of non-ionic surfactants are Octoxynol (also known as Macrogol tetramethylbutylphenyl ether, octylphenoxy polyethoxyethanol, or polyoxyethylene octylphenyl ether), such as Octoxynol 1, 3, 5, 8, 9, 10, 12, 13, 16, 30, 40, 70 (wherein the number indicates the number of repeating oxyethylene units), or other Octoxynols that comprise different numbers of repeating units of oxyethylene in the side chain, sorbitan esters (such as sorbitan monooleate and sorbitan monostearate, commonly known by their trade names Span 80 and Span 60), polysorbates (such as polysorbate 80 (polyoxyethylene sorbitan monooleate), polysorbate 60 (polyoxyethylene sorbitan monostearate), polysorbate 20 (polyoxyethylene sorbitan monolaurate), commonly known by their trade names of Tween® 80, Tween® 60, Tween® 20), poloxamers (synthetic block polymers of ethylene oxide and propylene oxide, such as those commonly known by their trade names of Pluronic®; e.g., Pluronic® F127 or Pluronic® F108), or poloxamines (synthetic block polymers of ethylene oxide and propylene oxide attached to ethylene diamine, such as those commonly known by their trade names of Tetronic®; e.g., Tetronic® 1508 or Tetronic® 908, etc.), other nonionic surfactants such as Brij® (polyoxyethylene alkyl ether having a formula of CH_3–$(CH_2)_{10-16}$–(O-

$C_2H_4)_{1-25}$–OH), Myrj® (stearic acid esterified with polyoxyethylene having 40-100 repeating oxyethylene units), and long chain fatty alcohols (e.g., oleyl alcohol, stearyl alcohol, myristyl alcohol, docosahexaenoyl alcohol, etc.) with carbon chains having about 12 or more carbon atoms (e.g., such as from about 12 to about 24 carbon atoms).

[0032] In addition, polymeric emulsifiers such as those known under the trade name Pemulen™ (The Lubrizol Corporation, Wickliffe, Ohio) may be used. These are polymers of acrylic acid, modified by long chain (C_{10}-C_{30}) alkyl acrylates, and crosslinked with allylpentaerythritol.

[0033] An anionic emulsifier may be used, such as sodium or potassium oleate, triethanolamine stearate, sodium lauryl sulfate, sodium dioctyl sulfosuccinate, and sodium docusate. Less preferred are cationic emulsifiers such as quaternary ammonium salts. Still other emulsifiers include glyceryl monostearate, polyoxyethylene monooleate, polyoxyethylene monostearate, polyoxyethylene monolaurate, potassium oleate, sodium lauryl sulfate, sodium oleate, sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, sorbitan trioleate, triethanolamine oleate, polyoxyethylene sorbitan monolaurate, polyoxyethylene sorbitan monopalmitate, polyoxyethylene sorbitan monostearate, polyoxyethylene sorbitan tristearate, polyoxyethylene sorbitan monooleate, and polyoxyethylene sorbitan trioleate.

[0034] The formulation desirably contains a dermatologically acceptable humectant such as glycerin, sorbitol, hexylene glycol, propylene glycol, or urea. In

addition, the formulation may contain an emollient such as petrolatum, lanolin, mineral oil, light mineral oil, stearic acid, cyclomethicone, or dimethicone. Chelating agents such as EDTA and citric acid and their salts may be included in a formulation of the present invention.

[0035] The liquid oil component of the composition includes one or more materials that are practically insoluble or insoluble in water and which are liquid at room temperature. For example, in one embodiment, the liquid oil component of the composition includes one or more materials that are practically insoluble or insoluble in water and which are liquid at room temperature of 22 °C. The liquid oil component may be selected from one or more ingredients from the group consisting of dicarboxylic acid esters ("DCAE"), monocarboxylic acid esters ("MCAE"), fish-liver oil, long-chain triglycerides (wherein each side chain has 14-18 carbons, such as peanut oil, sesame oil, coconut oil, sunflower oil, corn oil, olive oil, cotton seed oil, or derivatives thereof), propylene glycol diesters, medium-chain triglycerides (such as those wherein each side chains has 8-10 carbons; e.g., capric/caprylic acid triglycerides), hydrocarbons like mineral oil, light mineral oil, squalene, and squalane, fatty alcohols (such as octyldodecanol and isostearyl alcohol), and fatty acids (such as isostearic acid and oleic acid).

[0036] In some embodiments, the liquid oil component comprises a dicarboxylic acid ester and light mineral oil. In some other embodiments, the liquid oil component comprises one or more long-chain triglycerides.

[0037] The formulation may include other lipophilic liquids in an amount that is sufficient to be miscible with the dicarboxylic acid ester and/or monocarboxylic acid ester. The lipophilic liquid may be an emollient such as lanolin oil, mineral oil, light mineral oil, isostearic acid, squalene, octyldodecanol, fractionated coconut oil, cyclomethicone, or dimethicone.

[0038] In addition to the liquid oil component, the formulation may contain water insoluble or practically insoluble ingredients that are not liquid at room temperature, but are soluble in the liquid oil component.

[0039] A DCAE that is suitable for the present invention has the formula $R_1OOC\text{-}(CH_2)_n\text{-}COOR_2$, wherein R_1 and R_2 are alkyl groups containing between 1 and 4 carbons or aryl groups and may be the same or may be different and wherein $(CH_2)_n$ is a straight or branched chain and n is between 1 and 12. Examples of DCAEs containing one or more aryl groups are dibenzyl esters of dicarboxylic acids. A preferred dicarboxylic acid ester is diethyl sebacate, which has the formula $CH_3CH_2OOC\text{-}(CH_2)_8\text{-}COOCH_2CH_3$. Examples of other suitable dicarboxylic acid esters (where R_1 and R_2 are the same) are dimethyl, diethyl, dipropyl, diisopropyl, dibutyl and diisobutyl esters such as oxalate, malate, succinate, glutarate, adipate, pimelate, suberate, and azalate. Examples of suitable dicarboxylic acid esters (where R_1 is different from R_2) are methyl ethyl, methyl propyl, methyl butyl, methyl isopropyl, ethyl propyl, ethyl butyl, ethyl isopropyl, and propyl butyl esters such as oxalate, malate, succinate, glutarate, adipate, pimelate, suberate, azalate, and sebacate.

[0040] In some aspects, diethyl sebacate is included at 0.1 to 20 wt%, or at 0.5 to 10 wt%, or at 2 to 4 wt% of the weight of the composition.

[0041] Alternatively, or in combination with the DCAE, the formulation may contain a MCAE. The MCAE that is suitable for the present invention has the formula CH_3-$(CH_2)_n$-$COOR_1$, wherein R_1 is an alkyl group containing between 1 and 4 carbons or an aryl group, and wherein $(CH_2)_n$ is straight or branched chain and n is between 1 and 12. Examples of such monocarboxylic acid esters include methyl, ethyl, propyl, isopropyl, butyl, or an aryl such as benzyl formate, acetate, propionate, butyrate, valerate, laurate, myristate, palmitate, and stearate. Examples of preferred monocarboxylic acid esters are isopropyl palmitate and isopropyl myristate.

[0042] The liquid oil phase may beneficially be used to dissolve one or more of the active ingredients within the emulsion. In one embodiment the tazarotene component is dissolved in the liquid oil phase within the formulation at room temperature. In another embodiment the tazarotene component is suspended within the formulation at room temperature. In the case wherein the tazarotene component is suspended in the formulation, this suspended active ingredient may be micronized, namely that the mean particle size is preferably about 25 microns in diameter or less.

[0043] In one aspect, a composition of the present invention comprises the ingredients at the concentrations shown in Table 1.

Table 1

Compositions of the Present Invention for Treating Skin Diseases

Ingredient	Concentration (wt%)		
	Range 1	Range 2	Range 3
Tazarotene or Tazarotenic Acid Compound	0.01-0.049	0.02-0.045	0.03-0.045
Emollient, Solvent, and/or Thickener	0.5-40	1-25	2-20
Emulsifier	0.25-10	0.5-7	1-5
Humectant	0-15	2-12	3-10
Polymeric Thickener	0.05-2	0.1-1.5	0.3-1
Pharmaceutical Aids	q.s.	q.s.	q.s.
Purified water	q.s. to 100	q.s. to 100	q.s. to 100

[0044] Non-limiting examples of compositions of the present invention are shown in Table 2.

Table 2

Some Emulsion Compositions of the Present Invention for Treating Acne

Ingredient	Function	Concentration (wt%)			
		Range 1	Range 2	Range 3	Composition A
Tazarotene	Retinoid	0.02-0.049	0.03-0.049	0.04-0.049	0.045
Diethyl sebacate	Liquid Oil & Solvent	1-5	2-4	2.5-3.5	2.97
Light mineral oil	Liquid Oil & Co-Solvent	5-15	5-10	7.5-8.5	8.03
Sorbitan monooleate	Surfactant/ Emulsifying Agent	0.01-1	0.02-0.5	0.05-0.2	0.1
Sorbitol solution, 70%	Humectant	5-15	7-12	10-11	10.7
Methyl paraben	Antimicrobial Preservative(1)	0.05-0.3	0.1-0.3	0.1-0.2	0.17
Propyl paraben	Antimicrobial Preservative(1)	0.01-0.1	0.01-0.05	0.02-0.04	0.03
Edetate disodium dihydrate	Chelating Agent(1)	0.02-0.1	0.02-0.7	0.03-0.06	0.05
Carbomer copolymer type B (e.g., Pemulen™ TR-1)	Emulsifying Agent	0.1-1	0.2-0.7	0.3-0.5	0.4
Carbomer homopolymer type A (e.g., Carbomer 981)	Thickener	0.2-1.5	0.3-1	0.5-0.7	0.6
Sodium hydroxide, 10% Solution	pH-adjusting Agent(1)	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5
Purified water	Carrier	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100

Note: (1) These ingredients are broadly classified as Pharmaceutical Aids.

[0045] A lotion having a composition as shown Composition A of Table 2 may be prepared as follows.

[0046] A separate aqueous phase is made. In a manufacturing vessel equipped with a mixing implement (such as a propeller) and temperature control, purified

water and disodium edetate dihydrate are combined and the mixture is agitated until a clear solution is achieved. Sorbitol, methylparaben, and propylparaben are then added to the mixture. The mixture is continuously mixed and heated to approximately 75 °C. The mixture is agitated until a solution is obtained. The mixture is then removed from the heat source and allowed to cool to below 40 °C with continued mixing. With continuous mixing, Carbopol® 981 and Pemulen™ TR-1 carbomers are added to the mixture and dispersed. Mixing continues until the two carbomers are fully dispersed and hydrated.

[0047] A separate oil phase is made. In a vessel equipped with a mixing implement such as a propeller, diethyl sebacate, and tazarotene are combined. The mixture is agitated until a solution is achieved. With continuous mixing, light mineral oil and sorbitan monooleate are added. Mixing is continued until a solution is obtained.

[0048] In a separate vessel, an approximate 2.5 N solution of sodium hydroxide is prepared.

[0049] With high speed mixing, the oil phase containing the active ingredient (tazarotene) is added to the aqueous phase. Mixing is continued until a homogeneous emulsion is obtained. Mixing speed is decreased and mixing continued for an additional time of 10 minutes to 1 hour. With continuous mixing, an appropriate amount of the sodium hydroxide solution is added incrementally to obtain a pH of 5.5 ± 0.5. Mixing continues further until a homogeneous lotion is obtained, such as for 30 minutes to 3 hours.

[0050] A first clinical study in acne patients was conducted to compare the efficacy of a composition of the present invention containing tazarotene (the "Composition A" lotion of Table 2).

[0051] A first placebo ("Lotion Placebo") corresponded to and had a similar viscosity as Composition A but lacked tazarotene. A second placebo ("Cream Placebo") corresponded to the Lotion Placebo but employed carbomer homopolymer type C in place of carbomer homopolymer type A to yield a higher viscosity emulsion with a viscosity similar to 0.1% tazarotene cream employed in the study. This allows for better blinding of the test formulations and control of the clinical study. In the following results, data for Lotion Placebo and Cream Placebo may be combined and reported as "Combined Placebo".

[0052] Additionally, commercially available 0.1% tazarotene cream (Tazorac® 0.1% cream) was employed in this clinical study for comparison purposes.

[0053] A double blind, multi-site, randomized clinical study was conducted on patients suffering from acne vulgaris, whereby neither the acne patient nor the investigator knew the identity of the test composition assigned. 210 patients were randomized to receive either Composition A lotion, Tazorac® 0.1% cream, Placebo Lotion and Placebo Cream at a 2:2:1:1 randomization:

69 subjects "Composition A lotion"

72 subjects "Tazorac® 0.1% cream"

34 subjects "Lotion Placebo"

35 subjects "Cream Placebo".

[0054] Primary inclusion criteria were moderate to severe acne, inflammatory lesion count of at least 20 but no more than 40, and non-inflammatory lesion count of at least 20 but no more than 100. The blindly labeled lotions were applied to the affected area once daily for twelve weeks, with assessments at 2 weeks, 4 weeks, 8 weeks and 12 weeks.

[0055] The investigator monitored the efficacy at each study visit by assessing the treatable area, determining the Evaluator's Global Severity Score (EGSS), and determining the grade of improvement. EGSS included the following grades:

Clear = 0; Almost Clear = 1; Mild = 2; Moderate = 3; Severe = 4.

[0056] Clinical Efficacy was determined primarily based on the percentage of subjects who were treatment successes at 12 weeks. To be judged as a treatment success, as reported in Tables 4, 6, and 7, subjects had to show at least two-grade improvement from the baseline and EGSS score equating to "clear" or "almost clear". Also, the numbers of inflammatory and non-inflammatory lesions were assessed.

[0057] Table 3 reports Baseline Characteristics.

Table 3
Baseline Characteristics –
Inflammatory Lesions and Non-inflammatory lesions

	Combined Placebo N=69	Composition A N=69	Tazorac® 0.1% Cream N=72
Inflammatory Lesions Mean (SD) Median	 27.2 (5.49) 26.0	 28.3 (6.0) 27.0	 27.3 (5.95) 26.0
Non-inflammatory Lesions Mean (SD) Median	 36.6 (13.17) 34.0	 37.6 (14.70) 34.0	 36.6 (13.31) 34.0

[0058] Table 4 reports treatment % success on an intention-to-treat (ITT) basis.

Table 4
EGSS (Clear or Almost Clear) by Visit (ITT)

	Combined Placebo N=69	Composition A N=69	Tazorac® 0.1% Cream N=72
Week 2	0%	0%	0%
Week 4	0%	1.4%	1.4%
Week 8	4.3%	7.2%	5.6%
Week 12	10.1%	18.8%	16.7%

[0059] Table 5 reports absolute change in inflammatory lesions from baseline. Change in inflammatory and non-inflammatory lesions from baseline is reported in Figures 2 and 3.

Table 5
Inflammatory Lesions by Visit
Absolute Change from Baseline

	Combined Placebo N=69	Composition A N=69	Tazorac® 0.1% Cream N=72
Week 2	-4.7	-2.9	-2.4
Week 4	-7.2	-5.8	-7.8
Week 8	-10.9	-13.2	-12.0
Week 12	-14.0	-18.1	-16.8

[0060] Table 6 reports treatment % success for primary efficacy on an intention-to-treat basis for EGSS at week 12. For EGSS, to be judged as a treatment success, subjects had to show at least two-grade improvement from the baseline and EGSS score equating to "clear" or "almost clear". For inflammatory and non-inflammatory lesions, absolute change from baseline to week 12 in mean inflammatory and non-inflammatory counts is reported.

Table 6
Treatment % Success (ITT) at 12 Weeks

	Combined Placebo N=69	Composition A N=69	Tazorac® 0.1% Cream N=72
EGSS – Clear or Almost Clear	10.1%	18.8%	16.7%
Inflammatory Lesions Absolute Change % Change	 -14.0 -51.41%	 -18.1 -63.75%	 -16.8 -59.99%
Non-inflammatory Lesions Absolute Change % Change	 -13.1 -35.18%	 -21.6 -56.86%	 -20.3 -54.09%

[0061] Table 7 reports treatment % success on a per-protocol basis for EGSS. For lesions, absolute change from baseline to Week 12 in mean inflammatory and non-inflammatory counts is reported.

Table 7
Treatment % Success (PP)

	Combined Placebo N=57	Composition A N=54	Tazorac® 0.1% Cream N=56
EGSS – Clear or Almost Clear	12.3%	20.4%	16.1%
Inflammatory Lesions	-14.2	-18.3	-18.2
Non-inflammatory Lesions	-11.8	-20.8	-21.9

[0062] The compositions were tested for cutaneous safety and tolerability. Cutaneous tolerability was assessed by burning, stinging or itching reported by the subjects. This data is summarized in Figures 4A, 4B, and 4C. Cutaneous safety was assessed by scaling, erythema, hypo-pigmentation and hyper-pigmentations as evaluated by the investigator. This data is summarized in Figures 5A, 5B, 5C, and 5D.

[0063] Table 8 reports treatment emergent adverse event characteristics.

Table 8
Treatment Emergent Adverse Event Characteristics

	Combined Placebo	Composition A	Tazorac® 0.1% Cream
% Subjects Reporting Any Adverse Event	13.4%	14.7%	26.8%
% Subjects Reporting Any Serious Adverse Event	0%	0%	0%
% Subjects Discontinued Study Due to Adverse Event	0%	0%	1.4%

[0064] Notably, this clinical study showed that Composition A, containing less than half of the tazarotene active ingredient, had a numerically better efficacy than the Tazorac® 0.1% Cream. Also, the adverse event profile was lower for Composition A than for Tazorac® 0.1% Cream.

[0065] In another aspect, the present invention provides a method for treating acne. The method comprises topically applying to an affected area of the body of a subject suffering from acne any one of the compositions of the present invention, as disclosed herein, one or more times per day for a period of time sufficient to treat such acne. For example, such a period of time may be 1 to 30 days or longer as needed For example, such a period of time may be one week, two weeks, four weeks, eight weeks, twelve weeks, or longer as needed. For example, a composition of the present invention is applied topically to affected areas of the body once per day for 7-14 days. Alternatively, it may be applied two or three times per day for 7-14 days. Alternatively, it may be applied once per day for one week to six months. For example, it may be applied once per day for two weeks, four weeks, eight weeks, or twelve weeks. In one embodiment, the treatment may be stopped for 1-7 days (e.g., 2, 3, 4, 5, 6, or 7 days) after an extended treatment period before it is resumed for another extended treatment period. Such an extended period may be 7 days, 7-14 days, 7-21 days, 7-30 days, or longer before more treatment is needed or desired.

[0066] In yet another aspect, the present invention provides a method of treating acne topically with any of the pharmaceutical compositions of this invention, wherein the composition is applied once daily for more than 2 weeks, such as 4

weeks, for 6 weeks, for 8 weeks or for 12 weeks, without any serious adverse events, and/or with an improved adverse event profile compared to 0.1% tazarotene cream.

[0067] In yet another aspect, the present invention provides a method of treating acne topically with any of the pharmaceutical compositions of this invention, wherein the composition is applied once daily for 12 weeks, and has better clinical efficacy and a lower adverse event profile as compared to commercial compositions containing 0.1% tazarotene.

[0068] Two larger clinical studies (Studies 301 and 302) in acne patients were conducted to compare the efficacy of a composition of the present invention containing tazarotene (the "Composition A" Lotion of Table 2) to that of a placebo that was the vehicle of Composition A (i.e., without the active ingredient tazarotene).

[0069] These studies were phase-3, multi-center, randomized, double-blind, vehicle-controlled, two-arm, parallel group studies comparing the safety and efficacy of Composition A ("IDP-123 Lotion" or "Composition A Lotion") and IDP-123 vehicle lotion ("Placebo Lotion") in the treatment of acne vulgaris. Neither the acne patient nor the investigator knew the identity of the test composition assigned.

[0070] In the first study (Study 301), 813 patients were randomized to receive either Composition A Lotion or Placebo Lotion, as follows.

402 subjects receiving "Composition A Lotion,"

411 subjects receiving "Placebo Lotion."

[0071] In the second study (Study 302), 801 patients were randomized to receive either Composition A Lotion or Placebo Lotion, as follows.

397 subjects receiving "Composition A Lotion,"

404 subjects receiving "Placebo Lotion."

[0072] Primary inclusion criteria were moderate to severe acne, inflammatory lesion count of at least 20 but no more than 50, and non-inflammatory lesion count of at least 25 but no more than 100. The blindly labeled lotions were applied to the affected facial area once daily for twelve weeks, with assessments at 2 weeks, 4 weeks, 8 weeks and 12 weeks.

[0073] The investigator monitored the efficacy at each study visit by assessing the treatable area, determining the Evaluator's Global Severity Score ("EGSS"), and determining the grade of improvement. EGSS included the following grades:

Clear = 0; Almost Clear = 1; Mild = 2; Moderate = 3; Severe = 4.

[0074] Clinical Efficacy was determined primarily based on: (1) superiority in absolute change from baseline to week 12 in mean inflammatory counts; (2) superiority in absolute change from baseline to week 12 in mean non-inflammatory counts; and (3) percentage of subjects who achieve at least a two-grade reduction from baseline and are "Clear" or "Almost Clear" at week 12 in the EGSS.

[0075] Table 9 reports Baseline Characteristics.

Table 9

Subject Baseline Characteristics –
Inflammatory Lesions and Non-inflammatory Lesion Counts

	Study 301		Study 302	
	Composition A Lotion N=402(1)	Placebo Lotion N=411(1)	Composition A Lotion N=397(1)	Placebo Lotion N=404(1)
Inflammatory Lesions Mean (SD) Median	28.5(7.04) 26.0	28.1 (7.04) 26.0	28.0 (7.32) 26.0	27.9 (7.10) 26.0
Non-inflammatory Lesions Mean (SD) Median	41.1 (15.67) 36.0	40.7 (16.29) 34.0	41.8 (17.87) 36.0	40.6 (16.31) 35.0

[0076] Table 10 reports treatment % success at week 12 on an intention-to-treat (ITT) basis.

Table 10
EGSS (Clear or Almost Clear) at Week 12 (ITT)

	Study 301		Study 302	
	Composition A Lotion N=402	Placebo Lotion N=411	Composition A Lotion N=397	Placebo Lotion N=404
Week 12	25.5% (p<0.001)	13.0%	29.6% (p<0.001)	17.3

[0077] Table 11 reports absolute changes in inflammatory and non-inflammatory lesions from baseline at week 12.

Table 11
Inflammatory and Non-Inflammatory Lesions
Absolute Changes from Baseline at Week 12

	Study 301		Study 302	
	Composition A Lotion N=402	Placebo Lotion N=411	Composition A Lotion N=397	Placebo Lotion N=404
Inflammatory Lesions	-15.6 (p<0.001)	-12.4	-16.7 (p<0.001)	-13.4
Non-inflammatory Lesions	-21.0 (p<0.001)	-16.4	-24.6 (p<0.001)	-16.6

[0078] Table 12 reports assessment of treatment success on a per-protocol basis for EGSS. For lesions, absolute changes from baseline to week 12 in mean inflammatory and non-inflammatory counts are reported.

Table 12

Treatment Success (Per-Protocol Basis)

	Study 301		Study 302	
	Composition A Lotion N=402	Placebo Lotion N=411	Composition A Lotion N=397	Placebo Lotion N=404
EGSS – Clear or Almost Clear	26.8%	14.4%	30.6%	18.3%
Inflammatory Lesions	-15.8	-12.4	-16.4	-13.4
Non-inflammatory Lesions	-21.3	-16.3	-24.1	-15.4

[0079] The compositions were tested for cutaneous safety and tolerability. Cutaneous tolerability was assessed by itching, burning, or stinging reported by the subjects. Cutaneous safety was assessed by scaling, erythema, hypo-pigmentation, and hyper-pigmentations, as evaluated by the investigator.

[0080] Table 13 shows the number of subjects reporting moderate or severe itching, burning, or stinging; or being observed to have moderate or severe scaling, erythyma, hypopigmentation, or hyperpigmentation. In general, the reported numbers of these conditions are similar between those subjects using Composition A Lotion and Placebo Lotion.

Table 13

Cutaneous Safety and Tolerability

	Study 301		Study 302	
	Composition A Lotion N=387	Placebo Lotion N=392	Composition A Lotion N=392	Placebo Lotion N=399
Scaling				
Moderate	4	2	6	1
Severe	0	0	1	0
Erythema				
Moderate	7	8	13	6
Severe	0	0	1	0
Hypopigmentation				
Moderate	1	1	0	0
Severe	0	0	0	0
Hyperpigmentation				
Moderate	7	9	8	17
Severe	1	2	0	1
Itching				
Moderate	4	2	4	4
Severe	0	0	0	0
Burning				
Moderate	2	0	5	0
Severe	0	0	2	0
Stinging				
Moderate	1	1	3	0
Severe	0	0	1	0

[0081] Table 13 reports treatment emergent adverse event characteristics.

Table 13

Treatment Emergent Adverse Event Characteristics

	Study 301		Study 302	
	Composition A Lotion N=392[(1)]	Placebo Lotion N=399[(1)]	Composition A Lotion N=387[(1)]	Placebo Lotion N=392[(1)]
% Subjects Reporting Any Adverse Event	25.5%	19.5%	28.2%	18.6%
% Subjects Reporting Any Serious Adverse Event	0.8%	0.8%	0.3%	0.3%
% Subjects Discontinued Study Due to Adverse Event	3.1%	0.5%	2.6%	0.5%

Note: (1) safety population, which comprises all randomized subjects who were presumed to have used the study drug at least once and who provided at least one post-baseline safety evaluation.

[0082] Notably, these clinical studies showed that the percentages of subjects reporting any serious adverse event for Composition A are no higher than those for the Placebo Lotion, indicating the excellent safety of Composition A.

[0083] The treatment success, as measured by investigator's global assessment of Composition A Lotion (denoted as "EGSS" above) and some commercial products containing a retinoid (as gleaned from their package inserts) is shown in Table 14.

Table 14

Comparison of Treatment Success of Various Products Containing a Retinoid

		Number of Subjects	Treatment Success (%)
Tazarotene Products	Composition A Lotion, 0.045% tazarotene	402	25.5
		397	29.6
	Tazorac Cream, 0.1% tazarotene	218	18
		206	20
	Fabior Foam, 0.1% tazarotene	371	29
		373	28
Tretinoin Products	Altreno Lotion, 0.05% tretinoin	406	16.5
		413	19.8
	Atralin Gel, 0.05% tretinoin	375	21
		299	23
Adapalene Products	Adapalene Gel, 0.3%	258	21
	Adapalene Gel, 0.1%	261	16
	Adapalene Lotion, 0.1%	533	26.3
		535	24.1
	Epiduo Gel, 0.1% adapalene/2.5% benzoyl peroxide	149	21.5
		415	30.1
	0.1% Adapalene in Epiduo vehicle	148	12.2
		420	19.8

[0084] Surprisingly, Composition A Lotion achieved at least similar or higher success rate than other products that contain at least twice the concentration of the active ingredient.

[0085] In another aspect, the present invention provides a method for treating acne vulgaris (acne). The method comprises topically applying to an affected area of the body of a subject suffering from acne any one of the compositions of the present invention, as disclosed herein, one or more (such as 1, 2, 3, or more) times per day for a period of time sufficient to treat such acne vulgaris. For example, such a period of time may be 1 to 30 days or longer as needed. For example, such a period of time may be one week, two weeks, four weeks, eight weeks, twelve weeks, or longer as needed. For example, a composition of the present invention is applied topically to affected areas of the body once per day for 7-14 days.

Alternatively, it may be applied two or three times per day for 7-14 days. Alternatively, it may be applied once per day for one week to six months. For example, it may be applied once per day for two weeks, four weeks, eight weeks, or twelve weeks. In one embodiment, the treatment may be stopped for 1-7 days (e.g., 2, 3, 4, 5, 6, or 7 days) after an extended treatment period before it is resumed for another extended treatment period. Such an extended period may be 7 days, 7-14 days, 7-21 days, 7-30 days, or longer before more treatment is needed or desired.

[0086] In yet another aspect, the present invention provides a method of treating acne vulgaris topically with any of the pharmaceutical compositions of this invention, wherein the composition is applied once daily for more than 2 weeks, such as 4 weeks, for 6 weeks, for 8 weeks or for 12 weeks, without any serious adverse events, and/or with an improved adverse event profile compared to 0.1% tazarotene cream.

[0087] In yet another aspect, the present invention provides a method of treating acne vulgaris topically with any of the pharmaceutical compositions of this invention, wherein the composition is applied once daily for 12 weeks, and has better clinical efficacy and a lower adverse event profile as compared to commercial compositions containing 0.1% tazarotene (Tazorac® Cream).

[0088] While the present disclosure shows and describes a number of exemplary embodiments, it will be manifest to those skilled in the art that various further modifications may be made without departing from the spirit and scope of

the underlying inventive concept and that the same is not limited to particular compositions, processes, methods, or structures herein shown and described.

Electronic Patent Application Fee Transmittal	
Application Number:	16179561
Filing Date:	02-Nov-2018
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Angel Arturo
Filer:	Andrew James Anderson/Bethany Weber
Attorney Docket Number:	99336.000293-CIP

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	1202	3	100	300
Miscellaneous-Filing:				
LATE FILING FEE FOR OATH OR DECLARATION	1051	1	160	160
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**460**

Electronic Acknowledgement Receipt	
EFS ID:	34982036
Application Number:	16179561
International Application Number:	
Confirmation Number:	1370
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Angel Arturo
Customer Number:	134756
Filer:	Andrew James Anderson/Bethany Weber
Filer Authorized By:	Andrew James Anderson
Attorney Docket Number:	99336.000293-CIP
Receipt Date:	28-JAN-2019
Filing Date:	02-NOV-2018
Time Stamp:	16:52:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$460
RAM confirmation Number	012919INTEFSW00004387033875
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		99336-343_Response_Notice_File_Corrected_Papers.pdf	110864 7d4f598351d504546d9a86d0c913be185bd3906a	yes	3
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Applicant Response to Pre-Exam Formalities Notice		1	1	
	Specification		2	2	
	Applicant Arguments/Remarks Made in an Amendment		3	3	
Warnings:					
Information:					
2	Specification	99336-343-CIP_Sub_Spec_Marked_up.pdf	210874 66d9203c20190d137d3ce3fa9edfe5749249180c	no	29
Warnings:					
Information:					
3	Specification	99336-343-CIP_Sub_Spec_Clean_Copy.pdf	210593 0b1b63082ce06b72739fa7265ba1af310b3bc1df	no	29
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	32460 a010c959186e2aa03abbb6472a7ec6afd71e9554	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	564791		

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.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/179,561	11/02/2018	Angel Arturo	99336.000293-CIP

CONFIRMATION NO. 1370

134756
HSE/Valeant
1600 Bausch & Lomb Place
Rochester, NY 14604

FORMALITIES LETTER

OC000000104014742

Date Mailed: 11/26/2018

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Filing Date Granted

An application number and filing date have been accorded to this application. The application is informal since it does not comply with the regulations for the reason(s) indicated below. Applicant is given TWO MONTHS from the date of this Notice within which to correct the informalities indicated below. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

The required item(s) identified below must be timely submitted to avoid abandonment:

- A substitute specification in compliance with 37 CFR 1.52, 1.121(b)(3), and 1.125, is required. The substitute specification must be submitted with markings and be accompanied by a clean version (without markings) as set forth in 37 CFR 1.125(c) and a statement that the substitute specification contains no new matter (see 37 CFR 1.125(b)). The specification, claims, and/or abstract page(s) submitted is not acceptable and cannot be scanned or properly stored because:
  - The application contains drawings, but the specification does not contain a brief description of the several views of the drawings as required by 37 CFR 1.74 and 37 CFR 1.77(b)(9).
- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
  - The application contains drawings and the specification contains a brief description of the drawings. However, the specification does not contain a brief description of the several views of the drawings as required by 37 CFR 1.74 and 37 CFR 1.77(b)(7) and/or a drawing(s) has not been labeled in accordance with 37 CFR 1.84(u)(1). If each figure is not labeled "Fig." with a consecutive Arabic numeral (1, 2, etc.) or an Arabic numeral and capital letter in the English alphabet (A, B, etc.), then the drawing(s) must be relabeled in accordance with 37 CFR 1.84(u)(1). In addition, if the brief description of the several views of the drawings does not refer to the figure(s) as properly labeled, then the specification must be amended to correspond to the figure(s) as properly labeled and a substitute specification in compliance with 37 CFR 1.52, 1.121(b)(3), and 1.125, is required.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

- Additional claim fees of $ **300** as an undiscounted entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

- Surcharge as set forth in 37 CFR 1.16(f) must be submitted.
  The surcharge is due for any one of:
  - late submission of the basic filing fee, search fee, or examination fee,
  - late submission of inventor's oath or declaration,
  - filing an application that does not contain at least one claim on filing, or
  - submission of an application filed by reference to a previously filed application.

SUMMARY OF FEES DUE:

The fee(s) required within **TWO MONTHS** from the date of this Notice to avoid abandonment is/are itemized below. No entity status discount is in effect. If applicant is qualified for small entity status, a written assertion of small entity status must be submitted to establish small entity status. (See 37 CFR 1.27). If applicant is qualified for micro entity status, an acceptable Certification of Micro Entity Status must be submitted to establish micro entity status. (See 37 CFR 1.29 and forms PTO/SB/15A and 15B.)

- $ **160** surcharge.
- $ **300** for **3** total claims over 20.
- $(**0**) previous unapplied payment amount.
- $ **460** TOTAL FEE BALANCE DUE.

Items Required To Avoid Processing Delays:

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
  Angel Arturo
  Radhakrishnan Pillai

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

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

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web, including a copy of this Notice and selecting the document description "Applicant response to Pre-Exam Formalities Notice". https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/mgabre/

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 16/179,561

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	300
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	660
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	760
TOTAL CLAIMS (37 CFR 1.16(i))	23 minus 20 =	* 3			OR	x 100 =	300
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*				x 460 =	0.00
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	2020

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.

Padagis Ex. 1002
IPR Petition - USP 11,311,482

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
16/179,561	11/02/2018	1629	1720	99336.000293-CIP	23	2

CONFIRMATION NO. 1370

134756
HSE/Valeant
1600 Bausch & Lomb Place
Rochester, NY 14604

FILING RECEIPT

OC000000104014741

Date Mailed: 11/26/2018

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**

Inventor(s)

Angel Arturo, Santa Rosa, CA;
Radhakrishnan Pillai, Santa Rosa, CA;

Applicant(s)

Valeant Pharmaceuticals North America, Bridgewater, NJ;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CIP of 15/977,088 05/11/2018
which claims benefit of 62/505,421 05/12/2017

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 11/23/2018

Padagis Ex. 1002
IPR Petition - USP 11,311,482

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/179,561**

Projected Publication Date: To Be Determined - pending completion of Corrected Papers

Non-Publication Request: No

Early Publication Request: No

Title

TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

Preliminary Class

514

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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 (1-866-999-4258).

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).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	99336.000293-CIP
	Application Number	
Title of Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Angel		Arturo	

Residence Information (Select One) ● US Residency Non US Residency Active US Military Service

City	Santa Rosa	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	4953 Sheleen Court		
Address 2			
City	Santa Rosa	State/Province	CA
Postal Code	95409	Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Radhakrishnan		Pillai	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

City	Santa Rosa	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	6787 Owl Hill Avenue		
Address 2			
City	Santa Rosa	State/Province	CA
Postal Code	95409	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	99336.000293-CIP
	Application Number	
Title of Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES	

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	134756		
Email Address	patent@hselaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES		
Attorney Docket Number	99336.000293-CIP	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	10	**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	134756		

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	99336.000293-CIP
	Application Number	
Title of Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES	

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation in part of	15977088	2018-05-11
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
15977088	Claims benefit of provisional	62505421	2017-05-12

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	99336.000293-CIP
	Application Number	
Title of Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	99336.000293-CIP
	Application Number	
Title of Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 — Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	Valeant Pharmaceuticals North America		
Mailing Address Information For Applicant:			
Address 1	400 Somerset Corporate Boulevard		
Address 2			
City	Bridgewater	**State/Province**	NJ
Country	US	Postal Code	08807
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	99336.000293-CIP
	Application Number	
Title of Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Andrew J. Anderson/			Date (YYYY-MM-DD)	2018-11-02
First Name	Andrew J.	Last Name	Anderson	Registration Number	33564

Additional Signature may be generated within this form by selecting the Add button. Add

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	99336.000293-CIP
	Application Number	
Title of Invention	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES	

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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 records.

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 CooperationTreaty.

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.

ABSTRACT

Topical pharmaceutical compositions include tazarotene or a pharmaceutically acceptable salt of tazarotenic acid and an oil-in-water emulsion vehicle that forms a lotion. The compositions are used to treat skin diseases, such as acne vulgaris.

[0089] WHAT IS CLAIMED IS:

1. A topical pharmaceutical composition for treating a skin disease, comprising:

tazarotene or a pharmaceutically acceptable tazarotenic acid salt present in the composition at a concentration in the range from about 0.01 to 0.049 percent by weight of the composition; and

a dermatologically acceptable oil-in-water emulsion vehicle; wherein said composition is a lotion.

2. The topical pharmaceutical composition of claim 1, comprising tazarotene at a concentration from about 0.03 to 0.049 percent by weight of the composition.

3. The topical pharmaceutical composition of claim 1, comprising tazarotene at a concentration of about 0.045 percent by weight of the composition.

4. The topical pharmaceutical composition of claim 1, wherein the tazarotene or tazarotenic acid salt is dissolved in a liquid oil component of the emulsion.

5. The topical pharmaceutical composition of claim 1, containing the tazarotene or the tazarotenic acid salt as a sole active pharmaceutical ingredient.

6. The topical pharmaceutical composition of claim 1, wherein an oil phase of the emulsion comprises a liquid oil component comprising a dicarboxylic acid ester ("DCAE"), a monocarboxylic acid ester ("MCAE"), or combinations thereof.

7. The topical pharmaceutical composition of claim 1, wherein an oil phase of the emulsion comprises diethyl sebacate.

8. The topical pharmaceutical composition of claim 1, wherein an aqueous phase of the emulsion comprises water and a carbomer homopolymer.

9. The topical pharmaceutical composition of claim 1, wherein an aqueous phase comprises water, a carbomer homopolymer, and a polymeric emulsifier; and wherein an oil phase comprises at least one member selected from the group consisting of a dicarboxylic acid ester and a mineral oil.

10. The topical pharmaceutical composition of claim 1, wherein the oil phase comprises diethyl sebacate and mineral oil.

11. The topical pharmaceutical composition of claim 1, wherein the oil phase consists of diethyl sebacate and mineral oil.

12. The topical pharmaceutical composition of claim 1, having a pH of about 4 to about 6.

13. A method of treating acne vulgaris, the method comprising topically applying a pharmaceutical composition to an affected area of a body of a subject suffering from acne vulgaris; wherein the composition comprises:

tazarotene or a pharmaceutically acceptable tazarotenic acid salt present in the composition at a concentration from about 0.01 to 0.049 percent by weight of the composition; and

a dermatologically acceptable oil-in-water emulsion vehicle; wherein said composition is a lotion.

14. The method of claim 13, comprising tazarotene at a concentration from about 0.03 to 0.049 percent by weight of the composition.

15. The method of claim 13, comprising tazarotene at a concentration of about 0.045 percent by weight of the composition.

16. The method of claim 13, wherein said emulsion comprises:

an aqueous phase comprising water, a carbomer homopolymer, and a polymeric emulsifier; and

an oil phase comprising at least one member selected from the group consisting of a dicarboxylic acid ester and a mineral oil.

17. The method of claim 16, wherein the oil phase of the emulsion comprises diethyl sebacate.

18. The method of claim 13, wherein the oil phase of the emulsion comprises diethyl sebacate and mineral oil.

19. The method of claim 13, wherein the oil phase of the emulsion consists of diethyl sebacate and mineral oil.

20. The method of claim 13, wherein said applying is carried out once per day for at least eight weeks.

21. The method of claim 13, wherein said applying is carried out once per day for at least twelve weeks.

22. The method of claim 13, wherein said applying is carried out once per day for twelve weeks.

23. The method of claim 13, wherein the pharmaceutical composition contains the tazarotene or the tazarotenic acid salt as a sole active pharmaceutical ingredient.

P05877-2-C1

TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part application of U.S. Patent Application No. 15/977,088, filed May 11, 2018, which claims priority to U.S. Provisional Patent 62/505,421, filed May 12, 2017.

BACKGROUND

[0002] The present invention relates to topical compositions and methods for treating skin diseases such as acne and psoriasis. In particular, this invention relates to topical pharmaceutical compositions comprising tazarotene or a pharmaceutically acceptable tazarotenic acid salt, in an oil-in-water emulsion vehicle, for treating skin diseases.

[0003] The retinoid tazarotene has been commercially available and has been used to treat acne and psoriasis topically. However, tazarotene may cause significant local skin irritation, especially early in the first through fourth weeks of therapy, thus limiting its use for a prolonged period because many patients stop treatment due to skin irritation. The need exists for more effective and safer topical medicaments with reduced adverse effects for the management of acne, psoriasis and other skin diseases.

SUMMARY OF THE INVENTION

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[0004] In general, the present invention provides topical compositions and methods for treating skin diseases such as acne and psoriasis.

[0005] In one aspect, this invention provides a topical pharmaceutical composition for treating skin diseases, including acne and psoriasis, comprising: tazarotene or a pharmaceutically acceptable tazarotenic acid salt present in the composition at a positive concentration of less than 0.050 percent by weight of the composition; and a dermatologically acceptable oil-in-water emulsion vehicle.

[0006] In another aspect, this invention provides a method of treating skin diseases, including acne and psoriasis, comprising topically applying a pharmaceutical composition to an affected area of a body of a subject suffering from the skin disease, wherein the composition comprises: tazarotene or a pharmaceutically acceptable tazarotenic acid salt present in the composition at a positive concentration of less than 0.050 percent by weight of the composition; and a dermatologically acceptable oil-in-water emulsion vehicle.

[0007] According to other aspects, the topical pharmaceutical composition may comprise tazarotene or the salt thereof at 0.01 to 0.049 percent by weight of the composition, or at about 0.045 percent by weight of the composition.

[0008] According to another aspect, the tazarotene or tazarotenic acid salt may be dissolved in a liquid oil component of the emulsion.

[0009] According to another aspect, the topical pharmaceutical composition may contain the tazarotene or the tazarotenic acid salt as a sole active pharmaceutical ingredient.

[0010] According to various aspects, the oil phase of the emulsion may comprise a liquid oil component comprising a DCAE, a MCAE, or combinations thereof. In other aspects, the oil phase includes diethyl sebacate as the DCAE.

[0011] According to other aspects, the aqueous phase of the emulsion may comprise water and a carbomer homopolymer.

[0012] According to another aspect, the topical pharmaceutical composition may comprise: an aqueous phase comprising water, a carbomer homopolymer, and a polymeric emulsifier; an oil phase comprising at least one member selected from the group consisting of a dicarboxylic acid ester and a mineral oil, and the tazarotene or the tazarotenic acid salt. According to other aspects, the aqueous phase may further comprise a humectant or a preservative, such as at least one member selected from the group consisting of methylparaben, propylparaben and sorbitol.

[0013] According to other aspects, the topical pharmaceutical composition may have the form of a lotion, or of a cream.

[0014] According to another aspect, the topical pharmaceutical composition may have a pH of about 4 to about 6.

[0015] For the methods of this invention, the step of applying may be carried out once per day for at least eight weeks. According to one aspect, the applying is carried out once per day for at least twelve weeks.

[0016] According to other aspects, the composition may be applied is to an affected area of a body of a subject suffering from acne vulgaris in order to treat that condition.

[0017] Other features and advantages of the present invention will become apparent from the accompanying drawings and the following detailed description and claims.

BRIEF DESCRIPTION OF THE FIGURES

[0018] Figure 1 is a graph of EGSS by visit.

[0019] Figure 2 is a graph of change in inflammatory lesions from baseline.

[0020] Figure 3 is a graph of change in non-inflammatory lesions from baseline.

[0021] Figure 4 are graphs of cutaneous tolerability.

[0022] Figure 5 includes graphs of cutaneous safety.

DETAILED DESCRIPTION OF THE INVENTION

[0023] In general, the present invention provides topical compositions and methods for treating skin diseases, including acne and psoriasis.

[0024] Throughout this disclosure, unless otherwise indicated, the concentration of an ingredient of the composition is in percent by weight of the total composition.

[0025] In one aspect, the topical pharmaceutical composition comprises tazarotene, or a pharmaceutically acceptable salt of tazarotenic acid, at a concentration below that which is presently utilized in topical formulations. For example, tazarotene or the tazarotenic acid salt is included in a composition at a positive concentration less than 0.05 wt%.

[0026] In certain embodiments of the present invention, tazarotene or the tazarotenic acid salt is present in the composition at a positive concentration of less than 0.05% based on the weight of the composition ("wt%"). For example, this component is present in the range from about 0.01 to about 0.049 wt%, or from about 0.01 to about 0.045 wt%, or from about 0.02 to about 0.045 wt%, or from about 0.03 to about 0.045 wt%, or at about 0.045 wt%. Specific concentrations of this component may be 0.01 wt%, 0.015 wt%, 0.02 wt%, 0.025 wt%, 0.03 wt% 0.035 wt%, 0.04 wt%, and 0.045 wt%.

[0027] In one aspect, the topical pharmaceutical composition comprises an oil-in-water emulsion as a carrier vehicle, in which an internal oil phase is dispersed in a continuous aqueous phase. The emulsion may be a macroemulsion, a

microemulsion, or a nanoemulsion. The composition may have the dosage form of gel, lotion, or cream, or ointment, or liquid, or oil, or spray or foam.

[0028] In addition to the tazarotene active ingredient, the composition of the present invention may comprise one or more dermatologically acceptable excipients, such as liquid oils, waxes viscosity-modifying agents, thickening agents, gelling agents, alcohols, surfactants, chelating agents, buffers, preservatives, humectants, emollients, stabilizers, diluents, dispersing agents, emulsifiers, wetting agents, stabilizers, pH adjusters, solvents or cosolvents.

[0029] The composition of the invention may desirably contain a thickening agent to provide viscosity so that the formulation may be provided in the form of a gel, lotion, cream, or ointment. The thickening agent may be miscible or soluble in an aqueous fluid. Non-limiting examples of suitable thickening agents include acacia, alginic acid and its salts, hyaluronic acid and its salts, carbomers (also known as carboxy vinyl polymers, which are cross-linked polyacrylic acid), carboxymethylcellulose, ethylcellulose, gelatin, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methylcellulose, poloxamers, polyvinylpyrrolidone, polyvinyl alcohol, tragacanth, xanthan gum, magnesium aluminum silicate, and bentonite. The thickening agent may also reside in the oil or lipophilic portion of the formulation. Examples of suitable lipophilic thickening agents include cetyl alcohol, stearyl alcohol, glyceryl stearate, white beeswax, microcrystalline wax, hydrogenated polyisobutane polymers, and emulsifying wax.

[0030] A suitable group of thickening agents is carbomers, such as Carbopol® and polycarbophil (The Lubrizol Corporation, Wickliffe, Ohio). Carbopol® homopolymers are polymers of acrylic acid crosslinked with allyl sucrose or allylpentaerythritol. Carbopol® copolymers are polymers of acrylic acid and C_{10}-C_{30} alkyl acrylate crosslinked with allylpentaerythritol. Carbopol® interpolymers are carbomer homopolymers or copolymers that contain a block copolymer of polyethylene glycol and a long chain alkyl acid ester. Noveon® polycarbophil is a polymer of acrylic acid crosslinked with divinyl glycol.

[0031] A surfactant or emulsifier is optionally included, if desired or required. Pharmaceutically acceptable anionic, cationic, or non-ionic surfactants may be included in a composition of the present invention. Non-ionic surfactants are preferred. Non-limiting examples of non-ionic surfactants are Octoxynol (also known as Macrogol tetramethylbutylphenyl ether, octylphenoxy polyethoxyethanol, or polyoxyethylene octylphenyl ether), such as Octoxynol 1, 3, 5, 8, 9, 10, 12, 13, 16, 30, 40, 70 (wherein the number indicates the number of repeating oxyethylene units), or other Octoxynols that comprise different numbers of repeating units of oxyethylene in the side chain, sorbitan esters (such as sorbitan monooleate and sorbitan monostearate, commonly known by their trade names Span 80 and Span 60), polysorbates (such as polysorbate 80 (polyoxyethylene sorbitan monooleate), polysorbate 60 (polyoxyethylene sorbitan monostearate), polysorbate 20 (polyoxyethylene sorbitan monolaurate), commonly known by their trade names of Tween® 80, Tween® 60, Tween® 20), poloxamers (synthetic block polymers of ethylene oxide and propylene oxide, such as those commonly known by their trade

names of Pluronic®; e.g., Pluronic® F127 or Pluronic® F108), or poloxamines (synthetic block polymers of ethylene oxide and propylene oxide attached to ethylene diamine, such as those commonly known by their trade names of Tetronic®; e.g., Tetronic® 1508 or Tetronic® 908, etc.), other nonionic surfactants such as Brij® (polyoxyethylene alkyl ether having a formula of CH_3–$(CH_2)_{10-16}$–$(O-C_2H_4)_{1-25}$–OH), Myrj® (stearic acid esterified with polyoxyethylene having 40-100 repeating oxyethylene units), and long chain fatty alcohols (e.g., oleyl alcohol, stearyl alcohol, myristyl alcohol, docosahexaenoyl alcohol, etc.) with carbon chains having about 12 or more carbon atoms (e.g., such as from about 12 to about 24 carbon atoms).

[0032] In addition, polymeric emulsifiers such as those known under the trade name Pemulen™ (The Lubrizol Corporation, Wickliffe, Ohio) may be used. These are polymers of acrylic acid, modified by long chain (C_{10}-C_{30}) alkyl acrylates, and crosslinked with allylpentaerythritol.

[0033] An anionic emulsifier may be used, such as sodium or potassium oleate, triethanolamine stearate, sodium lauryl sulfate, sodium dioctyl sulfosuccinate, and sodium docusate. Less preferred are cationic emulsifiers such as quaternary ammonium salts. Still other emulsifiers include glyceryl monostearate, polyoxyethylene monooleate, polyoxyethylene monostearate, polyoxyethylene monolaurate, potassium oleate, sodium lauryl sulfate, sodium oleate, sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, sorbitan trioleate, triethanolamine oleate, polyoxyethylene

sorbitan monolaurate, polyoxyethylene sorbitan monopalmitate, polyoxyethylene sorbitan monostearate, polyoxyethylene sorbitan tristearate, polyoxyethylene sorbitan monooleate, and polyoxyethylene sorbitan trioleate.

[0034] The formulation desirably contains a dermatologically acceptable humectant such as glycerin, sorbitol, hexylene glycol, propylene glycol, or urea. In addition, the formulation may contain an emollient such as petrolatum, lanolin, mineral oil, light mineral oil, stearic acid, cyclomethicone, or dimethicone. Chelating agents such as EDTA and citric acid and their salts may be included in a formulation of the present invention.

[0035] The liquid oil component of the composition includes one or more materials that are practically insoluble or insoluble in water and which are liquid at room temperature. For example, in one embodiment, the liquid oil component of the composition includes one or more materials that are practically insoluble or insoluble in water and which are liquid at room temperature of 22 °C. The liquid oil component may be selected from one or more ingredients from the group consisting of dicarboxylic acid esters ("DCAE"), monocarboxylic acid esters ("MCAE"), fish-liver oil, long-chain triglycerides (wherein each side chain has 14-18 carbons, such as peanut oil, sesame oil, coconut oil, sunflower oil, corn oil, olive oil, cotton seed oil, or derivatives thereof), propylene glycol diesters, medium-chain triglycerides (such as those wherein each side chains has 8-10 carbons; e.g., capric/caprylic acid triglycerides), hydrocarbons like mineral oil, light mineral oil, squalene, and

squalane, fatty alcohols (such as octyldodecanol and isostearyl alcohol), and fatty acids (such as isostearic acid and oleic acid).

[0036] In some embodiments, the liquid oil component comprises a dicarboxylic acid ester and light mineral oil. In some other embodiments, the liquid oil component comprises one or more long-chain triglycerides.

[0037] The formulation may include other lipophilic liquids in an amount that is sufficient to be miscible with the dicarboxylic acid ester and/or monocarboxylic acid ester. The lipophilic liquid may be an emollient such as lanolin oil, mineral oil, light mineral oil, isostearic acid, squalene, octyldodecanol, fractionated coconut oil, cyclomethicone, or dimethicone.

[0038] In addition to the liquid oil component, the formulation may contain water insoluble or practically insoluble ingredients that are not liquid at room temperature, but are soluble in the liquid oil component.

[0039] A DCAE that is suitable for the present invention has the formula $R_1OOC\text{-}(CH_2)_n\text{-}COOR_2$, wherein R_1 and R_2 are alkyl groups containing between 1 and 4 carbons or aryl groups and may be the same or may be different and wherein $(CH_2)_n$ is a straight or branched chain and n is between 1 and 12. Examples of DCAEs containing one or more aryl groups are dibenzyl esters of dicarboxylic acids. A preferred dicarboxylic acid ester is diethyl sebacate, which has the formula $CH_3CH_2OOC\text{-}(CH_2)_8\text{-}COOCH_2CH_3$. Examples of other suitable dicarboxylic acid esters (where R_1 and R_2 are the same) are dimethyl, diethyl, dipropyl, diisopropyl,

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dibutyl and diisobutyl esters such as oxalate, malate, succinate, glutarate, adipate, pimelate, suberate, and azalate. Examples of suitable dicarboxylic acid esters (where R_1 is different from R_2) are methyl ethyl, methyl propyl, methyl butyl, methyl isopropyl, ethyl propyl, ethyl butyl, ethyl isopropyl, and propyl butyl esters such as oxalate, malate, succinate, glutarate, adipate, pimelate, suberate, azalate, and sebacate.

[0040] In some aspects, diethyl sebacate is included at 0.1 to 20 wt%, or at 0.5 to 10 wt%, or at 2 to 4 wt% of the weight of the composition.

[0041] Alternatively, or in combination with the DCAE, the formulation may contain a MCAE. The MCAE that is suitable for the present invention has the formula CH_3-$(CH_2)_n$-$COOR_1$, wherein R_1 is an alkyl group containing between 1 and 4 carbons or an aryl group, and wherein $(CH_2)_n$ is straight or branched chain and n is between 1 and 12. Examples of such monocarboxylic acid esters include methyl, ethyl, propyl, isopropyl, butyl, or an aryl such as benzyl formate, acetate, propionate, butyrate, valerate, laurate, myristate, palmitate, and stearate. Examples of preferred monocarboxylic acid esters are isopropyl palmitate and isopropyl myristate.

[0042] The liquid oil phase may beneficially be used to dissolve one or more of the active ingredients within the emulsion. In one embodiment the tazarotene component is dissolved in the liquid oil phase within the formulation at room temperature. In another embodiment the tazarotene component is suspended within the formulation at room temperature. In the case wherein the tazarotene component

is suspended in the formulation, this suspended active ingredient may be micronized, namely that the mean particle size is preferably about 25 microns in diameter or less.

[0043] In one aspect, a composition of the present invention comprises the ingredients at the concentrations shown in Table 1.

Table 1

Compositions of the Present Invention for Treating Skin Diseases

Ingredient	Concentration (wt%)		
	Range 1	Range 2	Range 3
Tazarotene or Tazarotenic Acid Compound	0.01-0.049	0.02-0.045	0.03-0.045
Emollient, Solvent, and/or Thickener	0.5-40	1-25	2-20
Emulsifier	0.25-10	0.5-7	1-5
Humectant	0-15	2-12	3-10
Polymeric Thickener	0.05-2	0.1-1.5	0.3-1
Pharmaceutical Aids	q.s.	q.s.	q.s.
Purified water	q.s. to 100	q.s. to 100	q.s. to 100

[0044] Non-limiting examples of compositions of the present invention are shown in Table 2.

Table 2

Some Emulsion Compositions of the Present Invention for Treating Acne

Ingredient	Function	Concentration (wt%)			
		Range 1	Range 2	Range 3	Composition A
Tazarotene	Retinoid	0.02-0.049	0.03-0.049	0.04-0.049	0.045
Diethyl sebacate	Liquid Oil & Solvent	1-5	2-4	2.5-3.5	2.97
Light mineral oil	Liquid Oil & Co-Solvent	5-15	5-10	7.5-8.5	8.03
Sorbitan monooleate	Surfactant/ Emulsifying Agent	0.01-1	0.02-0.5	0.05-0.2	0.1
Sorbitol solution, 70%	Humectant	5-15	7-12	10-11	10.7
Methyl paraben	Antimicrobial Preservative(1)	0.05-0.3	0.1-0.3	0.1-0.2	0.17
Propyl paraben	Antimicrobial Preservative(1)	0.01-0.1	0.01-0.05	0.02-0.04	0.03
Edetate disodium dihydrate	Chelating Agent(1)	0.02-0.1	0.02-0.7	0.03-0.06	0.05
Carbomer copolymer type B (e.g., Pemulen™ TR-1)	Emulsifying Agent	0.1-1	0.2-0.7	0.3-0.5	0.4
Carbomer homopolymer type A (e.g., Carbomer 981)	Thickener	0.2-1.5	0.3-1	0.5-0.7	0.6
Sodium hydroxide, 10% Solution	pH-adjusting Agent(1)	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5	q.s. to pH of 5.5 ± 0.5
Purified water	Carrier	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100

Note: (1) These ingredients are broadly classified as Pharmaceutical Aids.

[0045] A lotion having a composition as shown Composition A of Table 2 may be prepared as follows.

[0046] A separate aqueous phase is made. In a manufacturing vessel equipped with a mixing implement (such as a propeller) and temperature control, purified

water and disodium edetate dihydrate are combined and the mixture is agitated until a clear solution is achieved. Sorbitol, methylparaben, and propylparaben are then added to the mixture. The mixture is continuously mixed and heated to approximately 75 °C. The mixture is agitated until a solution is obtained. The mixture is then removed from the heat source and allowed to cool to below 40 °C with continued mixing. With continuous mixing, Carbopol® 981 and Pemulen™ TR-1 carbomers are added to the mixture and dispersed. Mixing continues until the two carbomers are fully dispersed and hydrated.

[0047] A separate oil phase is made. In a vessel equipped with a mixing implement such as a propeller, diethyl sebacate, and tazarotene are combined. The mixture is agitated until a solution is achieved. With continuous mixing, light mineral oil and sorbitan monooleate are added. Mixing is continued until a solution is obtained.

[0048] In a separate vessel, an approximate 2.5 N solution of sodium hydroxide is prepared.

[0049] With high speed mixing, the oil phase containing the active ingredient (tazarotene) is added to the aqueous phase. Mixing is continued until a homogeneous emulsion is obtained. Mixing speed is decreased and mixing continued for an additional time of 10 minutes to 1 hour. With continuous mixing, an appropriate amount of the sodium hydroxide solution is added incrementally to obtain a pH of 5.5 ± 0.5. Mixing continues further until a homogeneous lotion is obtained, such as for 30 minutes to 3 hours.

[0050] A first clinical study in acne patients was conducted to compare the efficacy of a composition of the present invention containing tazarotene (the "Composition A" lotion of Table 2).

[0051] A first placebo ("Lotion Placebo") corresponded to and had a similar viscosity as Composition A but lacked tazarotene. A second placebo ("Cream Placebo") corresponded to the Lotion Placebo but employed carbomer homopolymer type C in place of carbomer homopolymer type A to yield a higher viscosity emulsion with a viscosity similar to 0.1% tazarotene cream employed in the study. This allows for better blinding of the test formulations and control of the clinical study. In the following results, data for Lotion Placebo and Cream Placebo may be combined and reported as "Combined Placebo".

[0052] Additionally, commercially available 0.1% tazarotene cream (Tazorac® 0.1% cream) was employed in this clinical study for comparison purposes.

[0053] A double blind, multi-site, randomized clinical study was conducted on patients suffering from acne vulgaris, whereby neither the acne patient nor the investigator knew the identity of the test composition assigned. 210 patients were randomized to receive either Composition A lotion, Tazorac® 0.1% cream, Placebo Lotion and Placebo Cream at a 2:2:1:1 randomization:

69 subjects "Composition A lotion"

72 subjects "Tazorac® 0.1% cream"

34 subjects "Lotion Placebo"

35 subjects "Cream Placebo".

[0054] Primary inclusion criteria were moderate to severe acne, inflammatory lesion count of at least 20 but no more than 40, and non-inflammatory lesion count of at least 20 but no more than 100. The blindly labeled lotions were applied to the affected area once daily for twelve weeks, with assessments at 2 weeks, 4 weeks, 8 weeks and 12 weeks.

[0055] The investigator monitored the efficacy at each study visit by assessing the treatable area, determining the Evaluator's Global Severity Score (EGSS), and determining the grade of improvement. EGSS included the following grades:

Clear = 0; Almost Clear = 1; Mild = 2; Moderate = 3; Severe = 4.

[0056] Clinical Efficacy was determined primarily based on the percentage of subjects who were treatment successes at 12 weeks. To be judged as a treatment success, as reported in Tables 4, 6, and 7, subjects had to show at least two-grade improvement from the baseline and EGSS score equating to "clear" or "almost clear". Also, the numbers of inflammatory and non-inflammatory lesions were assessed.

[0057] Table 3 reports Baseline Characteristics.

Table 3
Baseline Characteristics –
Inflammatory Lesions and Non-inflammatory lesions

	Combined Placebo N=69	Composition A N=69	Tazorac® 0.1% Cream N=72
Inflammatory Lesions Mean (SD) Median	 27.2 (5.49) 26.0	 28.3 (6.0) 27.0	 27.3 (5.95) 26.0
Non-inflammatory Lesions Mean (SD) Median	 36.6 (13.17) 34.0	 37.6 (14.70) 34.0	 36.6 (13.31) 34.0

[0058] Table 4 reports treatment % success on an intention-to-treat (ITT) basis.

Table 4
EGSS (Clear or Almost Clear) by Visit (ITT)

	Combined Placebo N=69	Composition A N=69	Tazorac® 0.1% Cream N=72
Week 2	0%	0%	0%
Week 4	0%	1.4%	1.4%
Week 8	4.3%	7.2%	5.6%
Week 12	10.1%	18.8%	16.7%

[0059] Table 5 reports absolute change in inflammatory lesions from baseline. Change in inflammatory and non-inflammatory lesions from baseline is reported in Figures 2 and 3.

Table 5
Inflammatory Lesions by Visit
Absolute Change from Baseline

	Combined Placebo N=69	Composition A N=69	Tazorac® 0.1% Cream N=72
Week 2	-4.7	-2.9	-2.4
Week 4	-7.2	-5.8	-7.8
Week 8	-10.9	-13.2	-12.0
Week 12	-14.0	-18.1	-16.8

[0060] Table 6 reports treatment % success for primary efficacy on an intention-to-treat basis for EGSS at week 12. For EGSS, to be judged as a treatment success, subjects had to show at least two-grade improvement from the baseline and EGSS score equating to "clear" or "almost clear". For inflammatory and non-inflammatory lesions, absolute change from baseline to week 12 in mean inflammatory and non-inflammatory counts is reported.

Table 6
Treatment % Success (ITT) at 12 Weeks

	Combined Placebo N=69	Composition A N=69	Tazorac® 0.1% Cream N=72
EGSS – Clear or Almost Clear	10.1%	18.8%	16.7%
Inflammatory Lesions			
Absolute Change	-14.0	-18.1	-16.8
% Change	-51.41%	-63.75%	-59.99%
Non-inflammatory Lesions			
Absolute Change	-13.1	-21.6	-20.3
% Change	-35.18%	-56.86%	-54.09%

[0061] Table 7 reports treatment % success on a per-protocol basis for EGSS. For lesions, absolute change from baseline to Week 12 in mean inflammatory and non-inflammatory counts is reported.

Table 7
Treatment % Success (PP)

	Combined Placebo N=57	Composition A N=54	Tazorac® 0.1% Cream N=56
EGSS – Clear or Almost Clear	12.3%	20.4%	16.1%
Inflammatory Lesions	-14.2	-18.3	-18.2
Non-inflammatory Lesions	-11.8	-20.8	-21.9

[0062] The compositions were tested for cutaneous safety and tolerability. Cutaneous tolerability was assessed by burning, stinging or itching reported by the subjects. This data is summarized in Figure 4. Cutaneous safety was assessed by scaling, erythema, hypo-pigmentation and hyper-pigmentations as evaluated by the investigator. This data is summarized in Figure 5.

[0063] Table 8 reports treatment emergent adverse event characteristics.

Table 8
Treatment Emergent Adverse Event Characteristics

	Combined Placebo	Composition A	Tazorac® 0.1% Cream
% Subjects Reporting Any Adverse Event	13.4%	14.7%	26.8%
% Subjects Reporting Any Serious Adverse Event	0%	0%	0%
% Subjects Discontinued Study Due to Adverse Event	0%	0%	1.4%

[0064] Notably, this clinical study showed that Composition A, containing less than half of the tazarotene active ingredient, had a numerically better efficacy than

the Tazorac® 0.1% Cream. Also, the adverse event profile was lower for Composition A than for Tazorac® 0.1% Cream.

[0065] In another aspect, the present invention provides a method for treating acne. The method comprises topically applying to an affected area of the body of a subject suffering from acne any one of the compositions of the present invention, as disclosed herein, one or more times per day for a period of time sufficient to treat such acne. For example, such a period of time may be 1 to 30 days or longer as needed For example, such a period of time may be one week, two weeks, four weeks, eight weeks, twelve weeks, or longer as needed. For example, a composition of the present invention is applied topically to affected areas of the body once per day for 7-14 days. Alternatively, it may be applied two or three times per day for 7-14 days. Alternatively, it may be applied once per day for one week to six months. For example, it may be applied once per day for two weeks, four weeks, eight weeks, or twelve weeks. In one embodiment, the treatment may be stopped for 1-7 days (e.g., 2, 3, 4, 5, 6, or 7 days) after an extended treatment period before it is resumed for another extended treatment period. Such an extended period may be 7 days, 7-14 days, 7-21 days, 7-30 days, or longer before more treatment is needed or desired.

[0066] In yet another aspect, the present invention provides a method of treating acne topically with any of the pharmaceutical compositions of this invention, wherein the composition is applied once daily for more than 2 weeks, such as 4 weeks, for 6 weeks, for 8 weeks or for 12 weeks, without any serious adverse

events, and/or with an improved adverse event profile compared to 0.1% tazarotene cream.

[0067] In yet another aspect, the present invention provides a method of treating acne topically with any of the pharmaceutical compositions of this invention, wherein the composition is applied once daily for 12 weeks, and has better clinical efficacy and a lower adverse event profile as compared to commercial compositions containing 0.1% tazarotene.

[0068] Two larger clinical studies (Studies 301 and 302) in acne patients were conducted to compare the efficacy of a composition of the present invention containing tazarotene (the "Composition A" Lotion of Table 2) to that of a placebo that was the vehicle of Composition A (i.e., without the active ingredient tazarotene).

[0069] These studies were phase-3, multi-center, randomized, double-blind, vehicle-controlled, two-arm, parallel group studies comparing the safety and efficacy of Composition A ("IDP-123 Lotion" or "Composition A Lotion") and IDP-123 vehicle lotion ("Placebo Lotion") in the treatment of acne vulgaris. Neither the acne patient nor the investigator knew the identity of the test composition assigned.

[0070] In the first study (Study 301), 813 patients were randomized to receive either Composition A Lotion or Placebo Lotion, as follows.

402 subjects receiving "Composition A Lotion,"

411 subjects receiving "Placebo Lotion."

[0071] In the second study (Study 302), 801 patients were randomized to receive either Composition A Lotion or Placebo Lotion, as follows.

397 subjects receiving "Composition A Lotion,"

404 subjects receiving "Placebo Lotion."

[0072] Primary inclusion criteria were moderate to severe acne, inflammatory lesion count of at least 20 but no more than 50, and non-inflammatory lesion count of at least 25 but no more than 100. The blindly labeled lotions were applied to the affected facial area once daily for twelve weeks, with assessments at 2 weeks, 4 weeks, 8 weeks and 12 weeks.

[0073] The investigator monitored the efficacy at each study visit by assessing the treatable area, determining the Evaluator's Global Severity Score ("EGSS"), and determining the grade of improvement. EGSS included the following grades:

Clear = 0; Almost Clear = 1; Mild = 2; Moderate = 3; Severe = 4.

[0074] Clinical Efficacy was determined primarily based on: (1) superiority in absolute change from baseline to week 12 in mean inflammatory counts; (2) superiority in absolute change from baseline to week 12 in mean non-inflammatory counts; and (3) percentage of subjects who achieve at least a two-grade reduction from baseline and are "Clear" or "Almost Clear" at week 12 in the EGSS.

[0075] Table 9 reports Baseline Characteristics.

Table 9

Subject Baseline Characteristics –
Inflammatory Lesions and Non-inflammatory Lesion Counts

	Study 301		Study 302	
	Composition A Lotion N=402(1)	Placebo Lotion N=411(1)	Composition A Lotion N=397(1)	Placebo Lotion N=404(1)
Inflammatory Lesions Mean (SD) Median	28.5(7.04) 26.0	28.1 (7.04) 26.0	28.0 (7.32) 26.0	27.9 (7.10) 26.0
Non-inflammatory Lesions Mean (SD) Median	41.1 (15.67) 36.0	40.7 (16.29) 34.0	41.8 (17.87) 36.0	40.6 (16.31) 35.0

[0076] Table 10 reports treatment % success at week 12 on an intention-to-treat (ITT) basis.

Table 10
EGSS (Clear or Almost Clear) at Week 12 (ITT)

	Study 301		Study 302	
	Composition A Lotion N=402	Placebo Lotion N=411	Composition A Lotion N=397	Placebo Lotion N=404
Week 12	25.5% (p<0.001)	13.0%	29.6% (p<0.001)	17.3

[0077] Table 11 reports absolute changes in inflammatory and non-inflammatory lesions from baseline at week 12.

Table 11
Inflammatory and Non-Inflammatory Lesions
Absolute Changes from Baseline at Week 12

	Study 301		Study 302	
	Composition A Lotion N=402	Placebo Lotion N=411	Composition A Lotion N=397	Placebo Lotion N=404
Inflammatory Lesions	-15.6 (p<0.001)	-12.4	-16.7 (p<0.001)	-13.4
Non-inflammatory Lesions	-21.0 (p<0.001)	-16.4	-24.6 (p<0.001)	-16.6

[0078] Table 12 reports assessment of treatment success on a per-protocol basis for EGSS. For lesions, absolute changes from baseline to week 12 in mean inflammatory and non-inflammatory counts are reported.

Table 12

Treatment Success (Per-Protocol Basis)

	Study 301		Study 302	
	Composition A Lotion N=402	Placebo Lotion N=411	Composition A Lotion N=397	Placebo Lotion N=404
EGSS – Clear or Almost Clear	26.8%	14.4%	30.6%	18.3%
Inflammatory Lesions	-15.8	-12.4	-16.4	-13.4
Non-inflammatory Lesions	-21.3	-16.3	-24.1	-15.4

[0079] The compositions were tested for cutaneous safety and tolerability. Cutaneous tolerability was assessed by itching, burning, or stinging reported by the subjects. Cutaneous safety was assessed by scaling, erythema, hypo-pigmentation, and hyper-pigmentations, as evaluated by the investigator.

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[0080] Table 13 shows the number of subjects reporting moderate or severe itching, burning, or stinging; or being observed to have moderate or severe scaling, erythyma, hypopigmentation, or hyperpigmentation. In general, the reported numbers of these conditions are similar between those subjects using Composition A Lotion and Placebo Lotion.

Table 13

Cutaneous Safety and Tolerability

	Study 301		Study 302	
	Composition A Lotion N=387	Placebo Lotion N=392	Composition A Lotion N=392	Placebo Lotion N=399
Scaling				
Moderate	4	2	6	1
Severe	0	0	1	0
Erythema				
Moderate	7	8	13	6
Severe	0	0	1	0
Hypopigmentation				
Moderate	1	1	0	0
Severe	0	0	0	0
Hyperpigmentation				
Moderate	7	9	8	17
Severe	1	2	0	1
Itching				
Moderate	4	2	4	4
Severe	0	0	0	0
Burning				
Moderate	2	0	5	0
Severe	0	0	2	0
Stinging				
Moderate	1	1	3	0
Severe	0	0	1	0

[0081] Table 13 reports treatment emergent adverse event characteristics.

Table 13

Treatment Emergent Adverse Event Characteristics

	Study 301		Study 302	
	Composition A Lotion N=392(1)	Placebo Lotion N=399(1)	Composition A Lotion N=387(1)	Placebo Lotion N=392(1)
% Subjects Reporting Any Adverse Event	25.5%	19.5%	28.2%	18.6%
% Subjects Reporting Any Serious Adverse Event	0.8%	0.8%	0.3%	0.3%
% Subjects Discontinued Study Due to Adverse Event	3.1%	0.5%	2.6%	0.5%

Note: (1) safety population, which comprises all randomized subjects who were presumed to have used the study drug at least once and who provided at least one post-baseline safety evaluation.

[0082] Notably, these clinical studies showed that the percentages of subjects reporting any serious adverse event for Composition A are no higher than those for the Placebo Lotion, indicating the excellent safety of Composition A.

[0083] The treatment success, as measured by investigator's global assessment of Composition A Lotion (denoted as "EGSS" above) and some commercial products containing a retinoid (as gleaned from their package inserts) is shown in Table 14.

Table 14

Comparison of Treatment Success of Various Products Containing a Retinoid

		Number of Subjects	Treatment Success (%)
Tazarotene Products	Composition A Lotion, 0.045% tazarotene	402	25.5
		397	29.6
	Tazorac Cream, 0.1% tazarotene	218	18
		206	20
	Fabior Foam, 0.1% tazarotene	371	29
		373	28
Tretinoin Products	Altreno Lotion, 0.05% tretinoin	406	16.5
		413	19.8
	Atralin Gel, 0.05% tretinoin	375	21
		299	23
Adapalene Products	Adapalene Gel, 0.3%	258	21
	Adapalene Gel, 0.1%	261	16
	Adapalene Lotion, 0.1%	533	26.3
		535	24.1
	Epiduo Gel, 0.1% adapalene/2.5% benzoyl peroxide	149	21.5
		415	30.1
	0.1% Adapalene in Epiduo vehicle	148	12.2
		420	19.8

[0084] Surprisingly, Composition A Lotion achieved at least similar or higher success rate than other products that contain at least twice the concentration of the active ingredient.

[0085] In another aspect, the present invention provides a method for treating acne vulgaris (acne). The method comprises topically applying to an affected area of the body of a subject suffering from acne any one of the compositions of the present invention, as disclosed herein, one or more (such as 1, 2, 3, or more) times per day for a period of time sufficient to treat such acne vulgaris. For example, such a period of time may be 1 to 30 days or longer as needed. For example, such a period of time may be one week, two weeks, four weeks, eight weeks, twelve weeks, or longer as needed. For example, a composition of the present invention is

applied topically to affected areas of the body once per day for 7-14 days. Alternatively, it may be applied two or three times per day for 7-14 days. Alternatively, it may be applied once per day for one week to six months. For example, it may be applied once per day for two weeks, four weeks, eight weeks, or twelve weeks. In one embodiment, the treatment may be stopped for 1-7 days (e.g., 2, 3, 4, 5, 6, or 7 days) after an extended treatment period before it is resumed for another extended treatment period. Such an extended period may be 7 days, 7-14 days, 7-21 days, 7-30 days, or longer before more treatment is needed or desired.

[0086] In yet another aspect, the present invention provides a method of treating acne vulgaris topically with any of the pharmaceutical compositions of this invention, wherein the composition is applied once daily for more than 2 weeks, such as 4 weeks, for 6 weeks, for 8 weeks or for 12 weeks, without any serious adverse events, and/or with an improved adverse event profile compared to 0.1% tazarotene cream.

[0087] In yet another aspect, the present invention provides a method of treating acne vulgaris topically with any of the pharmaceutical compositions of this invention, wherein the composition is applied once daily for 12 weeks, and has better clinical efficacy and a lower adverse event profile as compared to commercial compositions containing 0.1% tazarotene (Tazorac® Cream).

[0088] While the present disclosure shows and describes a number of exemplary embodiments, it will be manifest to those skilled in the art that various

further modifications may be made without departing from the spirit and scope of the underlying inventive concept and that the same is not limited to particular compositions, processes, methods, or structures herein shown and described.

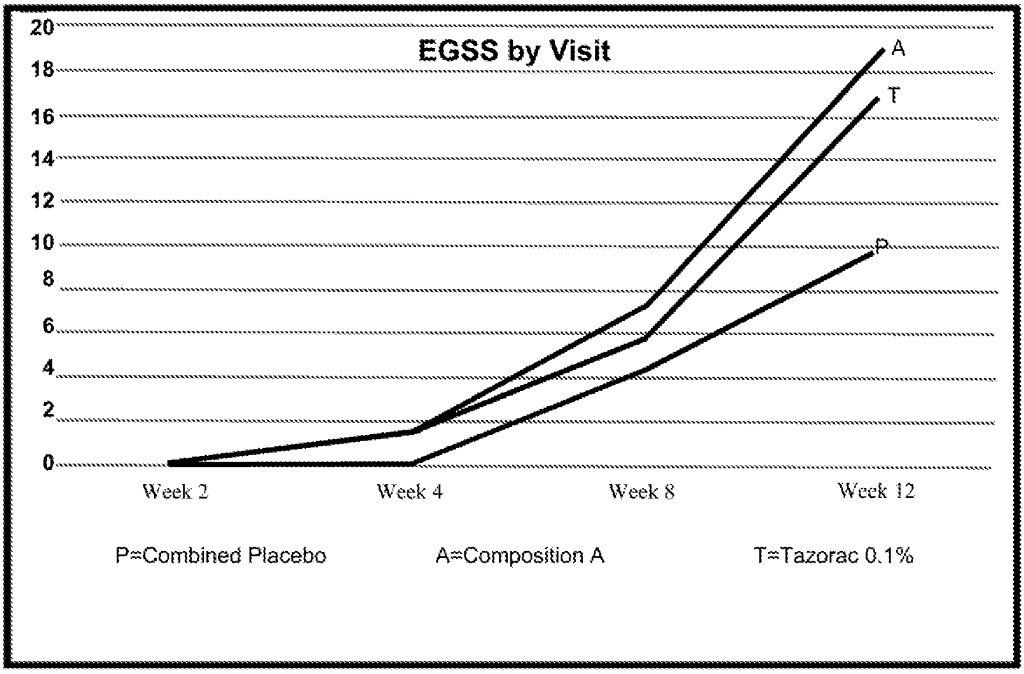


FIG. 1

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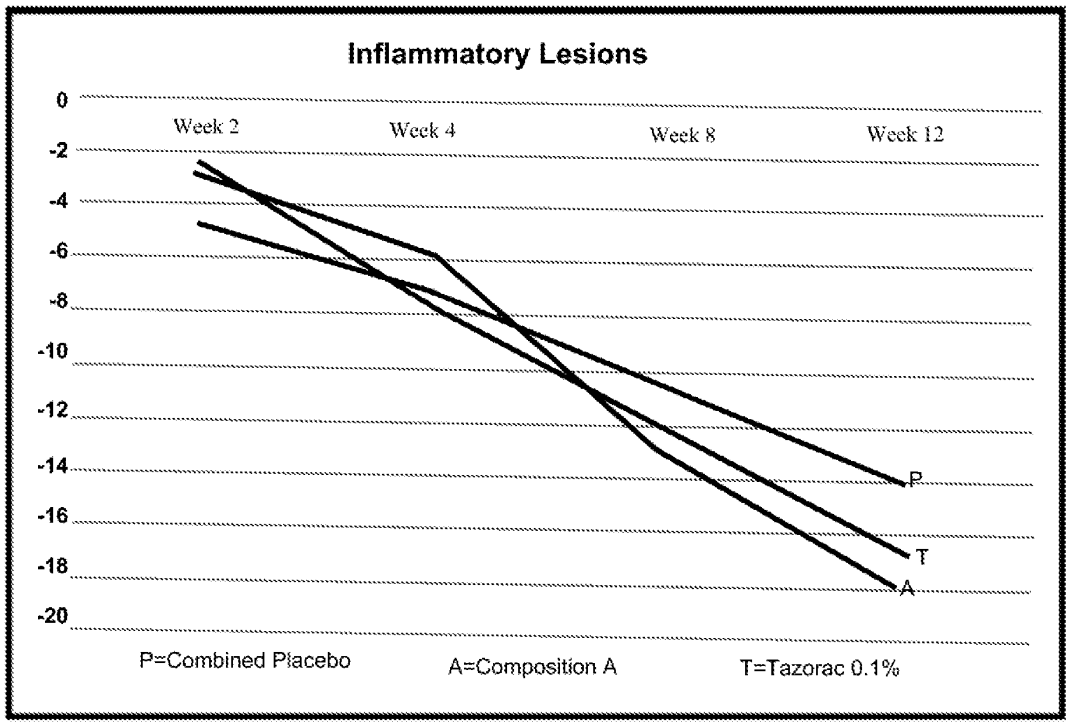


FIG. 2

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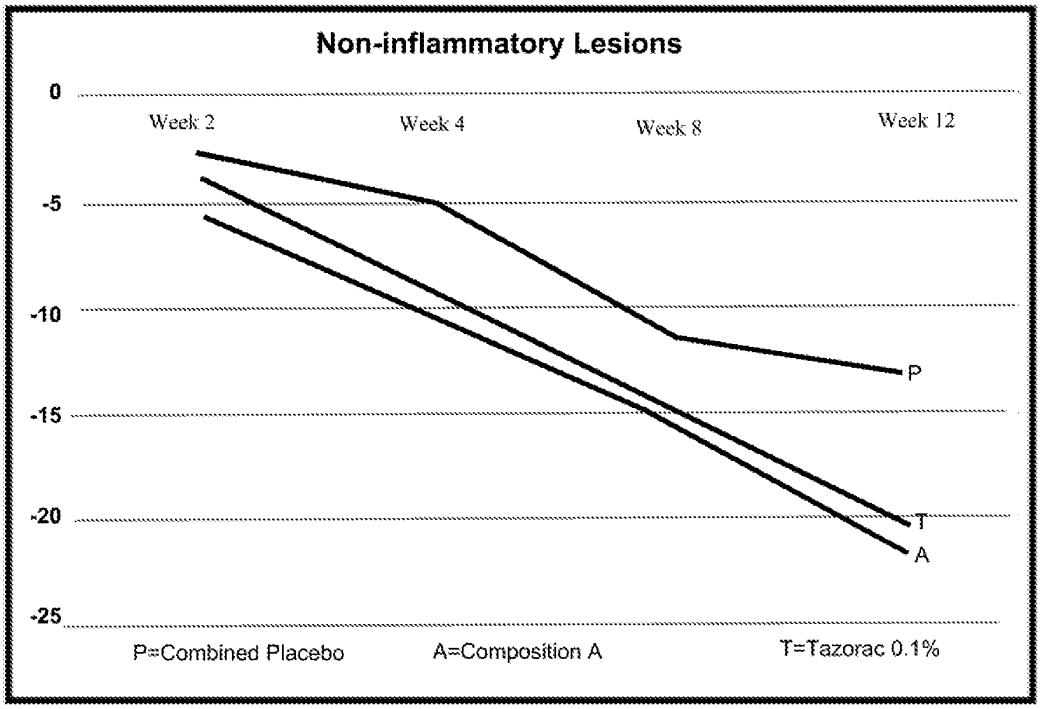

Non-inflammatory Lesions
0
-5
-10
-15
-20
-25
Week 2
Week 4
Week 8
Week 12
P
T
A
P=Combined Placebo
A=Composition A
T=Tazorac 0.1%

FIG. 3

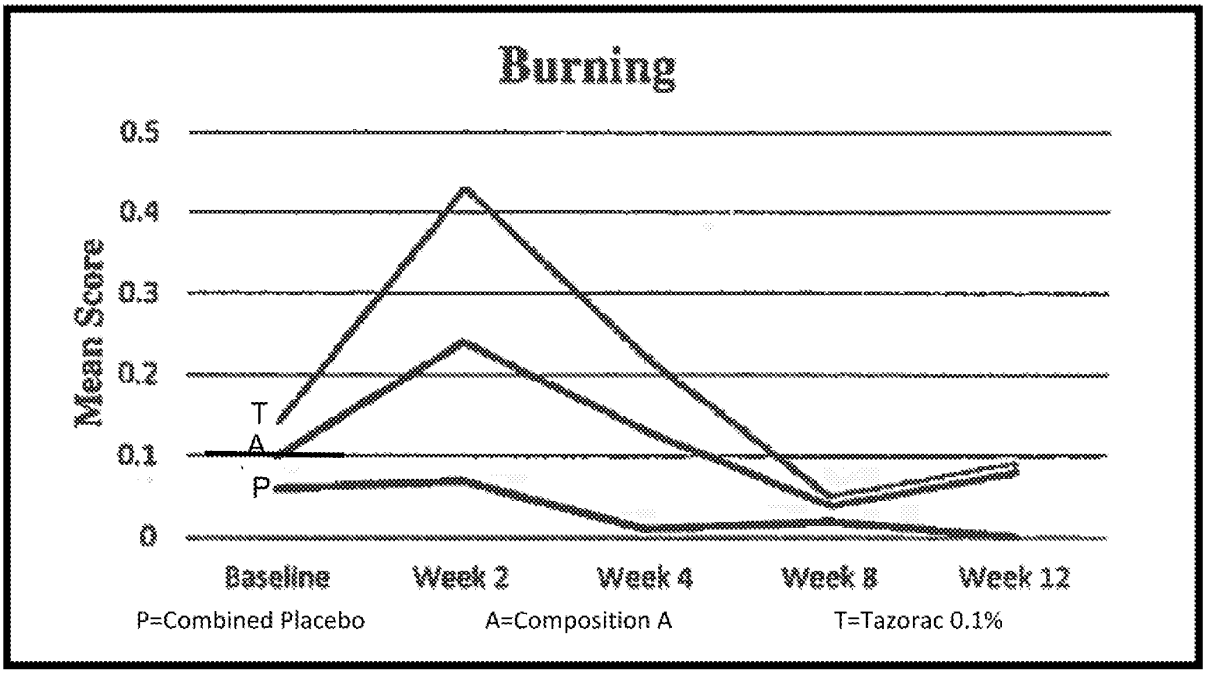


FIG. 4A

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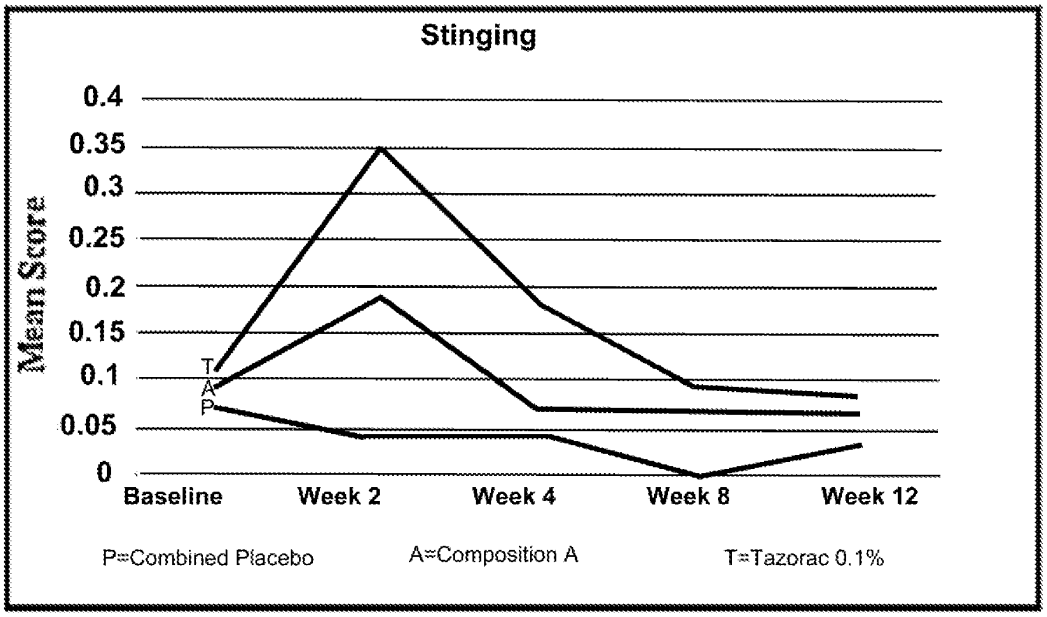

Stinging
Mean Score
0.4
0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
T
A
P
Baseline
Week 2
Week 4
Week 8
Week 12
P=Combined Placebo
A=Composition A
T=Tazorac 0.1%

FIG. 4B

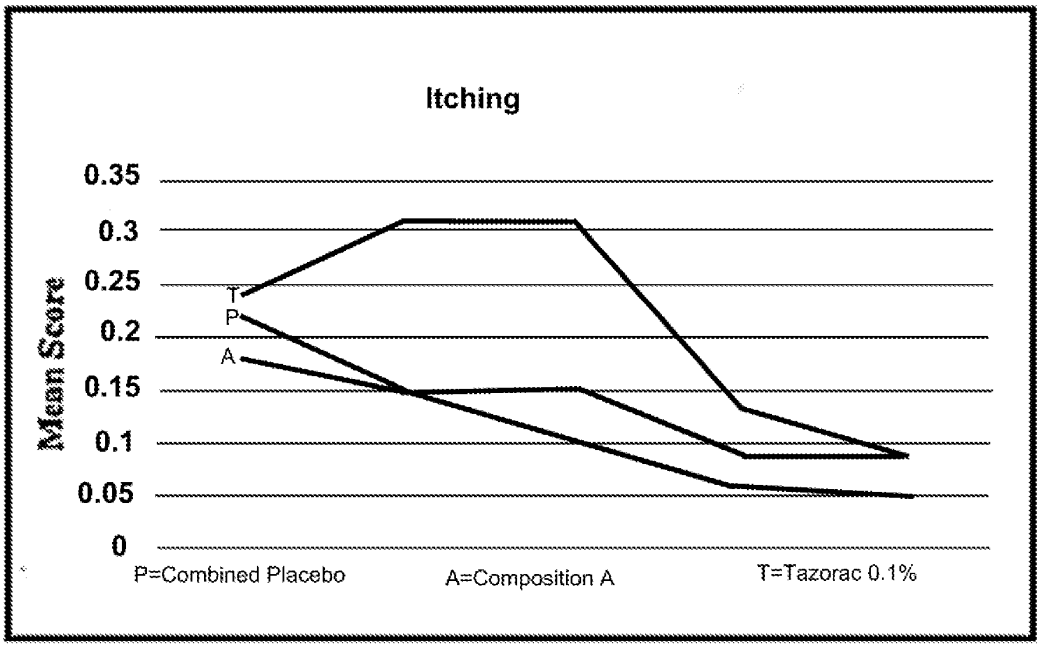


FIG. 4C

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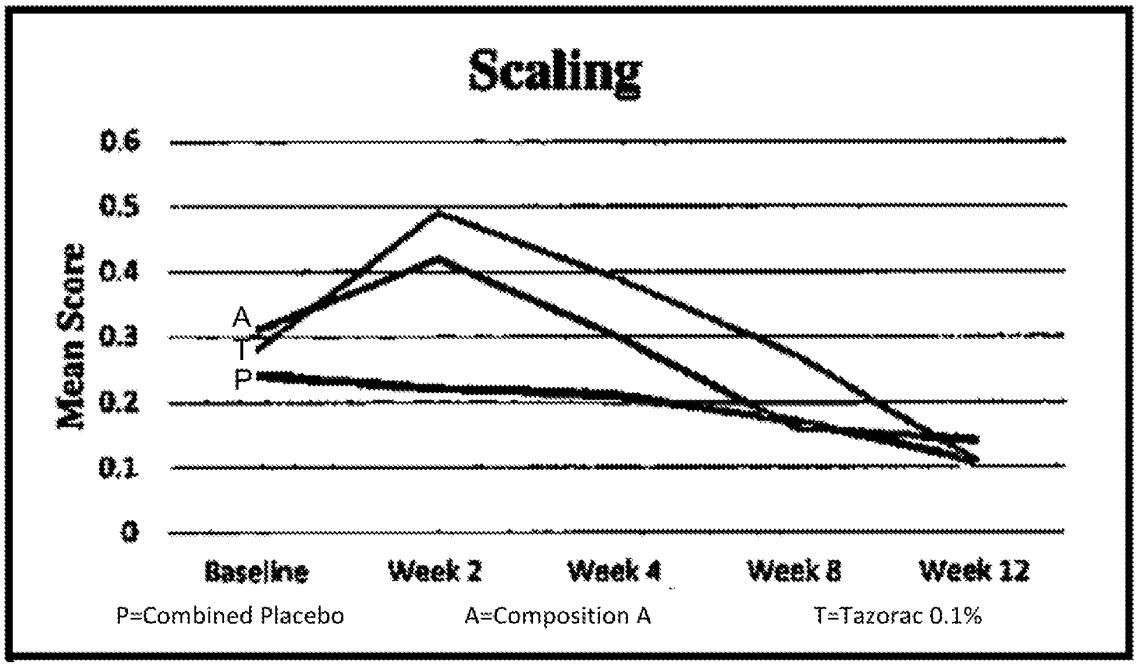

Scaling
Mean Score
0.6
0.5
0.4
0.3
0.2
0.1
0
A
T
P
Baseline
Week 2
Week 4
Week 8
Week 12
P=Combined Placebo
A=Composition A
T=Tazorac 0.1%

FIG. 5A

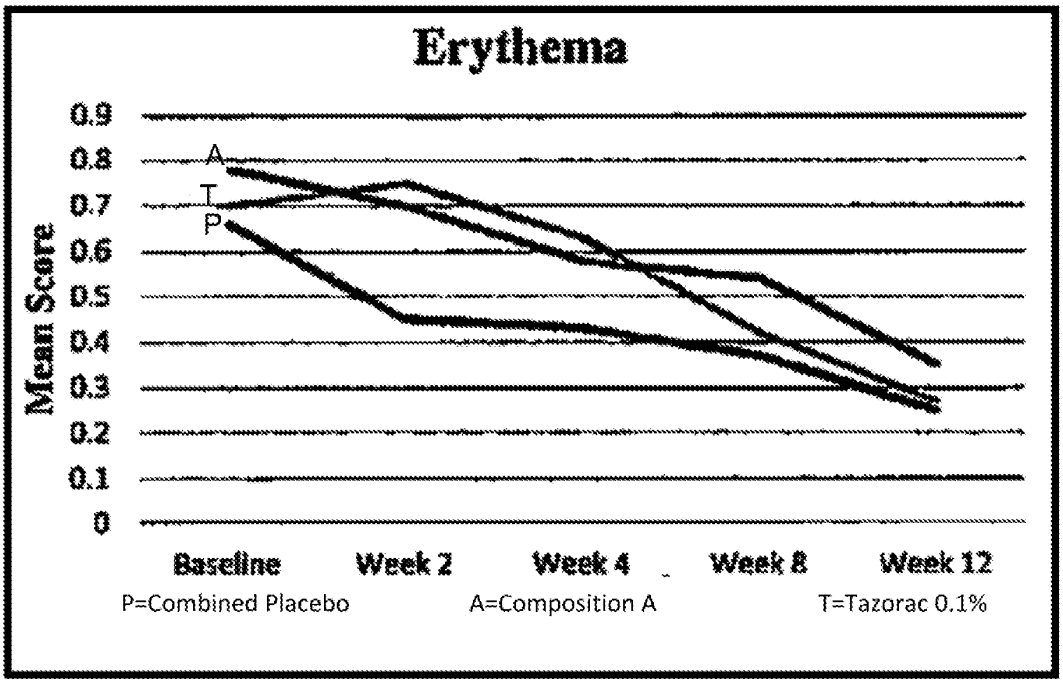

Erythema
Mean Score
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
A
T
P
Baseline
Week 2
Week 4
Week 8
Week 12
P=Combined Placebo
A=Composition A
T=Tazorac 0.1%

FIG. 5B

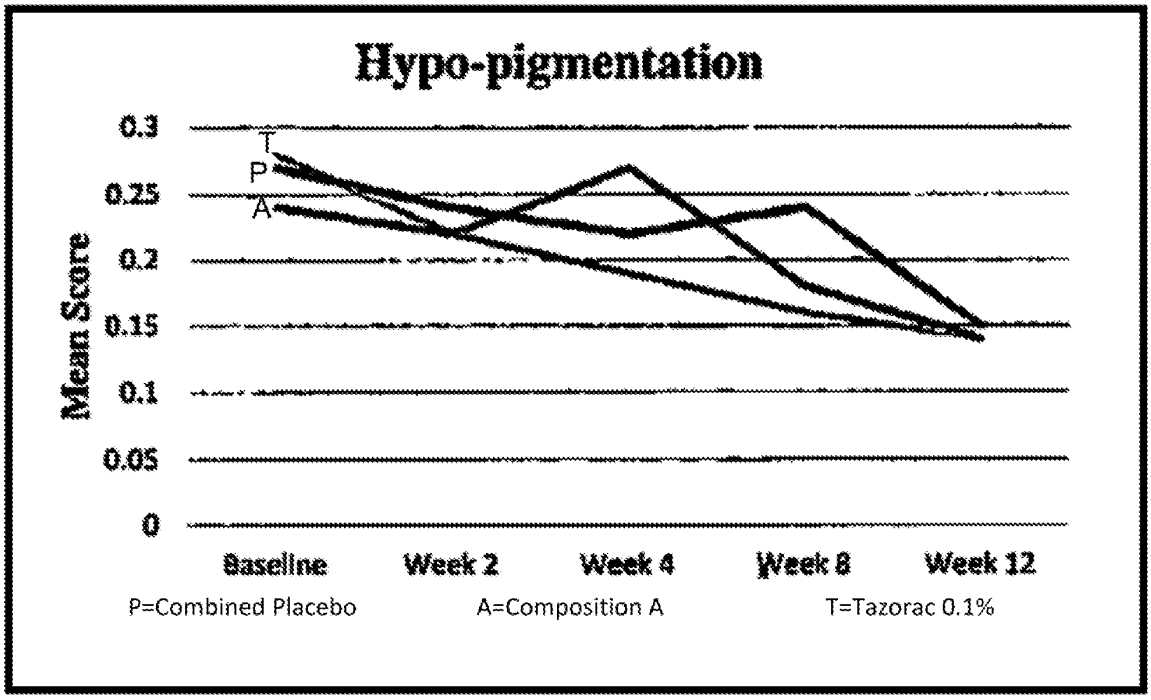

Hypo-pigmentation
Mean Score
0.3
0.25
0.2
0.15
0.1
0.05
0
T
P
A
Baseline
Week 2
Week 4
Week 8
Week 12
P=Combined Placebo
A=Composition A
T=Tazorac 0.1%

FIG. 5C

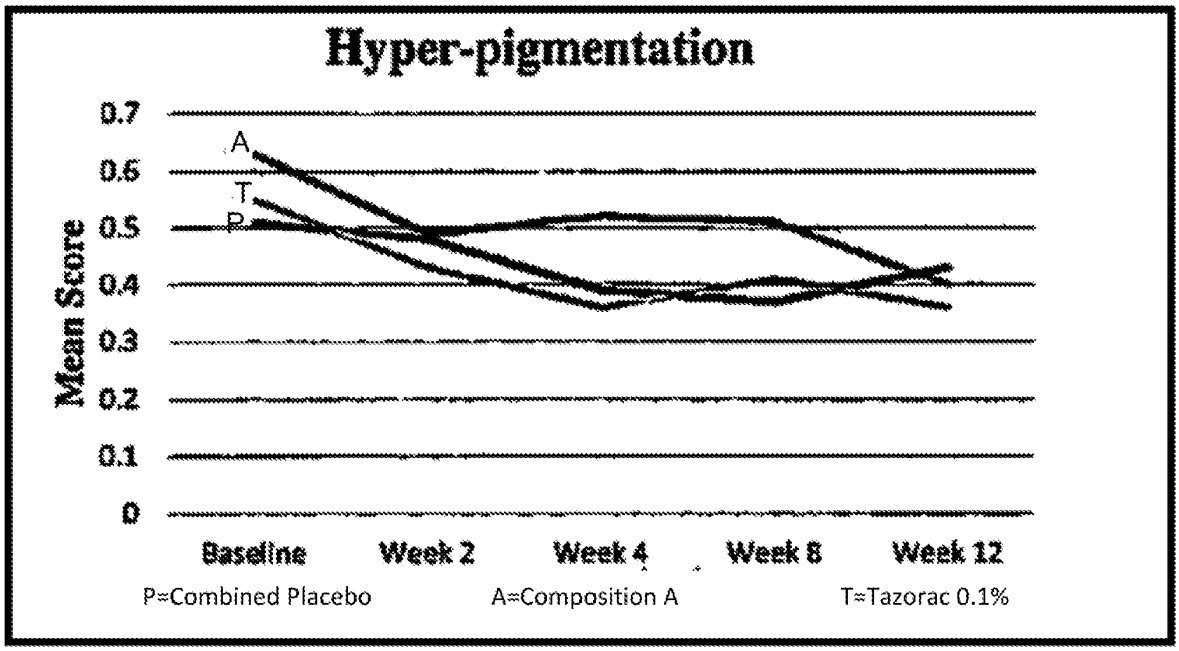


FIG. 5D

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Electronic Patent Application Fee Transmittal	
Application Number:	
Filing Date:	
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Angel Arturo
Filer:	Andrew James Anderson/Bethany Weber
Attorney Docket Number:	99336.000293-CIP

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY APPLICATION FILING	1011	1	300	300
UTILITY SEARCH FEE	1111	1	660	660
UTILITY EXAMINATION FEE	1311	1	760	760
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1720**

Electronic Acknowledgement Receipt	
EFS ID:	34201879
Application Number:	16179561
International Application Number:	
Confirmation Number:	1370
Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR TREATING SKIN DISEASES
First Named Inventor/Applicant Name:	Angel Arturo
Customer Number:	134756
Filer:	Andrew James Anderson/Bethany Weber
Filer Authorized By:	Andrew James Anderson
Attorney Docket Number:	99336.000293-CIP
Receipt Date:	02-NOV-2018
Filing Date:	
Time Stamp:	17:21:34
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$1720
RAM confirmation Number	110518INTEFSW00004122033875
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	99336-293-CIP_ADS.pdf	1424099 f5bacd855a497f5405a5e644551c76e41d39380e	no	8
Warnings:					
Information:					
2		99336-293-CIP_Spec.pdf	198792 0d7e69d4ee81a223c0463131b666b5b157f0969d	yes	35

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Abstract	35	35
	Claims	31	34
	Specification	1	30

Warnings:					
Information:					
3	Drawings-only black and white line drawings	99336-293-CIP_Figures.pdf	2273353 45c40d35536324c0968dda20e14e69686c710de4	no	10
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Warnings:					
Information:					
		Total Files Size (in bytes):	3931444		

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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.